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Impact of Using Patient-reported Outcome Measures in Routine Clinical Care of Pediatric Patients with Chronic Conditions: A Systematic Review Protocol

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Impact of Using Patient-reported Outcome Measures in Routine Clinical Care of Pediatric Patients with Chronic Conditions: A Systematic Review Protocol

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Abstract:

Introduction:

Chronic diseases among children are associated with lower health-related quality of life (HRQOL) and higher utilisation of healthcare services. Integrating Patient-Reported Outcomes Measures (PROMs) in routine clinical care has been shown to reduce utilisation of healthcare services while improving patient outcomes. The objectives of our study are to: 1) identify previously implemented and evaluated PROMs for chronic conditions in pediatric settings; 2) Consolidate the evidence to evaluate the impact of using PROMs on health-related quality of life, healthcare utilisation, patient outcomes (e.g., symptoms control) and quality of care among pediatric patients with chronic conditions. The findings from this review will inform the future integration of PROMs in pediatric clinical practice.

Methods and analysis:

We will systematically search the following electronic databases: MEDLINE, EMBASE, CINAHL, PsychINFO and Cochrane library. Reference lists of included studies will also be searched in Web of Science (Thomson Reuters) database to ensure more complete coverage. Two reviewers will independently screen the studies and abstract the data using standardized form. Extracted data will be analysed and synthesized. Finally, a narrative synthesis of summaries data will be presented.

Ethics and dissemination:

Ethical approval is not required, as the proposed systematic review will use data from published research articles. The results of this study will be disseminated through publication in peer-

reviewed journals, scientific conferences and meetings, and the lead author's doctoral dissertation.

Strengths and limitations of this study:

- A key strength of this study is that it is a first systematic review to evaluate the impact of Patient-reported Outcome Measures (PROMs) on the Health-related Quality of Life (HRQOL), utilisation of healthcare services, patient outcomes, and quality of care amongst pediatric patients with chronic conditions.
- The findings of this study will provide crucial evidence for integration of PROMs in pediatric clinical care.
- Another strength of this systematic review is that patient-partners will be consulted throughout the process to assess the face validity of the included studies verify if the extracted data is meaningful from the patient's perspective.
- Exclusion of studies that are not published in English is a potential limitation of this systematic review.

Introduction:

Children with chronic diseases report having a lower health related quality of life (HRQOL) and higher utilisation of healthcare services compared to their healthy peers; they require complex care [1]. Higher utilisation of healthcare services, including higher rates of hospitalization for these populations, poses a challenge for healthcare systems to provide quality care to children with chronic diseases[2, 3].

Patient-reported outcome (PRO) are defined as - " the measurement of any aspect of a patient's health status that comes directly from the patient (i.e., without the interpretation of the patient's responses by a physician or anyone else)"[4]. Patient-reported Outcomes (PROMs) are the tools or instruments used to measure PROs. Evidence from adult populations suggests that the integration of PROMs in clinical care enhances patient-clinician communication, reduces the use of healthcare services, and improves HRQOL[5-8].

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PROMs are mostly self-completed questionnaires that measure the patient's health status by asking them about outcomes, such as their symptoms and aspects that may be affected by the disease(s) and/or treatment, including physical, psychological, social, overall wellbeing and HRQOL [4, 9, 10]. PROMs are standardized and validated questionnaires that are either generic or condition-specific. Generic PROMs can be used for all patients which allows comparison of outcomes between different patient groups[11]. One the other hand, condition-specific PROMs are used for specific conditions, making it more sensitive to outcomes associated with that particular condition. This systematic review aims to identify previously implemented and evaluated generic or diseases-specific PROMs in pediatric settings.

PROMs also generate 'patient-centered data', so PROMs are increasingly being used as organizational performance measures by clinicians and healthcare administrators to enhance the quality of care [12, 13] Although PROMs are being used to assess the effectiveness of new treatment regimens or surgical procedures, or improve quality of care, evidence around their effectiveness in pediatric clinical care are still scarce [14]. Due to the scarcity of evidence, they have not been systematically integrated into clinical care [15, 16]. To fill this evidence gap, the current systematic review aims to evaluate the impact of PROMs on HRQOL, utilisation of healthcare services, patient outcomes, and quality of care amongst pediatric patients with chronic conditions.

Impact of PROMs on:

1. Health Related Quality of Life (HRQOL):

According to the World Health Organization, HRQOL is "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [17]. Chronic conditions pose a greater risk for psychosocial issues among children[18], so the use of PROMs in clinical care may be helpful in identifying, discussing and eventually resolving aspects associated with HRQOL for these populations. Therefore, it is important to consolidate evidence on the use of PROMs and assess whether their implementation in clinical care can feasibly improve HRQOL and outcomes among children with chronic diseases.

2. Healthcare Utilisation:

Chronic diseases among children are associated with higher use of health care services including higher hospitalisation rates and length of stay in comparison to healthy children [19, 20]. Evidence from adult patient populations suggests that the lower scores on PROMs were strongly associated with higher risk of death and hospitalisation[21]. The use of PROMs is associated with improved symptom control and increased supportive care measures [22]. Further, using PROMs in clinical care enables patients in the self-management of their long-term chronic conditions [23]. For the parents of pediatric patients, caring for their hospitalised child often results in lost income and additional strain [22]. This is in addition to the detrimental impacts hospitalisation can have on the social and economic status for the child in adulthood [24, 25]. Considering the capacity of PROMs to predict adverse events and identify patients at greater risk for hospitalisation, it is essential to gather evidence regarding the role of PROMs on healthcare utilisation.

3. Quality of Care:

Researchers are increasingly utilizing PROMs to assess performance of healthcare providers to improve the quality of care and patient satisfaction [26]. PROMs can play an important role in providing patient-centered care by focusing on the patient's health goals and guiding therapeutic decisions [27]. Healthcare systems have been incorporating advanced electronic platforms to support and simplify the implementation of PROMs in the clinical setting [14, 28, 29]. The use of PROMs data in an integrated manner would enable healthcare systems to orient evidence-based and patient-centered care. Evidence gathered through this systematic review will help healthcare systems to support quality improvement initiatives and develop effective strategies to further enhance quality of care.

Objectives:

The objectives of our study are to: 1) identify previously implemented and evaluated generic or specific PROMs for chronic conditions in pediatric settings; 2) consolidate the evidence to evaluate the impact of using PROMs on HRQOL, healthcare utilisation, patient outcomes (e.g., symptoms control), and quality of care amongst pediatric patients with chronic conditions.

Methods and Analysis:

Design:

This protocol was developed according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISM-P) checklist[30], while the administration of the review and reporting will be carried out according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines[31]. The protocol for this review has been registered with PROSPERO, an international database of prospectively registered systematic reviews in health and social care (Registration number: CRD42018109035). Patient-partners will be consulted throughout the process to work with researchers to assess the face validity of the included studies and develop data extraction forms and an accompanying guidance document. The patient-partners are five individuals (3 patients and 2 family-caregivers) that are members of the larger patient and family advisor group at the Alberta Children's Hospital.

Search strategy:

Our search strategy was developed according to the research question and guided by the study objectives. Keywords used for each key domains of the research question are as follows:

Population: Keywords like 'child', 'adolescent', and 'pediatric care' will be used to identify studies focusing on pediatric populations (18 years or younger).

Intervention: The interventions of interest for this review are Patient-Reported Outcome Measures (PROMs), so keywords like 'patient-reported outcomes', 'patient outcome assessment' and combination of 'outcome' and 'measures' along with the associated abbreviations (PRO, PROM) will be used to capture studies implementing these measures in clinical care.

Medical Outcomes: The medical outcomes of interest for the systematic review are the impact of PROMs on HRQOL, healthcare utilisation, patient outcomes, and quality of care. Keywords associated with the use of healthcare services including 'visits to emergency services', 'length of stay', 'patient admission', and 'patient readmission' to capture studies focusing on the overall utilisation of these services.

Keywords associated with patient outcomes such as HRQL, and the indicators for the quality of healthcare will be used to build a robust search strategy which will include studies reporting these outcomes. The Boolean operator 'OR' will be used to combine terms within each outcome category and then the Boolean operator 'AND' will be used to combine these concepts.

Information sources:

We will systematically search MEDLINE (Ovid interface,1950 onwards), EMBASE (Ovid Interface, 1974 onwards), CINAHL Plus with Full Text (EBSCOhost interface, 1982 onwards), PsycINFO (Ovid interface, 1803 onwards) and Cochrane Library (Ovid Interface, 1991 onwards). In addition to these electronic bibliographic databases, the reference lists of included studies will be searched in Web of Science (Thomson Reuters) database to ensure more complete coverage of the literature.

The search strategy for MEDLINE was developed iteratively with input from this systematic review team and support from a medical sciences librarian who has expertise in systematic review searching at the University of Calgary. As part of this iterative process, a primary search strategy was applied and 100 randomly chosen abstracts were reviewed by the systemic review team. These randomly chosen abstracts helped to specify the search strategy to ensure that it retrieves a high proportion of the eligible and key studies in this area. This revised search strategy was finalised after consulting again with the medical sciences librarian at the University of Calgary, and again after reviewing it with the senior researchers on the systemic review team with expertise in patient-oriented research.

Study design limits will not be imposed on the search. Due to limited capacity in translating non-English articles, our literature search will be limited to the English language. Based on the recent evidence [32], we do not expect to introduce a systematic bias due the use of language restrictions in our systematic review. The MEDLINE strategy [See supplementary appendix for the full MEDLINE (Ovid interface,1950 onwards) search strategy] will be tested and adapted to the syntax of all other databases.

Selection of studies:

Specific inclusion and exclusion criteria outlined below was developed after reviewing 100 randomly chosen abstracts by the members of the systematic review team (BM, AC, SB) and through consultations with the librarian (DL) and senior researchers (MS, LH).

Inclusion criteria:

1. Studies including pediatric population and questionnaires completed by pediatric patients with chronic conditions (up to 18 years old)

2. Studies focusing primarily on the implementation and use of PROMs in pediatric chronic care
3. Prospective studies
4. At least one of the following outcomes was reported: effects on patient outcomes such as HRQOL, symptom control, mortality, healthcare utilization, quality of care, and related measures.

Exclusion criteria:

1. Studies reporting the use of PROMs for acute conditions, dental problems, pharmaceutical drug testing or surgical outcomes assessment.
2. Studies utilising secondary or retrospective data on PROMs.
3. Studies validating PROMs or testing methods for collecting/analysing PROMs
4. Descriptive studies and reviews on PROMs to describe burden of disease and treatment
5. Studies reporting findings in languages other than English
6. Studies published prior to the year 2000

Data Management:

Literature search results will be uploaded to EndNote Reference Management Software (V.8). EndNote will be used to remove duplicate references, screen, and manage all the references throughout the review process. A PRISMA flow diagram will be constructed to summarise the selection process.

Selection process:

For the primary screening stage, the titles and abstracts of the studies retrieved will be independently screened by two reviewers working in pairs (SB, AC and BM) using the pre-

determined eligibility criteria. This will reduce the potential for individual bias and the possibility of excluding relevant articles. Following the primary screening of the abstracts, full-text articles will be retrieved for studies meeting eligibility criteria or where titles or abstracts do not provide sufficient information to warrant their exclusion. Disagreements between reviewers will be resolved through discussion, and a third reviewer will be approached if the disagreement persists. Neither of the reviewers will be blind to the journal titles, study authors or the institutions.

At the full-text review stage, reasons for excluding studies will be recorded. Included full-text studies will be circulated within the systematic review team and our patient-partners to assess the face validity of the included studies, to develop a data extraction form and an accompanying guidance document. This form will be pilot tested by two reviewers (SB, AC) who will independently extract data from at least two selected articles. Extracted data from these articles will be presented to the whole research team to ensure consistency in data extraction. At this stage, a patient partner will be consulted to verify that the extracted data is meaningful from the patient's perspective, ensuring that our study conforms to patient-oriented research.

Data extraction:

Two reviewers (SB, AC) will independently extract data from the included studies using a standardized data extraction form to reduce errors in data extraction. The data extraction form will include definitions of the variables to be extracted.

The following data will be extracted:

1. Summary data of included studies (Including author, year of publication, pediatric setting (tertiary, community care), location, patient population characteristics, chronic condition under study
2. Type of PROM identified with descriptive statistics summarizing general characteristics (Including name of the PROM, generic vs. specific and mode of administration, collection and reporting)
3. Reported outcome(s) of interest (Including impact on HRQOL, healthcare utilisation, patient outcomes and quality of care)

Data synthesis:

Extracted data will be presented in tables to summarise the results. Meta-analysis will be conducted using a random-effects model if there is sufficient homogeneity in terms of study design, type of intervention, comparators, and outcomes among included studies.

Dissemination:

The findings of this review will be disseminated through peer-reviewed publications, conference presentations and included in the lead author's doctoral dissertation.

Discussion:

Potential limitations of this study relate to the inability of predicting the strength of the evidence from the systematic review, however we will try to overcome this limitation by following a rigorous methodology and capitalize on our team members' expertise in knowledge synthesis.

This systematic review serves as a crucial step in the direction of integrating PROMs in pediatric clinical care. It will also reveal the extent to which PROMs were successful in affecting HRQOL, healthcare services utilization, patient outcomes and quality of care for chronic diseases in pediatric population. Results of this review will guide healthcare policy and clinical care practices to incorporate pediatric patients' perspectives to deliver patient-centred care.

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Contributions:

MS conceived the idea. SB drafted the manuscript. All authors provided comments on the manuscript. All authors contributed to the development of the selection criteria and data extraction criteria. SB, BM and AC developed the search strategy. MS and LH provided expertise on the use of patient-reported outcomes in clinical practice. All authors read, provided feedback, and approved the final manuscript.

Acknowledgements: The authors thank Lorraine Toews, Medical Sciences Librarian, University of Calgary for her assistance in development of the search strategy as detailed in the methods section of the protocol.

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Competing interests: None declared

Appendix I: Search strategy for Medline

1. adolescen*.tw,kf.
2. child*.tw,kf.
3. (p?ediatric adj care).tw,kf.
4. Child Health Services/
5. Child/
6. Adolescent/
7. Child, Hospitalized/
8. Adolescent, Hospitalized/
9. or/1-8
10. patient outcome assessment*.tw,kf.
11. patient reported outcome measure*.tw,kf.
12. patient reported treatment outcome*.tw,kf.
13. (PROs or PROMs or PROMIS).tw,kf.
14. self-report* measure*.tw,kf.
15. self-report* outcome*.tw,kf.
16. Patient Reported Outcome Measures/
17. patient reported outcome*.tw,kf.
18. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. (emergency adj (admission* or attendance or attender* or readmission* or re-admission* or visit*)).tw,kf.
20. (hospital adj (admission* or readmission* or re-admission* or visit*)).tw,kf.
21. hospital length of stay.tw,kf.
22. Emergency Service, Hospital/ut, td, sn, ec [Utilization, Trends, Statistics & Numerical Data, Economics]
23. Hospitalization/
24. hospitali*.tw,kf.
25. length of stay/
26. Patient Admission/
27. Patient Readmission/
28. (quality adj2 (care or healthcare)).tw,kf.
29. (quality adj2 health adj2 care).tw,kf.
30. Quality Indicators, Health Care/
31. Quality of Health Care/
32. quality of life.tw,kf.
33. HRQOL.tw,kf.
34. Quality of Life/
35. *nurse-patient relations/ or *physician-patient relations/
36. or/19-35
37. 9 and 18 and 36
38. limit 37 to (yr="2000 -Current" and english)

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25. length of stay/
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Strengths and limitations of this study:

- A key strength of this study is that it is a first systematic review to evaluate the impact of Patient-reported Outcome Measures (PROMs) on the Health-related Quality of Life (HRQOL), utilisation of healthcare services, patient outcomes, and quality of care amongst pediatric patients with chronic conditions.
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- Exclusion of studies that are not published in English is a potential limitation of this systematic review.

Introduction:

Children with chronic diseases report having a lower health related quality of life (HRQOL) and higher utilisation of healthcare services compared to their healthy peers; they require complex care [1]. Higher utilisation of healthcare services, including higher rates of hospitalization for these populations, poses a challenge for healthcare systems to provide quality care to children with chronic diseases[2, 3]. According to the World Health Organization's definition, chronic diseases are those that are not passed from person to person, they are of long duration and generally slow have progression[4].

Patient-reported outcome (PRO) are defined as - " the measurement of any aspect of a patient's health status that comes directly from the patient (i.e., without the interpretation of the patient's responses by a physician or anyone else)"[5]. Patient-reported Outcome Measures (PROMs) are the tools or instruments used to measure PROs. Evidence from adult populations suggests that the integration of PROMs in clinical care enhances patient-clinician communication by increasing the frequency of discussion of patient outcomes during consultations[6]. Among patients with metastatic cancer, integration of PROMs in routine clinical care was associated with increased survival compared with usual care[7], among patients with arthritis, it improved self-perceived health and disease activity[8]. It also reduces the use of healthcare services by improving symptom control, increasing patient satisfaction ultimately improves HRQOL[6, 9-12]. PROMs are mostly self-completed questionnaires that measure the patient's health status by asking them about outcomes, such as their symptoms and aspects that may be affected by the disease(s) and/or treatment, including physical, psychological, social, overall wellbeing and HRQOL [5, 13, 14]. PROMs are standardized and validated questionnaires that are either generic

or condition-specific. Generic PROMs can be used for all patients which allows comparison of outcomes between different patient groups[15]. One the other hand, condition-specific PROMs are used for specific conditions, making it more sensitive to outcomes associated with that particular condition. This systematic review aims to identify previously implemented and evaluated generic or condition-specific PROMs in pediatric settings including home, community, outpatient and inpatient healthcare settings.

PROMs also generate 'patient-centered data', so PROMs are increasingly being used as organizational performance measures by clinicians and healthcare administrators to enhance the quality of care [16, 17] Although PROMs are being used to assess the effectiveness of new treatment regimens or surgical procedures, or improve quality of care, evidence around their effectiveness in pediatric clinical care are still scarce [18]. Due to the scarcity of evidence, they have not been systematically integrated into clinical care [19, 20]. To fill this evidence gap, the current systematic review aims to evaluate the impact of PROMs on HRQOL, utilisation of healthcare services, patient outcomes, and quality of care amongst pediatric patients with chronic conditions.

Health Related Quality of Life (HRQOL): According to the World Health Organization, HRQOL is "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [21]. Chronic conditions pose a greater risk for psychosocial issues among children[22], so the use of PROMs in clinical care may be helpful in identifying, discussing and eventually resolving aspects associated with HRQOL for these populations. Therefore, it is important to consolidate

evidence on the use of PROMs and assess whether their implementation in clinical care can feasibly improve HRQOL and outcomes among children with chronic diseases.

Healthcare Utilisation: Chronic diseases among children are associated with higher use of health care services including higher hospitalisation rates and length of stay in comparison to healthy children [23, 24]. Evidence from adult patient populations suggests that the lower scores on PROMs were strongly associated with higher risk of death and hospitalisation[25]. The use of PROMs is associated with improved symptom control and increased supportive care measures [6]. Further, using PROMs in clinical care enables patients in the self-management of their long-term chronic conditions [26]. For the parents of pediatric patients, caring for their hospitalised child often results in lost income and additional strain [22]. This is in addition to the detrimental impacts hospitalisation can have on the social and economic status for the child in adulthood [27, 28]. Considering the potential of PROMs to identify patients at greater risk for healthcare utilization[7], it is essential to gather evidence regarding the role of PROMs on healthcare utilisation.

Quality of Care: Researchers are increasingly utilizing PROMs to assess performance of healthcare providers to improve the quality of care and patient satisfaction [29]. PROMs can play an important role in providing patient-centered care by focusing on the patient's health goals and guiding therapeutic decisions [30]. Healthcare systems have been incorporating advanced electronic platforms to support and simplify the implementation of PROMs in the clinical setting [18, 31, 32]. The use of PROMs data in an integrated manner would enable healthcare systems to orient evidence-based and patient-centered care. Evidence gathered through this systematic

review will help healthcare systems to support quality improvement initiatives and develop effective strategies to further enhance quality of care.

Objectives:

The objectives of our study are to: 1) identify previously implemented and evaluated generic or condition-specific self-reported PROMs for chronic conditions in pediatric settings; 2) consolidate the evidence to evaluate the impact of using PROMs on HRQOL, healthcare utilisation, patient outcomes (e.g., symptoms control), and quality of care amongst pediatric patients with chronic conditions.

Methods and Analysis:

Design:

This protocol was developed according to the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISM-P) checklist[33], while the administration of the review and reporting will be carried out according to the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines[34]. The protocol for this review has been registered with PROSPERO, an international database of prospectively registered systematic reviews in health and social care (Registration number: CRD42018109035).

Patient and public involvement:

Patient-partners will be consulted to assess face validity of the included studies. The patient-partners are five individuals (3 patients and 2 family-caregivers) that are members of the larger patient and family advisory group at the Alberta Children's Hospital. They will not be involved in developing research question, design and conduct of this review.

Search strategy:

Our search strategy was developed according to the research question and guided by the study objectives. Keywords used for each key domains of the research question are as follows:

Population: Keywords 'child', 'adolescent', and'pediatric care' will be used to identify studies focusing on pediatric populations (18 years or younger).

Intervention: The interventions of interest for this review are Patient-Reported Outcome Measures (PROMs), so keywords 'patient-reported outcomes', 'patient outcome assessment' and combination of 'outcome' and 'measures' along with the associated abbreviations (PRO, PROM) will be used to capture studies implementing these measures in clinical care.

Outcomes: The medical outcomes of interest for the systematic review are the impact of PROMs on HRQOL, healthcare utilisation, patient outcomes, and quality of care. Keywords associated with the use of healthcare services including 'visits to emergency services', 'length of stay', 'patient admission', and 'patient readmission' nurse-patient relations' and 'physician-patient communication' are used to capture studies focusing on the overall utilisation of these services. Keywords associated with patient outcomes -' HRQoL','quality of life' and the indicators for the quality of healthcare will be used to build a robust search strategy which will include studies reporting these outcomes. The Boolean operator 'OR' will be used to combine terms within each outcome category. Finally, the Boolean operator 'AND' will be used to combine these concepts. English language filter will be applied on the final search results.

Information sources:

We will systematically search MEDLINE (Ovid interface,1950 onwards), EMBASE (Ovid Interface, 1974 onwards), CINAHL Plus with Full Text (EBSCOhost interface, 1982 onwards), PsycINFO (Ovid interface, 1803 onwards) and Cochrane Library (Ovid Interface, 1991 onwards). In addition to these electronic bibliographic databases, the reference lists of included studies will be searched in Web of Science (Thomson Reuters) database to ensure more complete coverage of the literature.

The search strategy for MEDLINE was developed iteratively with input from this systematic review team and support from a medical sciences librarian who has expertise in systematic review searching at the University of Calgary. As part of this iterative process, a primary search strategy was applied and 100 randomly chosen abstracts were reviewed by the systemic review team. These randomly chosen abstracts helped to specify the search strategy to ensure that it retrieves a high proportion of the eligible and key studies in this area. This revised search strategy was finalised after consulting again with the medical sciences librarian at the University of Calgary, and again after reviewing it with the senior researchers on the systemic review team with expertise in patient-oriented research.

Study design limits will not be imposed on the search. Implementation of PROMs in routine clinical practice mainly started after the year 2000, so will apply the time limit to exclude studies before the year 2000. Due to limited capacity in translating non-English articles, our literature search will be limited to the English language. Based on the recent evidence [35], we do not expect to introduce a systematic bias due the use of language restrictions in our systematic review. The MEDLINE strategy [See supplementary appendix for the full MEDLINE (Ovid

interface,1950 onwards) search strategy] will be tested and adapted to the syntax of all other databases.

Selection of studies:

Specific inclusion and exclusion criteria outlined below was developed after reviewing 100 randomly chosen abstracts by the members of the systematic review team (BM, AC, SB) and through consultations with the librarian (DL) and senior researchers (MS, LH).

Inclusion criteria:

1. Studies including pediatric population and questionnaires completed by pediatric patients with chronic conditions (up to 18 years old)
2. Studies focusing primarily on the implementation and use of PROMs in pediatric chronic diseases.
3. Studies reporting primary data
4. At least one of the following outcomes was reported: HRQOL, symptom control, mortality, healthcare utilization, quality of care.

Exclusion criteria:

1. Studies reporting the use of PROMs for acute conditions, dental problems, pharmaceutical drug testing or surgical outcomes assessment.
2. Studies utilising secondary or retrospective data on PROMs.
3. Studies validating PROMs or testing methods for collecting/analysing PROMs
4. Descriptive studies and reviews on PROMs to describe burden of disease and treatment
5. Studies reporting findings in languages other than English
6. Studies published prior to the year 2000

Data Management:

Literature search results will be uploaded to EndNote Reference Management Software (V.8). EndNote will be used to remove duplicate references, screen, and manage all the references throughout the review process. A PRISMA flow diagram will be constructed to summarise the selection process.

Selection process:

For the primary screening stage, titles and abstracts of the studies retrieved will be independently screened in duplicate by two reviewers working in pairs (SB, AC and BM) using the pre-determined eligibility criteria. This will reduce the potential for individual bias and the possibility of excluding relevant articles. Following the primary screening of the abstracts, full-text articles will be retrieved for studies meeting eligibility criteria or where titles or abstracts do not provide sufficient information to warrant their exclusion. Disagreements between reviewers will be resolved through discussion, and a third reviewer will be approached if the disagreement persists. Neither of the reviewers will be blind to the journal titles, study authors or the institutions. At the full-text review stage, reasons for excluding studies will be recorded.

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Data extraction:

Two reviewers (SB, AC) will independently extract data from the included studies using a standardized data extraction form to reduce errors in data extraction. This form will be pilot tested by two reviewers (SB, AC). The data extraction form will include definitions of the variables to be extracted.

The following data will be extracted:

1. Summary data of included studies (Including author, year of publication, pediatric setting (tertiary, community care), location, patient population characteristics, chronic condition under study
2. Type of PROM identified with descriptive statistics summarizing general characteristics (Including name of the PROM, generic vs. condition-specific and mode of administration, collection and reporting)
3. Reported outcome(s) of interest (Including impact on HRQOL, healthcare utilisation, patient outcomes and quality of care)

Extracted data from included studies will be presented to the whole research team to ensure consistency in data extraction. At this stage, patient partners will be consulted to verify if the extracted data is meaningful from the patient's perspective, ensuring that our study conforms to patient-oriented research. Consultation sessions will be organized with the patient-partners, where they will be briefed on the process of synthesizing evidence through systematic review. The process and extracted data will be presented to them in lay terms. Then face validity will be assessed by asking them if this systematic review measures what it purports to measure and if those findings make sense from patient's perspective.

Data synthesis: Finally, a PRISMA flow diagram will be presented to report the number of studies identified, screened and included in the final synthesis. Extracted data including participant characteristics, type of PROMs, geographical location, type of healthcare setting will be summarized in a tables. Considering the scarcity of studies assessing the effectiveness of PROMs in routine clinical care of pediatric patients with chronic conditions, we do not anticipate

conducting a subgroup analysis of generic vs. disease specific PROMs intervention. Post-hoc analysis will be conducted to explore the effectiveness of PROMs on each outcome of interest.Narrative synthesis of the summarized data will be conducted to present the results of the review. Meta-analysis will be conducted using a random-effects model if there is sufficient homogeneity in terms of study design, type of intervention, comparators, and outcomes among included studies. Risk of bias in individual studies will be assessed independently by two reviewers (SB, AC) using the COSMIN Guideline for systematic reviews of PROMs[36]Discrepancies will be resolved by discussion and/or involvement of a third reviewer.

Dissemination:

The findings of this review will be disseminated through peer-reviewed publications, conference presentations and included in the lead author's doctoral dissertation.

Discussion:

Potential limitations of this study relate to the inability of predicting the strength of the evidence from the systematic review, however we will try to overcome this limitation by following a rigorous methodology and capitalize on our team members' expertise in knowledge synthesis. This systematic review serves as a crucial step in the direction of integrating PROMs in pediatric clinical care. It will also reveal the extent to which PROMs were successful in affecting HRQOL, healthcare services utilization, patient outcomes and quality of care for chronic diseases in pediatric population. Results of this review will guide healthcare policy and clinical care practices to incorporate pediatric patients' perspectives to deliver patient-centred care.

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Contributions:

MS conceived the idea. SB drafted the manuscript. All authors provided comments on the manuscript. All authors contributed to the development of the selection criteria and data extraction criteria. SB, BM and AC developed the search strategy. MS and LH provided expertise on the use of patient-reported outcomes in clinical practice. All authors read, provided feedback, and approved the final manuscript.

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Competing interests: None declared

Appendix I: Search strategy for Medline

1. adolescen*.tw,kf.
2. child*.tw,kf.
3. (p?ediatric adj care).tw,kf.
4. Child Health Services/
5. Child/
6. Adolescent/
7. Child, Hospitalized/
8. Adolescent, Hospitalized/
9. or/1-8
10. patient outcome assessment*.tw,kf.
11. patient reported outcome measure*.tw,kf.
12. patient reported treatment outcome*.tw,kf.
13. (PROs or PROMs or PROMIS).tw,kf.
14. self-report* measure*.tw,kf.
15. self-report* outcome*.tw,kf.
16. Patient Reported Outcome Measures/
17. patient reported outcome*.tw,kf.
18. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. (emergency adj (admission* or attendance or attender* or readmission* or re-admission* or visit*)).tw,kf.
20. (hospital adj (admission* or readmission* or re-admission* or visit*)).tw,kf.
21. hospital length of stay.tw,kf.
22. Emergency Service, Hospital/ut, td, sn, ec [Utilization, Trends, Statistics & Numerical Data, Economics]
23. Hospitalization/
24. hospitali*.tw,kf.
25. length of stay/
26. Patient Admission/
27. Patient Readmission/
28. (quality adj2 (care or healthcare)).tw,kf.
29. (quality adj2 health adj2 care).tw,kf.
30. Quality Indicators, Health Care/
31. Quality of Health Care/
32. quality of life.tw,kf.
33. HRQOL.tw,kf.
34. Quality of Life/
35. *nurse-patient relations/ or *physician-patient relations/
36. or/19-35
37. 9 and 18 and 36
38. limit 37 to (yr="2000 -Current" and english)

BMJ Open

Impact of Using Patient-reported Outcome Measures in Routine Clinical Care of Pediatric Patients with Chronic Conditions: A Systematic Review Protocol

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Impact of Using Patient-reported Outcome Measures in Routine Clinical Care of Pediatric Patients with Chronic Conditions: A Systematic Review Protocol

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Abstract:

Introduction:

Chronic diseases among children are associated with lower health-related quality of life (HRQOL) and higher utilisation of healthcare services. Integrating Patient-Reported Outcomes Measures (PROMs) in routine clinical care has been shown to reduce utilisation of healthcare services while improving patient outcomes. The objectives of our study are to: 1) identify previously implemented and evaluated PROMs for chronic conditions in pediatric settings; 2) Consolidate the evidence to evaluate the impact of using PROMs on health-related quality of life, healthcare utilisation, patient outcomes (e.g., symptoms control) and quality of care among pediatric patients with chronic conditions. The findings from this review will inform the future integration of PROMs in pediatric clinical practice.

Methods and analysis:

We will systematically search the following electronic databases: MEDLINE, EMBASE, CINAHL, PsychINFO and Cochrane library. Reference lists of included studies will also be searched in Web of Science (Thomson Reuters) database to ensure more complete coverage. Two reviewers will independently screen the studies and abstract the data using standardized form. Extracted data will be analysed and synthesized. Finally, a narrative synthesis of summarized data will be presented. The protocol for this review has been registered on the International Prospective Register of Systematic Reviews database (PROSPERO) (CRD42018109035).

Ethics and dissemination:

Ethical approval is not required, as the proposed systematic review will use data from published research articles. The results of this study will be disseminated through publication in peer-reviewed journals, scientific conferences and meetings, and the lead author's doctoral dissertation.

Strengths and limitations of this study:

- A key strength of this study is that it is a first systematic review to evaluate the impact of Patient-reported Outcome Measures (PROMs) on the Health-related Quality of Life (HRQOL), utilisation of healthcare services, patient outcomes, and quality of care amongst pediatric patients with chronic conditions.
- The findings of this study will provide crucial evidence for integration of PROMs in pediatric clinical care.
- Another strength of this systematic review is that patient-partners will be consulted to assess the face validity of the included studies to verify if the extracted data is meaningful from patients' perspective.
- Exclusion of studies that are not published in English is a potential limitation of this systematic review.

Introduction:

Children with chronic diseases report having a lower health related quality of life (HRQOL) and higher utilisation of healthcare services compared to their healthy peers; they require complex care [1]. Higher utilisation of healthcare services, including higher rates of hospitalization for these populations, poses a challenge for healthcare systems to provide quality care to children with chronic diseases[2, 3]. According to the World Health Organization's definition, chronic diseases are those that are not passed from person to person, they are of long duration and generally slow have progression[4].

Patient-reported outcome (PRO) are defined as - " the measurement of any aspect of a patient's health status that comes directly from the patient (i.e., without the interpretation of the patient's responses by a physician or anyone else)"[5]. Patient-reported Outcome Measures (PROMs) are the tools or instruments used to measure PROs. Evidence from adult populations suggests that the integration of PROMs in clinical care enhances patient-clinician communication by increasing the frequency of discussion of patient outcomes during consultations[6]. Among patients with metastatic cancer, integration of PROMs in routine clinical care was associated with increased survival compared with usual care[7], among patients with arthritis, it improved self-perceived health and disease activity[8]. It also reduces the use of healthcare services by improving symptom control, increasing patient satisfaction ultimately improves HRQOL[6, 9-12]. PROMs are mostly self-completed questionnaires that measure the patient's health status by asking them about outcomes, such as their symptoms and aspects that may be affected by the disease(s) and/or treatment, including physical, psychological, social, overall wellbeing and HRQOL [5, 13, 14]. PROMs are standardized and validated questionnaires that are either generic

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PROMs also generate 'patient-centered data', so PROMs are increasingly being used as organizational performance measures by clinicians and healthcare administrators to enhance the quality of care [16, 17] Although PROMs are being used to assess the effectiveness of new treatment regimens or surgical procedures, or improve quality of care, evidence around their effectiveness in pediatric clinical care are still scarce [18]. Due to the scarcity of evidence, they have not been systematically integrated into clinical care [19, 20]. To fill this evidence gap, the current systematic review aims to evaluate the impact of PROMs on HRQOL, utilisation of healthcare services, patient outcomes, and quality of care amongst pediatric patients with chronic conditions.

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Quality of Care: Researchers are increasingly utilizing PROMs to assess performance of healthcare providers to improve the quality of care and patient satisfaction [29]. PROMs can play an important role in providing patient-centered care by focusing on the patient's health goals and guiding therapeutic decisions [30]. Healthcare systems have been incorporating advanced electronic platforms to support and simplify the implementation of PROMs in the clinical setting [18, 31, 32]. The use of PROMs data in an integrated manner would enable healthcare systems to orient evidence-based and patient-centered care. Evidence gathered through this systematic

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Search strategy:

Our search strategy was developed according to the research question and guided by the study objectives. Keywords used for each key domains of the research question are as follows:

Population: Keywords 'child', 'adolescent', and'pediatric care' will be used to identify studies focusing on pediatric populations (18 years or younger).

Intervention: The interventions of interest for this review are Patient-Reported Outcome Measures (PROMs), so keywords 'patient-reported outcomes', 'patient outcome assessment' and combination of 'outcome' and 'measures' along with the associated abbreviations (PRO, PROM) will be used to capture studies implementing these measures in clinical care.

Outcomes: The medical outcomes of interest for the systematic review are the impact of PROMs on HRQOL, healthcare utilisation, patient outcomes, and quality of care. Keywords associated with the use of healthcare services including 'visits to emergency services', 'length of stay', 'patient admission', and 'patient readmission' nurse-patient relations' and 'physician-patient communication' are used to capture studies focusing on the overall utilisation of these services. Keywords associated with patient outcomes -' HRQoL','quality of life' and the indicators for the quality of healthcare will be used to build a robust search strategy which will include studies reporting these outcomes. The Boolean operator 'OR' will be used to combine terms within each outcome category. Finally, the Boolean operator 'AND' will be used to combine these concepts. English language filter will be applied on the final search results.

Information sources:

We will systematically search MEDLINE (Ovid interface,1950 onwards), EMBASE (Ovid Interface, 1974 onwards), CINAHL Plus with Full Text (EBSCOhost interface, 1982 onwards), PsycINFO (Ovid interface, 1803 onwards) and Cochrane Library (Ovid Interface, 1991 onwards). In addition to these electronic bibliographic databases, the reference lists of included studies will be searched in Web of Science (Thomson Reuters) database to ensure more complete coverage of the literature.

The search strategy for MEDLINE was developed iteratively with input from this systematic review team and support from a medical sciences librarian who has expertise in systematic review searching at the University of Calgary. As part of this iterative process, a primary search strategy was applied and 100 randomly chosen abstracts were reviewed by the systemic review team. These randomly chosen abstracts helped to specify the search strategy to ensure that it retrieves a high proportion of the eligible and key studies in this area. This revised search strategy was finalised after consulting again with the medical sciences librarian at the University of Calgary, and again after reviewing it with the senior researchers on the systemic review team with expertise in patient-oriented research.

Study design limits will not be imposed on the search. Implementation of PROMs in routine clinical practice mainly started after the year 2000, so will apply the time limit to exclude studies before the year 2000. Due to limited capacity in translating non-English articles, our literature search will be limited to the English language. Based on the recent evidence [35], we do not expect to introduce a systematic bias due the use of language restrictions in our systematic review. The MEDLINE strategy [See supplementary appendix for the full MEDLINE (Ovid

interface,1950 onwards) search strategy] will be tested and adapted to the syntax of all other databases.

Selection of studies:

Specific inclusion and exclusion criteria outlined below was developed after reviewing 100 randomly chosen abstracts by the members of the systematic review team (BM, AC, SB) and through consultations with the librarian (DL) and senior researchers (MS, LH).

Inclusion criteria:

1. Studies including pediatric population and questionnaires completed by pediatric patients with chronic conditions (up to 18 years old)
2. Studies focusing primarily on the implementation and use of PROMs in pediatric chronic diseases.
3. Studies reporting primary data
4. At least one of the following outcomes was reported: HRQOL, symptom control, mortality, healthcare utilization, quality of care.

Exclusion criteria:

1. Studies reporting the use of PROMs for acute conditions, dental problems, pharmaceutical drug testing or surgical outcomes assessment.
2. Studies utilising secondary or retrospective data on PROMs.
3. Studies validating PROMs or testing methods for collecting/analysing PROMs.
4. Descriptive studies and reviews on PROMs to describe burden of disease and treatment
5. Studies reporting findings in languages other than English
6. Studies published prior to the year 2000

Data Management:

Literature search results will be uploaded to EndNote Reference Management Software (V.8). EndNote will be used to remove duplicate references, screen, and manage all the references throughout the review process. A PRISMA flow diagram will be constructed to summarise the selection process.

Selection process:

For the primary screening stage, titles and abstracts of the studies retrieved will be independently screened in duplicate by two reviewers working in pairs (SB, AC and BM) using the pre-determined eligibility criteria. This will reduce the potential for individual bias and the possibility of excluding relevant articles. Following the primary screening of the abstracts, full-text articles will be retrieved for studies meeting eligibility criteria or where titles or abstracts do not provide sufficient information to warrant their exclusion. Disagreements between reviewers will be resolved through discussion, and a third reviewer will be approached if the disagreement persists. Neither of the reviewers will be blind to the journal titles, study authors or the institutions. At the full-text review stage, reasons for excluding studies will be recorded.

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Data extraction:

Two reviewers (SB, AC) will independently extract data from the included studies using a standardized data extraction form to reduce errors in data extraction. This form will be pilot tested by two reviewers (SB, AC). The data extraction form will include definitions of the variables to be extracted.

The following data will be extracted:

1. Summary data of included studies (Including author, year of publication, pediatric setting (tertiary, community care), location, patient population characteristics, chronic condition under study
2. Type of PROM identified with descriptive statistics summarizing general characteristics (Including name of the PROM, generic vs. condition-specific and mode of administration, collection and reporting)
3. Reported outcome(s) of interest (Including impact on HRQOL, healthcare utilisation, patient outcomes and quality of care)

Extracted data from included studies will be presented to the whole research team to ensure consistency in data extraction. At this stage, patient partners will be consulted to verify if the extracted data is meaningful from the patients' perspective, ensuring that our study conforms to patient-oriented research. Consultation sessions will be organized with the patient-partners, where they will be briefed on the process of synthesizing evidence through systematic review. The process and extracted data will be presented to them in lay terms. Then face validity will be assessed by asking them if this systematic review measures what it purports to measure and if those findings make sense from patient's perspective.

Data synthesis: Finally, a PRISMA flow diagram will be presented to report the number of studies identified, screened and included in the final synthesis. Extracted data including participant characteristics, type of PROMs, geographical location, type of healthcare setting will be summarized in a table. Considering the scarcity of studies assessing the effectiveness of PROMs in routine clinical care of pediatric patients with chronic conditions, we do not anticipate

conducting a subgroup analysis of generic vs. condition specific PROMs intervention. Post-hoc analysis will be conducted to explore the effectiveness of PROMs on each outcome of interest. Narrative synthesis of the summarized data will be conducted to present the results of the review. Meta-analysis will be conducted using a random-effects model if there is sufficient homogeneity in terms of study design, type of intervention, comparators, and outcomes among included studies. Publication bias will be assessed using funnel plot. Risk of bias in individual studies will be assessed independently by two reviewers (SB, AC) using the COSMIN Guideline for systematic reviews of PROMs.[36]. Assessing the methodological quality of included studies is important, but it is also recommended to assess the quality of PROMs included in the studies[36]. This review might identify studies which used unvalidated PROMs, so we plan to use COSMIN Checklist to assess the risk of bias for both methodological quality of studies and PROMs included in those studies. iscrepancies will be resolved by discussion and/or involvement of a third reviewer Additionally, the strength of body of evidence will be assessed as high, moderate or low using Grading of Recommendations Assessment, Development, and Evaluation (GRADE) guidelines[37].

Dissemination:

The findings of this review will be disseminated through peer-reviewed publications, conference presentations and included in the lead author's doctoral dissertation.

Discussion:

Potential limitations of this study relate to the inability of predicting the strength of the evidence from the systematic review, however we will try to overcome this limitation by following a rigorous methodology and capitalize on our team members' expertise in knowledge synthesis. This systematic review serves as a crucial step in the direction of integrating PROMs in pediatric clinical care. It will also reveal the extent to which PROMs were successful in affecting HRQOL, healthcare services utilization, patient outcomes and quality of care for chronic diseases in pediatric population. Results of this review will guide healthcare policy and clinical care practices to incorporate pediatric patients' perspectives to deliver patient-centred care.

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Contributions:

MS conceived the idea. SB drafted the manuscript. All authors provided comments on the manuscript. All authors contributed to the development of the selection criteria and data extraction criteria. SB, BM and AC developed the search strategy. MS and LH provided expertise on the use of patient-reported outcomes in clinical practice. All authors read, provided feedback, and approved the final manuscript.

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Competing interests: None declared

Appendix I: Search strategy for Medline

1. adolescen*.tw,kf.
2. child*.tw,kf.
3. (p?ediatric adj care).tw,kf.
4. Child Health Services/
5. Child/
6. Adolescent/
7. Child, Hospitalized/
8. Adolescent, Hospitalized/
9. or/1-8
10. patient outcome assessment*.tw,kf.
11. patient reported outcome measure*.tw,kf.
12. patient reported treatment outcome*.tw,kf.
13. (PROs or PROMs or PROMIS).tw,kf.
14. self-report* measure*.tw,kf.
15. self-report* outcome*.tw,kf.
16. Patient Reported Outcome Measures/
17. patient reported outcome*.tw,kf.
18. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. (emergency adj (admission* or attendance or attender* or readmission* or re-admission* or visit*)).tw,kf.
20. (hospital adj (admission* or readmission* or re-admission* or visit*)).tw,kf.
21. hospital length of stay.tw,kf.
22. Emergency Service, Hospital/ut, td, sn, ec [Utilization, Trends, Statistics & Numerical Data, Economics]
23. Hospitalization/
24. hospitali*.tw,kf.
25. length of stay/
26. Patient Admission/
27. Patient Readmission/
28. (quality adj2 (care or healthcare)).tw,kf.
29. (quality adj2 health adj2 care).tw,kf.
30. Quality Indicators, Health Care/
31. Quality of Health Care/
32. quality of life.tw,kf.
33. HRQOL.tw,kf.
34. Quality of Life/
35. *nurse-patient relations/ or *physician-patient relations/
36. or/19-35
37. 9 and 18 and 36
38. limit 37 to (yr="2000 -Current" and english)

Impact of Using Patient-reported Outcome Measures in Routine Clinical Care of Pediatric Patients with Chronic Conditions: A Systematic Review Protocol

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	(Page No.#)
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2 and 8
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	17
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	17
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	6
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	6
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years	9

		considered, language, publication status) to be used as criteria for eligibility for the review	
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	10
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	9 and Appendix-I
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	12
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	12
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	12
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	13
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	13
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	14
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	13-14
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	14
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	14

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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