## Supplementary material 1: Systematic review search strategy

EBM Reviews - Cochrane Central Register of Controlled Trials <March 2022>
Ovid MEDLINE(R) ALL <1946 to March 09, 2022>
[mp=ti, ot, ab, sh, hw, kw, tn, dm, mf, dv, kf, fx, dq, nm, ox, px, rx, an, ui, sy]
1 exp Pneumonia/
2 pneumonia.mp
3 community-acquired pneumonia.mp.
4 bronchitis/ or bronchiolitis/
5 bronchi*.mp.
6 Influenza, Human/
7 lower respiratory adj2 infection*.mp.
8 patient reported outcome measures/
9 Self Report/
10 patient report*.mp.
11 patient adj2 report* outcome measure*.mp.
12 PRO.mp.
13 PROM.mp.
14 patient-based outcome measure*.mp.
15 patient-report*.mp.
16 patient reported experience measure*.mp.
17 subjective assessment.mp.
18 symptom measure*.mp.
19 symptom score*.mp.
20 Patient Health Questionnaire/
21 Adolescent/
22 Child/
23 Child, Preschool/
24 Infant/
25 (Child* or adolescen* or teen* or p?ediatric or baby or babies or infan* or juvenile* or newborn).mp.
26 1 or 2 or 3 or 4 or 5 or 6 or 7
27 21 or 22 or 23 or 24 or 25
28 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
29 26 and 27 and 28
30 limit 29 to english language
31 limit 30 to human
32 remove duplicates from 31

## Supplementary material 2: Systematic review record characteristics

| First Author | Date of publication and (years of stud) | Setting (location/ socioeconomics) and context (community or hospital) | Patient population and sample size | Study outcome measures | Study design | Disease(s) studied |
|---|---|---|---|---|---|---|
| Heinonen | 2010 (2007 - 2009) | Finland (Primary care clinic) | N = 98. Aged between 1 and 3 years | Development of acute otitis media, time to resolution of illness (symptom diaries) | RCT | Influenza |
| Jacobs | 1999 (1997 - 1998) | Canada (Primary care outpatients) | N = 206. Aged up to 12 years | CARIFS, temperature, Visual analogue scale, Yale observations scale, healthcare usage | PROM development study | Respiratory infection |
| Whitley | 2001 (1998 - 1999) | United States and Canada (Hospital outpatients) | N = 695. Aged between 1 and 12 | Time to resolution and severity of illness (CARIFS), return to daily activity, temperature, illness incidence | RCT | Influenza |
| Little | 2021 (2016 - 2020) | England (General practice) | N = 432. Aged between 6 months and 12 years | Duration of symptoms (daily diary), severity, new complications, side-effects, healthcare usage, and medication adherence | RCT | Acute lower respiratory infections |
| Sarrell | 2010 (2005 - 2008) | Israel (Clinic outpatients) | N = 330. Aged between 1.5 and 14 months | Change in Bronchiolitis Caregiver Diary score and PaO2, hospitalisation, days lost (from day-care and work) for patient and parents | RCT | RSV bronchiolitis |
| Williams | 2018 (2014 - 2015) | United States (Hospital outpatients) | N = 103. Aged less than 24 months | Midulla RSV score, CGIS score, GRCD, PGIS and PGIC | PROM development study | RSV |
| Lewis | 2018 (2013 - 2014) | United States (Outpatient sites) | N = NA. Aged less than 24 months | NA | PROM development study | RSV |

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| Bisgaard | 2008 (2003 - 2006) | International (Hospital outpatients) | N = 745. Aged between 3 and 24 months | Daily caregiver diary, exacerbations / complications, healthcare use, medication use | RCT | RSV bronchiolitis |
| Bruyndonckx | 2022 (2015 - 2018) | Europe (Primary care clinic) | N = 363. Aged between 1 and 13 years | Health status via the EuroQol-5Dimesions and Visual analogue scale | RCT (Secondary analysis) | Influenza-like illness |
| Wat | 2008 (2002 - 2004) | Wales (Hospital outpatients) | N = 80. Aged under 18 years | Pathogen, patient reported symptoms via a diary card | Cohort | Respiratory tract infections in cystic fibrosis patients |
| Tran | 2019 (2015 - 2016) | Germany (Community) | N = 135. Aged between 5 and 87 | General health score, Bronchitis Severity Scale, Integrative Medicine Outcome Scale | Cohort | Acute bronchitis and respiratory infections |
| Santanello | 2005 (NA) | Denmark (RCT Clinic outpatients) | N = 116. Aged between 6.6 and 13.8 months | Symptom score | PROM development study | RSV bronchiolitis |
| Mattila | 2021 (2017 - 2018) | Finland (Hospital outpatients) | N = 116. Infants born in 2017 | Pathogen identification and load, symptom scores and adverse events | Cohort | Influenza |
| Kruizinga | 2021 (2018-2020) | The Netherlands (Hospital outpatients) | N = NR. Aged 2 to 12 years | Temperature, steps, heart rate, sleep pattern, symptom questionnaire, Asthma Control Diary, and spirometry | Cohort | Community-Acquired Pneumonia, Preschool wheezing, and asthma exacerbation |
| Johnston | 2005 (1998 - 1999) | International (Hospital outpatients) | N = 335. Aged between 6 and 12 years | Symptom diary, return to normal activity | RCT | Influenza among asthmatic patients |

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| Chen | 2022 (2020 - 2021) | China (Hospital outpatients) | N = NR. Aged between 28 days and 18 years | Pathogen identification, healthcare use, CARIFS and Cough score | Surveillance study | Respiratory tract infections |
| Barratt | 2021 (NR) | United Kingdom and Ireland (Hospital outpatients) | N = 814. Children older than 6 months | Indicated treatment, resistance, severity and duration of symptoms, interference with normal activity, medication adherence, adverse events | RCT | Community-Acquired Pneumonia |
| Bongard | 2018 (2015-2018) | Europe (General practice) | N = NA. <12 and between 12 and 64 years | Patient reported outcomes. Healthcare use, Health related quality of life, healthcare use, complications, medication use, return to usual activities | RCT (proposal) | Influenza-like illness |

*CARIFS: Canadian Acute Respiratory Illness and Flu Scale, CGIS: Clinician Global Impression of Severity, GRCD: Gilead RSV Caregiver Diary, NA: Not Applicable, NR: Not Reported, PGIC: Parent Global Impression of Change, PGIS: Parent Global Impression of Severity, PRO: Patient-Reported Outcome, PROM: Patient Reported Outcome Measure, RCT: Randomised Controlled Trial, RSV: Respiratory Syncytial Virus.*

## Appendix A: Adapted COSMIN definitions and criteria for PROM properties of measurement

| Measurement domain | Measurement property | Definition | Assessment | Criteria |
|---|---|---|---|---|
| Reliability | | The extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: e.g., using different sets of items from the same PROM (internal consistency); over time (test-retest); by different persons on the same occasion (inter-rater); or by the same persons (i.e., raters or responders) on different occasions (intra-rater) | Intraclass correlation coefficient<br>Pearson correlation co-efficient (r) | Intraclass correlation coefficient or weighted Kappa ≥ 0.70 |
| | Internal consistency | The degree of the interrelatedness among the items | Cronbach's alpha for summary scores<br>Item-total correlations | At least limited evidence for unidimensionality or positive structural validity AND Cronbach's alpha(s) ≥ 0.70 and ≤ 0.95 |
| | Measurement error | The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured | | Smallest detectable change or limits of agreement < minimally important change |
| Validity | | The degree to which a PROM measures the construct(s) it purports to measure | | |
| | Content validity | The degree to which the content of a PROM is an adequate reflection of the construct to be measured | Derivation of all items<br>Qualitative interview schedule<br>Interview or focus group transcripts<br>Items derived from the transcripts<br>Composition of patients used to develop content<br>Cognitive interview transcripts to evaluate patient understanding | All items refer to relevant aspects of the construct to be measured AND are relevant for the target population AND are relevant for the context of use AND together comprehensively reflect the construct to be measured |

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| | Construct validity | The degree to which the scores of a PROM are consistent with hypotheses based on the assumption that the PROM validly measures the construct to be measured | Strength of correlation testing a priori hypotheses (discriminant and convergent validity)<br>Degree to which the PRO instrument can distinguish among groups hypothesized a priori to be different (known groups validity) | The result is in accordance with the hypothesis |
| | | Structural validity: The degree to which the scores of a measurement instrument are an adequate reflection of the dimensionality of the construct to be measured | Classical test theory:<br>Comparative Fit Index<br>Tucker Lewis Index<br>Root Means Square Error of Approximation<br><br>Item response theory:<br>Residual correlations<br>Model fit<br><br>Rasch:<br>Infit and outfit mean squares<br>Z-standardised values | Classical test theory: Comparative fit index or Tucker-Lewis index or comparable measure >0.95 AND root mean square error of approximation <0.08<br>Item response theory: no violation of unidimensionality, residual correlations among the items after controlling for the dominant factor < 0.20 OR Q3's < 0.37 AND no evidence for violation of monotonicity: adequate looking graphs OR item scalability >0.30 AND adequate model fit<br>Rasch: infit and outfit mean squares ≥ 0.5 and ≤ 1.5 OR Z-standardized values > -2 and < 2 |
| | | Convergent validity: The degree to which 2 measures that are theoretically related are in fact related | Spearman rank inter-correlations (rs) or Pearson product moment correlations (r) coefficients or logistic regression (r2) | Acceptable correlation with changes in instruments measuring similar constructs is > 0.50; the convergent validity. Acceptable correlation for related but dissimilar constructs is 0.3 - 0.5 or < 0.5 for unrelated constructs; the discriminant validity |
| | | Discriminant validity: The ability of the test to discriminate among populations that are likely to score differently with reference to the construct | | |
| | Criterion validity | The degree to which the scores of a PROM are an adequate reflection of a ‘gold standard’ | | Convincing arguments that gold standard is “gold” AND correlation with gold standard ≥ 0.70 |

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| Responsiveness | | The ability of a PROM to detect change over time in the construct to be measured | Change over time, responsiveness ratio<br>Effect size statistic<br>Standardised response mean | The result is in accordance with the hypothesis OR area under the curve ≥ 0.70 |
| | Minimal Important Difference | The smallest difference in outcome in the domain of interest that patients perceive as important. | | |

*PRO: Patient-Reported Outcome, PROM: Patient Reported Outcome Measure*. From: Prinsen CAC, Mokkink LB, Bouter LM, Alonso J, Patrick DL, de Vet HCW, et al. COSMIN guideline for systematic reviews of patient-reported outcome measures. Quality of life research. 2018;27(5):1147-57.

## Appendix B: PRISMA checklist

| Section and Topic | Item # | Checklist item | Location where item is reported |
|---|---|---|---|
| **TITLE** | | | |
| Title | 1 | Identify the report as a systematic review.<br>• Manuscript subtitle: "A systematic review"<br>• Article summary: "Through systematically reviewing…"<br>• Research methods: "…systematic review was conducted." | Page 1, 3 |
| **ABSTRACT** | | | |
| Abstract | 2 | See the PRISMA 2020 for Abstracts checklist.<br>Identify the report as a systematic review:<br>• Data sources: "A systematic review…"<br>Provide an explicit statement of the main objective(s) or question(s) the review addresses<br>• Objective: "To systematically identify and characterise PROs and PROMs used in studies in children with ALRIs and summarise their properties of measurement"<br>Specify the inclusion and exclusion criteria for the review<br>• Study selection: "...original studies reporting on the development or use of a PRO or PROM, involving children with ALRIs".<br>Specify the information sources (such as databases, registers) used to identify studies and the date when each was last searched<br>• Data sources: "…Medline, EMBASE and Cochrane (from inception until 18th of April 2022) databases was supplemented by citation searching through Scopus and Google Scholar."<br>Specify the methods used to assess risk of bias in the included studies<br>• Not applicable. Formal risk of bias not performed.<br>Specify the methods used to present and synthesise results<br>• Data extraction: "Data regarding study and population, PRO and PROM characteristics and quality characteristics of each identified PRO and PROM were extracted."<br>• Meta-analysis not performed.<br>Give the total number of included studies and participants and summarise relevant characteristics of studies<br>• Results: "Of 2798 articles captured, 18 were eligible for inclusion. Twelve PROMs were identified from the included articles. Of these, only 2 ALRI specific PROMs were used in the intended setting in which they were validated".<br>Present results for main outcomes, preferably indicating the number of included studies and participants for each. If meta-analysis was done, report the summary estimate and confidence/credible interval. If comparing groups, indicate the direction of the effect (that is, which group is favoured)<br>• Results: "The Canadian Acute Respiratory Illness and Flu Scale (CARIFS) as the most used disease-specific PROM and the EQ-5D-Y the most used generic PROM".<br>Provide a brief summary of the limitations of the evidence included in the review (such as study risk of bias, inconsistency, and imprecision)<br>• Limitations: "The variety of nomenclature for a 'PRO' likely introduced selection bias into the review. Data reporting heterogeneity | Page 1 |

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| | | prevented a risk of bias assessment".<br>Provide a general interpretation of the results and important implications<br>• Conclusion: "Few PROMs exist that are acceptable for use in studies involving children with ALRIs. There is a pressing need to develop a PROM for use in ALRI studies in children as one measure of treatment success, one that will also be fit for use in Australian children".<br>Specify the primary source of funding for the review<br>• Not applicable. Funding not required for the review.<br>Provide the register name and registration number<br>• Publisher limited – see research methods. | |
| **INTRODUCTION** | | | |
| Rationale | 3 | Describe the rationale for the review in the context of existing knowledge.<br>• Introduction: "Common cause of morbidity and mortality… substantial health impacts…economic costs…critical knowledge gaps exist", "[trial outcomes are] typically those that can be objectively captured… while important, their infrequent occurrence presents a challenge", "PROMs suggested [as an endpoint in a trial]… there is a lack of validated PROMs for use" | Page 2 |
| Objectives | 4 | Provide an explicit statement of the objective(s) or question(s) the review addresses.<br>• Introduction: "We aim to systematically identify and characterise PROs and PROMs (self or proxy-report by guardian/career) used in studies in children with ALRIs and summarise their properties of measurement". | Page 2, 3 |
| **METHODS** | | | |
| Eligibility criteria | 5 | Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.<br>• Research methods: "Articles were included if they…Exclusion criteria were…" | Page 3 |
| Information sources | 6 | Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.<br>• Research methods: "Three primary databases… were searched from creation until 18th of April 2022…Scopus and Google scholar" | Page 3, 4 |
| Search strategy | 7 | Present the full search strategies for all databases, registers and websites, including any filters and limits used.<br>• Research methods: "…search strategy to capture PRO and PROM use in paediatric studies (see S1, Supplementary material 1)". | Page 3 |
| Selection process | 8 | Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.<br>• Research methods: "Two authors individually screened each article to identify potentially eligible articles… a third reviewer… [resolved] discrepancies", "imported to Covidence (https://www.covidence.org/)". | Page 4 |
| Data collection process | 9 | Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.<br>• Research methods: "The second author cross-checked 25% of eligible articles…", "imported to Covidence (https://www.covidence.org/)". | Page 4 |
| Data items | 10a | List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.<br>• Research methods: "…Data from each record was extracted according to predetermined fields. This included…" | Page 4 |

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| | 10b | List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.<br>• Research methods: "…Data from each record was extracted according to predetermined fields. This included…" | Page 4 |
| Study risk of bias assessment | 11 | Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process. | NA |
| Effect measures | 12 | Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results. | NA |
| Synthesis methods | 13a | Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)). | NA |
| | 13b | Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions. | N/A |
| | 13c | Describe any methods used to tabulate or visually display results of individual studies and syntheses. | N/A |
| | 13d | Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used. | N/A |
| | 13e | Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression). | NA |
| | 13f | Describe any sensitivity analyses conducted to assess robustness of the synthesized results. | NA |
| Reporting bias assessment | 14 | Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases). | NA |
| Certainty assessment | 15 | Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome. | NA |
| **RESULTS** | | | |
| Study selection | 16a | Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.<br>• Results: "We identified 2793 articles, of which 18 met the criteria for inclusion."<br>• Figure 1: PRISMA-S flow diagram reporting the systematic review results | Page 5 |
| | 16b | Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.<br>• PRISMA-S flow diagram "records excluded: n = 95"… Reasons for exclusion… | Figure 1 |
| Study characteristics | 17 | Cite each included study and present its characteristics.<br>• Table 1. Characteristics of patient-reported outcome measures identified through systematic review | Table 1 |
| Risk of bias in studies | 18 | Present assessments of risk of bias for each included study.<br>• As the data reported in the manuscript were not individual outcomes, rather which PRO/PROMs were used and how they were used, a formal risk of bias assessment was not performed. | NA |
| Results of individual studies | 19 | For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots. | NA |
| Results of syntheses | 20a | For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies. | NA |
| | 20b | Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. | NA |

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| | | confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect. | |
| | 20c | Present results of all investigations of possible causes of heterogeneity among study results. | NA |
| | 20d | Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results. | NA |
| Reporting biases | 21 | Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed. | NA |
| Certainty of evidence | 22 | Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed. | NA |
| **DISCUSSION** | | | |
| Discussion | 23a | Provide a general interpretation of the results in the context of other evidence.<br>• Discussion: "Few validated PROMs exist for use in studies involving children with ALRIs.", "Considerable heterogeneity… recommendations… emerged recently.", "None…developed for use in First Nations children, who disproportionally bear highest burden", "Only seven… articles captured… identified validated paediatric ALRI PROM use in a setting that was intended.", "Validation processes inconsistently applied". | Page 8, 9 |
| | 23b | Discuss any limitations of the evidence included in the review.<br>• Discussion: "…properties of measurement for PROMs were inconsistently reported across different studies." | Page 11 |
| | 23c | Discuss any limitations of the review processes used.<br>• Discussion: "…complexity of how ALRI is defined in medical research" (a systematic review can be limited by key word / subject heading terms) | Page 13 |
| | 23d | Discuss implications of the results for practice, policy, and future research.<br>• Discussion: "PROM development should be informed by consultation with end-users", "…pressing need to develop a PROM for use in ALRI studies in children" | Page 10, 11 |
| **OTHER INFORMATION** | | | |
| Registration and protocol | 24a | Provide registration information for the review, including register name and registration number, or state that the review was not registered.<br>• Title page: "Registry: PROSPERO - CRD42022308619…"<br>• Research methods: "…PROSPERO registered (CRD42022308619)…" | Page 1, 3 |
| | 24b | Indicate where the review protocol can be accessed, or state that a protocol was not prepared.<br>• Research methods: "The review protocol can be accessed through this [PROSPERO] registration". | Page 3 |
| | 24c | Describe and explain any amendments to information provided at registration or in the protocol.<br>• Not applicable. All amendments (and explanations) to the original registration were updated in the registration. | NA |
| Support | 25 | Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.<br>• Acknowledgments: "…the study was supported by the assistance of UWA staff, especially librarian Kylie Black, who provided expert advice for review search strategy". | Page 12 |
| Competing interests | 26 | Declare any competing interests of review authors.<br>• Conflict of interest disclosure: "The authors have no conflicts of interest to disclose". | Page 1 |
| Availability of data, code and | 27 | Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review. | N/A |

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| other materials | | • No original data were synthesised. All reported data were referenced. | |

*ALRI: Acute Lower Respiratory Infection, PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses, PRO: Patient-Reported Outcome, PROM: Patient Reported Outcome Measure. From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/.*