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Development of *Preferred Reporting Items for Systematic reviews and Meta-Analysis* - Protocols for Children (PRISMA-PC) and Reporting (PRISMA-C)

Project Team: This project is led by Dr. Mufiza Kapadia (Postdoctoral Fellow, EnRICH Lab, Child Health Evaluation Sciences, The Hospital for Sick Children) under the supervision of Dr. Martin Offringa (Senior Scientist, Child Health Evaluation Sciences, The Hospital for Sick Children and Professor of Pediatrics, University of Toronto)

Background: Systematic reviews (SRs) and meta-analyses are keys to decision making by healthcare providers and policy makers. However, the methodological quality of SR has been questioned recently, even for those published in high impact factor journals. In 2009, the *Preferred Reporting Items for Systematic reviews and Meta-Analysis* **(**PRISMA) statement was published to provide guidance on elements to enhance *reporting* of systematic reviews and meta-analyses of treatment comparisons in order to maximize the transparency, replicability, and quality of such studies. Yet, the reporting stage is too late to correct errors in design and conduct. SR protocols are seldom published with the exception of a current initiative, an international *Prospective Register of Ongoing Systematic Reviews protocols* (PROSPERO), launched in 2011. In 2014, a guideline for reporting of systematic review *protocols*, namely PRISMA-P was developed; it is currently under review for publication. The problem gets greater in child health SRs, the evidence shows that there usually lack a sub-group analysis for pediatric sub-populations, and health outcomes are used that are neither qualified nor validated in the pediatric sub-populations. The lack of guidance for the design and reporting specific methodological features of these SRs impairs decision making in child health. Through this project for my postdoctoral fellowship, I aim to develop an extension of Preferred Reporting Items for Systematic reviews and Meta-Analysis - *Protocols* for Children (PRISMA-*PC*) and *Reporting* (PRISMA-C).

Methods: This research project will be conducted in five phases and will follow the process for guideline development designed by the well known Enhancing the QUAlity and Transparency Of health Research (EQUATOR) group. The first phase (project launch) will consist of the establishment of a Project Team and International Advisory Group (IAG) that will comprise of authors and methodologists with vast experience in pediatric SRs. In the second phase (Delphi Process) we will synthesize existing evidence on quality of reporting of pediatric clinical trials, SRs and meta-analyses, and compile a preliminary list of pediatric-specific topics which may require detailed guidance to enhance the quality and consistency of designing and reporting pediatric SRs. A two phase Delphi process will then generate a short-list of possible pediatric extension items to include in the PRISMA-PC and PRISMA-C extensions. Next, in phase 3, these items will be presented, discussed in a formal consensus meeting, debated and refined into a final checklist for the extensions. Furthermore, in the consensus meeting, knowledge translation avenues will be identified for wide implementation of the final products. Participants for the consensus meeting will include leading national and international experts in SR methodology, reporting guideline developers, journal editors, representatives from Cochrane and PROSPERO, and end-users of pediatric SRs. Fourth, the guideline documents PRISMA-PC and PRISMA-C will be written, including an *explanation and elaboration (E&E) document* containing detailed reporting recommendations for each item and examples. In the final phase 5, a multiphase evaluation will be designed to explore the impact of PRISMA-PC and PRISMA-C guidelines on the quality of pediatric SR protocols and reports respectively. A

survey of SR authors in pediatric clinical trials 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 SR, and gather feedback on the usefulness of the extension items, including facilitators and barriers of its use.

Conclusion: The resultant pediatric extension PRISMA-PC and PRISMA-C will 1) help authors write clear protocols and reports of their pediatric SRs, 2) create a framework for reviewers that assess publications, 3) expedite funding evaluations, 4) provide a tool for training students and researchers on pediatric SR methodology, and 5) help end-users of the SR such as pediatricians and policy makers to better evaluate SR's validity and applicability in their decision making process.