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KEY WORDS

asthma, asthma control, epidemiologic measurements, guidelines questionnaire, pediatric, preschool children, risk, validation studies, wheezing

ABBREVIATIONS

NAEPP EPR 3—National Asthma Education and Prevention Program Expert Panel Report 3
TRACK—Test for Respiratory and Asthma Control in Kids
OCS—oral corticosteroid
QuIIN— Quality Improvement Innovation Network

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WHAT'S KNOWN ON THIS SUBJECT: The 5 items in the Test for Respiratory and Asthma Control in Kids were identified and validated in a previous development study of caregivers and their children, younger than 5 years, who were primarily cared for by asthma specialists.

WHAT THIS STUDY ADDS: This study extends the psychometric properties and utility of the Test for Respiratory and Asthma Control in Kids tool by demonstrating its reliability, validity, and responsiveness to change in respiratory-control status over time in preschool-aged children with symptoms consistent with asthma who are treated by pediatricians.

abstract

OBJECTIVE: The 5-item, caregiver-completed Test for Respiratory and Asthma Control in Kids (TRACK) was developed and validated primarily in asthma-specialist practices to monitor respiratory control in preschool-aged children. This longitudinal study in children treated by pediatricians evaluated the responsiveness of TRACK to changes in respiratory- and asthma-control status over time and further assessed TRACK's reliability and validity.

PATIENTS AND METHODS: Caregivers of children younger than 5 years with symptoms consistent with asthma within the past year ($N = 438$) completed TRACK at 2 clinic visits separated by 4 to 6 weeks. Physicians were blinded to caregiver assessment, completed a guidelines-based respiratory-control survey at both visits, and were asked whether the visit resulted in a change in therapy. Responsiveness of TRACK to change in respiratory-control status over time was evaluated; reliability and discriminant validity were assessed.

RESULTS: Mean changes in TRACK scores from the initial to follow-up visits differed in the expected direction in subsets of children whose clinical status improved, remained unchanged, or worsened based on physicians' and caregivers' assessments ($P < .001$). Mean TRACK scores also differed significantly ($P < .001$) across patient subsets, with lower scores (indicating poorer control) in children classified as very poorly controlled, in those who required a step-up in therapy, and in those who had 4 or more episodes or attacks of wheezing, coughing, or shortness of breath per week in the past 3 months.

CONCLUSIONS: The present study extends the validity and reliability of TRACK by demonstrating its responsiveness to change in respiratory-control status over time in preschool-aged children with symptoms consistent with asthma. *Pediatrics* 2011;127:e737–e747

The National Asthma Education and Prevention Program Expert Panel Report 3 (NAEPP EPR 3) guidelines recommend the assessment of asthma control, including the use of assessment tools, to obtain the family's perspective on a child's asthma control.[1] The diagnosis of asthma and the assessment of control of respiratory symptoms in preschool-aged children who may or may not have a diagnosis of asthma can be challenging because of a lack of objective measures of pulmonary function and symptom similarity to common childhood illnesses.[1] The measurement of asthma and respiratory control is of special concern in preschool-aged children because of their higher rates of health care use and morbidity compared with older children.[2,3] The Test for Respiratory and Asthma Control in Kids (TRACK) is a 5-item, caregiver-completed questionnaire that was developed and validated to meet the need for a respiratory- and asthma-control tool for children younger than 5 years with symptoms consistent with asthma (Fig 1).[4] TRACK is based on the impairment and risk domains of the NAEPP guidelines.[4]

The TRACK items were selected from a 33-item draft questionnaire in a cross-sectional, nonrandomized development study of 486 caregivers of children younger than 5 years who were under the care of an asthma specialist (65% of sites) or pediatrician.[4] In the development study, the performance of the draft items was evaluated to identify and validate the subset of items that showed the greatest ability in identifying children with respiratory- and asthma-control problems. Five items were selected and then evaluated for reliability and validity. Each item is scored from 0 to 20 points on the basis of a 5-point Likert-type scale for a total score of 0 to 100. The development study showed that

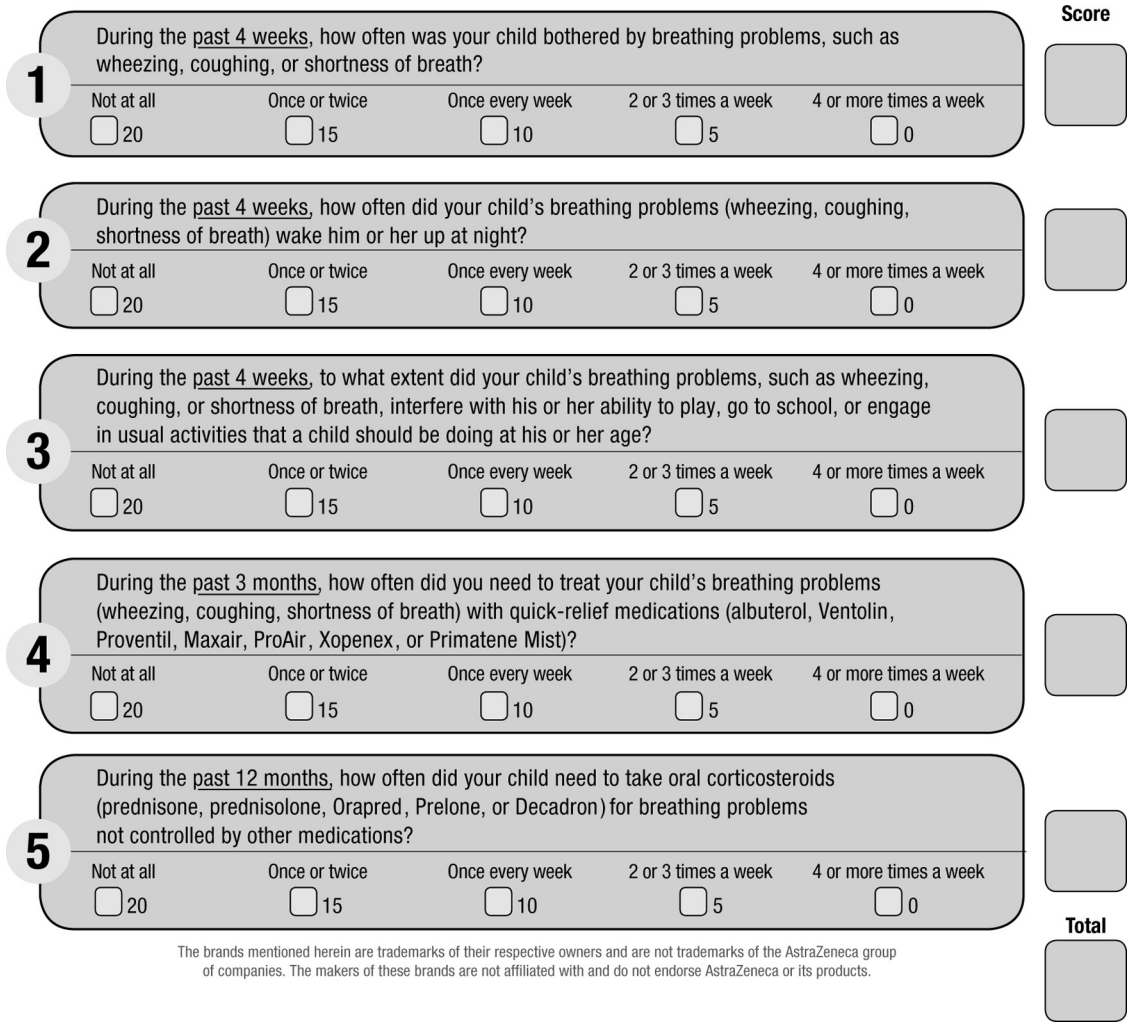

FIGURE 1
Test for Respiratory and Asthma Control in Kids (TRACK). TRACK is a trademark of the AstraZeneca group of companies. ©2009 AstraZeneca LP. All rights reserved 278650 5/09.

a cut point score of 80 provided the best discrimination between children with controlled and uncontrolled respiratory symptoms.

In the present longitudinal study, the reliability and validity of the fully developed TRACK measurement tool was assessed to obtain additional validation of the 5 selected items and to examine, for the first time, the responsiveness of TRACK to changes in respiratory and asthma control over time in an independent sample. We hypothesized that TRACK control scores would significantly reflect the direction of change in criterion measures of control assessed by physicians and caregivers. In addition, the study was conducted exclusively among general pediatric practices to demonstrate the potential usefulness of TRACK in such practices.

METHODS

TRACK Questionnaire

Details regarding the development and validation of the TRACK questionnaire have been described previously.[4] The caregiver-completed TRACK questionnaire (Fig 1) contains 4 items to assess impairment ([1] symptom frequency, [2] frequency of waking up at night because of symptoms, [3] frequency of interference of symptoms with the child's activities, and [4] frequency of rescue medication use) and 1 item to assess risk ([5] frequency of oral corticosteroid [OCS] use over the past year). Higher scale scores indicate better respiratory and asthma control, with a score of less than 80 suggesting that a child's breathing problems may not be controlled. The copyrighted questionnaire and background information are available at http://asthmatracktest.com/pdf/Track_Tearpad.pdf and http://asthmatracktest.com/pdf/Backgrounder.pdf, respectively.

Study Design and Sites

This prospective, cross-validation, nonrandomized, observational, longitudinal survey study was conducted from January to May 2009 at 20 sites in the United States selected from the American Academy of Pediatrics' Quality Improvement Innovation Network (QuIIN). Eligible principal investigators completed a 30-minute training course and passed a test on the NAEPP EPR 3 guidelines. This study was approved by the Academy of Pediatrics' Institutional Review Board.

Study Population

Adult caregivers of children younger than 5 years who had either a scheduled or unscheduled visit to a study site were invited to participate and given a brief 1-page description of the study. Interested caregivers were screened for study inclusion. Children had to have a history of 2 or more episodes of wheezing, shortness of breath, or cough lasting longer than 24 hours (with 1 episode having occurred in the past year) and either a diagnosis of asthma or improvement of respiratory symptoms when using a prescription bronchodilator. Caregivers had to be able to read and write in English and provide informed consent. Children were excluded if they had a respiratory disease other than asthma, were involved in another interventional study, or if their caregiver had a history of psychiatric disease, intellectual deficiency, poor motivation, substance abuse, or other conditions that would limit the validity of informed consent.

Data Collection

Caregivers completed the TRACK questionnaire at the initial physician visit (baseline) and 4 to 6 weeks later at a follow-up visit. In addition, at baseline, the caregivers were asked, "During the past 3 months, how often did your child have an episode or attack that lasted longer than 24 hours involving wheezing, coughing, or shortness of breath resulting from activity?" with answer choices of "not at all," "once or twice," "once or twice every week," "2 or 3 times a week," or "4 or more times a week." At follow-up, caregivers were asked whether the child's current respiratory symptoms were "a lot better," "a little better," "about the same," "a little worse," or "a lot worse" than those present at the initial visit. The quality of the data was evaluated by examining the patient response patterns described in the Appendix.

Physicians blinded to caregiver responses completed a survey at the initial and follow-up visits. As in the development study,[4] the surveys included 5 specific questions (Appendix: Table A1) based on the NAEPP EPR 3 asthma-control table for 0- to 4-year-old children[1] (Appendix: Table A2) and a question regarding whether the current visit resulted in a step-up in therapy, no change, or a step-down in therapy. The 5 control table questions have been described previously.[4] Briefly, each question was scored on a 3-point Likert-type scale, with answers corresponding with well-controlled, not well-controlled, or very poorly controlled respiratory symptoms. The total score also was based on a 3-point scale, where 1 = well controlled (well controlled selected for all 5 questions), 2 = not well controlled (not well controlled selected for 1 or more questions and very poorly controlled not selected for any question), and 3 = very poorly controlled (very poorly controlled selected for any question). The survey given at the initial visit also included yes-or-no questions about the child's history of respiratory and atopic problems (Appendix: Table A3).

ASSESSMENTS

Responsiveness

The known-groups validity approach,[5] based on the assumption that subsets

of children differing on a known criterion will receive different TRACK scores, was used to evaluate the responsiveness of TRACK scale scores from baseline to the follow-up visit. Using this approach, 5 mutually exclusive subsets of patients were formed on the basis of 2 criteria: change in control status from the physician's guidelines-based control table rating (improved 2 levels, improved 1 level, stayed the same, worsened 1 level, worsened 2 levels) and caregiver-reported change in respiratory symptom status (a lot better now, a little better now, about the same, a little worse now, a lot worse now). It was hypothesized that mean TRACK scale scores would increase among subsets of patients whose control status improved on the basis of physician or caregiver ratings of control. For evaluation purposes, 3 subsets were formed (improvement, unchanged, or worsening of respiratory- and asthma-control status). Analysis of variance was used to evaluate differences in TRACK scale scores across the subsets of patients who differed on each criterion measure.

Reliability

Cronbach's α was used to assess internal consistency reliability for the entire scale and for the scale with deletion of 1 TRACK item at a time. Test-retest reliability was assessed by calculating the intraclass correlation between TRACK scores at the initial and follow-up visits in the subset of children whose physician-reported asthma-control status was unchanged between the 2 visits.

Discriminant Validity

Discriminant validity also was evaluated with criterion-based methods using the known-groups validity approach.[5] It was based on the following 4 validation criteria: (1) physician's guidelines-based control table rating; (2) physician therapy recommendation; (3) caregiver report of the frequency of episodes or attacks of coughing, wheezing, or shortness of breath lasting longer than 24 hours in the past 3 months; and (4) physician report of the child having 4 or more episodes of wheezing lasting longer than 24 hours in the past 12 months. Differences in TRACK scores across subsets of patients stratified by how they scored on these validation criteria were evaluated using analysis of variance.

Screening Accuracy

This information is provided in the Appendix.

Differential Item Functioning

To evaluate if measurement properties of the tool varied among subsets of the population, uniform and nonuniform differential item functioning tests using logistic regression assessed the association of caregiver demographic characteristics and results for each TRACK item (Appendix).

RESULTS

Demographics

A total of 462 caregiver-child pairs were screened for the study; 16 (3.4%) pairs did not pass screening, and 8 (1.7%) pairs did not provide complete answers to every question, leaving a sample size of 438 pairs. Most (89%) caregivers were female (Table 1). Twenty-eight percent of children were younger than 2 years old. Most (71%) children had a provider diagnosis of asthma on the basis of caregiver report. According to physician report, more than half the children had coughing or wheezing episodes more than 2 days a week (Table 2).

Because of missing responses to additional survey items needed for analysis, TRACK scores were assessed for 426 children at baseline and 396 children at the follow-up visit. Additional information about the number of respondents selecting answers to each TRACK survey question are described in the Appendix.

TABLE 1 Caregiver and Child Demographic Characteristics

Characteristic	Caregiver Responses, *n* (%)[a]
Caregiver gender, $n = 437$	
Male	50 (11.4)
Female	387 (88.6)
Caregiver age, $n = 434$, y	
18–24	64 (14.7)
25–34	222 (51.2)
35–44	124 (28.6)
≥45	24 (5.5)
Caregiver education, $n = 433$	
Not a high school graduate	26 (6.0)
High school graduate or some college	176 (40.6)
College graduate or higher	231 (53.3)
Caregiver ethnicity, $n = 425$	
White	252 (59.3)
Black	68 (16.0)
Hispanic	74 (17.4)
Other	31 (7.3)
Child age, $n = 393$, y	
0–1	110 (28.0)
2	104 (26.4)
3	93 (23.7)
4	86 (21.9)
Child has asthma (caregiver report), $n = 433$	306 (70.7)

[a] Although 438 caregiver-child pairs participated in the study, percentages are based on the number of caregivers who answered each question as indicated.

TRACK Responsiveness

Evidence of the responsiveness of TRACK scores was demonstrated by evaluating mean changes from baseline to follow-up in relation to physician- and caregiver-reported changes in respiratory- and asthma-control status. Mean changes in TRACK scores differed significantly across patient subsets that differed in change status (better, same, or worse) on the basis of the physician's guidelines-based control table ratings ($P < .001$) and caregivers' reports ($P < .001$) (Table 3).

TABLE 2 Clinical Characteristics of Children Based on Physician Responses to Respiratory-Control Survey[a]

Characteristic	Physician Responses, *n* (%)
Days per week the child had cough or wheeze in the past 4 wk, *n* = 438	
≤2	192 (43.8)
>2	188 (42.9)
Throughout the day	58 (13.2)
How often the child's sleep was disrupted in the past 4 wk, *n* = 438	
≤1 time per mo	157 (35.8)
>1 time/mo	166 (37.9)
>1 time/wk	115 (26.3)
How limited the child was in performing normal activities in the past 4 wk, *n* = 438	
No limitation	243 (55.5)
Some limitation	185 (42.2)
Extremely limited	10 (2.3)
Days per week the child used albuterol in the past 4 wk, *n* = 437	
≤2	231 (52.9)
>2	133 (30.4)
Several times per day	73 (16.7)
Times the child used OCS in the past year, *n* = 438	
0–1	308 (70.3)
2–3	100 (22.8)
≥4	30 (6.9)

[a] The survey included 5 specific respiratory-control questions (Appendix: Table A1) based on the NAEPP's asthma control table for 0- to 4-year-old children (Appendix: Table A2).

TABLE 3 Responsiveness of TRACK Scores Based on Change in Control Status (Physician's Guidelines-Based Control Table Ratings and Caregiver Report)

	Change in TRACK Score, Mean (SD)	
	Physician Control Table Ratings	Caregiver Report
Better	*n* = 168	*n* = 272
	20.7 (19.8)	15.6 (21.6)
Same	*n* = 163	*n* = 92
	7.0 (18.8)	4.4 (16.6)
Worse	*n* = 56	*n* = 21
	−2.9 (20.8)	−9.8 (14.7)
F test	38.3[a]	22.7[a]

[a] $P < .001$.

Reliability

Internal consistency reliability was 0.68 at baseline ($n = 426$) and 0.64 at follow-up ($n = 396$). When item 5 (OCS use in the past 12 months) was deleted, the internal consistency reliability increased to 0.76 at baseline and 0.74 at follow-up. The intraclass correlation for test-retest reliability was 0.63 for the subsample of children whose physician's guidelines-based control table status stayed the same at both visits (stable sample; $n = 151$).

Discriminant Validity

Significant differences in mean TRACK scores among children categorized according to the physician's guidelines-based control table ratings at baseline ($P < .001$) and follow-up ($P < .001$) support the discriminant validity of TRACK scores (Table 4). Children classified as having well-controlled symptoms had the highest mean scores, whereas children classified as having very poorly controlled symptoms had the lowest mean scores. Children who received a recommendation for a step-up in therapy from their physician likewise scored significantly lower on TRACK at baseline and follow-up (both $P < .001$) than children who received a recommendation for maintained or stepped-down therapy (Table 5). On the basis of the caregiver survey at baseline, children with 4 or more episodes or attacks per week in the past 3 months had significantly lower mean scores than those with less frequent episodes or attacks ($P < .001$) (Table 6). Finally, on the basis of the physician survey, children with 4 or more episodes of wheezing in the past 12 months at baseline had significantly ($P < .001$) lower mean scores than children with less frequent episodes.

Screening Accuracy and Differential Item Functioning

Results for screening accuracy at different TRACK cut point scores are provided in the Appendix: Tables A4 and A5. A TRACK cut point score of 80 provided the most consistent balance between sensitivity and specificity at baseline and follow-up visits. In addition, the results of the differential item–functioning tests suggested that the items in the TRACK questionnaire performed similarly across caregiver demographic groups (Appendix).

DISCUSSION

The present study documents the responsiveness of TRACK in reflecting changes in respiratory and asthma control over a short-term follow-up period. In addition, these results extend the reliability and validity of TRACK in children younger than 5 years beyond those evaluated primarily in asthma specialist sites[4] to those children seen in general pediatric settings.

Previous studies have demonstrated frequent respiratory impairment, such as recurrent cough, wheeze, and breathlessness, in preschool-aged children.[6,7] Children younger than 5 years with asthma or with frequent severe intermittent wheezing experience hospitalizations, emergency-department visits, and disability.[2,7] These findings underscore the need for a reliable and valid caregiver tool like TRACK to help physicians monitor uncontrolled respiratory and asthma symptoms in preschool-aged children, especially considering the variability in how parents interpret and report these symptoms.[8] For patients who cannot respond for themselves, the US Food and Drug Administration's guidance on patient-reported outcomes in clinical trials encourages observer re-

TABLE 4 Comparison of TRACK Scores Across Subsets Differing in Physician's Guidelines-Based Control

	Control Rating			
	Very Poorly Controlled	Not Well Controlled	Well Controlled	Statistical F Test, *df*, *P*
Baseline TRACK score, mean (SD)	$n = 151$	$n = 179$	$n = 96$	
	48.1 (18.6)	62.8 (18.6)	76.1 (16.9)	71.6, 2, <.001
Follow-up TRACK score, mean (SD)	$n = 68$	$n = 158$	$n = 170$	
	55.8 (17.2)	70.1 (15.2)	81.3 (13.0)	80.1, 2, <.001

df indicates degree of freedom.

TABLE 5 Comparison of TRACK Scores Across Subsets Differing in Pediatrician-Recommended Change in Child's Therapy

	Change in Therapy			
	Step Down	No Change	Step Up	Statistical F Test, *df*, *P*
Baseline TRACK score, mean (SD)	$n = 10$	$n = 191$	$n = 224$	
	67.0 (18.7)	66.8 (20.5)	54.9 (19.9)	18.1, 2, <.001
Follow-up TRACK score, mean (SD)	$n = 56$	$n = 256$	$n = 83$	
	79.3 (12.5)	75.6 (15.5)	59.2 (18.7)	39.7, 2, <.001

df indicates degree of freedom.

TABLE 6 Comparison of TRACK Scores Across Subsets Differing in Caregiver-Reported Frequency of Episodes or Attacks in Past 3 mo at Baseline

	Symptom Frequency					Statistical F Test, *df*, *P*
	Not At All, $n = 123$	Once or Twice, $n = 221$	Once Every Week, $n = 21$	2 or 3 Times a Week, $n = 40$	4 or More Times a Week, $n = 15$	
TRACK score, mean (SD)	71.5 (20.5)	61.8 (17.3)	45.9 (18.7)	38.5 (15.1)	37.3 (17.2)	35.7, 4, <.001

df indicates degree of freedom.

ports of events or behaviors instead of proxy-reported outcome measures, such as a parent's perception of the intensity of their child's symptoms.[9] In accordance with the concepts in the guidance, all of the items in TRACK measure observable events (eg, frequency of breathing problems) and demonstrate content validity, which is evidence of appropriateness and comprehensiveness relative to the intended measurement concept, population, and use.[4,9] In addition, the guidance states that patient-reported outcome tools also should demonstrate the ability to detect change.[9]

The results of this study extend the findings of the initial TRACK development and validation study[4] by demonstrating its responsiveness to change in respiratory or asthma control (Table 3) and its use in the practicing pediatrician's office. The NAEPP EPR 3 control table for 0- to 4-year-old children[1] was selected as the criterion validity measure for assessing change in control status in preschool-aged children because of a lack of a gold standard.[9] The item regarding OCS use might have been expected to have a negative impact on the short-term responsiveness of the tool assessed in this study because it assesses change over a 12-month period. However, this item is important to include because it measures the domain of risk, and young children who otherwise do not have respiratory symptoms can experience exacerbations. Our results showed that there were children who had a change in the OCS item, with fewer caregivers reporting "never" at follow-up than at baseline (Appendix). The importance of the risk domain was demonstrated in the TENOR (The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens) study, which showed that recent severe asthma exacerbations were an important predictor of future severe asthma exacerbations in young patients (aged 6–11 years) with severe or difficult-to-treat asthma regardless of long-term controller use.[10] Inclusion of a risk domain is additionally supported by evidence from the TENOR study that showed a high incidence of severe exacerbations and OCS use in children with severe or difficult-to-treat asthma with normal lung function.[11] Overall, the 5-item TRACK tool performed moderately well compared with change in respiratory- and asthma-control status as assessed by pediatricians using the NAEPP EPR 3 algorithm and compared with caregiver self-report of change in their child's respiratory symptom status. Using the criterion-based, known-groups validity approach, this study showed that children whose control status deteriorated over the evaluation period had decreased TRACK scores and those whose control improved had increased TRACK scores, confirming the study's hypothesis.

The results of the present study cannot be compared directly with the findings of the initial cross-sectional development study because of differences in study populations. Children in the development study only had to have 2 respiratory episodes in their lifetime and either a diagnosis of asthma or treatment with a bronchodilator.[4] In contrast, children in the present study were required to have respiratory symptoms in the past year and could have had either a diagnosis of asthma or symptom improvement with a bronchodilator.

In the initial development study, a cut point of 80 provided the best balance between sensitivity and specificity for discriminating between patients with uncontrolled versus controlled respiratory symptoms.[4] In the present study, a cut point score of 80 provided reasonable screening statistics at the initial visit and follow-up visit, whereas a cut point score of 85 had reasonable screening statistics at the follow-up visit but not the initial visit, and a cut point score of 75 had a reasonable screening statistic at the initial visit but not the follow-up visit (Appendix: Tables A4 and A5). Overall findings from this study support the initial study finding that TRACK scores lower than 80 will identify children with suboptimal asthma or respiratory control. Whether these patients need additional evaluation, step-up therapy, or both remains to be determined.

Internal consistency reliability estimates how well questionnaire items measure the same concept, such as respiratory or asthma control, and test-retest reliability measures stability of a test over time. At baseline and follow-up, Cronbach α values were below the recommended reliability for multi-item scales of 0.7.[12] Internal consistency reliability was adversely affected by TRACK item 5 (ie, OCS use in past year). Internal consistency reliability was above the 0.7 threshold when item 5 was deleted from the scale. Additional discussion of these findings is presented in the Appendix.

Other patient-administered asthma-control questionnaires have been validated on the basis of clinician assessment.[13–16] The rate at which control status was classified correctly in the TRACK longitudinal study population ($\geq$70%) was consistent with results achieved using the Asthma Control Test at a cutoff of 19 or lower in adults with asthma previously treated by an asthma specialist (74% correctly classified)[14] and those 12 years or older who were newly treated by asthma specialists (71% correctly classified).[15] The Childhood Asthma Control Test, which was designed to identify children 4 to 11 years with poorly controlled asthma, achieved correct classification in 72% and 83% of development and confirmatory sample populations, respectively, at the same cutoff.[16] Importantly, these tools have been validated in older children[16] or adolescents and adults[14,15,17,18] with a diagnosis of asthma. TRACK, however, has demonstrated validity and reliability in children younger than 5 years with respiratory symptoms with or without a diagnosis of asthma, which has important implications in these very young children in whom assessment of respiratory and asthma control is especially challenging because of the lack of reliable objective markers[1] as well as the inability of these children to adequately communicate their symptoms or relative impairment caused by respiratory illness. Thus, TRACK is unique because it is the only tool validated to assess control specifically in preschool-aged children. It also is the only respiratory- and asthma-control tool that includes the NAEPP EPR 3–defined risk domain of asthma control. Moreover, TRACK is easy to use, has limited burden for the caregiver in terms of completion time, and can be completed in the physician's office or at home. However, if TRACK is adapted for use by a different mode of administration or in a different language, evidence that the measurement properties are comparable between the original and revised instruments would need to be established.[9]

CONCLUSIONS

Evaluation of TRACK responsiveness to changes in respiratory or asthma control over 4 to 6 weeks in the present study demonstrated a significant positive association of the change in TRACK score with pediatrician- and caregiver-reported change in child respiratory-control status. These data, and the findings of others, support the role of using tools that are responsive to change in respiratory-control status, which should facilitate therapeutic decision making to reduce the risk for worsening respiratory control and its consequences. The present findings extend the reliability and validity of TRACK by demonstrating that it is responsive to changes in asthma or respiratory control over time, specifically in a general pediatric setting. The TRACK tool should facilitate efforts to improve assessment of respiratory control in children younger than 5 years with a history of asthma-like symptoms. TRACK addresses both impairment and risk, 2 domains that are recommended to assess asthma control in the current NAEPP EPR 3 guidelines. Given TRACK's properties as a practical, reliable, valid, and responsive respiratory-control tool for young children, it has the potential to assist with monitoring respiratory and asthma control in this patient population. Furthermore, the use of TRACK allows for improved caregivers' awareness of areas important to their child's respiratory control and thus promotes a focused caregiver-physician dialogue.

APPENDIX

Study Design and Sites

This prospective, cross-validation, nonrandomized, observational, longitudinal survey study was conducted at 20 US sites selected from the American Academy of Pediatrics' Quality Improvement Innovation Network (QuIIN). QuIIN consists of practicing pediatricians whose mission is to test practical tools, measures, and strategies used in everyday

clinical practice. The QuIIN sites were screened for their experience in treating young children with respiratory illness and in participating in clinical research studies. Each pediatrician was asked to complete a site certification form to determine whether the site has an adequate volume of patients meeting the requirements of the inclusion criteria and if the pediatrician has sufficient experience in clinical research and adequate staffing to assist in the recruitment of patients for the study. To participate, sites were expected to be able to enroll 20 patients who would meet the study inclusion criteria over 2–3 months.

Data Collection and Quality: Caregivers

Methods

Quality of the data was evaluated by examining the percentage of patients who complete all items and by studying patterns of responses to each item to determine if all response choices were utilized. The percentage of patients who completed all items and patterns of responses to each item were evaluated for ceiling (>40% scoring at the highest item response category) and floor (>40% scoring at the lowest item response category) effects.

Results

The missing item response rate was less than 1%, except for item 5 at baseline (2.1%) and item 1 at follow-up (1.2%). Item 5 showed a floor effect (ie, >40% of responders chose the lowest score) at baseline, with 43% of caregivers reporting that their children never received an oral corticosteroid. At follow-up, items 2, 3, and 5 displayed floor effects (45%, 64%, and 40% selected never, respectively). There was no evidence of ceiling effects at either time period (>40% of responders choosing the highest score).

Data Collection: Physicians

Physicians blinded to caregiver responses completed a survey at the initial and follow-up visits that included 5 specific respiratory control questions (Table A1) based on the National Asthma Education and Prevention Program's asthma control table for 0- to 4-year-olds (Table A2). The survey given at the initial visit also included yes or no questions about the child's history of respiratory and atopic problems (Table A3).

Results

Screening Accuracy

The criterion measure for screening sensitivity was the physician's guidelines-based control table rating. Sensitivity, specificity, and positive and negative predictive values were calculated at various cut points along the TRACK scale score distribution. Screening accuracy of TRACK at baseline and follow-up based on physician's guidelines-based control table ratings is shown in Table A4 and Table A5, respectively.

Differential Item Functioning

Differential item functioning occurs when respondents from different demographic groups answer differently to questionnaire items even though the trait being measured is generally similar. Differential item functioning tests for an interaction between each TRACK item and demographic characteristics showed no significant influence of caregivers' age, age group, gender, education, or ethnicity on TRACK test results (data not shown). In addition, the interaction between these traits and TRACK item responses each accounted for less than 2% of the variance explained in the total TRACK score for each of the 5 TRACK items.

TABLE A1 First 5 Items of Physicians' Questionnaire Assessing Respiratory Control

Respiratory Control Assessment	Control Rating Categories[a]		
	(1)	(2)	(3)
1. During the past 4 weeks, how many days a week did the child have cough or wheeze (for example, breathing that makes a high pitched whistling or squeaking sound from the chest)?	≤2 d/wk ☐1	>2 d/wk ☐2	Throughout the day ☐3
2. During the past 4 weeks, how often was the child's sleep disrupted by cough or wheeze?	≤1 ×/mo ☐1	>1 ×/mo ☐2	>1 ×/wk ☐3
3. During the past 4 weeks, how limited was the child in performing normal activities by cough or wheeze?	No limitation ☐1	Some limitation ☐2	Extremely limited ☐3
4. During the past 4 weeks, how many days a week did the child use albuterol to treat his or her respiratory symptoms, such as cough or wheeze?	≤2 d/wk ☐1	>2 d/wk ☐2	Several ×/d ☐3
5. In the past year, how many times did the child take oral steroids to treat episodes of cough or wheeze?	0–1 ×/y ☐1	2–3 ×/y ☐2	>3 ×/y ☐3

[a] 1 = well controlled, 2 = not well controlled, 3 = poorly controlled.

Reprinted from *Journal of Allergy and Clinical Immunology*, 123/4, 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, pages 833–839 (2009), with permission from Elsevier.[4]

TABLE A2 National Asthma Education and Prevention Program Expert Panel Report 3 Classification of Asthma Control in Children Aged 0–4 Years[a]

Components of Control	Classification of Asthma Control (0–4 Years of Age)		
	Well-controlled	Not well-controlled	Very poorly controlled
Impairment			
Symptoms	≤2 d/wk	>2 d/wk	Throughout the day
Nighttime awakenings	≤1 ×/mo	>1 ×/mo	>1 ×/wk
Interference with normal activity	None	Som limitation	Extremely limited
SABA use for symptom control (not prevention of EIB)	≤2 d/wk	>2 d/wk	Several times per day
Risk			
Exacerbations requiring OCS	0–1/y	2–3/y	>3/y
Treatment-related adverse effects	Medication adverse effects can vary in intensity from none to very troublesome and worrisome. The level of intensity does not correlate to specific levels of control but should be considered in the overall assessment of risk.		

[a] Derived from the National Heart, Lung, and Blood Institute/National Asthma Education and Prevention Program *Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma: Full Report 2007*.[1] SABA indicates short-acting β_2-adrenergic agonist; EIB, exercise-induced bronchospasm.

TABLE A3 Physician Survey of the Child's History of Respiratory-Related Problems and Atopy

Please complete the following questions about the child's history with respiratory-related problems	Yes	No
Has the child had 4 or more episodes of wheezing in the past 12 months?	☐1	☐2
Has either of the child's parents been diagnosed with asthma?	☐1	☐2
Has the child ever been diagnosed with eczema by a doctor?	☐1	☐2
Does the child have any allergies to foods?	☐1	☐2
Is the child allergic to dust, furred pets, mold, cockroaches, rodents or pollens?	☐1	☐2
Does the child have a diagnosis of allergic rhinitis?	☐1	☐2
Has the child had allergy skin tests or allergy blood tests?	☐1	☐2
If "No," skip to the next section; If "Yes," continue.		
Was the child positive to food?	☐1	☐2
Was the child positive to inhalants (dust, furred pets, mold, cockroaches, or pollens)?	☐1	☐2

TABLE A4 Screening Accuracy of TRACK at Baseline[a] (Physician's Guidelines—Based Control Table Ratings)

TRACK	Odds ratio	Sensitivity	Specificity	Positive predictive value	Negative predictive value	False positive rate	Percentage correctly classified	Area under ROC curve
Continuous scale	0.94	81.8	52.1	85.4	45.5	47.9	75.1	0.78
Cut point scores								
<85	6.3	90.9	38.5	83.6	55.2	61.5	79.1	0.65
<80	4.9	81.5	52.1	85.4	45.5	47.9	75.1	0.67
<75	4.8	73.3	63.5	87.4	40.9	36.5	71.1	0.68
<70	6.2	67.3	75.0	90.2	40.0	25.0	69.0	0.71
<65	6.1	60.0	80.2	91.2	36.8	19.8	64.5	0.70

ROC indicates receiver operating characteristic.
[a] Controlled, $n = 96$; not controlled, $n = 330$.

Discussion

Screening Accuracy

Overall findings from this study support the initial study finding that TRACK scores less than 80 will identify children with suboptimal asthma or respiratory control. Whether these patients need additional evaluation, step-up therapy, or both, remains to be determined. If TRACK is to be used for a different purpose, a different cutoff score may be appropriate, such as a higher score for a screening program[4] or a lower score to identify those with the poorest control. A recent evaluation of the Childhood Asthma Control Test validated a second, lower cut point that would identify children with the lowest level of control who are at risk for poorer outcomes.[19] As use of TRACK becomes more widespread, it may lead to a more accurate assessment of respiratory status, especially if physicians reconcile the discordance between their own control assessment and that suggested by the caregivers' TRACK scores. In addition, although the differential item functioning showed no significant influence of caregivers' education, caregivers in this study

TABLE A5 Screening Accuracy of TRACK at Follow-Up[a] (Physician's Guidelines—Based Control Table Ratings)

TRACK	Odds ratio	Sensitivity	Specificity	Positive predictive value	Negative predictive value	False positive rate	Percentage correctly classified	Area under ROC curve
Continuous scale	0.93	57.9	82.9	81.9	59.8	17.1	68.7	0.78
Cut point scores								
<85	7.0	84.9	55.3	71.6	73.4	44.7	72.2	0.70
<80	5.9	71.2	70.6	76.3	64.9	29.4	71.0	0.71
<75	6.7	57.9	82.9	81.9	59.8	17.1	68.7	0.70
<70	7.0	46.9	88.8	84.8	55.7	11.2	64.9	0.68
<65	7.0	38.5	91.8	86.1	52.9	8.2	61.4	0.65

ROC indicates receiver operating characteristic.
[a] Controlled, $n = 170$; not controlled, $n = 226$.

population were highly educated; thus, TRACK may not be as responsive in a population whose caregivers are not as well educated.

Reliability

Internal consistency reliability estimates how well questionnaire items measure the same concept, such as respiratory or asthma control, and test-retest reliability measures stability of a test over time. At baseline and follow-up, Cronbach α values (0.68 and 0.64) were below recommended reliability for multi-item scales of 0.7.[12] Internal consistency reliability was adversely affected by TRACK item 5 (ie, OCS use in past year); it was above the 0.7 threshold when item 5 was deleted from the scale. These findings suggest that the first 4 TRACK items are consistent in the detection of respiratory or asthma control problems. This finding was expected because TRACK item 5 assesses risk, whereas TRACK items 1 to 4 assess impairment, and these 2 aspects of control can vary independently and are considered separate domains in the NAEPP EPR 3 guidelines.[1] The test-retest reliability value seen in this study could be considered "good" but not "excellent."[20] Although the time period between the baseline and follow-up visits was designed to evaluate changes in respiratory control, it was not optimal for evaluating test-retest reliability, which requires that the recall of the second assessment overlap with the baseline assessment and typically is 2 weeks.

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