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Development of guidelines for the conduct and reporting of systematic reviews and meta-analyses of newborn and child health research: protocol for PRISMA-PC and PRISMA-C

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ABSTRACT

Introduction: Pediatric systematic reviews differ from adult systematic reviews in several key aspects such as considerations related to child tailored interventions, justifiable comparators, valid outcomes and child sensitive search strategies. Available guidelines, including PRISMA-P (2015) and PRISMA (2009), do not cover the complexities associated with reporting systematic reviews in the pediatric population. We aim to develop a minimal set of evidence- and consensus-based PRISMA-PC (Protocol for Children) and PRISMA-C (Children) Extension to guide pediatric systematic review protocol and completed review reporting.

Methods and Analysis: This project's methodology follows published recommendations for developing reporting guidelines and involves the following six phases; i) establishment of a steering committee comprised of representation from key stakeholder groups; ii) a scoping review to identify potential Extension items; iii) three types of consensus activities including meetings of the steering committee to achieve high-level decisions on the content and methodology of the Extensions, a survey of key stakeholders to generate a list of possible items to include in the Extensions, and a formal consensus meeting to select the reporting items to add to, or modify for, the Extension; iv) the preliminary checklist items generated in phase III will be evaluated against the existing evidence and reporting practices in pediatric systematic reviews; v) extension statements and explanation and elaboration documents will provide detailed advice for each item and examples of good reporting; vi) development and implementation of effective knowledge translation of extension checklist, and an evaluation of the Extensions by key stakeholders.

Ethics and Dissemination: This protocol was considered a quality improvement project by the Hospital for Sick Children's Ethics Committee and did not require ethical review. The resultant checklists, jointly developed with all relevant stakeholder will be disseminated through peer-reviewed journals, national and international conference presentations. Endorsement of the checklist will be sough simultaneously in multiple journals.

KEYWORDS

PRISMA-PC, PRISMA-C, Protocol, Pediatric, Systematic Review

Strengths and Limitations

- The methods chosen for the development of PRISMA-PC and PRISMA-C extensions are based on evidence-based principles of reporting guideline development.
- The simultaneous development of reporting guideline for both protocol and reports of pediatric systematic reviews will ensure that relevant items in the protocol (PRISMA-PC) are reflected in the report (PRISMA-C).

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- Identification of pediatric systematic reviewers from published reports for the Delphi survey will help in identifying an un-biased selection of participants than the project steering committee could provide alone.
- The involvement of various stakeholders in guideline development will ensure that a wide range of perspectives are captured and will help maximize the impact and implementation of the guideline by relevant stakeholders.

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BACKGROUND

Systematic reviews and meta-analyses are considered the highest level in the hierarchy of scientific evidence and are of fundamental importance in decision making by healthcare providers and policy makers. Systematic reviews may also identify the need for further research to establish evidence in a particular population or a sub-set of population. Over the past decade, several evaluations of the methodological quality of systematic reviews have shown limitations, even for those published in high impact factor journals (1, 2). The Preferred Reporting Items in Systematic Review and Meta-Analysis (PRISMA 2009) (3) and PRISMA-P(rotocol-2015) (4) statements were developed to provide guidance on minimal elements needed for optimal reporting of systematic reviews and meta-analyses and their protocols, respectively, in order to maximize the completeness of reporting, transparency and replicability of such studies. An evaluation of the impact of endorsement of the PRISMA statement by specialty journals showed a significant increase of completeness of reporting and methodological quality of systematic reviews in those journals (5).

Rationale for "newborn and child specific" extension of PRISMA

Pediatric systematic reviews differ from adult systematic reviews in several key aspects, as they need to address considerations related to the age specific growth and developmental stages of the patients, newborn and child tailored interventions, justifiable comparators and valid outcomes, and newborn and child sensitive search strategies. Search strategies may need to incorporate specific age related MESH and key search terms such as "neonate", "infant", "adolescent", etc. Furthermore, for systematic reviews with a mixed adult and pediatric population, statistical analyses need to consider subgroup analyses according to targeted pediatric age groups to examine differences in intervention effects (6). These pediatric specific methodological considerations play a role throughout the design, conduct and reporting of pediatric systematic reviews to permit adequate interpretation. Hence, systematic reviews relating to newborn and/or children, including those with mixed adult and pediatric population, require modified and additional standards for reporting items.

The currently available guidelines, including PRISMA-P (2015) and PRISMA (2009), do not cover the complexities associated with reporting (protocols for) systematic reviews in the pediatric population. A scoping review conducted in 2015 identified a need for pediatric extensions of PRISMA (6). This review synthesized evidence on existing evaluations of the quality of reporting of pediatric systematic review protocols and reports. The need for pediatric-specific items in reporting guidelines is also evident from a recent international Consensus meeting on Standard Protocol Items for Randomized Trials in Children (SPIRIT-C) and Consolidated Standards of Reporting Trials in Children (CONSORT-C) held in Toronto in 2014, that agreed on 8 and 14 "pediatric-specific" extension items, respectively, for the design and conduct (SPIRIT-C) and reporting (CONSORT-C) (7) of pediatric clinical trials. At the same meeting, a call was made for guidance to enable scientists to improve the conduct and reporting of systematic reviews in newborn and child health. Limited empirical evidence has shown that the quality of some domain specific pediatric systematic reviews may be low (8, 9). Furthermore, only a small

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fraction of systematic reviews are done in children (10), indicating a need to improve the quantity of systematic reviews in children.

Objectives

Our primary objectives are: 1. to develop a minimal set of evidence- and consensus-based PRISMA-PC (**P**rotocol for **C**hildren) and PRISMA-C (**C**hildren) checklist items to guide pediatric systematic review protocol development and completed review reporting, and 2. to develop and launch a knowledge translation and implementation strategy that encompasses education, dissemination, endorsement and implementation of the final PRISMA-PC and PRISMA-C checklists and accompanying guidance documents by key stakeholders.

Definition and scope of newborn and child relevant systematic reviews

PRISMA-PC and PRISMA-C have adopted the same definition of a "systematic review" and "protocol" as PRISMA-P (4) and PRISMA (3). A systematic review collates all relevant evidence that fits pre-specified eligibility criteria to answer a specific research question. It uses explicit, systematic methods to minimize bias in the identification, selection, synthesis, and summary of relevant studies. A protocol is a document that presents an explicit plan for a systematic review and details the rationale and a priori methodological and analytical approaches for the review. The PRISMA-PC and PRISMA-C checklists will be applicable to pediatric systematic reviews with or without a meta-analysis; and for systematic reviews of randomised controlled trials and/or observational studies.

Table 1: Scope of newborn and child relevant systematic reviews with examples

A newborn and/or child relevant systematic review meets one or more of the following criteria:	
i)	A systematic review with intended population of children only (0-18 years of age). Examples: "Late (> 7 days) inhalation corticosteroids to reduce bronchopulmonary dysplasia in preterm infants (11)" and "The effect of beta-blocker therapy on progressive aortic dilatation in children and adolescents with Marfan's syndrome: a meta-analysis (12)".
ii)	A systematic review with intended population including both children and adult. Examples: "Addition of long-acting beta2-agonists to inhaled steroids versus higher dose inhaled steroids in adults and children with persistent asthma (13)" and "Micronutrient supplementation in children and adults with HIV infection (14)".
iii)	A systematic review of family based interventions intended to improve the health and well-being of children. Examples: "Group-based parent-training programmes for improving emotional and behavioural adjustment in children from birth to three years old (15)" and "Parent-only vs parent-child (family-focused) approaches for weight loss in obese and overweight children: a systematic review and meta-analysis" (16).
iv)	A systematic review of interventions in pregnancy with objectives to measure outcomes in the neonate. Examples: "Hepatitis B vaccination during pregnancy for preventing infant infection (17)" and "Routine iron/folate supplementation during pregnancy: effect on maternal anaemia and birth outcomes" (18).

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METHODS/DESIGN

The project methodology follows published recommendations for developing reporting guidelines (19) and involves the following five phases (see also Figure 1):

Phase I – Project launch

A steering committee comprised of pediatric systematic review authors, methodologists and guidelines developers from leading research institutions (Child Health Evaluation Sciences, and Centre for Global Child Health, The Hospital for Sick Children; Ottawa Hospital Research Institute (OHRI), Alberta Research Centre for Health Evidence (ARCHE), Canada; Stanford University, USA; NHMRC Clinical Trials Centre, University of Sydney, Australia; Cochrane Child Health Field; Cochrane Childhood Cancer Group; Cochrane Neonatology Group) has been identified. The selection of the steering committee members was based on their extensive publication of pediatric systematic reviews and leadership role in systematic review methodology. The steering committee will manage the project via face-to-face (video conferencing) online meetings to discuss and finalize key steps of the guideline development process. They will also help recruit participants for the Delphi survey and Consensus meeting.

Phase II – Review of Evidence and compilation of pediatric specific topics

Based on the results of the scoping review that identified a need of pediatric extensions of PRISMA and PRISMA-P, a preliminary list of pediatric specific methodological issues will be compiled which may require detailed guidance to enhance the quality and consistency of reporting of pediatric systematic review protocols and reports. Furthermore, items that are relevant to pediatric systematic reviews will also be identified from the SPIRIT-C and CONSORT-C checklists.

Phase III – Consensus Process

The PRISMA-PC and PRISMA-C guideline development will involve three streams of consensus activities complemented by evidence gathering as follows:

Meetings of the steering committee: Steering committee meetings will be held regularly throughout the project to achieve high-level decisions on the content and methodology of the pediatric extensions of PRISMA guidelines. Following the synthesis of evidence in phase II, a formal meeting will be held with the steering committee to discuss each topic that requires further guidance. A further meeting will be held following a survey (described below) in which items will be discussed for which strong objection for their omission or inclusion has been received.

1. **Survey**: An electronic survey of international experts in systematic reviews will lead to the preliminary list of potential pediatric extension items for conducting (PRISMA-PC) and reporting (PRISMA-C) pediatric systematic reviews. Survey methodology has been used as an initial step of guideline development in other guideline extensions, such as PRISMA-IPD (20) and PRISMA-Equity (21). Survey participants will be identified through the editorial boards of Cochrane Child Health, Cochrane Neonatal Group, leading systematic reviewers in the child health field, editorial boards of leading pediatric and other journals and through

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networks of our steering committee members. Potential survey participants will be invited by email to complete a web-based survey. The survey will remain open for 3 weeks. Eligibility criteria for survey participation will include a combination of experience in pediatric clinical research and systematic reviews or guideline development. In the survey, each item will be rated as "omit," "possible," "desirable," or "essential" to include in the final checklists (22). The ranked items will then be divided into three groups. *Group I* will contain items with the highest rankings (rated as "essential" by ≥70% participants or "essential or desirable" by ≥90%), and these items will be included for a discussion in the Consensus meeting. *Group II* will contain items with moderate rankings ("essential" or "desirable" by ≥80% to <90%) and will be further discussed by the Steering Committee members for their inclusion or exclusion in the Consensus meeting. *Group III* will contain items with low rankings (i.e., <80% "essential" or "desirable", or >70% "omit" or ≥85% "possible" or "omit"), and these items will be removed and will not be discussed further. Participants will have the opportunity to suggest new items that will be considered by the Steering Committee members to decide whether they should be discussed at the Consensus meeting. In addition, participants will be given an opportunity to comment on each item's wording or provide general comments on its concept. We considered the need for several (usually three) rounds of the Delphi survey as unnecessary, as a similar multi-round Delphi survey exercise was recently undertaken for the development of SPIRIT-C (Children) and the concepts and feedback on pediatric specific items were already captured by experts in pediatric research and other stakeholders such as journal editors. The feedback for SPIRIT-C items was further reviewed by the steering committee while identifying PRISMA-PC and PRISMA-C relevant topics. However, a survey will establish its applicability to pediatric systematic reviews from the perspective of relevant end users such as pediatric systematic reviewers, clinicians and methodologists.

2. **Systematic Review**: Two preliminary checklists for PRISMA-PC and PRISMA-C that will be complied following the survey will then be evaluated against the existing evidence and reporting practices in pediatric systematic reviews. The proposed knowledge synthesis will be completed using a 'conventional' systematic review approach. The search strategy will be adopted from tested search filters developed for "systematic review", "pediatric" and "protocol" (23). The Cochrane Database of Systematic Review and Database of Abstracts of Reviews of Effects (DARE) databases will be searched from January 2010 to December 2014. The reason for limiting the search from 2010 and beyond is because the steering committee decided to review the quality of evidence following the publication of a widely endorsed systematic review reporting guideline i.e., the PRISMA statement, which was published in 2009 (3). The titles and abstracts will be screened for the following eligibility criteria: i) a child-relevant systematic review (as per the definitions provided in Table 1); ii) published in English language; iii) not a commentary or editorial. A random sample of 300 pediatric systematic reviews will be included for this evidence synthesis. The screening of full text will continue until the desired sample size is achieved. We anticipate a limited number of published pediatric systematic review protocols, therefore, all the identified protocols that meet the inclusion criteria will be included. Data will be extracted on; i) the characteristics

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of the review; ii) whether the review fulfilled the reporting criteria identified in the proposed items; iii) examples of good reporting.

3. **Consensus meeting**: A Consensus development meeting will be held to reach consensus regarding the minimum items required in a pediatric extension of PRISMA-PC and PRISMA-C. The Cochrane Colloquium will provide the ideal venue to host this Consensus meeting, since this annual meeting is attended by systematic reviewers, representatives from Cochrane and Prospective Register of Systematic Reviews (PROSPERO), and end-users of pediatric systematic reviews such as patients and clinicians, funders, methodologists, guideline developers and journal editors, allowing them to gather under one umbrella for scientific exchange regarding systematic reviews and their methodology, as well as the opportunity to further develop methods. Hence the Cochrane Colloquium will facilitate the meeting of our goals and objectives to gather a wide range of stakeholders for the Consensus process.

   The voting process will follow methods used in previous Consensus meetings of guideline development. A preliminary round of voting will take place for each candidate item. Each item will be presented sequentially and debated in the light of the results from the Delphi survey and a summary of literature findings. Votes will be carried out anonymously using an online m-clicker voting system. In order to reach consensus, a classification scheme for selecting items to include in the checklists will be used, similar to the one used in developing the original PRISMA checklist. Briefly, a candidate item will be included within the final checklist if ≥80% of voters agree on its inclusion. Items with ≤20% votes for inclusion will be excluded from the final checklist. For items that do not reach consensus through the preliminary votes, round table discussions will be held, whereby participants will be given the opportunity to express their points of view in support for or against the inclusion of the item of interest. Discussions will be followed by a second round of voting with the same qualification criteria for inclusion. An experienced moderator not directly involved in this project (to allow unbiased facilitation of the consensus process) will facilitate the meeting.

Phase IV – Write up

Following the Consensus meeting, the proposed checklists for PRISMA-PC and PRISMA-C will be reviewed by the project Steering Committee to draft final checklists using concise, unambiguous, and comprehensive wording, taking into account of any comments obtained in the Delphi survey and the Consensus meeting regarding the wording of the items. Guideline documents will be written, separately for PRISMA-PC and PRISMA-C, including statement and an explanation and elaboration document that will provide detailed advice for each item and examples of good reporting in pediatric systematic review protocols and reports, respectively. The systematic review from Phase III will provide empirical evidence about the relevance and rationale to support pediatric specific reporting items of a systematic review. Results from this review will also provide an evidence base of studies about good reporting practice cited in an accompanying explanation and elaboration documents. Drafts of the statements and the explanation and elaboration manuscripts will be circulated to Consensus meeting participants

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to ensure that the documents accurately represent the decisions made during the meeting and provide examples of good reporting for specific items.

Phase V – Evaluation

A survey of pediatric systematic review authors will be conducted to introduce them to the new items in PRISMA-PC and PRISMA-C, establish the extent to which they had historically addressed those items in their own systematic reviews, and gather feedback on the usefulness of the extension items, including facilitators and barriers of its use. The survey participants will be identified through the database of corresponding authors maintained by Cochrane Child Health.

Phase VI – Integrated Knowledge Translation and Implementation

PRISMA-PC and PRISMA-C's potential for impacting clinical care in children can only be realized with an effective knowledge translation (KT) and implementation plan. The Steering Committee has been carefully selected to include principal knowledge users who will participate in all stages of the research process. Furthermore, a knowledge translation and dissemination plan will be developed and launched during the Consensus meeting that encompasses education, dissemination and endorsement by various key stakeholders. A Knowledge Translation Planning Template (24) will be followed to develop a KT plan for building awareness and understanding of the guideline (KT goals) with identified knowledge users (e.g. researchers, funders, journal editors). Active involvement of partners will be achieved by bringing representatives together from diverse international stakeholder groups in the development of the checklists, keeping them engaged throughout the development and evaluation process, and providing them with an active role in the strategic planning of actions to amplify the impact of PRISMA-PC and PRISMA-C. Beyond translating the guidelines, evidence based implementation strategies and processes will be developed to encourage its use.

A special session will be held in the Cochrane Colloquium to disseminate the meeting findings. All known (Cochrane) systematic reviewers that are active in child health will be invited to attend this KT meeting. In addition to disseminating knowledge about the need for a newborn and child extension of PRISMA and the method involved in developing this extension, attendees of this session will be invited to offer feedback on the checklist items and facilitators and barriers of its uptake. The goal of the dissemination plan is to maximize awareness, understanding, and use of the PRISMA extensions when reporting protocols and results of pediatric systematic reviews. The potential KT strategies that have been used and proved successful in other guideline development processes such as CONSORT, SPIRIT and PRISMA will be used. These include open access publication and endorsement of the guideline in multiple journals including targeted pediatric journals, endorsement by funding agencies and systematic review registration portals such as PROSPERO, presentations at conferences and other meetings, webinars, short (e.g. 5 minute) you-tube videos explaining each extension item with examples, and a dedicated website that will facilitate feedback about the guideline by end users. The findings will also be shared with the WHO guideline development group and experts

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dealing with Child & Adolescent health interventions and action plans. The final checklists will be copyrighted by the PRISMA-PC and PRISMA-C Groups under the Creative Commons License.

DISCUSSION

The methods employed in developing the PRISMA-PC and PRISMA-C checklists and the accompanying explanation and elaboration documents are based on best practice and evidence-based principles which are widely used in developing reporting guidelines (19). The selection of the Steering Committee will ensure that systematic reviewers, guideline developers and knowledge users with leadership roles in pediatric systematic reviews have actively participated throughout the project. The active recruitment of key stakeholder groups in the Delphi survey and the Consensus Meeting will ensure that a wide perspective is captured and will facilitate endorsement and implementation of the guidelines, hence maximizing their impact. Moreover, in accordance with the EQUATOR network recommendations, consensus on the checklist items will be achieved through an iterative process involving a combination of Delphi survey and Consensus meeting, thereby minimizing potential bias associated with less structured Consensus methods. The gathering of partners, health researchers, and knowledge users in the Consensus meeting will also lead to new and improved collaboration of stakeholders involved in pediatric systematic reviews, including funders, regulators, and journal editors. A systematic review informing the checklist item, with examples of best reporting practice, will ensure that evidence-based practical guidance is available to facilitate its implementation. By employing a validated framework of knowledge translation, we will enable active engagement of key stakeholders by assigning leading roles in the knowledge translation process for their respective stakeholders groups.

The resultant PRISMA-PC and PRISMA-C statements and explanation and elaboration documents will help authors write clear protocols and reports of pediatric systematic reviews and create a framework for reviewers and funders to assess publications and protocols. These checklists will be applicable to both Cochrane and non-Cochrane pediatric systematic reviews involving newborn and children. These checklists will also provide a tool for training students and researchers on pediatric systematic review methodology. Furthermore, end-users of the systematic review, such as pediatricians, policy makers, and other decision makers, will be able to evaluate systematic review validity and applicability in their evidence-based decision making process, thereby increasing the uptake of relevant evidence and ultimately improving child health outcomes.

Competing Interest

LA is a co-convener of the Cochrane Prospective Meta-analysis Methods Group, a member of the Cochrane Individual Participant Data Meta-analysis Methods Group, an author on many (Cochrane and non-Cochrane) pediatric systematic reviews and a member of the PRISMA-IPD extension working group; RS is the Coordinating Editor of the Cochrane Neonatal Group and is President and Director of Clinical Trials of the Vermont Oxford Network; ZB was a member of PRISMA-Equity extension. There are no other competing interests to declare by the authors.

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Author's Contribution

MZK conceived the study and made substantial contributions to design of the manuscript, acquisition of data; MZK and MO participated in the design and coordination to draft the manuscript, analysis and interpretation of data; MZK, MO, LA, LH, RS and DCI have been involved in drafting the manuscript or revising it critically for important intellectual content; All authors read and approved the final manuscript.

REFERENCES

1. Polkki T, Kanste O, Kaariainen M, Elo S, Kyngas H. The methodological quality of systematic reviews published in high-impact nursing journals: a review of the literature. Journal of clinical nursing. 2014;23(3-4):315-32.
2. Gagnier JJ, Kellam PJ. Reporting and methodological quality of systematic reviews in the orthopaedic literature. The Journal of bone and joint surgery American volume. 2013;95(11):e771-7.
3. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS medicine. 2009;6(7):e1000097.
4. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews. 2015;4(1):1.
5. Panic N, Leoncini E, de Belvis G, Ricciardi W, Boccia S. Evaluation of the endorsement of the preferred reporting items for systematic reviews and meta-analysis (PRISMA) statement on the quality of published systematic review and meta-analyses. PloS one. 2013;8(12):e83138.
6. Kapadia MZ, Askie L, Hartling L, Contopoulos-Ioannidis D, Bhutta ZA, Soll R, et al. Do systematic reviews on pediatric topics need special methodological considerations? Under Review. 2015.
7. Clyburne-Sherin A, Thurairajah P, Sampson M, Chan W, Offringa M, Kapadia MZ. Recommendations and evidence for reporting items in pediatric clinical trial protocols and reports: two systematic reviews. Trials. 2015.
8. Braga LH, Pemberton J, Demaria J, Lorenzo AJ. Methodological concerns and quality appraisal of contemporary systematic reviews and meta-analyses in pediatric urology. The Journal of urology. 2011;186(1):266-71.
9. Lundh A, Knijnenburg SL, Jorgensen AW, van Dalen EC, Kremer LC. Quality of systematic reviews in pediatric oncology--a systematic review. Cancer treatment reviews. 2009;35(8):645-52.
10. Cramer K, Wiebe N, Moyer V, Hartling L, Williams K, Swingler G, et al. Children in reviews: methodological issues in child-relevant evidence syntheses. BMC pediatrics. 2005;5:38.
11. Onland W, Offringa M, van Kaam A. Late (? 7 days) inhalation corticosteroids to reduce bronchopulmonary dysplasia in preterm infants. Cochrane Database of Systematic Reviews: Reviews; 2012.
12. Gao L, Mao Q, Wen D, Zhang L, Zhou X, Hui R. The effect of beta-blocker therapy on progressive aortic dilatation in children and adolescents with Marfan's syndrome: a meta-analysis. Acta Paediatrica. 2011;100(9):e101-e5.
13. Ducharme Francine M, Ni Chroinin M, Greenstone I, Lasserson Toby J. Addition of long-acting beta2-agonists to inhaled steroids versus higher dose inhaled steroids in adults and children with persistent asthma. Cochrane Database of Systematic Reviews: Reviews; 2010.
14. Irlam James H, Visser Marianne ME, Rollins Nigel N, Siegfried N. Micronutrient supplementation in children and adults with HIV infection. Cochrane Database of Systematic Reviews: Reviews; 2010.
15. Barlow J, Smailagic N, Ferriter M, Bennett C, Jones H. Group-based parent-training programmes for improving emotional and behavioural adjustment in children from birth to three years old. Cochrane Database of Systematic Reviews: Reviews; 2010.

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16. Jull A, Chen R. Parent-only vs parent-child (family-focused) approaches for weight loss in obese and overweight children: a systematic review and meta-analysis. Obesity Reviews. 2013;14(9):761-8.
17. S. Sangkomkamhang Ussanee PL, Laopaiboon M. Hepatitis B vaccination during pregnancy for preventing infant infection. Cochrane Database of Systematic Reviews. 2014.
18. Imdad A, Bhutta ZA. Routine iron/folate supplementation during pregnancy: effect on maternal anaemia and birth outcomes. Paediatric and Perinatal Epidemiology. 2012;26(Supplement 1):168-77.
19. Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. PLoS medicine. 2010;7(2):e1000217.
20. Stewart LA, Clarke M, Rovers M, Riley RD, Simmonds M, Stewart G, et al. Preferred Reporting Items for Systematic Review and Meta-Analyses of individual participant data: the PRISMA-IPD Statement. Jama. 2015;313(16):1657-65.
21. Welch V, Petticrew M, Tugwell P, Moher D, O'Neill J, Waters E, et al. PRISMA-Equity 2012 extension: reporting guidelines for systematic reviews with a focus on health equity. PLoS medicine. 2012;9(10):e1001333.
22. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. Bmj. 2014;348:g1687.
23. Boluyt N, Tjosvold L, Lefebvre C, Klassen TP, Offringa M. USefulness of systematic review search strategies in finding child health systematic reviews in medline. Archives of pediatrics & adolescent medicine. 2008;162(2):111-6.
24. Barwick M, inventorKnowledge Translation Planning Template. Ontario2013.

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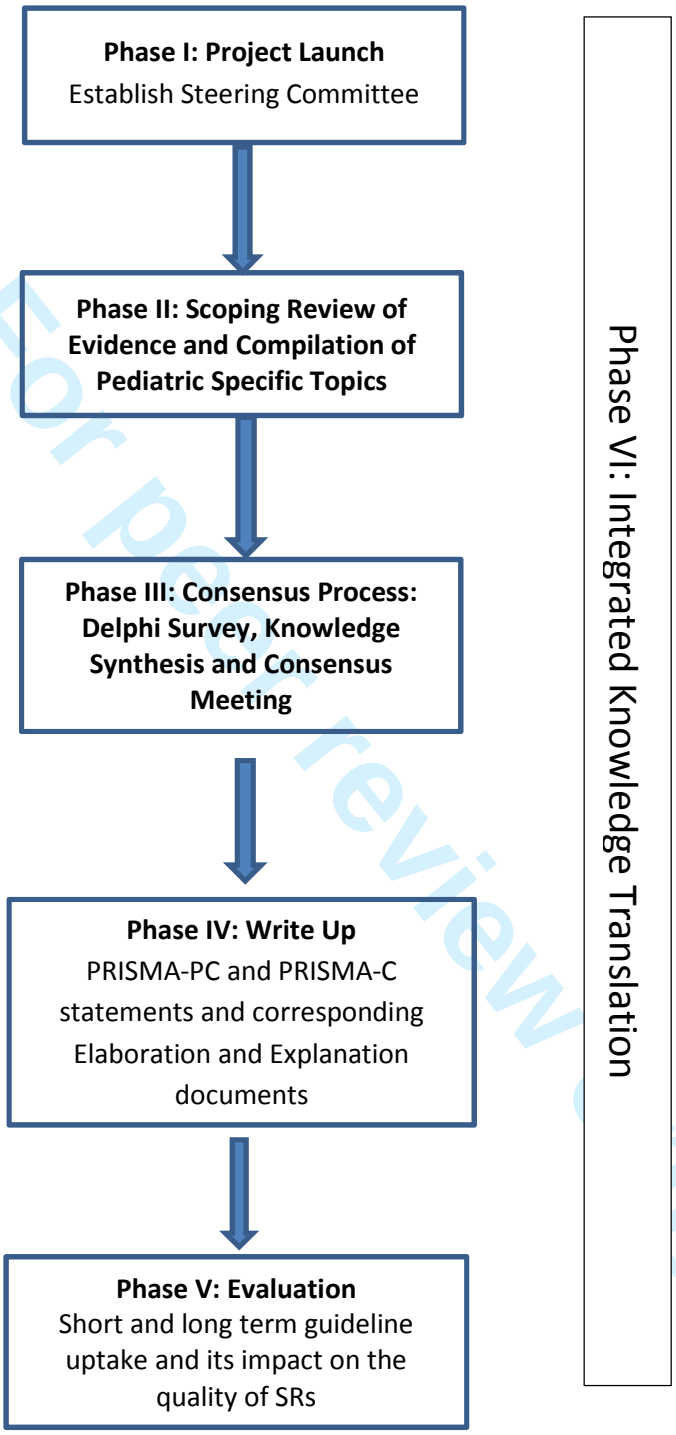
Figure 1: Workflow for PRISMA-PC and PRISMA-C



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PRISMA-Children (C) and PRISMA-Protocol for Children (P-C) Extensions: A study protocol for the development of guidelines for the conduct and reporting of systematic reviews and meta-analyses of newborn and child health research.

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Protocol

PRISMA-Children (C) and PRISMA-Protocol for Children (P-C) Extensions: A study protocol for the development of guidelines for the conduct and reporting of systematic reviews and meta-analyses of newborn and child health research

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ABSTRACT

Introduction: Pediatric systematic reviews differ from adult systematic reviews in several key aspects such as considerations of child tailored interventions, justifiable comparators, valid outcomes and child sensitive search strategies. Available guidelines, including PRISMA-P (2015) and PRISMA (2009), do not cover all the complexities associated with reporting systematic reviews in the pediatric population. Using a collaborative, multi-disciplinary structure, we aim to develop evidence- and consensus-based PRISMA-P-C (Protocol for Children) and PRISMA-C (Children) Extensions to guide pediatric systematic review protocol and completed review reporting.

Methods and Analysis: This project's methodology follows published recommendations for developing reporting guidelines and involves the following six phases; i) establishment of a steering committee representing key stakeholder groups; ii) a scoping review to identify potential Extension items; iii) three types of consensus activities including meetings of the steering committee to achieve high-level decisions on the content and methodology of the Extensions, a survey of key stakeholders to generate a list of possible items to include in the Extensions, and a formal consensus meeting to select the reporting items to add to, or modify for, the Extension; iv) the preliminary checklist items generated in phase III will be evaluated against the existing evidence and reporting practices in pediatric systematic reviews; v) extension statements and explanation and elaboration documents will provide detailed advice for each item and examples of good reporting; vi) development and implementation of effective knowledge translation of extension checklist, and an evaluation of the Extensions by key stakeholders.

Ethics and Dissemination: This protocol was considered a quality improvement project by the Hospital for Sick Children's Ethics Committee and did not require ethical review. The resultant checklists, jointly developed with all relevant stakeholder will be disseminated through peer-reviewed journals, national and international conference presentations. Endorsement of the checklist will be sought simultaneously in multiple journals.

KEYWORDS

PRISMA-P-C, PRISMA-C, Protocol, Pediatric, Systematic Review

Strengths and Limitations

- The methods chosen for the development of PRISMA-P-C and PRISMA-C extensions are based on evidence-based principles of reporting guideline development.
- The simultaneous development of reporting guideline for both protocol and reports of pediatric systematic reviews will ensure that relevant items in the protocol (PRISMA-P-C) are reflected in the report (PRISMA-C).

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- Identification of pediatric systematic reviewers from published reports for the Delphi survey will help in identifying an un-biased selection of participants than the project steering committee could provide alone.
- The involvement of various stakeholders in guideline development will ensure that a wide range of perspectives are captured and will help maximize the impact and implementation of the guideline by relevant stakeholders.

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BACKGROUND

Systematic reviews and meta-analyses are considered the highest level in the hierarchy of scientific evidence and are of fundamental importance in decision making by healthcare providers and policy makers. Systematic reviews may also identify the need for further research to establish evidence in a particular population or a sub-set of population. In order to maximize the potential use of synthesized evidence, there had been repeated calls for transparent and consistent reporting of systematic review (1-3). The Preferred Reporting Items in Systematic Review and Meta-Analysis (PRISMA 2009) (4) and PRISMA-P(rotocol-2015) (5) statements were developed to provide guidance on key elements needed for optimal reporting of systematic reviews and meta-analyses and their protocols, respectively, in order to maximize the completeness of reporting, transparency and replicability of such studies. An evaluation of the impact of endorsement of the PRISMA statement by specialty journals showed a significant increase of completeness of reporting and methodological quality of systematic reviews in those journals (6). Although the PRISMA statement was designed to improve the completeness of reporting of systematic reviews and meta-analyses, there are still other areas e.g., network (7), equity (8) and individual patient data (9) studies that were not fully addressed by the original statement, resulting in PRISMA extensions in these areas.

Rationale for "newborn and child specific" extension of PRISMA

Pediatric systematic reviews differ from adult systematic reviews in several key aspects. Some key issues identified relate to age specific growth and developmental stages of the patients, newborn and child tailored interventions. Since placebo response rates in drug trials appear to be higher in children compared to adults (10, 11), consequently pooled response rates are higher in children than for adults with similar conditions (12). The synthesis of evidence from trials into pediatric systematic reviews is impaired by the use of outcome measurement instruments that are neither qualified nor validated in pediatric sub-populations (13). Pediatric systematic reviews have also been reported weak in terms of the comprehensiveness in their search to identify primary studies (2). Consequently, search filters have been developed to ensure comprehensiveness of pediatric search terms (14-16). Other studies have used search hedges that cover concepts using terms, i.e. neonates, infants, adolescents, harvested from standard term indices to identify more potential relevant articles (17).Furthermore, for systematic reviews with a mixed adult and pediatric population, statistical analyses need to consider subgroup analyses according to targeted pediatric age groups to examine differences in intervention effects (18) . These pediatric specific methodological considerations play a role throughout the design, conduct and reporting of pediatric systematic reviews to permit adequate interpretation. The currently available guidelines, including PRISMA-P (2015) and PRISMA (2009), do not cover the complexities associated with reporting (protocols for) systematic reviews in the pediatric population. Hence, systematic reviews relating to newborn and/or children, including those with mixed adult and pediatric population, require modified and additional standards for reporting items.

The need for pediatric-specific items in reporting guidelines is also evident from a recent international Consensus meeting on Standard Protocol Items for Randomized Trials in Children

(SPIRIT-C) and Consolidated Standards of Reporting Trials in Children (CONSORT-C) held in Toronto in 2014, that agreed on 8 and 14 "pediatric-specific" extension items, respectively, for the design and conduct (SPIRIT-C) and reporting (CONSORT-C) of pediatric clinical trials (19). At the same meeting, a call was made for guidance to enable scientists to improve the conduct and reporting of systematic reviews in newborn and child health. Our goal is, therefore, to develop evidence based reporting guidelines for child relevant systematic review protocols and reports in order to improve transparency, quality and quantity of child relevant systematic review.

Objectives

Our primary objectives are: 1. to develop an evidence- and consensus-based PRISMA-P-C (**P**rotocol for **C**hildren) and PRISMA-C (**C**hildren) checklist items to guide pediatric systematic review protocol development and completed review reporting, and 2. to develop and launch a knowledge translation and implementation strategy that encompasses education, dissemination, endorsement and implementation of the final PRISMA-P-C and PRISMA-C checklists and accompanying guidance documents by key stakeholders.

Definition and scope of newborn and child relevant systematic reviews

PRISMA-P-C and PRISMA-C have adopted the same definition of a "systematic review" and "protocol" as PRISMA-P (5) and PRISMA (4). A systematic review collates all relevant evidence that fits pre-specified eligibility criteria to answer a specific research question. It uses explicit, systematic methods to minimize bias in the identification, selection, synthesis, and summary of relevant studies. A protocol is a document that presents an explicit plan for a systematic review and details the rationale and a priori methodological and analytical approaches for the review. The PRISMA-P-C and PRISMA-C checklists will be applicable to pediatric systematic reviews with or without a meta-analysis; and for systematic reviews of randomised controlled trials and/or observational studies.

Table 1: Scope of newborn and child relevant systematic reviews with examples

A newborn and/or child relevant systematic review meets one or more of the following criteria:
i) A systematic review with intended population of children only (0-18 years of age). Examples: "Late (> 7 days) inhalation corticosteroids to reduce bronchopulmonary dysplasia in preterm infants (20)" and "The effect of beta-blocker therapy on progressive aortic dilatation in children and adolescents with Marfan's syndrome: a meta-analysis (21)".
ii) A systematic review with intended population including both children and adult. Examples: "Addition of long-acting beta2-agonists to inhaled steroids versus higher dose inhaled steroids in adults and children with persistent asthma (22)" and "Micronutrient supplementation in children and adults with HIV infection (23)".
iii) A systematic review of family based interventions intended to improve the health and well-being of children. Examples: "Group-based parent-training programmes for improving emotional and behavioural adjustment in children from birth to three years old (24)" and "Parent-only vs parent-child (family-focused) approaches for weight loss in obese and overweight children: a systematic review and meta-analysis" (25).

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iv)	A systematic review of interventions in pregnancy with objectives to measure outcomes in the neonate. Examples: “Hepatitis B vaccination during pregnancy for preventing infant infection (26)” and “Routine iron/folate supplementation during pregnancy: effect on maternal anaemia and birth outcomes” (27).

METHODS/DESIGN

The project methodology follows published recommendations for developing reporting guidelines (28) and involves the following five phases (see also Figure 1):

Phase I – Project launch

A steering committee, who are also the authors of the current article, comprised of pediatric systematic review authors, methodologists and guidelines developers from leading research institutions (Child Health Evaluation Sciences, and Centre for Global Child Health, The Hospital for Sick Children; Ottawa Hospital Research Institute (OHRI), Alberta Research Centre for Health Evidence (ARCHE), Canada; Stanford University, USA; NHMRC Clinical Trials Centre, University of Sydney, Australia; Cochrane Child Health Field; Cochrane Childhood Cancer Group; Cochrane Neonatology Group) has been identified. An experienced librarian from the Hospital for Sick Children, Toronto with expertise in developing search strategies for such methodological systematic reviews will be added to the steering committee. The selection of the steering committee members was based on their extensive publication of pediatric systematic reviews and leadership role in systematic review methodology. The steering committee will manage the project via face-to-face (video conferencing) online meetings to discuss and finalize key steps of the guideline development process. They will also help recruit participants for the Delphi survey and Consensus meeting.

Phase II – Review of Evidence and compilation of pediatric specific topics

Based on the results of the scoping review that identified a need of pediatric extensions of PRISMA and PRISMA-P, a preliminary list of pediatric specific methodological issues will be compiled which may require detailed guidance to enhance the quality and consistency of reporting of pediatric systematic review protocols and reports. Furthermore, items that are relevant to pediatric systematic reviews will also be identified from the SPIRIT-C and CONSORT-C checklists. The two preliminary checklists for PRISMA-P-C and PRISMA-C will then be evaluated against the existing evidence and reporting practices in pediatric systematic reviews. The proposed knowledge synthesis will be completed using a recommended methodology for systematic review. The search strategy will be adopted from tested search filters developed for “systematic review”, “pediatric” and “protocol” (14). The Cochrane Database of Systematic Review and Database of Abstracts of Reviews of Effects (DARE) databases will be searched from January 2010 to December 2014. The reason for limiting the search from 2010 and beyond is because the steering committee decided to review the quality of evidence following the publication of a the PRISMA statement in 2009 (4). The titles and abstracts will be screened for the following eligibility criteria: i) a child-relevant systematic review (as per the definitions provided in Table 1); ii) published in English language; iii) not a commentary or editorial. A random sample of 300 pediatric systematic reviews will be included for this evidence synthesis.

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The screening of full text will continue until the desired sample size is achieved. We anticipate a limited number of published pediatric systematic review protocols, therefore, all the identified protocols that meet the inclusion criteria will be included. Data will be extracted on; i) the characteristics of the review; ii) whether the review fulfilled the reporting criteria identified in the proposed items; iii) examples of good reporting.

Phase III – Consensus Process

The PRISMA-P-C and PRISMA-C guideline development will involve two streams of consensus activities as follows:

Meetings of the steering committee: Steering committee meetings will be held regularly throughout the project to achieve high-level decisions on the content and methodology of the pediatric extensions of PRISMA guidelines. Following the synthesis of evidence in phase II, a formal meeting will be held with the steering committee to discuss each topic that requires further guidance. A further meeting will be held following a survey (described below) in which items will be discussed for which strong objection for their omission or inclusion has been received.

1. **Survey**: An electronic survey of international experts in systematic reviews will lead to the preliminary list of potential pediatric extension items for conducting (PRISMA-P-C) and reporting (PRISMA-C) pediatric systematic reviews. Survey methodology has been used as an initial step of guideline development in other guideline extensions, such as PRISMA-IPD (9) and PRISMA-Equity (8). Survey participants will be identified through the editorial boards of Cochrane Child Health, Cochrane Neonatal Group, leading systematic reviewers in the child health field, editorial boards of leading pediatric and other journals and through networks of our steering committee members. Potential survey participants will be invited by email to complete a web-based survey. The survey will remain open for 3 weeks. Eligibility criteria for survey participation will include a combination of experience in pediatric clinical research and systematic reviews or guideline development. In the survey, each item will be rated as “omit,” “possible,” “desirable,” or “essential” to include in the final checklists (29). The ranked items will then be divided into three groups. *Group I* will contain items with the highest rankings (rated as “essential” by ≥70% participants or “essential or desirable” by ≥90%), and these items will be included for a discussion in the Consensus meeting. *Group II* will contain items with moderate rankings (“essential” or “desirable” by ≥80% to <90%) and will be further discussed by the Steering Committee members for their inclusion or exclusion in the Consensus meeting. *Group III* will contain items with low rankings (i.e., <80% “essential” or “desirable”, or >70% “omit” or ≥85% “possible” or “omit”), and these items will be removed and will not be discussed further. Participants will have the opportunity to suggest new items that will be considered by the Steering Committee members to decide whether they should be discussed at the Consensus meeting. In addition, participants will be given an opportunity to comment on each item’s wording or provide general comments on its concept. We considered the need for several (usually three) rounds of the Delphi survey as unnecessary, as a similar multi-round Delphi survey exercise was recently undertaken for the development of SPIRIT-C (Children) and the concepts and feedback on pediatric specific items were already captured by experts in

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pediatric research and other stakeholders such as journal editors. The feedback for SPIRIT-C items was further reviewed by the steering committee while identifying PRISMA-P-C and PRISMA-C relevant topics. However, a survey will establish its applicability to pediatric systematic reviews from the perspective of relevant end users such as pediatric systematic reviewers, clinicians and methodologists.

2. Consensus meeting: A Consensus development meeting will be held to reach consensus regarding the minimum items required in a pediatric extension of PRISMA-P-C and PRISMA-C. The Cochrane Colloquium will provide the ideal venue to host this Consensus meeting, since this annual meeting is attended by systematic reviewers, representatives from Cochrane and Prospective Register of Systematic Reviews (PROSPERO), and end-users of pediatric systematic reviews such as patients and clinicians, funders, methodologists, guideline developers and journal editors, allowing them to gather under one umbrella for scientific exchange regarding systematic reviews and their methodology, as well as the opportunity to further develop methods. Hence the Cochrane Colloquium will facilitate the meeting of our goals and objectives to gather a wide range of stakeholders for the Consensus process.

   Each item of the checklist will be discussed in the context of evidence synthesized through the systematic review and results of the Delphi surveys. The voting process will follow methods used in previous Consensus meetings of guideline development. A preliminary round of voting will take place for each candidate item. Each item will be presented sequentially and debated in the light of the results from the Delphi survey and a summary of literature findings. Votes will be carried out anonymously using an online m-clicker voting system. In order to reach consensus, a classification scheme for selecting items to include in the checklists will be used, similar to the one used in developing the original PRISMA checklist. Briefly, a candidate item will be included within the final checklist if ≥80% of voters agree on its inclusion. Items with ≤20% votes for inclusion will be excluded from the final checklist. For items that do not reach consensus through the preliminary votes, round table discussions will be held, whereby participants will be given the opportunity to express their points of view in support for or against the inclusion of the item of interest. Discussions will be followed by a second round of voting with the same qualification criteria for inclusion. An experienced moderator not directly involved in this project (to allow unbiased facilitation of the consensus process) will facilitate the meeting.

Phase IV – Write up

Following the Consensus meeting, the proposed checklists for PRISMA-P-C and PRISMA-C will be reviewed by the project Steering Committee to draft final checklists using concise, unambiguous, and comprehensive wording, taking into account of any comments obtained in the Delphi survey and the Consensus meeting regarding the wording of the items. Guideline documents will be written, separately for PRISMA-P-C and PRISMA-C, including statement and an explanation and elaboration document that will provide detailed advice for each item and examples of good reporting in pediatric systematic review protocols and reports, respectively. The systematic review from Phase III will provide empirical evidence about the relevance and rationale to support pediatric specific reporting items of a systematic review. Results from this review will also provide an evidence base of studies about good reporting practice cited in an

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accompanying explanation and elaboration documents. Drafts of the statements and the explanation and elaboration manuscripts will be circulated to Consensus meeting participants to ensure that the documents accurately represent the decisions made during the meeting and provide examples of good reporting for specific items.

Phase V – Evaluation

A survey of pediatric systematic review authors will be conducted to introduce them to the new items in PRISMA-P-C and PRISMA-C, establish the extent to which they had historically addressed those items in their own systematic reviews, and gather feedback on the usefulness of the extension items, including facilitators and barriers of its use. The survey participants who were initially recruited for phase III of the project will be invited again to respond to this evaluation survey. In addition, new authors will be identified through the database of corresponding authors maintained by Cochrane Child Health.

Phase VI – Integrated Knowledge Translation and Implementation

PRISMA-P-C and PRISMA-C's potential for impacting clinical care in children can only be realized with an effective knowledge translation (KT) and implementation plan. The Steering Committee has been carefully selected to include principal knowledge users who will participate in all stages of the research process. Furthermore, a knowledge translation and dissemination plan will be developed and launched during the Consensus meeting that encompasses education, dissemination and endorsement by various key stakeholders. A Knowledge Translation Planning Template (30) will be followed to develop a KT plan for building awareness and understanding of the guideline (KT goals) with identified knowledge users (e.g. researchers, funders, journal editors). Active involvement of partners will be achieved by bringing representatives together from diverse international stakeholder groups in the development of the checklists, keeping them engaged throughout the development and evaluation process, and providing them with an active role in the strategic planning of actions to amplify the impact of PRISMA-P-C and PRISMA-C. Beyond translating the guidelines, evidence based implementation strategies and processes will be developed to encourage its use.

A special session will be held in the Cochrane Colloquium to disseminate the meeting findings. All known (Cochrane) systematic reviewers that are active in child health will be invited to attend this KT meeting. In addition to disseminating knowledge about the need for a newborn and child extension of PRISMA and the method involved in developing this extension, attendees of this session will be invited to offer feedback on the checklist items and facilitators and barriers of its uptake. The goal of the dissemination plan is to maximize awareness, understanding, and use of the PRISMA extensions when reporting protocols and results of pediatric systematic reviews. The potential KT strategies that have been used and proved successful in other guideline development processes such as CONSORT, SPIRIT and PRISMA will be used. These include open access publication and endorsement of the guideline in multiple journals including targeted pediatric journals, endorsement by funding agencies and systematic review registration portals such as PROSPERO, presentations at conferences and other meetings, webinars, short (e.g. 5 minute) you-tube videos explaining each extension item with

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examples, and a dedicated website that will facilitate feedback about the guideline by end users. The findings will also be shared with the WHO guideline development group and experts dealing with Child & Adolescent health interventions and action plans. The final checklists will be copyrighted by the PRISMA-P-C and PRISMA-C Groups under the Creative Commons License.

DISCUSSION

The methods employed in developing the PRISMA-P-C and PRISMA-C checklists and the accompanying explanation and elaboration documents are based on best practice and evidence-based principles which are widely used in developing reporting guidelines (28). The selection of the Steering Committee will ensure that systematic reviewers, guideline developers and knowledge users with leadership roles in pediatric systematic reviews have actively participated throughout the project. The active recruitment of key stakeholder groups in the Delphi survey and the Consensus Meeting will ensure that a wide perspective is captured and will facilitate endorsement and implementation of the guidelines, hence maximizing their impact. Moreover, in accordance with the EQUATOR network recommendations, consensus on the checklist items will be achieved through an iterative process involving a combination of Delphi survey and Consensus meeting, thereby minimizing potential bias associated with less structured Consensus methods. The gathering of partners, health researchers, and knowledge users in the Consensus meeting will also lead to new and improved collaboration of stakeholders involved in pediatric systematic reviews, including funders, regulators, and journal editors. A systematic review informing the checklist item, with examples of best reporting practice, will ensure that evidence-based practical guidance is available to facilitate its implementation. By employing a validated framework of knowledge translation, we will enable active engagement of key stakeholders by assigning leading roles in the knowledge translation process for their respective stakeholders groups.

Potential challenges and mitigation strategies

A key challenge is maximising both the breath and the depth of this work to enhance comprehensiveness and rigor, while ensure timely completion of tasks. We anticipate two years for the completion of this project (May 2015 to April 2017) and the final PRISMA-P-C and PRISMA-C statements and E&E will be published in summer 2017. We have engaged a broad team of co-investigators and collaborators in pediatric systematic reviews and reporting guideline development who will provide support in all aspects of this project such as early critical review of the research findings. We will rely on our experience in conducting evidence synthesis for reporting guideline development such as CONSORT-C and SPIRIT-C (19). Though the current project examines in-depth reporting features of pediatric systematic reviews, based on our intimate knowledge on the subject matter, we are confident that the systematic review can be completed in a timely and efficient manner. Another challenge is ensuring integrated and end of project knowledge translation of new evidence generated by the synthesis and Delphi survey. Our ongoing collaborations with our knowledge users that comprised of the network of our steering committee as well as the potential Delphi participants who were the authors of recently published pediatric systematic review will ensure that the scope meets their decision-making needs and expectations, while adhering to timelines and deliverables. Our

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team has previously completed several successful collaborative projects with diverse stakeholders, and will be a highly effective team. Finally, implementation of the new reporting standard by pediatric systematic reviewers in their future studies may present challenges. Through our involvement of key research leaders and engaging diverse stakeholders and collaborators we hope to disseminate to a large audience in a timely and effective manner.

The resultant PRISMA-P-C and PRISMA-C statements and explanation and elaboration documents will help authors write clear protocols and reports of pediatric systematic reviews and create a framework for reviewers and funders to assess publications and protocols. These checklists will be applicable to both Cochrane and non-Cochrane pediatric systematic reviews involving newborn and children. These checklists will also provide a tool for training students and researchers on pediatric systematic review methodology. Furthermore, end-users of the systematic review, such as pediatricians, policy makers, and other decision makers, will be able to evaluate systematic review validity and applicability in their evidence-based decision making process, thereby increasing the uptake of relevant evidence and ultimately improving child health outcomes.

Competing Interest

LA is a co-convener of the Cochrane Prospective Meta-analysis Methods Group, a member of the Cochrane Individual Participant Data Meta-analysis Methods Group, an author on many (Cochrane and non-Cochrane) pediatric systematic reviews and a member of the PRISMA-IPD extension working group; RS is the Coordinating Editor of the Cochrane Neonatal Group and is President and Director of Clinical Trials of the Vermont Oxford Network; ZB was a member of PRISMA-Equity extension. There are no other competing interests to declare by the authors.

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Author's Contribution

MZK conceived the study and made substantial contributions to design of the manuscript, acquisition of data; MZK and MO participated in the design and coordination to draft the manuscript, analysis and interpretation of data; MZK, MO, LA, LH, RS and DCI have been involved in drafting the manuscript or revising it critically for important intellectual content; All authors read and approved the final manuscript.

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REFERENCES

1. Sacks HS, Berrier J, Reitman D, Ancona-Berk VA, Chalmers TC. Meta-Analyses of Randomized Controlled Trials. New England Journal of Medicine. 1987;316(8):450-5.
2. Moher D, Soeken K, Sampson M, Ben-Porat L, Berman B. Assessing the quality of reports of systematic reviews in pediatric complementary and alternative medicine. BMC pediatrics. 2002;2:3.
3. Moher D, Tetzlaff J, Tricco AC, Sampson M, Altman DG. Epidemiology and reporting characteristics of systematic reviews. PLoS medicine. 2007;4(3):e78.
4. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS medicine. 2009;6(7):e1000097.
5. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews. 2015;4(1):1.
6. Panic N, Leoncini E, de Belvis G, Ricciardi W, Boccia S. Evaluation of the endorsement of the preferred reporting items for systematic reviews and meta-analysis (PRISMA) statement on the quality of published systematic review and meta-analyses. PloS one. 2013;8(12):e83138.
7. Hutton B, Salanti G, Chaimani A, Caldwell DM, Schmid C, Thorlund K, et al. The quality of reporting methods and results in network meta-analyses: an overview of reviews and suggestions for improvement. PloS one. 2014;9(3):e92508.
8. Welch V, Petticrew M, Tugwell P, Moher D, O'Neill J, Waters E, et al. PRISMA-Equity 2012 extension: reporting guidelines for systematic reviews with a focus on health equity. PLoS medicine. 2012;9(10):e1001333.
9. Stewart LA, Clarke M, Rovers M, Riley RD, Simmonds M, Stewart G, et al. Preferred Reporting Items for Systematic Review and Meta-Analyses of individual participant data: the PRISMA-IPD Statement. Jama. 2015;313(16):1657-65.
10. Rheims S, Cucherat M, Arzimanoglou A, Ryvlin P. Greater response to placebo in children than in adults: a systematic review and meta-analysis in drug-resistant partial epilepsy. PLoS medicine. 2008;5(8):e166.
11. Fernandes R, Ferreira JJ, Sampaio C. The placebo response in studies of acute migraine. The Journal of pediatrics. 2008;152(4):527-33, 33 e1.
12. Weimer K, Gulewitsch MD, Schlarb AA, Schwille-Kiuntke J, Klosterhalfen S, Enck P. Placebo effects in children: a review. Pediatr Res. 2013;74(1):96-102.
13. Sinha I, Jones L, Smyth RL, Williamson PR. A systematic review of studies that aim to determine which outcomes to measure in clinical trials in children. PLoS medicine. 2008;5(4):e96.
14. Boluyt N, Tjosvold L, Lefebvre C, Klassen TP, Offringa M. USefulness of systematic review search strategies in finding child health systematic reviews in medline. Archives of pediatrics & adolescent medicine. 2008;162(2):111-6.
15. Kastner M, Wilczynski NL, Walker-Dilks C, McKibbon KA, Haynes B. Age-specific search strategies for Medline. Journal of medical Internet research. 2006;8(4):e25.
16. Leclercq E, Leeflang MM, van Dalen EC, Kremer LC. Validation of search filters for identifying pediatric studies in PubMed. The Journal of pediatrics. 2013;162(3):629-34 e2.
17. Levy PT, Machefsky A, Sanchez AA, Patel MD, Rogal S, Fowler S, et al. Reference Ranges of Left Ventricular Strain Measures by Two-Dimensional Speckle-Tracking Echocardiography in Children: A Systematic Review and Meta-Analysis. Journal of the American Society of Echocardiography.
18. Cramer K, Wiebe N, Moyer V, Hartling L, Williams K, Swingler G, et al. Children in reviews: methodological issues in child-relevant evidence syntheses. BMC pediatrics. 2005;5:38.

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19. Clyburne-Sherin AV, Thurairajah P, Kapadia MZ, Sampson M, Chan WW, Offringa M. Recommendations and evidence for reporting items in pediatric clinical trial protocols and reports: two systematic reviews. Trials. 2015;16:417.
20. Onland W, Offringa M, van Kaam A. Late (? 7 days) inhalation corticosteroids to reduce bronchopulmonary dysplasia in preterm infants. Cochrane Database of Systematic Reviews: Reviews; 2012.
21. Gao L, Mao Q, Wen D, Zhang L, Zhou X, Hui R. The effect of beta-blocker therapy on progressive aortic dilatation in children and adolescents with Marfan's syndrome: a meta-analysis. Acta Paediatrica. 2011;100(9):e101-e5.
22. Ducharme Francine M, Ni Chroinin M, Greenstone I, Lasserson Toby J. Addition of long-acting beta2-agonists to inhaled steroids versus higher dose inhaled steroids in adults and children with persistent asthma. Cochrane Database of Systematic Reviews: Reviews; 2010.
23. Irlam James H, Visser Marianne ME, Rollins Nigel N, Siegfried N. Micronutrient supplementation in children and adults with HIV infection. Cochrane Database of Systematic Reviews: Reviews; 2010.
24. Barlow J, Smailagic N, Ferriter M, Bennett C, Jones H. Group-based parent-training programmes for improving emotional and behavioural adjustment in children from birth to three years old. Cochrane Database of Systematic Reviews: Reviews; 2010.
25. Jull A, Chen R. Parent-only vs parent-child (family-focused) approaches for weight loss in obese and overweight children: a systematic review and meta-analysis. Obesity Reviews. 2013;14(9):761-8.
26. S. Sangkomkamhang Ussanee PL, Laopaiboon M. Hepatitis B vaccination during pregnancy for preventing infant infection. Cochrane Database of Systematic Reviews. 2014.
27. Imdad A, Bhutta ZA. Routine iron/folate supplementation during pregnancy: effect on maternal anaemia and birth outcomes. Paediatric and Perinatal Epidemiology. 2012;26(Supplement 1):168-77.
28. Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. PLoS medicine. 2010;7(2):e1000217.
29. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. Bmj. 2014;348:g1687.
30. Barwick M, inventorKnowledge Translation Planning Template. Ontario2013.

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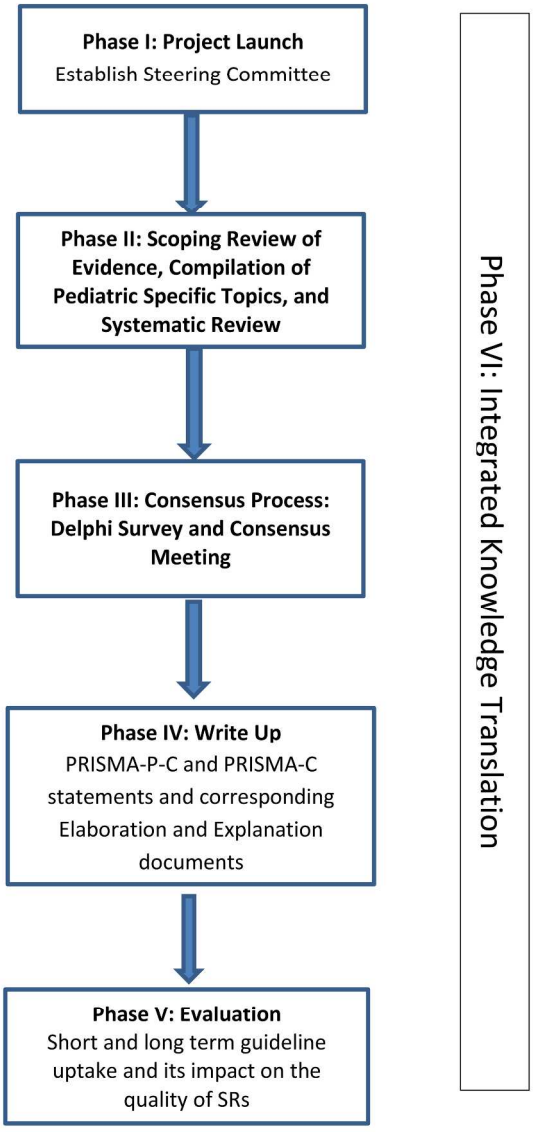
Figure 1: Workflow for PRISMA-P-C and PRISMA-C



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