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Validation of Parental Reports of Asthma Trajectory, Burden and Risk Using the Pediatric Asthma Control and Communication Instrument

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Abstract

Context—Despite a growing interest, few pediatric asthma questionnaires assess multiple dimensions of asthma morbidity, as recommended by national asthma guidelines, or use patient-reported outcomes.

Objective—To evaluate a questionnaire that measures multiple dimensions of parent-reported asthma morbidity (Direction, Bother and Risk).

Patients and Methods—We administered the Pediatric Asthma Control and Communication Instrument (PACCI) and assessed asthma control (PACCI Control), quality of life, and lung function among children presenting for routine asthma care. The PACCI was evaluated for discriminative validity.

Results—317 children participated (mean age 8.2 years; 58% male; 44% African American). As parent-reported PACCI Direction changed from “better” to “worse”, we observed poorer asthma

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control ($p < 0.001$), mean PACQLQ scores ($p < 0.001$) and $FEV_1\%$ ($p = 0.025$). Linear regression showed that for each change in PACCI Direction, the mean PACQLQ score decreased by -0.6 (95% CI: $-0.8, -0.4$). As parent-reported PACCI Bother changed from “not bothered” to “very bothered”, we observed poorer asthma control ($p < 0.001$) and mean PACQLQ scores ($p < 0.001$). Linear regression showed that for each change in PACCI Bother category, the mean PACQLQ score decreased by -1.1 (95% CI: $-1.3, -0.9$). Any reported PACCI Risk event (ED visit, hospitalization or use of an oral steroid) was associated with poorer asthma control ($p < 0.05$) and PACQLQ scores ($p < 0.01$).

Conclusions—PACCI Direction, Bother and Risk are valid measures of parent-reported outcomes and show good discriminative validity. The PACCI is a simple clinical tool to assess multiple dimensions of parent-reported asthma morbidity, in addition to risk and control.

Keywords

risk; children; burden; trajectory; survey; validation; PACCI; patient-reported outcomes

INTRODUCTION

Asthma guidelines published by the National Institutes of Health (NIH) suggest that health care providers assess multiple dimensions of patient asthma morbidity, including the signs and symptoms of asthma, quality of life/functional status, history of exacerbations, pharmacotherapy (adherence, side effects), lung function and patient-provider communication.⁽¹⁾ The guidelines encourage clinicians to use patient self-assessment questionnaires as a means of obtaining information on these dimensions of asthma control from the perspective of the patient and/or the patient's family. However, most currently available self-assessment questionnaires evaluate just one or two of these dimensions of morbidity⁽²⁻⁵⁾—always impairment, and rarely risk. Furthermore, these questionnaires do not capture the patient or parent perspectives regarding quality of life or changes (improvements or worsening) in disease morbidity.⁽⁶⁾

We have shown that clinicians do utilize multiple dimensions of asthma health in order to assess and treat asthma,⁽⁷⁻⁹⁾ including disease trajectory (e.g., direction of asthma getting worse or better), burden (bother) and risk for poor outcomes. Those findings, along with asthma guidelines and other published work, suggest that the treatment decisions made by health care providers involve a multiplicity of clinical assessments and cognitive tasks.⁽¹⁰⁾ Therefore, if clinicians are truly to provide care consistent with national asthma guidelines, then there may be a benefit to development and validation of tools that facilitate the work of clinicians to successfully carry out as many of these clinical assessments and tasks as possible.

The Pediatric Asthma Control and Communication Instrument (PACCI) is a parent-completed assessment questionnaire that assesses five dimensions of asthma health. The PACCI has been previously validated as a measure of asthma control,⁽¹¹⁾ as has the adult version, the ACCI⁽¹²⁾. The purpose of this study is to evaluate the validity of three other PACCI domains unique from control: disease trajectory (*direction {e.g., asthma getting worse or better}*), burden (*bother*) and risk domains (systemic use of steroids, emergency

department visits, hospitalizations) in a diverse pediatric sample, including Black, Latino and Spanish-speaking children, across the age spectrum (0 – 21 years).

METHODS

Questionnaire Development and Content

The development of the PACCI has been previously described.⁽¹¹⁾ It is written at a 5th grade reading level, has been validated to measure asthma control among diverse, English- and Spanish-speaking patient populations and is intended to help clinicians better utilize patient/parent reported information to guide asthma treatment.

The PACCI is a 12-item parent-completed questionnaire (see Online Repository Figures E1 and E2) that assesses five conceptual domains of asthma morbidity (direction, bother, risk, adherence and control). The assessments are based on parental report of the child's asthma since the last visit with the doctor (or over the past 2 months if the child has not previously seen the doctor). The current analysis focuses on three of the five domains:

1. **Direction**—the trajectory of how the child's asthma has changed (better, the same, or worse)
2. **Bother**—how much they are bothered by the child's asthma (not bothered, somewhat bothered, very bothered) as an indication of how burdensome asthma has been on the child's parents
3. **Risk**—the occurrence of emergency department visits, hospitalizations and/or oral steroid use for asthma;

Procedures

This was a cross-sectional study that took place between July, 2007 and September, 2010. This study was approved by the Johns Hopkins University and University of California, San Francisco (UCSF) Institutional Review Boards. Prior to the seeing a clinician, parents completed: the PACCI; established questionnaires measuring asthma morbidity (described below); and a demographic questionnaire. Spirometry was obtained only at the Johns Hopkins Children's Center (JHCC), at the discretion of the treating clinician.

Sample

A convenience sample of subjects was recruited among patients presenting for outpatient asthma care at JHCC or UCSF in established asthma specialty care clinics with practices modeled after NIH guidelines. Patients were seen by pediatric pulmonologists, general pediatricians, and nurse practitioners. Subjects were eligible if they: 1) had self-reported doctor-diagnosed asthma; 2) were accompanied by a caregiver who could give consent; and 3) spoke English or Spanish. Caregivers provided informed consent, and children older than 8 years of age provided assent in their preferred languages

Established Asthma Morbidity Measures

Asthma Control, using the PACCI Control domain, which has been validated previously.⁽¹¹⁾ For this analysis, control was scored in two ways:

- 1) *Sum Score* is a summation of the score assigned to each response option (0 – 5 for questions 7, 8, 10, 11; 0 – 4 for question 9), ranging from 0 (best asthma control) to 19 (worst asthma control).
- 2) *Problem Index* dichotomously scores each of the five Control items (questions 7 – 11) as zero (“green” responses) or one (all other responses), which are then summed, ranging from 0 (no control problems) to 5 (five control problems).

The Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ)⁽¹³⁾ consists of 13 questions that assess the impact of asthma on activity limitation (4 questions) and emotional function (9 questions) during the previous week. Each question is scored on a 7-point scale. The final PACQLQ score is a mean of the 13 scores, with higher scores indicating better quality of life. The PACQLQ has been shown to be a valid measure of asthma-specific quality of life for children with stable and unstable asthma, and with different levels of asthma severity.⁽¹⁴⁻¹⁶⁾ The emotional function domain of the PACQLQ is designed to capture a range of possible parental feelings that may be present due to their child's asthma, including feeling “helpless or frightened”, frustrated or impatient”, “upset”, “bothered” and “worried or concerned”. The total score for the emotional function domain is the mean of the item scores that make up that domain. The activities limitation domain inquires about the frequency of changed family plans, missed work, sleepless nights and nocturnal awakenings due to the child's asthma.

We examined total PACQLQ score, as well as total scores for the activity limitation and emotional function domains separately.

Spirometry was obtained at JHCC at the discretion of the clinician, for the 79 children (25% of the participants) who were able to perform it due to age (i.e., those who were ≥ 5 years of age).

Analysis

Descriptive statistics (means and proportions) were used to characterize the socio-demographic and clinical characteristics of the study population. To test for discriminative properties, we examined mean asthma PACCI Control (sum score; problem index), PACQLQ and lung function (FEV₁ percent predicted {FEV₁%} and FEV₁/FVC ratio) values across the PACCI domains of Direction (better, same, worse), Bother (not bothered, somewhat bothered, very bothered), and Risk (yes vs. no for reports of ED visits, hospitalization and/or use of oral steroids for asthma), using Analysis of Variance (ANOVA). To further explore the relationship of the parent-reported outcomes and quality of life, we created simple linear regression models to examine how quality of life scores (and sub-domain scores) varied across the categories of Direction and Bother. Because there were few hospitalizations reported among the participating subjects, a post hoc Any Risk variable was constructed to further evaluate the discriminative properties of the PACCI Risk domain. Any Risk is a composite measure that combines all three Risk indicators. A “yes” response for the Any Risk variable is based upon parental report of the occurrence of at least one of the three indicators of risk, while a “no” response is based upon the absence of occurrence of all three risk indicators. We used chi squared analyses to examine the

associations of Direction, Bother and Risk domains to each other. Specifically, we looked at the proportion of patients reporting: 1) a given level of Direction by levels of Bother and Risk; 2) a given level of Bother by levels of Risk. Analyses were performed using STATA 11 (Stata Corp, College Station, TX). All analyses were 2-sided and a p-value of less than 0.05 was considered to be statistically significant.

RESULTS

Respondent Characteristics

There were a total of 317 participants, representing a variety of ethnicities and parental education levels (Table 1), of whom 79 patients performed spirometry. Parents reported that during the prior two months, or since their child's most recent asthma outpatient visit, 33% of study participants used oral steroids (95% confidence interval {CI}, 28% - 38%), 20% had an ED visit for asthma (95% CI, 15% - 24%) and 10% were hospitalized for asthma (95% CI, 6% - 13%) (Table 1).

In terms of parent-reported outcomes: 1) half of the parents reported that their child's asthma had improved ("better"), while less than 10% reported that their child's asthma had declined ("worse")—the remainder reported their child's asthma as being unchanged; 2) for the Bother domain, 60% of parents reported being "bothered" about their child's asthma, with most being "somewhat bothered" rather than "very bothered". Mean scores and 95% confidence intervals were similar among overall quality of life (PACQLQ) and the emotional function and activity limitation sub-domains.

Discriminative Properties

In general, we observed significant associations of each PACCI domain with various valid indicators of asthma morbidity, particularly the indicators of asthma control and quality of life. More detailed findings are described below.

Direction—Parents' reports of the direction of their child's asthma were associated with indicators of asthma morbidity (Table 2). More specifically, as parent-reported PACCI Direction varied from "better" to "worse", mean PACCI Sum Scores and PACCI Problem Index scores increased (indicating poorer asthma control) ($p < 0.001$), while we observed decreased mean overall PACQLQ scores ($p < 0.001$) and FEV₁% ($p = 0.025$) (Table 2). A similar association was observed with the PACQLQ emotional function and activity limitations sub-domains, but more consistently with the emotional function domain. Linear regression showed that for each change in PACCI Direction category (from "better" to "same" to "worse"), the mean PACQLQ changes was -0.6 (95% CI: $-0.8, -0.4$), while the mean emotional function score decreased by -0.6 (95% CI: $-0.8, -0.3$), and the activities limitation score decreased by -0.8 (95% CI: $-1.0, -0.5$). There was no significant association with mean FEV₁/FVC as parent-reported asthma direction varied from "better" to "worse" ($p = 0.8$).

Bother—Mean PACCI Sum Score and PACCI Problem Index increased significantly (indicating poorer asthma control) as parent-reported PACCI Bother varied from "not

bothered” to “very bothered” ($p<0.001$) (Table 3). Mean PACQLQ values significantly decreased (indicating poorer quality of life) as parent reports of PACCI Bother varied from “not bothered” to “very bothered” ($p<0.001$). This pattern of findings held true for both the emotional function and activity limitations PACQLQ sub-domains. Linear regression showed that for each change in PACC I Bother category (from “not bothered” to “somewhat bothered” to “very bothered”), the mean PACQLQ changes was -1.1 (95% CI: $-1.3, -0.9$), while the mean emotional function score decreased by -1.0 (95% CI: $-1.3, -0.8$), and the activities limitation score decreased by -1.3 (95% CI: $-1.6, -1.0$). There was no significant change in FEV₁% and FEV₁/FVC across categories of PACC I Bother ($p>0.1$ for both lung function measures).

Risk—Each PACC I Risk measure was significantly associated with asthma control and quality of life scores (Table 4). Specifically, the mean PACC I Sum Score and Problem Index scores increased significantly for those who reported any occurrence of an ED visit, hospitalization or use of an oral steroid ($p<0.05$). Similarly, quality of life scores (PACQLQ: overall; emotional function and activity limitations sub-domains) decreased significantly in the presence of any reported indicator of risk ($p<0.01$). There were no significant associations between the individual PACC I measures of risk and the lung function measures ($p>0.05$), although significant associations were observed between the Any Risk composite variable and mean values for FEV₁% ($p<0.0001$), FEV₁/FVC ratio ($p<0.05$), as well as the measures of asthma control (PACC I Sum Score and Problem Index) ($p<0.0001$) and quality of life (PACQLQ) ($p<0.0001$).

Associations of Direction with Bother and Risk—Significant associations were observed between responses to the Direction and the Bother and Risk domains (Table 5; Online Repository Table E1). More specifically, we observed a higher proportion of parents reporting “better” asthma among those not reporting an ED visit or oral steroid use for asthma than among those who did report such an occurrence (Table 5). A similar, but statistically insignificant trend was observed for hospitalizations due to asthma. Conversely, a higher proportion of parents reported their child's asthma as “the same” or “worse” if their child had an ED visit or oral steroid use for asthma compared to parents who didn't report these two types of events. A similar, but statistically insignificant trend was observed for asthma-related hospitalizations. In terms of the PACC I Bother domain, a higher proportion of parents reported not being bothered about their child's asthma if they also didn't report an ED visit, hospitalization or oral steroid use for asthma ($p<0.005$) (Table 5). Conversely, a higher proportion of parents reported being “somewhat bothered” or “very bothered” about their child's asthma if they had also reported an ED visit, hospitalization or oral steroid use for asthma. Lastly, a decreasing proportion of parents reported that their child's asthma was “better” as the level of “bother” from asthma increased from “not bothered” to “somewhat bothered” to “very bothered” ($p<0.001$) (Online Repository Table E1). Conversely, an increasing proportion of parents reported that their child's asthma was “worse” as the level “bother” from asthma increased from “not bothered” to “very bothered” ($p<0.001$).

DISCUSSION

The PACCI is a valid means of measuring multiple indicators of asthma morbidity, including disease trajectory (Direction), disease burden (Bother) and indicators of Risk (emergency department visits, hospitalizations and use of prednisone for asthma). Therefore, the PACCI should facilitate the comprehensive collection of asthma morbidity data meaningful to parents of children with asthma and their health care providers. The collection of information regarding multiple dimensions of asthma morbidity is suggested in the NIH asthma guidelines, although no tools currently exist that capture more than two dimensions of asthma morbidity—typically asthma control and/or risk. Since the Direction, Bother, and Risk domains of the PACCI have already been shown to be important to medication treatment decision-making,^(8;9) it is reasonable to systematically incorporate these domains into a parent or patient questionnaire for routine clinical use by pediatric health care providers.

Although we observed an association of the PACCI Direction, Bother, and Risk domains with asthma control and quality of life, we believe that the PACCI domains are unique constructs to be assessed in addition to asthma control and quality of life. Previous research in our group has shown that the PACCI Direction, Bother and Risk constructs modify physician perceptions of asthma control and severity.⁽⁷⁾ The PACCI allows for the assessment of asthma control, risk and two parent-reported outcomes indicative of quality of life (Direction; Bother) by using a single questionnaire, a feasible advantage over other currently available questionnaires that tend to measure only control. For the purposes of validity testing, we were obligated to examine how the Direction, Bother and Risk dimensions of asthma morbidity relate to established measures of asthma morbidity (e.g., asthma control). However, we do not believe that simply measuring asthma control alone would provide insight into these dimensions of asthma morbidity. Focusing exclusively on asthma control does not get at unique perspectives of disease morbidity from the patient/parent point of view. This is indeed the purpose of developing patient-reported outcomes as well as developing patient-centered means of clinical evaluation, as promoted in asthma guidelines,⁽¹⁾ and by the NIH,⁽⁶⁾ the Patient Centered Outcomes Research Institute (PCORI)^(17;18) and the Food and Drug Administration (FDA).⁽¹⁹⁾

Direction (i.e., trajectory of asthma status) is not an NIH asthma guideline-based criterion for determining asthma morbidity. However, we propose that Direction should be considered, as it is a dimension of disease activity provided from the parent/patient's perspective, and it is consistent with the evolving interests for using patient-reported outcomes to evaluate patient response(s) to treatment.⁽¹⁹⁻²¹⁾ Although not evaluated in this study, additional data analyzed within our group suggests that the Direction domain is: 1) associated with longitudinal changes in other measures of asthma morbidity;⁽²²⁾ 2) a meaningful determinant of treatment decisions by pediatricians to step-down controller medication therapy.^(8;9;23)

NIH asthma guidelines recommend that “perceptions and experiences of patients must be assessed directly and not imputed from measures of clinical status”.⁽¹⁾ The PACCI Bother dimension is an indicator of disease burden as perceived by the family and appears to be a

valid indicator of quality of life. Bother has previously been incorporated into a published patient-reported outcome measurement tool.⁽²⁴⁾ The Bother construct is influential in pediatrician ratings of asthma severity and decisions to step-up and step-down treatment.^(7;9) Given that the Bother construct is also based on parent/patient perceptions, the PACCI offers two patient-reported outcomes (Bother and Direction) that could be useful in evaluating changes over time in patient clinical status from the patient's/parent's perspective.⁽²²⁾ Notably, there are no asthma quality of life measures that meet this criterion, as they are primarily focused on symptom assessment.⁽⁶⁾

NIH asthma guidelines suggest that health care providers routinely assess patient risk for poor outcomes as a component of asthma control or severity evaluations. The guidelines characterize risk as “exacerbations requiring oral systemic corticosteroids”. The PACCI provides for the assessment of three indicators of asthma exacerbations—emergency department visits, hospitalizations and oral steroid use—each of which independently should be of clinical importance to a health care provider who elicits a history of such an occurrence. Results from evaluation of the Any Risk variable (defined as a “yes” response to any one of the three risk indicators) suggests that these items could be collapsed into a single question, although further exploration of other measurement properties (e.g., predictive validity) is needed before doing so. We have previously observed how reports of a recent hospitalization result in more severe asthma ratings, poorer asthma control ratings and an increased likelihood of stepping up asthma treatment by pediatricians.^(7;9) More information is needed on the effect of reports of emergency department visits and/or oral steroid use on the clinical evaluations and treatment decisions by pediatricians.

There are several limitations to this study. First, these findings have been observed among children seeking care in asthma specialist settings, so these results may not be generalizable to children cared for in other settings. However, we included a broad cross-section of socio-demographic groups, including children seen at a federally qualified health center. Second, our data is based on parent self-report, so is subject to recall bias and reporting bias. However, parent report is a widely used clinical and research approach, and often times is the primary means to obtaining clinical information. Any reporting bias would likely be non-differential towards the null. Third, this was a cross-sectional study, so we do not know the predictive validity of the Direction, Bother and Risk domains of the PACCI in identifying patients at higher risk for poor outcomes in the future. This lack of information regarding the predictive ability of morbidity assessments is a common limitation among pediatric asthma questionnaires. Fourth, some of the comparisons utilizing were limited by small numbers of participants (e.g., there are only 4 and 2 subjects in the “Worse” and “Very bothered” subpopulations respectively who performed pulmonary function tests). Lastly, we do not know the impact of routine assessment of PACCI Direction, Bother and Risk on asthma care and asthma outcomes. However, there is a significant gap in the literature regarding the usefulness of any of the asthma assessment questionnaires in improving care and helping clinicians to provide care more consistent with national asthma guidelines.

In summary, the Direction, Bother and Risk domains of the PACCI are valid measures of asthma morbidity. Further research is needed to learn: 1) about the predictive and longitudinal implications of parent-reported Direction, Bother and Risk; and 2) if routine

assessment of these dimensions of asthma morbidity by pediatric health care providers results in improved asthma patient care and outcomes. The PACCI offers pediatric health care providers a comprehensive measure of asthma morbidity and parent-reported measures of pediatric asthma morbidity that should be useful in clinical care and research settings.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Abbreviations

NIH	National Institutes of Health
FEV1	forced expiratory volume in the first second

References

1. Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma-Summary Report 2007. *Journal of Allergy and Clinical Immunology*. 2007; 120(5, Supplement 1):S94–S138. [PubMed: 17983880]
2. Schatz M, Sorkness CA, Li JT, Marcus P, Murray JJ, Nathan RA, et al. Asthma Control Test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. *J Allergy Clin Immunol*. 2006; 117(3):549–56. [PubMed: 16522452]
3. Murphy KR, Zeiger RS, Kosinski M, Chipps B, Mellon M, Schatz M, et al. Test for respiratory and asthma control in kids (TRACK): a caregiver-completed questionnaire for preschool-aged children. *J Allergy Clin Immunol*. 2009; 123(4):833–9. [PubMed: 19348922]
4. Skinner EA, Diette GB, Algatt-Bergstrom PJ, Nguyen TT, Clark RD, Markson LE, et al. The Asthma Therapy Assessment Questionnaire (ATAQ) for children and adolescents. *Dis Manag*. 2004; 7(4):305–13. [PubMed: 15671787]
5. Liu AH, Zeiger R, Sorkness C, Mahr T, Ostrom N, Burgess S, et al. Development and cross-sectional validation of the Childhood Asthma Control Test. *Journal of Allergy and Clinical Immunology*. 2007; 119(4):817–25. [PubMed: 17353040]
6. Wilson SR, Rand CS, Cabana MD, Foggs MB, Halterman JS, Olson L, et al. Asthma outcomes: Quality of life. *Journal of Allergy and Clinical Immunology*. 2012; 129(3, Supplement):S88–S123. [PubMed: 22386511]
7. Demissie S, Riekert KA, Eakin MN, Bilderback A, Diette GB, Okelo SO. How Do Perceptions of Asthma Control and Severity Relate to Indicators of Asthma Status and Treatment Recommendations by Pediatricians? *Pediatr Allergy Immunol Pulmonol*. 2012; 25(1):17–23. [PubMed: 22454788]
8. Diette GB, Patino CM, Merriman B, Paulin L, Riekert KA, Okelo SO, et al. Patient Factors that Physicians Use to Assign Asthma Treatment. *Ann Intern Med*. 2007; 167(13):1360–6.
9. Okelo SO, Patino CM, Riekert KA, Merriman B, Bilderback A, Hansel NN, et al. Patient factors used by pediatricians to assign asthma treatment. *Pediatrics*. 2008; 122(1):e195–e201. [PubMed: 18595964]
10. Bracha Y, Brottman GM, Carlson A. Physicians, Guidelines, and Cognitive Tasks. *Eval Health Prof*. 2010
11. Okelo SO, Eakin MN, Patino CM, Teodoro AP, Bilderback AL, Thompson DA, et al. The Pediatric Asthma Control and Communication Instrument asthma questionnaire: For use in diverse children of all ages. *J Allergy Clin Immunol*. 2013

12. Patino CM, Okelo SO, Rand CS, Riekert KA, Krishnan JA, Thompson K, et al. The Asthma Control and Communication Instrument: a clinical tool developed for ethnically diverse populations. *J Allergy Clin Immunol*. 2008; 122(5):936–43. [PubMed: 18848721]
13. Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in the parents of children with asthma. *Qual Life Res*. 1996; 5(1):27–34. [PubMed: 8901364]
14. Juniper EF, Guyatt GH, Feeny DH, Ferrie PJ, Griffith LE, Townsend M. Measuring quality of life in children with asthma. *Quality of Life Research*. 1996; 5(1):35–46. [PubMed: 8901365]
15. Tauler E, Vilagut G, Grau G, Gonzalez A, Sanchez E, Figueras G, et al. The Spanish version of the Paediatric Asthma Quality of Life Questionnaire (PAQLQ): Metric characteristics and equivalence with the original version. *Quality of Life Research*. 2001; 10(1):81–91. [PubMed: 11508478]
16. Reichenberg K, Broberg AG. Quality of life in childhood asthma: use of the Paediatric Asthma Quality of Life Questionnaire in a Swedish sample of children 7 to 9 years old. *Acta Paediatrica*. 2000; 89(8):989–95. [PubMed: 10976845]
17. Selby JV, Beal AC, Frank L. The Patient-Centered Outcomes Research Institute (PCORI) national priorities for research and initial research agenda. *JAMA*. 2012; 307(15):1583–4. [PubMed: 22511682]
18. Barr P. Collaborative efforts: PCORI comparative-effectiveness awards add a new twist: patient input. *Mod Healthc*. 2012; 42(22):12–3.
19. Speight J, Barendse SM. FDA guidance on patient reported outcomes. *BMJ*. 2010; 340:c2921. [PubMed: 20566597]
20. Frampton GK, Shepherd J. Patient-reported outcomes in clinical trials of inhaled asthma medications: systematic review and research needs. *Qual Life Res*. 2011; 20(3):343–57. [PubMed: 20945162]
21. Rothman ML, Beltran P, Cappelleri JC, Lipscomb J, Teschendorf B. Patient-reported outcomes: conceptual issues. *Value Health*. 2007; 10(Suppl 2):S66–S75. [PubMed: 17995476]
22. Demissie SM, Bilderback A, Eakin MN, Riekert KA, Rand CS, Okelo SO. How Well Do Parental Reports Of Interval Changes In Well-Being Relate To Traditional Indicators Of Asthma Morbidity? *Am J Respir Crit Care Med*. 2011; 183(1_MeetingAbstracts):A3784.
23. Okelo SO, Siberry GK, Solomn BS, Yamazaki M, Hetzler T, Ferrell CL, et al. Survey of Pediatric Asthma Care Education in Residency (SPACER) Study. *Pediatric Academic Society Abstracts2View Online Archives*. 2009:E–PAS2009:3685.1.. Ref Type: Abstract.
24. Yeatts KB, Stucky B, Thissen D, Irwin D, Varni JW, Dewitt EM, et al. Construction of the Pediatric Asthma Impact Scale (PAIS) for the Patient-Reported Outcomes Measurement Information System (PROMIS). *J Asthma*. 2010; 47(3):295–302. [PubMed: 20394514]

Clinical implications

The results of this study support the validity of the PACCI as a multi-dimensional measure of parent-reported pediatric asthma morbidity.

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Capsule Summary

The PACCI is a multi-dimensional asthma morbidity assessment questionnaire that utilizes parent-reported outcomes. The PACCI can be used for more comprehensive assessments of asthma morbidity by pediatric health care providers than currently available questionnaires.

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Highlight Box

1. What is already known about this topic?

- National asthma guidelines recommend that clinicians routinely assess multiple dimensions of asthma morbidity
- Patient-reported outcomes are emerging as an important clinical measure
- Most asthma questionnaires measure only asthma control

2. What does this article add to our knowledge?

- The PACCI domains of Direction, Bother and Risk are valid and discriminating measures of parent-reported asthma morbidity
- A brief questionnaire can be used by clinicians to simultaneously multiple dimensions of asthma morbidity

3. How does this study impact current management guidelines?

- The PACCI offers clinicians a new means to meet guideline recommendations to assess multiple dimensions of asthma health

Table 1

Socio-Demographic and Asthma Morbidity Characteristics of Participants (n = 317)

Age in Years: Mean (SD), range	8.2 (4.8) 0.48-20.54
Sex: Female (%)	42*
Ethnicity (%)	
African American	42.6
Caucasian	31.2
Latino	15.5
Other	5.4
Unknown	4.4
Parental Education (%)	
Less than 12th grade	7.3
High School Graduate	19.8
Some college/technical school	25.8
College graduate	14.5
Post-college graduate	17.9
Unknown	14.5
Asthma Morbidity Indicator	Percentage of Patients
Level of Asthma Control by PACCI Controlled	39.1%
Partly Controlled	25.2%
Uncontrolled	25.6%
Poorly Controlled	10.1%
Parent-reported Disease Trajectory	
Better	50.8%
Same	40.6%
Worse	8.6%
Parent-reported Disease Burden	
Not Bothered	40%
Somewhat Bothered	51%
Very Bothered	9%
Quality of Life (PACQLQ)	Mean (95% CI)
Overall	5.5 (5.3 - 5.6)
Emotional Function	5.5 (5.3 - 5.6)
Activity Limitation	5.1 (4.9 - 5.3)

Asthma Control PACCI Sum Score: Mean (95% CI)	4.3 (3.9 - 4.8)
PACCI Problem Index: Mean (95% CI)	1.7 (1.5 - 1.8)

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Table 2

Discriminant properties of PACCI Direction domain: Mean values (95% CI) of asthma control (PACCI Sum Score and Problem Index), quality of life (PACQLQ), and lung function (FEV₁%, FEV₁/FVC) values across PACCI Direction[‡] categories using ANOVA.

PACCI Direction Categories	Better (n = 159)	Same (n = 127)	Worse (n = 27)	p- value
PACCI Sum Score				
	2.8 (2.3 - 3.4)	5.3 (4.6 - 6)	8.2 (7 - 9.4)	<.0001
PACCI Problem Index				
	1 (0.8 - 1.2)	2.1 (1.8 - 2.4)	3.5 (2.9 - 4)	<.0001
Quality of Life-Overall (PACQLQ)				
	5.8 (5.6 - 6.0)	5.2 (4.9 - 5.4)	4.7 (4.2 - 5.3)	<.0001
Quality of Life-Emotional Function (PACQLQ)				
	5.8 (5.6 - 6.0)	5.2 (5.0 - 5.5)	4.7 (4.2 - 5.3)	<.0001
Quality of Life -Activity Limitation (PACQLQ)				
	5.7 (5.4 - 5.9)	4.6 (4.3 - 4.9)	4.6 (3.9 - 5.3)	<.0001
FEV₁ %	n=28	n=47	n=4	
	90% (90% - 100%)	80% (80% - 90%)	80% (60% - 110%)	.025
FEV₁/FVC	n=28	n=47	n=4	
	90% (80% - 90%)	80% (80% - 90%)	80% (70% - 90%)	.7744

[‡]-the parent is asked to report how the child's asthma has been since the last prior doctor visit or over the past two months if not previously seen by the doctor

Table 3

Discriminant properties of PACCI Bother domain: Mean values (95% CI) of asthma control (PACCI Sum Score and Problem Index), quality of life (PACQLQ), and lung function (FEV₁%, FEV₁/FVC) values across PACCI Bother categories using ANOVA.

PACCI Bother Categories	Not Bothered (n = 126)	Somewhat Bothered (n = 160)	Very Bothered (n = 29)	p- value
PACCI Sum Score				
	1.7 (1.3 – 2.2)	5.2 (4.7 – 5.8)	10.1 (8.9 – 11.2)	<.0001
PACCI Problem Index				
	.6 (.4 - .8)	2.1 (1.8 – 2.3)	3.9 (3.4 – 4.4)	<.0001
Quality of Life-Overall (PACQLQ)				
	6.2 (6.1 – 6.4)	5.1 (4.9 – 5.3)	4.2 (3.6 – 4.7)	<.0001
Quality of Life-Emotional Function (PACQLQ)				
	6.3 (6.1 – 6.4)	5.1 (4.9 – 5.3)	4.3 (3.7 – 4.9)	<.0001
Quality of Life-Activity Limitation (PACQLQ)				
	6.1 (5.9 – 6.4)	4.6 (4.4 – 4.9)	3.8 (3.1 – 4.5)	<.0001
FEV₁ %	n=33	n=44	n=2	
	90% (80% - 100%)	80% (80% - 90%)	80% (60% - 100%)	.1372
FEV₁/FVC	n=33	n=44	n=2	
	90% (80% - 90%)	80% (80% - 90%)	80% (70% - 90%)	.6022

Table 4

Discriminant properties of PACCI Risk domain: Mean values (95% CI) of asthma control (PACCI Sum Score, Problem Index), quality of life (PACQLQ), and lung function (FEV₁%, FEV₁/FVC) values across PACCI Risk categories * using ANOVA **.

PACCI Risk Category	ED Visit		Hospitalization		Prednisone Use		Any Risk	
	No (n = 252)	Yes (n = 62)	No (n = 284)	Yes (n = 31)	No (n = 211)	Yes (n = 103)	No (n = 196)	Yes (n = 121)
PACCI Sum Score								
	3.9 (3.5 - 4.4)	5.8 [£] (4.8 - 6.8)	4.1 (3.7 - 4.6)	5.8 [#] (4.6 - 7.1)	3.3 (2.8 - 3.8)	6.3 [£] (5.5 - 7.1)	3.2 (2.7 - 3.6)	6.1 [£] (5.4 - 6.8)
PACCI Problem Index								
	1.5 (1.3 - 1.7)	2.3 [£] (1.9 - 2.7)	1.6 (1.4 - 1.8)	2.3 [#] (1.7 - 2.8)	1.2 (1.0 - 1.5)	2.5 [£] (2.1 - 2.8)	1.2 (1.0 - 1.4)	2.5 [£] (2.1 - 2.8)
Overall Quality of Life PACQLQ								
	5.6 (5.4 - 5.8)	4.8 [£] (4.4 - 5.1)	5.5 (5.4 - 5.7)	4.6 [£] (4.0 - 5.1)	5.8 (5.6 - 5.9)	4.8 [£] (4.6 - 5.1)	5.8 (5.7 - 6.0)	4.8 [£] (4.6 - 5.1)
Emotional Function Quality of Life PACQLQ								
	5.6 (5.4 - 5.8)	4.9 [£] (4.6 - 5.3)	5.5 (5.4 - 5.7)	4.7 [£] (4.0 - 5.3)	5.7 (5.6 - 5.9)	4.9 [£] (4.6 - 5.2)	5.8 (5.6 - 6.0)	4.9 [£] (4.6 - 5.1)
Activity Limitation Quality of Life PACQLQ								
	5.4 (5.1 - 5.6)	4.2 [£] (3.8 - 4.6)	5.2 (5.0 - 5.5)	4.0 [£] (3.3 - 4.6)	5.6 (5.4 - 5.8)	4.1 [£] (3.8 - 4.4)	5.7 (5.5 - 5.9)	4.2 [£] (3.9 - 4.5)
FEV ₁ %	n=64	n=15	n=64	n=15	n=64	n=15	n=64	n=15
	90% (80% - 90%)	80% (70% - 90%)	90% (80% - 90%)	90% (70% - 100%)	90% (80% - 90%)	80% (70% - 90%)	90% (80% - 90%)	80% [#] (70% - 90%)
FEV ₁ /FVC	n=64	n=15	n=64	n=15	n=64	n=15	n=64	n=15
	80% (80% - 90%)	80% (70% - 90%)	90% (80% - 90%)	80% (80% - 90%)	90% (80% - 90%)	80% [#] (80%)	90% (80% - 90%)	80% [#] (80% - 90%)

* Risk categories inquire about the occurrence of an emergency department visit, hospitalization or use of oral steroids for asthma since the last prior visit with the doctor or over the prior 2 months if not previously seen by the doctor

** For statistical comparisons in mean values between those who answered “yes” and those who “no”

£ p <.0001

p .05

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§
p<.01

Any Risk is a composite variable indicating that a parent responded “yes,” to any one of the PACCI Risk measures (an emergency department visit for asthma, a hospitalization for asthma, or oral steroid use for asthma)

Table 5

Discriminant properties of PACCI Direction and Bother domains: Categories of PACCI Risk across levels of Direction and Bother, using Chi Square Test for Trend.

Risk Categories	ED Visit		Hospitalization		Prednisone Use		Any Risk	
	No (n = 252)	Yes (n = 62)	No (n = 284)	Yes (n = 31)	No (n = 211)	Yes (n = 103)	No (n = 196)	Yes (n = 121)
Direction Categories								
Better (n=159)	54%	37%	52%	35%	58%	36%	58%	39%
Same (n=127)	38%	50%	39%	55%	35%	52%	35%	50%
Worse (n=26)	8%	13%	8%	10%	7%	12%	7%	11%
p-value	0.05 *		0.2 *		0.002 *		0.005 *	

Risk Categories	ED Visit		Hospitalization		Prednisone Use		Any Risk	
	No (n = 252)	Yes (n = 62)	No (n = 284)	Yes (n = 31)	No (n = 211)	Yes (n = 103)	No (n = 196)	Yes (n = 121)
Bother Categories								
Not Bothered (n=124)	45%	16%	43%	13%	51%	15%	54%	17%
Somewhat Bothered (n=159)	47%	69%	48%	77%	42%	70%	40%	69%
Very Bothered (n=29)	8%	14%	9%	10%	7%	15%	6%	14%
p-value	<0.001 *		0.004 *		<0.001 *		<0.001 *	

* Statistical comparison is proportions of those who answered "yes," compared to those who answered "no"