


Does the routine use of spirometry improve clinical outcomes in children?—A systematic review

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Abstract

Spirometry provides a quantitative measure of lung function and its use is recommended as an adjunct to enhance pediatric respiratory healthcare in many clinical practice guidelines. However, there is limited evidence confirming the benefits (or otherwise) of using spirometry from either clinician or patient perspectives. This systematic review aimed to determine the impact of spirometry on change in clinical decision making and patient-reported outcome measures. We searched PubMed, Embase, Cochrane Central Register of Controlled Trials, www.clinicaltrials.gov, and World Health Organization International Clinical Trials Registry Platform, from inception to July 2021. We included randomized controlled trials (RCTs) comparing the use versus non-use of spirometry during standard clinical review in children aged <18 years with respiratory problems in clinics. We used Cochrane methodology. The search identified 3475 articles; 8 full-text articles were reviewed but only 1 study fulfilled the inclusion criteria. The single study involved two cluster RCTs of spirometry for children with asthma in general practice. The included study did not find any significant intergroup difference at the 12-month follow-up for asthma-related quality-of-life and clinical endpoints. However, the findings were limited by methodological weaknesses and high risks of bias. With a paucity of data, the clinical benefits of spirometry remain unclear. Thus, there is a clear need for RCTs that provide high-quality evidence to support the routine use of spirometry in children with suspected or known lung disease. Pending the availability of better evidence, we recommend that clinicians adhere to the current clinical practice recommendations.

KEYWORDS

child, lung, randomized controlled trial, respiratory, spirometry

Abbreviations: ATS, American Thoracic Society; CI, confidence interval; ERS, European Respiratory Society; FEV₁, forced expiratory volume in 1 s; FVC, forced vital capacity; MD, mean difference; OR, odds ratio; QoL, quality of life; RCT, randomized controlled trial; STAI, State-Trait Anxiety Inventory.

PROSPERO registration: CRD42020171219

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1 | INTRODUCTION

Spirometry is a portable and relatively simple test designed to identify and quantify abnormalities in respiratory function. The measurements derived from spirometry are measures of airflow and exhaled lung volumes. Spirometry can generally be reliably performed by children >6 years of age and by some preschoolers under modified criteria.^{1,2}

Data from spirometry add to clinical management in numerous ways, including assisting in characterizing respiratory pathophysiology, grading the severity of lung disorders, monitoring disease, and determining the effectiveness of therapy.^{1,3} Hence, its use is recommended in pediatric clinical guidelines as part of clinical management including guidelines for chronic cough,⁴ bronchopulmonary dysplasia and recurrent wheezing,⁵ asthma,⁶ bronchiectasis,⁷ and cystic fibrosis.^{8,9} Other diagnoses and conditions in which spirometry aids in management include, but are not limited to, oncology conditions, connective tissue disorders, neuromuscular weakness, and scoliosis.¹⁰

Although spirometry is widely advocated in pediatric guidelines and routine in most respiratory clinics, there is evidence of under-utilization of spirometry in primary care settings.¹¹ For example, only half of all family physicians and general pediatricians use spirometry in patients with asthma and only 21% routinely use it in asthma guideline-recommended situations, that is, establishing an asthma diagnosis, severity, or control.¹¹ Although pediatricians used spirometry 66% of the time, only 10% performed the test consistently on each asthma visit.¹² In another survey of children with asthma, only a third were referred for spirometry and only one-half of hospitalized children underwent spirometry during follow-up.¹³

Clarification of the value and impact of spirometry in routine consultations, with systematic review evidence, is essential for integrating spirometry into routine clinical practice. Thus, our systematic review aimed to evaluate the question “In children with suspected or known respiratory diseases, does the routine use of spirometry improve health-related quality of life (QoL) outcome and guide clinical management, compared to not using spirometry?”

2 | METHODS

2.1 | Protocol and registration

Cochrane methodology for systematic reviews of interventions was used and the protocol prospectively registered (PROSPERO, CRD42020171219).

2.2 | Eligibility criteria

The inclusion and exclusion criteria were based on the following population-intervention-comparator-outcome framework.

2.2.1 | Population

Children aged 4–18 years with a suspected or diagnosed lung disease in primary, secondary, or tertiary care settings. Exclusion criteria were nonrespiratory disorders as primary diagnosis or unable to perform spirometry due to contraindications (e.g., haemoptysis, lung cyst, pneumothorax, or recent chest/eye surgery).

2.2.2 | Intervention

The intervention was limited to spirometry as part of a routine doctor visit. Routine visits are defined as pre-arranged clinical reviews, other than for acute illnesses. Spirometry is defined as measurements taken on commercially available spirometers (measuring forced vital capacity [FVC], forced expiratory volume in 1s [FEV₁], FEV₁/FVC ratio) undertaken in accordance with standard guidelines (American Thoracic Society [ATS] and European Respiratory Society [ERS] criteria for lung function testing).^{14–16} We excluded home spirometry and peak flow meters, as the quality of measurement is not standardized.

2.2.3 | Comparator

We included studies comparing nonuse of spirometry as part of routine medical visits as the control group.

2.2.4 | Outcome measures

We planned to obtain data on at least one of the following outcome measures.

Primary outcomes:

- 1) Change in clinical decision making that consists of any change in assessment (such as principal diagnosis and severity classification) and/or management (such as treatment, investigation, follow-up schedule, education/counseling).
- 2) Change in health-related QoL assessed by validated patient-reported outcome measure, including but not limited to disease-specific questionnaires (e.g., asthma-specific QoLs, parent-proxy QoL questionnaire for chronic cough) and generic health questionnaires (e.g., State-Trait Anxiety Inventory, Short Form-36, Euro-QoL, PedsQL).

Secondary outcomes:

- 1) Change in other clinical endpoints defined by the study author's criteria, for example, functional status, disease/symptom control, exacerbations, and mortality.
- 2) Change in lung function test indices, for example, FEV₁, FVC, and FEV₁/FVC.
- 3) Severe adverse events during the routine use of spirometry.

2.3 | Study design

We included all randomized controlled trials (RCTs) and quasi-RCTs. We excluded studies not published in English, case reports, and studies published in abstract only.

2.4 | Information sources

Literature searches were undertaken within PubMed, Embase, Cochrane Central Register of Controlled Trials, US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov), and World Health Organization International Clinical Trials Registry Platform. Reference lists of included primary studies were hand searched for additional relevant references.

3 | SEARCH STRATEGY

We searched publications of the listed databases and trial registries from their inception to 27 July 2021 using the following search terms adapted to suit each database: (spirometry OR lung function) AND (child OR pediatric) AND (Lung OR Respiratory) AND (trial OR RCT). The review was restricted to publications in English. The complete search strategy terms are listed in Supporting Material. In addition to searching the electronic databases, we checked the reference lists of all included primary studies and review articles for additional relevant references.

4 | STUDY SELECTION

The first phase of study selection involved removing duplicate articles. All remaining abstracts were then reviewed by two authors (WB and JM) independently in the second phase. In the third phase, full texts of the articles identified as being potentially eligible for inclusion were retrieved and assessed by both reviewers independently for inclusion/exclusion. If the information published was insufficient to finalize inclusion, we contacted the authors to obtain additional information. Disagreements that could not be resolved by consensus were adjudicated by involving a third review author (AC).

5 | DATA COLLECTION AND ANALYSIS

The two review authors (WB and JM) independently extracted study characteristics and assessed risk of bias for each study using Cochrane methodology in the Cochrane Handbook for Systematic Reviews.¹⁷ Each potential source of bias was judged as high, low or unclear. Any disagreements were resolved by consensus or involving another review author (AC).

For dichotomous data, we planned to report the proportion of children with any change in clinical decision making and other clinical outcomes in comparison between intervention and control groups

reported as odds ratios (ORs). For continuous data, such as QoL scores and lung function indices, we planned to report each value with its unit and change from baseline to postintervention if data were available, as mean differences (MDs) or standardized MDs.

We intended to undertake subgroup analysis based on outpatient setting (primary care, secondary care, tertiary hospital), patient status (new or review patients), and principal diagnosis (asthma, bronchiectasis, cystic fibrosis). Further details of data collection and analysis are described in the supplement.

6 | RESULTS

6.1 | Description of studies

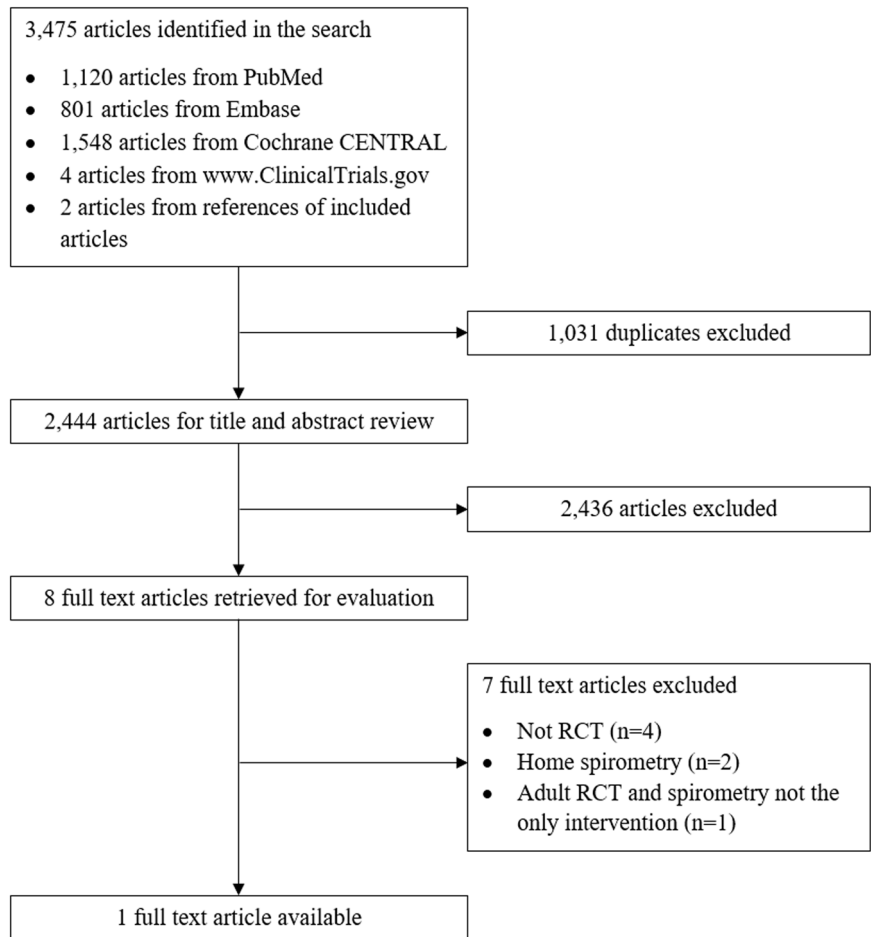
The search identified a total of 3475 potentially relevant articles (PRISMA diagram, Figure 1). After duplicates were removed, 2444 articles were screened for eligibility. Eight articles were selected for further evaluation by full-text review. Subsequently, seven articles were excluded and only one article was included.

Of the seven articles excluded by full-text review, four were observational studies.^{18–21} The three remaining articles were RCTs but did not fulfill our inclusion criteria. One assessed the influence of spirometry in general practice on the success rate of smoking cessation in adults²² (excluded as incorrect population). The remaining two studies^{23,24} assessed the outcome of treatment based on spirometry for children with asthma but used daily home spirometry, an exclusion criterion.

The single included study was derived from two trials (hereafter referred to as the parent trials), which were cluster RCTs of spirometry in general practice, to determine whether it improved asthma outcomes in children and adolescents (Table 1a,b).²⁵ The authors of the included study²⁵ decided to pool data as neither parent-trial recruited adequate participants to draw a firm conclusion. Details of the included study²⁵ and the two parent trials^{26,27} are shown in Table 2. The trials enrolled children and adolescents aged 7–17 years, who had been diagnosed with asthma and prescribed an inhaled medication in preceding 6 months. They excluded potential participants who were not contactable by telephone, with infrequent episodes of asthma, and with co-existing complex medical conditions. General practices involved in the trials were randomized to either the intervention group where spirometry was used in addition to regular clinical review or the control group that provided only clinical review.²⁵ For the first parent trial,²⁶ the intervention was 3-monthly spirometry reports interpreted by a respiratory specialist and sent to general practices. For the second parent trial,²⁷ the intervention was 2–6 hours formal spirometry training for general practice staff, who applied this knowledge with follow-up support.

The primary outcome of the included study²⁵ was asthma-QoL measured using the Pediatric Asthma Impact Scale in the first parent trial²⁶ and the Juniper Pediatric Asthma-QoL Questionnaire in the second parent trial.²⁷ Secondary outcomes included asthma exacerbations, nocturnal cough, physical and social activity limitation, anxiety, and written asthma plan. Although the outcomes were

FIGURE 1 Preferred reporting items for systematic reviews and meta-analyses (PRISMA) diagram.



measured every 3 months in the first parent trial²⁶ and 6 months in the second parent trial,²⁷ authors of the included study²⁵ only evaluated baseline and 12-months data.

6.2 | Risk of bias in the included study

We assessed all domains of risk of bias of the sole included study²⁵ and the two parent trials^{26,27} from which the data were pooled for the included study. We assessed that the risk of selection bias regarding randomization and allocation concealment was low. In the first parent trial,²⁶ randomization was performed by the study statistician using block randomized by computer and stratified according to location of practices. Group allocation was concealed until after the practices had recruited their first participant. In the second parent trial,²⁷ randomization was performed by an independent blinded statistician using SAS data management software and stratified by state and urban/rural. However, the risk of performance and detection bias in both parent trials^{26,27} was unclear. Given that the intervention could not be blinded, blinding was not applied for either participants or personnel in the trials. There was no information indicating whether the outcome assessor was blinded or not.

There was a low participation rate; 838 of 925 eligible patients declined to participate in the first parent trial²⁶ and ~4–5 patients per

practice participated in the second parent trial.²⁷ Six participants in the first parent trial²⁶ were found to have not received the allocated intervention and were subsequently excluded. Many children withdrew or were lost to follow-up, accounting for 3 of 81 (11%) and 41 of 163 (25%) participants recruited in each trial, respectively. We thus assessed that the risk was high for attrition bias in the included study.²⁵ It was unknown how representative the participants were of children with asthma due to the low rate of participation and high rate of exclusion.

We assessed that the risk of selective outcome reporting was high. The study protocols registered with trial registration and the original articles^{26,27} differed to that reported in the included study.²⁵ Some outcomes in the parent-trials were omitted in the pooled study, whereas some outcomes were shown in the pooled study without being mentioned previously in trial registration or the parent trials.

6.3 | Effects of the intervention

The included study²⁵ reported the QoL scores at baseline and 12 months in both parent trials.^{26,27} Overall, the QoL scores had improved over the study period, but there was no significant difference between groups. The adjusted difference between intervention and control at 12 months was -0.2 (95% confidence interval [CI]: $-4.9, 4.6$; $p = 0.95$) for Pediatric Asthma Impact Scale in the first parent trial²⁶ and was

TABLE 1a Risk of bias in the included study

	Allocation of intervention (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective outcome reporting (reporting bias)	Other bias
Abramson, 2015*	●	●	●	●	●	●	Unknown

Note: Grading system: ● = low risk of bias, ● = unclear risk of bias, ● = high risk of bias.

*Unlike most RCTs, the included trial²³ consisted of two parent trials^{24,25} to create a larger pooled data. Risk of bias was also judged by the assessment of each parent trial and its protocol registration.

TABLE 1b Risk of bias in the parent trials

	Allocation of intervention (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective outcome reporting (reporting bias)	Other bias
Abramson, 2010	●	●	●	●	NA*	NA*	Unknown
Holton, 2011	●	●	●	●	NA*	NA*	Unknown

*NA as the trials focused on different participants (adults) or outcomes.

TABLE 2 Details of each RCT included in this systematic review

Study	Participants	Intervention	Comparison	N	Outcomes measured	Assessment timepoint	Main results
Parent trials							
Abramson, 2010	Aged 18–70 years with asthma (Protocol reported ACTRN12606000378527)	3-monthly spirometry reports interpreted by a respiratory specialist that were sent to general practices	A: 3-monthly spirometry reports with regular review B: Spirometry only at baseline and 12 months with no report C: Usual care	305 enrolled and 253 completed	Primary: QoL measured by the 36-item Short Form (SF-36) questionnaire Secondary: Respiratory symptoms, asthma attacks, written asthma action plans, days lost from usual activities, emergency presentations, and hospital admissions	At baseline then every 3 months At baseline and 12 months	No significant changes in SF-36 from baseline to 12 months No significant differences between groups. Also, no significant differences in clinical endpoints
Holton, 2011	Aged ≥18 years with asthma (Protocol reported ACTRN12606000093583)	2–6 hours formal spirometry training for general practice staff. The staff then applied this knowledge with follow-up support from the training center	A: 6 hours training B: 2 hours training C: Usual care	397 enrolled and 323 completed (378 case note audit)	Primary: Juniper's Mini Asthma QoL, days off work due to asthma, exacerbations in the previous 4 weeks Secondary: Self-reported patient symptoms, lung function, the process of care and rating of acceptability and usefulness of spirometry	At baseline, 6, and 12 months	No significant differences between groups at 12 months
Included trial							
Abramson, 2015	Aged 7–17 years with asthma	3-monthly spirometry reports interpreted by a respiratory specialist that were sent to general practices	A: 3-monthly spirometry reports with regular review B: Usual care	81 enrolled and 72 completed	Primary: Pediatric Asthma Impact Scale Secondary: Asthma exacerbations, nocturnal cough, physical and social activity limitations, anxiety, written asthma plans, and self-reported adherence	At baseline and 12 months	QoL improved over 12 months but no significant difference between groups No significant differences between groups in other clinical endpoints
	Aged 7–17 years with asthma	2–6 hours formal spirometry training for general practice staff then the staff applied this knowledge with follow-up support from the training center	A: 2–6 hours formal spirometry training B: Usual care	163 enrolled and 122 completed	Primary: Juniper Pediatric Asthma QoL Questionnaire Secondary: Nocturnal cough, physical and social activity limitations, anxiety and written asthma plans		

Abbreviations: ACTRN, Australian–New Zealand Clinical Trials Registry Number; QoL, quality of life.

0.17 (95% CI: -0.15, 0.5; $p = 0.29$) for Pediatric Asthma QoL Questionnaire in the second parent trial.²⁷ As QoLs were measured using different tools, the data were not combined.

The reported secondary outcomes were clinical changes which were collected by questionnaires and dichotomized as “none” or “some” at 12 months. The analysis revealed no statistically significant difference between intervention and control in “asthma attacks” OR = 0.78 (95% CI: 0.36, 1.67; $p = 0.52$), “limitation of usual activity” OR = 1.34 (95% CI: 0.69, 2.60; $p = 0.39$), “nocturnal cough” OR = 0.95 (95% CI: 0.46, 1.98; $p = 0.90$), “bothered during physical activity” OR = 1.57 (95% CI: 0.86, 2.85; $p = 0.14$), “worry about asthma” OR = 0.97 (95% CI: 0.53, 1.79; $p = 0.93$), or “written asthma action plan” OR = 1.11 (95% CI: 0.43, 2.87; $p = 0.83$).

7 | DISCUSSION

Our systematic review of the current literature assessing the benefits of using spirometry in children found only one eligible study. The sole included study combined data from two parent studies that were cluster RCTs of spirometry in general practice. The authors of the included study concluded that the widespread use of spirometry for the management of childhood asthma in general practice is currently not supported.²⁵ However, the strengths and weaknesses of the study warrant discussion before this statement can be made.

Spirometry in the included study²⁵ applied quality control in accordance with the ATS/ERS recommendations to minimize technical shortcomings and undertook a cluster RCT with a good spread of general practice participation in terms of size and geographic location. However, the included study²⁵ has several limitations, which include methodological diversity and evaluation of study outcomes. Although both parent trials^{26,27} aimed to study the impact of spirometry, the intervention was delivered in a substantially different way in each trial (Table 2). Neither parent trials included an algorithm nor training for general practices to direct management of children with abnormal lung function, which may dull the benefits of spirometry-based monitoring. In addition, QoL as a primary outcome measure was unlikely to demonstrate an effect of spirometry added on clinical review for patients with mild asthma, as all QoL scores clustered toward the best score and it was assessed at only baseline and 12 months. For changes in clinical outcomes, dichotomizing the change as “none” or “some” might be inadequate to detect a difference between groups than a more refined scale would have permitted. Importantly, the included study did not assess the effect of spirometry on outcomes until 12 months. During the long study period, the outcomes could be confounded by multiple factors, such as seeing other practices and adherence to therapy. Hence, we believe the results of this single study do not conclusively answer whether the routine use of spirometry improves health-related QoL and/or guides clinical management. We restrict the search to studies in English only, but otherwise we are not aware of other limitations in our review processes.

Other pediatric data on the use of spirometry in clinical practice, obtained from non-RCTs, show varying clinical outcomes. A large observational study in 2688 children revealed in multivariate analysis

(adjusting for age, gender, severity, and insurance) found that spirometry was not associated with an increase or decrease in emergency department attendance (relative hazard ratio = 1.07, 95% CI: 0.74, 1.53).²⁸ In contrast, a study of 367 children with asthma aged 4–18 years performing spirometry before clinical evaluation found that spirometry changed management in 15% of visits that were more likely to increase (75%) than maintain (20%) or decrease (5%) therapy.²⁹ Another study included 56 children who presented with an asthma exacerbation and found that 30.4% of treatment plans were changed after clinicians viewed their spirometry, with an increased percentage of patients receiving steroids, bronchodilator, or “yellow zone” treatment.³⁰

The shortage of RCTs evaluating the benefits of routine spirometry use in clinical review may, in part, be explained by its almost universal inclusion into current standards of care in many conditions including common illnesses such as childhood asthma.⁶ Hence, to undertake an RCT regarding the benefits of using spirometry, the study design cannot exclude its routine use, that is, the controls should receive the same standard of care. One possible design would be evaluation of the delayed use of spirometry and indeed, an RCT protocol that evaluates outcomes in a single visit is currently underway.³¹ An alternative trial model is a cluster or stepwise RCT that compares data from centers using spirometry to data from centers not using spirometry.

8 | CONCLUSIONS

Our systematic review has shown the paucity of data on the benefits of using spirometry in children in routine clinical practice. With multiple guidelines advocating its use, we recommend this advice should be followed in the absence of any evidence to inform practitioners otherwise. It is likely but remain unknown if better evidence and implementation will enhance its routine use. Thus, there is a critical need for high-quality RCTs to inform practice on the impact of routine spirometry use in all healthcare settings.

AUTHOR CONTRIBUTIONS

Anne B. Chang conceptualized the review. Wicharn Boonjindasup undertook the search strategy. Wicharn Boonjindasup and Julie M. Marchant independently reviewed and assessed articles. Wicharn Boonjindasup composed the first draft. Julie M. Marchant, Anne B. Chang, Margaret S. McElrea, and Stephanie T. Yerkovich subsequently revised the manuscript. All authors approved the manuscript before submission for publication.

ACKNOWLEDGEMENTS

We are grateful to the librarian of the University of Queensland for providing guidance on the systematic review process. We also thank members of Cough & Airway Research Group at Australian Centre for Health Services Innovation for supporting this study. This study was not funded. Wicharn Boonjindasup is supported by a Charles Darwin University PhD scholarship. Anne B. Chang is supported by an Australian National Health and Medical Research Council (NHMRC) Practitioner Fellowship (APP1058213) and a top-up fellowship from the Children's

Hospital Foundation (Grant 50286). Julie M. Marchant is supported by an Early Career Fellowship Grant from Queensland Children's Hospital Foundation (RPC0772019). Open access publishing facilitated by Charles Darwin University, as part of the Wiley - Charles Darwin University agreement via the Council of Australian University Librarians.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article, as no new data were created or analyzed in this study.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Boonjindasup W, Chang AB, McElrea MS, Yerkovich ST, Marchant JM. Does the routine use of spirometry improve clinical outcomes in children?—A systematic review. *Pediatric Pulmonology*. 2022;57:2390-2397. doi:10.1002/ppul.26045