Test for Respiratory and Asthma Control in Kids (TRACK): A caregiver-completed questionnaire for preschool-aged children

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Background: A validated questionnaire is needed to monitor respiratory control in preschool-aged children.
Objective: We sought to develop and validate a caregiver-completed questionnaire that measures respiratory control in young children.
Methods: A 33-item questionnaire that included asthma impairment and risk items was administered to 486 caregivers of children aged younger than 5 years with a current, recent, or past history of respiratory symptoms. Stepwise regression was used to select a subset of items with the greatest discriminant validity in relation to guidelines-defined asthma control in a random two-thirds development sample. Reliability, validity, and ability to screen for respiratory control problems were tested in development and validation samples (remaining one-third sample).
Results: The content of the 5 items selected, the Test for Respiratory and Asthma Control in Kids (TRACK), included frequency of respiratory symptoms (wheeze, cough, shortness of breath), activity limitation, and nighttime awakenings in the past 4 weeks; rescue medication use in the past 3 months; and oral corticosteroid use in the previous year. Reliability was greater than 0.70 in both samples. ANOVA showed that mean scores differed significantly ($P < .001$) in the expected direction across both samples for 3 levels of guidelines-based respiratory control, physician-recommended change in therapy, and symptom status. In the development and validation samples, screening analyses revealed areas under the receiver operating characteristic curve of 0.88 and 0.82, respectively; control status was correctly classified in 81% and 78% of cases.
Conclusion: TRACK is a valid, easy-to-administer, caregiver-completed questionnaire of respiratory control in preschool-aged children with symptoms consistent with asthma. (J Allergy Clin Immunol 2009;123:833-39.)

Key words: *Asthma, respiratory symptoms, asthma control, TRACK, validated questionnaire, asthma guidelines, young children*

Asthma in children is a leading cause of activity limitation, hospitalizations, and medical costs,[1-7] with 80% of children aged 5 to 18 years having symptoms before 5 years of age.[8] Compared with older children with asthma, young children have greater risk, as evidenced by increased health care use and mortality,[1-7] and experience less favorable responses to asthma management strategies.[9-11] The Expert Panel Report-3 (EPR-3)[12] of the National Asthma Education and Prevention Program (NAEPP) and the Global Initiative for Asthma[13] now emphasize 2 major domains of asthma control: risk and impairment.[12] Asthma risk addresses the frequency and severity of exacerbations, progressive loss of lung function, and medication side effects. Asthma impairment refers to current pulmonary function, symptom burden, nighttime awakenings, activity limitations, and school/work absences.

Determining asthma control has been facilitated with the development of specific control assessments in children aged 4 to 11 years,[14] children aged 5 to 17 years,[15] and adolescents and adults.[16-18] All existing control tools were developed before the issuance of the new guidelines that recommend the inclusion of a risk domain to the usually assessed impairment domain in the determination of asthma control. Furthermore, no validated asthma control tool is available for young children with recurrent wheezing or respiratory symptoms consistent with asthma. Although discordance between parental and school-aged children's reports of symptoms has been shown,[19] the reliance on a caregiver proxy for symptom assessment is necessary in younger patients with asthma who are not as cognitively developed.

We now describe the development and validation of the Test for Respiratory and Asthma Control in Kids (TRACK), a questionnaire for caregivers that encompasses both the risk and impairment domains of respiratory control in preschool-aged children with either physician-diagnosed asthma or recurrent respiratory episodes consistent with asthma.

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Abbreviations used
C-ACT: Childhood Asthma Control Test
CFA: Confirmatory factor analysis
EFA: Exploratory factor analysis
EPR-3: Expert Panel Report-3
NAEPP: National Asthma Education and Prevention Program
ROC: Receiver operating characteristic
TRACK: Test for Respiratory and Asthma Control in Kids

METHODS

Draft questionnaire development

Development of the draft questionnaire was based on input from a working group, caregiver and physician interviews, and subsequent qualitative research (see the Methods section in this article's Online Repository at www.jacionline.org). Items for the draft questionnaire were based on content generated from 2 focus groups, each consisting of 8 primary caregivers of preschool-aged children with recurring respiratory problems or asthma. Physical signs of respiratory problems most often reported (>75% of respondents) were wheeze, cough, depressed abdomen, shallow breathing, fatigue, mood changes, susceptibility to illness, dark rings around eyes, clinginess, and sleep disruption. Significant activity limitation (eg, missed school, interference with usual play) was often reported as a consequence of such physical signs, and failure of over-the-counter drugs to reduce these physical signs was the main reason for unscheduled physician/emergency department visits. Based on this information, a 33-item draft questionnaire was developed for further testing in the TRACK development study described below. This draft questionnaire included 18 items on the frequency and severity of respiratory symptoms, 8 on the effect of these symptoms on the child's life, and 7 on respiratory medication and health care use (see the Methods section in this article's Online Repository at www.jacionline.org).

Study design and sample

A cross-sectional nonrandomized study was conducted to identify and validate a subset of questions from the 33-item draft questionnaire to include in the final TRACK instrument. Study participants were recruited from 11 asthma specialist sites and 6 primary care sites across the United States. Institutional review boards for each site approved the study; all caregivers provided written informed consent.

Caregivers of children younger than 5 years who met the study inclusion/exclusion criteria at the time of a scheduled or unscheduled visit to the physician were invited to participate in the study. Caregivers were eligible to participate if they were at least 18 years old and if their young child had a history of 2 or more episodes of wheezing, shortness of breath, or cough that lasted more than 24 hours and either a diagnosis of asthma or receipt of treatment for respiratory symptoms with a prescription bronchodilator. Exclusions to participation were patient respiratory conditions not consistent with asthma, other significant chronic disorders or congenital abnormalities, or enrollment in a clinical trial.

Data collection

Data were obtained from eligible caregivers and physicians regarding the child's respiratory/asthma control problems. During the child's visit to the physician, caregivers completed screening questions on symptom frequency and the 33-item draft questionnaire (see Fig E1 in this article's Online Repository at www.jacionline.org). Answers to the screening questions were used to stratify the sample into categories of current symptomatic (episodes of wheezing, shortness of breath, or coughing in the past 4 weeks), recent past symptomatic (episodes of wheezing, shortness of breath, or coughing in the past year but not within the past 4 weeks), or asymptomatic (without symptoms for > 1 year).

Separately, physicians blinded to the caregiver questionnaire responses completed a 15-item questionnaire; their answers were used to establish criterion and construct validity of the items in the caregiver-completed questionnaire. Five specific items that were based on the risk and impairment factors from the NAEPP EPR-3's asthma control table for 0- to 4-year-old children[12] assessed the frequency of wheeze, nighttime awakenings from respiratory symptoms, activity limitation caused by respiratory symptoms, use of rescue medications for respiratory symptom flares, and oral corticosteroid use in the past year (see Table E1 in this article's Online Repository at www.jacionline.org). Based on guidelines-defined asthma control (impairment and risk), responses to each item were scored on a 3-point scale (1, well controlled; 2, not well controlled; 3, very poorly controlled). "Very poorly controlled" was assigned if a score of 3 was selected for *any* question. "Not well controlled" was assigned if a score of 2 was selected for 1 or more questions. "Well controlled" was assigned if a score of 1 was selected for *all* 5 questions. The criterion measure of controlled versus uncontrolled respiratory status was based on the dichotomized responses to the physician questionnaire: controlled (well controlled rating) and uncontrolled (not well controlled or very poorly controlled ratings). One question that asked physicians whether therapy needed to be stepped up, be stepped down, or remain the same was used in analyses of construct validity.

Data analysis

Data from the cross-sectional study were used to develop and then validate the TRACK instrument. Two thirds (n = 321) of caregivers who completed the questionnaires were randomly selected for the item development sample and one third (n = 165) for the validation sample.

Item selection and scoring. Stepwise logistic regression with the backwards selection method was used to identify the subset of the 33 items that showed the greatest validity in discriminating between the guidelines-based controlled and uncontrolled ratings. All items were entered in the model. Based on an *a priori*–defined significance level of $P < .05$, items that were deemed nonsignificant (ie, $P \geq .05$) were then iteratively eliminated. The subset of items identified was further evaluated for clinical validity and refined to eliminate redundancy in item content. Each item was scored on a 5-point scale; the total score was the sum of individual scores on each item. These scores were then transformed to a 0- to 100-point scale for the final TRACK instrument (0, 5, 10, 15, or 20 points for each item response), with higher scores indicating better respiratory control.

Reliability and validity. Tests for questionnaire reliability and validity were conducted separately in both the development and validation samples. Internal consistency reliability was evaluated with the Cronbach α statistic. Tests of validity were designed to evaluate how well TRACK discriminated among groups of children who differed in terms of respiratory control. This standard method of construct validation follows the logic of "known groups" validity.[20] For these tests, children were categorized into groups known to differ in respiratory control derived from 3 criteria measures. The first criterion measure was based on the previously described NAEPP EPR-3 definition of control. As previously described, responses to the first 5 items on the physician questionnaire were used to categorize children into 3 categories of control (well controlled, not well controlled, and very poorly controlled). The second criterion measure was whether the physician changed the child's therapy as a result of the visit. Children were categorized into the following 3 groups: stepped-down therapy, no change in therapy, or stepped-up therapy. The third criterion measure was symptom status, which was derived from the study screening criteria (ie, current symptomatic, recent past symptomatic, or asymptomatic).

We hypothesized that the groups of children classified as well controlled would have higher TRACK scores than the groups of children classified as not well controlled or very poorly controlled. Similarly, we hypothesized that children categorized as stepped-down therapy or no change in therapy would have higher TRACK scores than children categorized as stepped-up therapy. Lastly, we hypothesized that TRACK scores would be lowest for the symptomatic group and highest for the asymptomatic group. ANOVA methods were used to test these hypotheses. Exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) methods were used to confirm the

TABLE I. Caregiver and patient demographics and baseline clinical characteristics

Characteristic	Total (N = 486), no. (%)	Specialist site (n = 284), no. (%)	Primary care site (n = 202), no. (%)
Female	432 (88.9)	251 (88.4)	181 (89.6)
Caregiver age (y)*			
18-24	41 (8.4)	21 (7.4)	20 (9.9)
25-34	241 (49.6)	131 (46.1)	110 (54.5)
35-44	183 (37.7)	120 (42.3)	63 (31.2)
≥45	19 (3.9)	10 (3.5)	9 (4.5)
Caregiver education*			
Not a high school graduate	13 (2.7)	8 (2.8)	5 (2.5)
High school graduate or some college	165 (34.0)	83 (29.2)	82 (40.6)
College graduate or higher	301 (61.9)	187 (65.8)	114 (56.4)
Caregiver ethnicity*			
White	349 (71.8)	206 (72.5)	143 (70.8)
African American	54 (11.1)	24 (8.5)	30 (14.9)
Hispanic	41 (8.4)	24 (8.5)	14 (6.9)
Other	37 (7.6)	26 (9.2)	11 (5.4)
Child age (y)			
0-2	87 (17.9)	52 (18.2)	37 (18.3)
3-5	399 (82.1)	232 (81.8)	165 (81.7)
Caregiver-assessed child symptom status			
Symptomatic (last 4 wk)	301 (61.9)	178 (62.7)	123 (60.9)
Asymptomatic (recent)	153 (31.5)	92 (32.4)	61 (30.2)
Asymptomatic (>1 y)	32 (6.6)	14 (4.9)	18 (8.9)
Caregiver-assessed child control status			
Well controlled	127 (26.1)	77 (27.1)	50 (24.8)
Not well controlled	197 (40.5)	120 (42.3)	77 (38.1)
Very poorly controlled	162 (33.3)	87 (30.6)	75 (37.1)

*Percentages total less than 100 because some caregivers did not answer every question.

construct validity of TRACK in relation to our conceptual model of respiratory control. These methods and the results of these analyses are available in the Methods section in this article's Online Repository (see Tables E2 and E3 in this article's Online Repository at www.jacionline.org).

Screening accuracy. The screening accuracy of TRACK as a tool to identify children with respiratory control problems was evaluated using logistic regression methods and receiver operating characteristic (ROC) curve analyses. The criterion measure of respiratory control was based on the responses to the physician questionnaire. Because the ability to detect "any" control problems was the objective of this analysis, a dichotomous variable of respiratory control problems was derived by grouping children categorized as uncontrolled (very poorly controlled and not well controlled) versus those categorized as well controlled. In addition, sensitivity, specificity, positive and negative predictive values, percentage correctly classified, and the area under the ROC curve were computed across various cutoffs along the TRACK score distribution in the total sample as a means of finding the optimal cutoff score for screening purposes.

RESULTS

Total sample

Characteristics of the total sample (N = 486) of caregivers who completed the draft 33-item questionnaire and their children are provided in Table I. Most caregivers were younger than 45 years of age (95.7%), female (88.9%), and white (71.8%). Most children were aged 3 to 5 years (82.1%); had 1 or more episodes of wheezing, coughing, or shortness of breath in the past 4 weeks (61.9%); and had symptoms that were either not well controlled or very poorly controlled (73.7%). Most (61.9%) children had a diagnosis of asthma; the remaining 38.1% had used a prescription bronchodilator but did not have an asthma diagnosis. More than half of the caregiver questionnaires (58.4%) were completed at asthma specialist sites; 41.6% were completed at primary care sites. Sample characteristics were generally similar between the 2 types of sites.

Item selection

Based on the results of analyses performed in the randomly selected development sample (n = 321), 6 items were identified as meeting the model selection entry criteria for predicting respiratory control (controlled versus uncontrolled). The items included 4 impairment questions on symptom burden and activity limitations over a 4-week period, 1 impairment question on rescue medication use over a 3-month period, and 1 risk question on oral corticosteroid use over the past 12 months.

The 6 items were further evaluated for relevance, meaning, language clarity, administrative burden, and feasibility. Based on these additional considerations, 2 items (Q1 and Q13) were deleted based on content redundancy, and 1 item was replaced (Q20) with a more comprehensive item (Q22). Additionally, an item (Q9) about the frequency of nighttime awakenings caused by respiratory problems was added because it is a component of asthma control in the NAEPP EPR-3 guidelines and was a relevant concept during qualitative interviews with physicians and caregivers. The measurement properties of the 5-item scale were retained (see Table E4 in this article's Online Repository at www.jacionline.org); the area under the ROC curves for both scales was 0.88. Additional logistic regression analysis showed the ability of each of the 5 items to independently contribute to the discrimination between uncontrolled and controlled asthma (Table II). This 5-item measure was selected as the final TRACK instrument and was tested further in the item development and validation samples.

TABLE II. Summary of logistic regression and item-selection analysis for the 5 final TRACK items*

Item text and response options	Odds ratio	SE	*z* Score	*P*
Q8: During the past 4 weeks, how often was your child bothered by breathing problems, such as wheezing, coughing, or shortness of breath?	2.21	0.39	4.52	.000
A8: Not at all, once or twice, once every week, 2 or 3 times a week, 4 or more times a week				
Q22: During the past 4 weeks, to what extent did your child's breathing problems, such as wheezing, cough, or shortness of breath, interfere with his or her ability to play, go to school, or engage in usual activities that a child should be doing at his or her age?	1.70	0.33	2.75	.006
A22: Not at all, slightly, moderately, quite a lot, extremely				
Q9: During the past 4 weeks, how often did your child's breathing problems (wheezing, coughing, shortness of breath) wake him or her up at night?	1.38	0.18	2.91	.004
A9: Not at all, once or twice, once every week, 2 or 3 times a week, 4 or more times a week				
Q30: During the past 3 months, how often did you need to treat your child's breathing problems (wheezing, coughing, shortness of breath) with rescue or quick-relief medications (Albuterol, Ventolin, Proventil, Maxair, proAIR, Xopenex, or Primatene Mist)?	1.61	0.16	4.75	.000
A30: Not at all, once or twice, once every week, 2 or 3 times a week, 4 or more times a week				
Q33: During the past 12 months, how often did your child need to take oral corticosteroids (prednisone, prednisolone, Orapred, Prelone, Decadron) for breathing problems not controlled by other medications?	1.42	0.15	3.21	.001
A33: Never, once, twice, 3 times, 4 or more times				

*The dependent variable was uncontrolled asthma based on physician questionnaire, and independent variables were each of the 5 questions.

TABLE III. Evaluation of the discriminant validity of TRACK: physicians' ratings of control

	Control rating			
	Well controlled	Not well controlled	Very poorly controlled	Statistical test *F, P* value
Development sample*	n = 102	n = 132	n = 80	
TRACK score, mean (SD)	85.1 (13.1)	64.0 (18.2)	47.4 (21.3)	105.1, <.001
Validation sample	n = 59	n = 60	n = 46	
TRACK score, mean (SD)	81.9 (15.4)	67.3 (14.7)	45.9 (20.9)	58.7, <.001

*n = 314. Data are missing for 7 patients.

TABLE IV. Evaluation of the discriminant validity of TRACK: recommended change in therapy

	Therapy recommendation			
	Stepped-down therapy	No change in therapy	Stepped-up therapy	Statistical test *F, P* value
Development sample*	n = 13	n = 196	n = 105	
TRACK score, mean (SD)	76.2 (17.8)	72.9 (20.3)	53.7 (22.2)	30.4, <.001
Validation sample	n = 11	n = 106	n = 48	
TRACK score, mean (SD)	59.4 (28.2)	73.9 (19.0)	52.0 (19.2)	21.2, <.001

*n = 314. Data are missing for 7 patients.

Reliability

The internal consistency reliability of the 5-item TRACK instrument was similar in the development (n = 321) and validation (n = 165) samples (Cronbach α coefficients = 0.75 and 0.71, respectively). In both samples, the Cronbach α coefficients were greater than the minimum accepted threshold for reliability of 0.70.[21]

Criterion validation

Based on the first criterion for respiratory control, determined by using the guidelines-based physician questionnaire, mean TRACK scores differed significantly in the hypothesized direction across the 3 groups of children (well controlled, not well controlled, or very poorly controlled) in the development ($F = 105.1$, $P < .001$) and validation ($F = 58.7$, $P < .001$) samples (Table III). As hypothesized, mean TRACK scores were highest among those with a well-controlled rating and lowest among those with a very poorly controlled rating.

Using the second criterion for respiratory control, based on physician-recommended changes to therapy, mean TRACK scores differed significantly in the hypothesized direction across the 3 groups of children (stepped-down therapy, no change in therapy, or stepped-up therapy) in the development ($F = 30.4$, $P < .001$) and validation ($F = 21.2$, $P < .001$) samples (Table IV).

TABLE V. Evaluation of the discriminant validity of TRACK: symptom status

	Symptom frequency			
	Symptomatic for last 4 wk	Symptomatic for >4 wk and ≤1 y	Asymptomatic for >1 y	Statistical test *F, P* value
Development sample*	n = 201	n = 96	n = 17	
TRACK score, mean (SD)	58.2 (21.2)	80.1 (17.4)	90.0 (11.0)	52.8, <.001
Validation sample	n = 95	n = 55	n = 15	
TRACK score, mean (SD)	56.2 (20.4)	78.0 (15.4)	90.7 (10.7)	39.3, <.001

*n = 314. Data are missing for 7 patients.

TABLE VI. Evaluation of cutoff scores: 5-item TRACK scale

Cutoff scores	Odds ratio	Sensitivity	Specificity	Positive predictive value	Negative predictive value	False-positive rate	Percent correctly classified	Area under ROC
Development sample								
<90	17.3	95.3	46.1	78.6	82.5	53.9	79.3	0.71
<85	13.8	89.2	62.8	83.3	73.6	37.2	80.6	0.76
<80	17.8	83.0	78.4	88.9	68.9	21.6	81.5	0.81
<75	19.1	73.6	87.3	92.3	61.4	12.7	78.0	0.80
<70	24.8	64.6	93.1	95.1	55.9	6.9	73.9	0.79
<65	23.4	54.7	95.1	95.9	50.3	4.9	67.8	0.75
Validation sample								
<90	35.5	97.2	50.9	78.0	90.9	49.1	80.6	0.74
<85	12.2	90.6	55.9	78.7	76.7	44.1	78.2	0.73
<80	6.5	78.3	64.4	79.8	62.3	35.6	78.3	0.74
<75	5.9	68.9	72.9	82.8	56.6	27.1	70.3	0.71
<70	5.5	63.2	76.3	82.7	53.6	23.7	67.8	0.70
<65	8.0	55.7	86.4	88.1	52.0	13.6	66.7	0.71

As hypothesized, mean TRACK scores were lowest in the group for whom a step up in therapy was recommended.

Mean TRACK scores also differed significantly in the hypothesized direction across the 3 groups of children who differed in symptom status according to the third criterion for respiratory control (frequency of symptoms at screening) in the development ($F = 52.8$, $P < .001$) and validation ($F = 39.3$, $P < .001$) samples (Table V). As hypothesized, mean TRACK scores were highest for those with the least frequent respiratory symptoms and lowest for those with the most frequent respiratory symptoms.

Screening accuracy

In the development and validation samples, respectively, analyses showed that the screening ability of the entire scale across all scores (0-100) provided an area under the ROC curve of 0.88 and 0.82; control status was correctly classified in 80.6% and 78.3% of cases. Table VI (development and validation samples) summarizes the performance of the TRACK instrument in screening for children with respiratory control problems at various cutoffs. Each TRACK score level represents a cutoff that separates children whose symptoms are well controlled from children whose symptoms are not well controlled or very poorly controlled. Statistics are presented beginning with score level 65. Score levels of less than 65 are not presented because they yielded poor classification statistics. In both samples, lower cutoff scores were associated with lower sensitivity and higher specificity. Conversely, higher cutoff scores were associated with relatively higher sensitivity and lower specificity, indicating that at higher cutoff scores, the TRACK instrument was better at detecting uncontrolled cases (higher sensitivity) but also identified more controlled cases as uncontrolled (low specificity). A cutoff score of less than 80 provided the best balance between sensitivity and specificity and the best discrimination between patients with controlled and uncontrolled symptoms based on the highest area under the ROC curve in both development and validation samples.

DISCUSSION

The objective of this study was to develop an instrument to measure respiratory and asthma control in preschool-aged children with symptoms consistent with asthma that included the impairment and risk domains of control recommended by the most recent NAEPP guidelines.[12] Regular assessment and monitoring of respiratory symptoms and activity limitations are essential in the care of asthma. However, standardized methods for measuring control in clinical settings are not available for preschool-aged children. The tools that do exist focus primarily on the adult population,[17,18,22] children and adolescents aged 1 to 18 years,[23] or children 4 to 11 years of age.[14] None of these tools considers both impairment and risk in defining asthma control.

The development of TRACK began with a comprehensive qualitative study designed to describe respiratory and asthma control issues from the perspectives of specialists, pediatricians, and caregivers of preschool-aged children. Content used to draft the questionnaire also reflected the NAEPP EPR-3 asthma management guidelines.[12] A content analysis was performed to ensure that essential elements of control were included in the draft

questionnaire before implementation in the present study. To be practical, however, the draft questionnaire tested in this study needed to be shortened considerably, from 33 items to 5 to 10 items, while maintaining content validity. The final 5 items selected for the TRACK survey are consistent with the current NAEPP EPR-3 asthma management guidelines for both the impairment domain of control assessment (ie, asthma symptoms, use of rescue medications, nighttime awakenings, and the effect of asthma on everyday functioning) and the risk domain of control assessment (ie, oral corticosteroid courses in the past 12 months).[12] As such, the TRACK instrument supports the premise that respiratory and asthma control is a multidimensional construct.

The TRACK instrument is the first respiratory control questionnaire to include an item to measure risk.[12,14] Capturing risk in a control tool for young children is novel and important given the frequency of exacerbations in this very young cohort with frequent intermittent episodes. Although the components of impairment assessed in the Childhood Asthma Control Test (C-ACT) and TRACK are similar (eg, nighttime awakenings, interference with activity), the wording of the questions and the populations studied are different. Because of the challenges in diagnosing asthma in preschool-aged children, TRACK was specifically developed for caregivers of children aged younger than 5 years with respiratory symptoms consistent with asthma but not necessarily with a specific diagnosis of asthma because health care providers are often hesitant to give young children diagnoses of asthma. The TRACK cohort consisted of young children with at least 2 episodes of respiratory symptoms consistent with asthma plus a physician's diagnosis of asthma (61.9%) or use of a bronchodilator (38.1%). In contrast, the C-ACT includes both child-completed and caregiver-completed items and was developed or validated for generally school-aged (mean age [SD], 8 [2.4] years) children with asthma.[14]

In this study, a scale constructed from the 5 items selected for TRACK was shown to be reliable and valid. In screening for control problems, the final instrument showed a good area under the ROC curve relative to the NAEPP EPR-3–based ratings of asthma control. The ROC value of 0.88 is consistent with the ROC values of 0.791 and 0.862 reported for the development and validation samples, respectively, of the Childhood Asthma Control Test.[14] The TRACK instrument is not a diagnostic screening tool. However, this study suggests that TRACK correctly classifies respiratory control levels in approximately 80% of children younger than 5 years with a history of 2 or more episodes of respiratory symptoms suggestive of asthma. Assessments of TRACK's screening accuracy for poor respiratory control suggest that children with a TRACK score of less than 80 are likely to have uncontrolled asthma. This score provided the optimum balance of sensitivity and specificity in both the development and validation samples. The sensitivity and specificity of TRACK at the less-than-80 cutoff are consistent with those reported for the Asthma Control Test at a cutoff of 19 or less (sensitivity, 69.2; specificity, 76.2).[17] For control status, the percentage correctly classified of approximately 80% is comparable with that reported at a cutoff score of 19 for the Asthma Control Test (74% correctly classified) and C-ACT (72% in development sample and 83% in confirmatory sample).[14,17] Therefore clinicians should be aware that control status potentially can be misclassified in approximately 20% of patients using currently available asthma control tools, including TRACK. To strengthen TRACK's clinical utility and improve the capture of true-positive results and, especially, false-negative results, further validation studies are needed to assess test-retest reliability, responsiveness to change in therapy, and the minimum important difference for improvement or worsening of asthma control. These instruments, however, are a useful starting point for identifying most patients who have suboptimal respiratory or asthma control. Therefore, in patients with a TRACK score of less than 80, one should consider the need for further evaluation, treatment adjustments, or both.

Recognizing that TRACK might be used for many different purposes in the future, we have provided screening statistics across various score levels of TRACK. For example, clinicians involved in a disease management program who plan to use TRACK as an initial screening tool might decide to choose a cutoff associated with a high degree of sensitivity (higher TRACK score cutoff). Such a cutoff would ensure that most children with respiratory or asthma control problems are identified for inclusion in the program. More resource-intensive screening (to identify false-positive results) could then be applied to those who were selected through the initial screening with TRACK.

The reliability of the 5-item TRACK instrument was tested by using internal consistency methods. The Cronbach α coefficients of the 5-item TRACK instrument were relatively low in the development (0.75) and validation (0.71) samples. These results were not surprising because the 5 items of TRACK were not designed to be internally consistent and because they represent 3 different dimensions of control. A more appropriate method for assessing the reliability of TRACK is to assess the test-retest reliability. A follow-up longitudinal study is currently being conducted to evaluate the stability of TRACK scores over time and to determine TRACK's responsiveness to change in control.

Given the increasingly limited physician-child-caregiver interaction time and that objective measures of lung function are not readily available for young children, an accurate, reliable, and easy-to-use control tool is essential in the management of respiratory symptoms of young children. A brief standardized instrument for preschool-aged children should be considered for collecting basic information about respiratory and asthma control before a visit (eg, in the waiting room) to a health care provider, thereby saving time for more in-depth and focused discussions. TRACK was specifically designed to raise awareness of respiratory control problems in young children for both the health care provider and caregiver and might be most useful in clinical practice by facilitating a dialogue between the health care provider and caregiver to identify strategies to better manage the child's respiratory symptoms. Furthermore, use of TRACK over time might prove useful in monitoring trends in respiratory and asthma control for use in clinical care and research. However, further research is necessary before the role of TRACK in clinical practice and research can be established clearly.

Recruitment of young children and their caregivers into clinical trials can be challenging. The number of patients in the present study, however, is as large as or larger than the number of patients in published development/validation studies of patient-reported asthma control tools for children aged 4 to 11 years,[14] children and adolescents aged 5 years and older,[15] and adolescents and adults.[17,24] The number of children who were severely affected or younger than 2 years was small in the current study, and therefore, these subgroups will require additional study. Another limitation is that the study population was English-speaking only,

mostly white, and mostly college educated. Efforts are underway to translate and test TRACK in Spanish.

In conclusion, the results of this study provide evidence of the reliability and validity of TRACK. In addition, TRACK might be very useful in identifying young children with respiratory control problems, which is important in this population because objective measures are either too difficult for children to perform or have not been standardized. The 5-question TRACK tool is easy to administer and score and addresses both the impairment and risk domains of asthma control consistent with current asthma guidelines. The establishment of a cutoff score for identifying children with respiratory control problems makes TRACK a valuable aid to health care providers and caregivers in monitoring young children with symptoms consistent with asthma. This study provides the first evidence for the validation of TRACK to assess respiratory and asthma control in children aged younger than 5 years.

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Clinical implications: Clinicians now have a validated, easy-to-administer, caregiver-completed questionnaire to evaluate respiratory control in preschool-aged children. This tool aids clinicians in evaluating respiratory control in young children with symptoms consistent with asthma.

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METHODS

Working group and qualitative development

Development of the draft questionnaire was based on input from a working group, caregiver and physician interviews, and subsequent qualitative research. A working group of pediatric asthma specialists (n = 5) advised on the study protocol, identification and recruitment of study sites, site training and inclusion and exclusion criteria and provided direction on item development for the caregiver and physician questionnaires. Results from in-depth structured telephone interviews with 5 pediatric asthma specialists, 5 pediatricians, and 13 caregivers of children with asthma concluded that both physicians and caregivers agreed on the need for a brief, standardized, caregiver-completed questionnaire to assist in detecting respiratory control problems in preschool-aged children (<5 years). The working group decided to base the criterion measure of respiratory control for this instrument on the definitions in the National Asthma Education and Prevention Program Expert Panel Report-3 asthma control table for 0- to 4-year-old children.[E1] Additionally, they reviewed the results of the item-selection analysis to ensure that the final set of items selected for the instrument appropriately represented the components of control for children aged 0-4 years.[E1]

Data collection and analysis

Data were obtained from eligible caregivers and physicians regarding the child's respiratory/asthma control problems. Physicians completed a 15-item questionnaire that included 5 specific items (Table E1) based on the risk and impairment factors in the previously described control table.[E1] During the child's visit to the physician, caregivers answered 10 questions about the child's medical and clinical history and completed the 33-item draft questionnaire (Fig E1).

Construct validity

During the qualitative phase of this study, a conceptual model for respiratory control problems in preschool-aged children was developed. This model was derived from feedback from clinicians and caregivers of preschool-aged children with asthma, the literature, and the asthma management guidelines. Our conceptual model of respiratory control included 3 major components. The first component consists of the frequency and severity of respiratory symptoms (cough, wheeze, and shortness of breath). The second component of respiratory control consists of the physical and emotional effect of respiratory symptoms. Items that comprise this component measure the extent to which the child's respiratory problems interfere with daily activities, such as play and other normal routines, and the extent to which they cause distress, irritability, and fatigue. The third component consists of exacerbations, which were defined by items that assessed the frequency with which the child used care and services to treat and control respiratory symptoms (rescue medications, emergency department visits, unscheduled visits to the physician, hospitalizations, and oral corticosteroid use).

Exploratory factor analyses first were conducted to investigate whether there was a general structure underlying the item responses from the caregiver questionnaire. In addition, confirmatory factor analyses were conducted to confirm whether the correlations among items supported common factors in our conceptual model of respiratory control in preschool-aged children. We hypothesized that items Q1 though Q18 on the caregiver survey would be strongly correlated ($r > 0.7$) with the "symptom" factor. We also hypothesized that items Q19 through Q26 would be strongly correlated ($r > 0.7$) with the "impact" factor. Lastly, we hypothesized that items Q27 through Q33 would be strongly correlated ($r > 0.7$) with the "exacerbation" factor.

RESULTS

Construct validity

The first 5 eigenvalues from the EFA are presented in Table E2 (development and validation samples). In both samples, the first 5 factors had eigenvalues that were greater than unity, and thus there were 5 potential factors underlying the pattern of associations among the caregiver item responses. The first factor (eigenvalue) accounted for the majority of variance in item responses (>59%) in both samples, meaning that there was something common to all items in the survey, namely the concept of respiratory control. The second and third factors explained more than 5% of the variance in item responses, which allowed for determining the true number of factors in a factor analytic model. Combined, the first 3 factors accounted for 75% of the variance in item responses in both samples. The fourth and fifth factors accounted for less than 5% of the variance in item responses and thus are not likely to be true factors.

Table E3 (development and validation samples) summarizes the CFA results. In both samples, the correlations between each item and their *a priori* hypothesized factor were all greater than 0.70, supporting the conceptual model developed for respiratory control in young children. In addition, the model fit statistics suggest adequate fit of the model in both samples. The Confirmatory Fit Index and the Tucker-Lewis Index values in the development sample were 0.89 and 0.96, respectively. The Confirmatory Fit Index and the Tucker-Lewis Index values in the validation sample were 0.90 and 0.95, respectively. Overall, the results of the EFA and CFA lend support that the items developed for the draft TRACK questionnaire appropriately measure the concepts derived for the model of respiratory control.

TRACK item modification

The 6 items identified by the model and the final 5-item TRACK instrument demonstrated similar measurement properties when evaluated for variance, sensitivity, specificity, positive and negative predictive value, false-positive rate, percentage correctly classified, and area under the ROC curve (Table E4).

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SURVEY INSTRUCTIONS FOR CAREGIVERS

This survey asks for your views about your child's respiratory problems. For each question please mark an ☒ in the one box that best describes your answer. Please answer all of the questions, even if some questions seem repetitive. There are no right or wrong answers to each question. Your participation is voluntary and all of your answers will be kept confidential.

When you have completed the survey, please give it back to the physician or office staff.

The following questions are about your child's respiratory symptoms. Select the response that best indicates how often your child experienced each respiratory symptom during the past 4 weeks. Please answer all of the questions, even if some questions seem repetitive.

	Never ▼	Rarely ▼	Sometimes ▼	Very often ▼	Always ▼
1. During the past 4 weeks, how often was your child bothered with wheezing (for example, breathing that makes a high pitched whistling or squeaking sound from the chest)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
2. During the past 4 weeks, how often was your child bothered with coughing caused by activity, exercise, or play?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
3. During the past 4 weeks, how often was your child bothered with coughing at night during sleep?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Never ▼	Rarely ▼	Sometimes ▼	Very often ▼	Always ▼
4. During the past 4 weeks, how often was your child bothered with shortness of breath (for example, heavy or shallow breathing) resulting from activity, exercise, or play?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
5. During the past 4 weeks, how often was your child bothered with breathing problems such as wheezing, coughing or shortness of breath resulting from activity, exercise, or play?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
6. During the past 4 weeks, how often were your child's breathing problems (wheezing, coughing, shortness of breath) made worse during high activity or play?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Not at all ▼	Once or twice ▼	Once every week ▼	2 or 3 times a week ▼	4 or more times a week ▼
7. During the past 4 weeks, how often did your child have the following breathing problems?					
a. Wheezing (breathing that makes a high pitched whistling or squeaking sound from the chest)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Coughing associated with activity, exercise, or play	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Coughing at night during sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. Shortness of breath (heavy or shallow breathing)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
8. During the past 4 weeks, how often was your child bothered by breathing problems, such as wheezing, coughing, or shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

FIG E1. Draft 33-item caregiver questionnaire.

	Not at all	Once or twice	Once every week	2 or 3 times a week	4 or more times a week
9. During the past 4 weeks, how often did your child's breathing problems (wheezing, coughing, shortness of breath) wake him or her up at night	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
10. During the past 4 weeks, how often did your child's breathing problems (wheezing, coughing, shortness of breath) wake you up at night?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
11. During the past 4 weeks, how often did your child wake up in the morning with breathing problems (wheezing, coughing, shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
12. During the past 4 weeks, how often did your child have to stay indoors because of breathing problems (wheezing, coughing, shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
13. During the past 4 weeks, how often was your child limited in going outdoors to play because of breathing problems (wheezing, coughing, shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following questions are about the severity of your child's respiratory symptoms. Select the response that best indicates how severe your child's respiratory symptoms were during the past 4 weeks. Please answer all of the questions, even if some questions seem repetitive.

	No wheezing	Mild	Moderate	Severe	Very severe
14. During the past 4 weeks, how severe was your child's wheezing (for example, breathing that makes a high pitched whistling or squeaking sound from the chest)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	No coughing	Mild	Moderate	Severe	Very severe
15. During the past 4 weeks, how severe was your child's coughing that was brought on by activity, play or exercise?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	No shortness of breath	Mild	Moderate	Severe	Very severe
16. During the past 4 weeks, how severe was your child's shortness of breath (for example, breathing that was heavy or shallow)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	No breathing problems	Mild	Moderate	Severe	Very severe
17. During the past 4 weeks, how severe was your child's breathing problems, such as wheezing, or coughing brought on by activity, or shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Not at all	Once or twice	Once every week	2 or 3 times a week	4 or more times a week
18. During the past 4 weeks, how often did your child have an episode or attack that lasted more than 24 hours? By episode or attack we mean difficulty breathing that interfered with normal activities or sleep and that may have been accompanied by coughing, wheezing, or shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

FIG E1. *(Continued)*

The following questions are about how much your child's respiratory symptoms affect their life. Select the response that best indicates how much your child's respiratory symptoms affected their life during the past 4 weeks. Please answer all of the questions, even if some questions seem repetitive.

	Not at all	Slightly	Moderately	Quite a lot	Extremely
19. During the past 4 weeks, to what extent did your child's wheezing (for example, breathing that makes a high pitched whistling or squeaking sound from the chest) interfere with his or her ability to play, go to school, or engage in usual activities that a child should be doing at his or her age?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20. During the past 4 weeks, to what extent did your child's cough (for example, coughing brought on by activity, exercise, or play) interfere with his or her ability to play, go to school, or engage in usual activities that a child should be doing at his or her age?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21. During the past 4 weeks, to what extent did your child's shortness of breath (for example, heavy or shallow breathing) interfere with his or her ability to play, go to school, or engage in usual activities that a child should be doing at his or her age?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22. During the past 4 weeks, to what extent did your child's breathing problems such as wheezing, coughing, or shortness of breath interfere with his or her ability to play, go to school, or engage in usual activities that a child should be doing at his or her age?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Never	Rarely	Sometimes	Very often	Always
23. During the past 4 weeks, how often did your child seem irritable, grumpy or clingy because of his or her breathing problems (wheezing, coughing, shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
24. During the past 4 weeks, how often did your child seem tired or less playful because of his or her breathing problems (wheezing, coughing, shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
25. During the past 4 weeks, how often was your child limited in going to certain places that might be bad for his or her breathing problems (wheezing, coughing, shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26. During the past 4 weeks, how often did you have to modify your normal daily routine because of your child's breathing problems (wheezing, coughing, shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

FIG E1. *(Continued)*

The following questions are about actions you have taken to care of your child's respiratory symptoms during the past 3 months. Please answer all of the questions, even if some questions seem repetitive.

	Never	Rarely	Sometimes	Very often	Always
27. During the past 3 months, how often did your child have a breathing problem (wheezing, coughing, shortness of breath) that could not be treated successfully with medications that do not require a prescription?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Never	Once	Twice	3 times	4 or more times
28. During the past 3 months, how many unscheduled or same day visits to the doctor were made to treat your child's breathing problems (wheezing, coughing, shortness of breath) because medication did not work?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
29. During the past 3 months, how often did you need to take your child to the emergency room for breathing problems (wheezing, cough, shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

	Never	Once or twice	Once a week	2 to 3 times a week	4 or more times a week
30. During the past 3 months, how often did you need to treat your child's breathing problems (wheezing, coughing, shortness of breath) with rescue or quick-relief medications (Albuterol, Ventolin, Proventil, Maxair, proAIR, Xopenex or Primatene Mist)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following questions are about actions you have taken to care of your child's respiratory symptoms during the past 12 months. Please answer all of the questions, even if some questions seem repetitive.

	Never	Once	Twice	3 times	4 or more times
31. During the past 12 months, how many times was your child hospitalized overnight for breathing problems (wheezing, coughing, or shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32. During the past 12 months, how often did your child need to use rescue medications (Albuterol, Ventolin, Proventil, Maxair, or Primatene Mist), have an unscheduled visit to the doctor, or go to the emergency room to treat his or her breathing problem (wheezing, coughing, or shortness of breath)?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33. During the past 12 months, how often did your child need to take oral corticosteroids (prednisone, prednisolone, Orapred, Prelone Decadron) for breathing problems not controlled by other medications?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

FIG E1. *(Continued)*

TABLE E1. First 5 items of physicians' questionnaire assessing respiratory control

Respiratory control assessment	Control rating categories* (1)	(2)	(3)
	≤2 days/week	>2 days/week	Throughout the day
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)?	☐ 1	☐ 2	☐ 3
	1 time/month	>1 time/month	>1 time/week
2. During the past 4 weeks, how often was the child's sleep disrupted by cough or wheeze?	☐ 1	☐ 2	☐ 3
	No limitation	Some limitation	Extremely limited
3. During the past 4 weeks, how limited was the child in performing normal activities by cough or wheeze?	☐ 1	☐ 2	☐ 3
	≤2 days/week	>2 days/week	Several times/day
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?	☐ 1	☐ 2	☐ 3
	0-1 time/year	2-3 times/year	>3 times/year
5. In the past year, how many times did the child take oral steroids to treat episodes of cough or wheeze?	☐ 1	☐ 2	☐ 3

**1*, Well controlled; *2*, not well controlled; *3*, very poorly controlled.

TABLE E2. Eigenvalue analysis* of caregiver survey responses

	Factors				
	1	**2**	**3**	**4**	**5**
Development sample					
Eigenvalue	20.8	2.3	2.0	1.3	1.1
Variance explained (%)	63	7	6	3.9	3.3
Total variance explained (%)	63	70	76	79.9	83.2
Validation sample					
Eigenvalue	19.7	2.9	2.2	1.7	1.4
Variance explained (%)	59.7	8.8	6.6	4.8	4.2
Total variance explained (%)	59.7	68.5	75.1	79.9	84.1

*Exploratory factor analysis.

TABLE E3. Confirmatory factor analysis

Symptom factor		Impact factor		Utilization factor	
Item no.	**Item-factor correlation**	**Item no.**	**Item-factor correlation**	**Item no.**	**Item-factor correlation**
Development sample					
Q11	0.90	Q29	0.95	Q37	0.60
Q12	0.88	Q30	0.93	Q38	0.81
Q13	0.78	Q31	0.92	Q39	0.54
Q14	0.85	Q32	0.95	Q40	0.77
Q15	0.92	Q33	0.88	Q41	0.47
Q16	0.89	Q34	0.88	Q42	0.55
Q17a	0.88	Q35	0.82	Q43	0.61
Q17b	0.88	Q36	0.91		
Q17c	0.81				
Q17d	0.77				
Q18	0.79				
Q19	0.95				
Q20	0.87				
Q21	0.81				
Q22	0.94				
Q23	0.93				
Q24	0.85				
Q25	0.81				
Q26	0.79				
Q27	0.81				
Q28	0.76				
Validation sample					
Q11	0.92	Q29	0.93	Q37	0.55
Q12	0.72	Q30	0.95	Q38	0.85
Q13	0.79	Q31	0.93	Q39	0.73
Q14	0.84	Q32	0.97	Q40	0.78
Q15	0.87	Q33	0.89	Q41	0.51
Q16	0.80	Q34	0.91	Q42	0.52
Q17a	0.88	Q35	0.87	Q43	0.60
Q17b	0.79	Q36	0.88		
Q17c	0.86				
Q17d	0.75				
Q18	0.84				
Q19	0.86				
Q20	0.83				
Q21	0.68				
Q22	0.90				
Q23	0.90				
Q24	0.87				
Q25	0.77				
Q26	0.85				
Q27	0.83				
Q28	0.84				

Development sample: Confirmatory Fit Index = 0.89; Tucker-Lewis Index = 0.96.
Validation sample: Confirmatory Fit Index = 0.90; Tucker-Lewis Index = 0.95.

TABLE E4. Comparison of the screening accuracy of TRACK scales: 5-item TRACK scale versus 6 items identified from stepwise logistic regression (backward selection method)

Item	5-Item scale (TRACK)	6-Item scale
Variance explained (%)	35.4	36.2
Sensitivity	89.2	91.0
Specificity	62.8	62.7
Positive predictive value	83.3	83.6
Negative predictive value	73.6	77.1
False-positive rate	37.3	37.3
Percentage correctly classified	80.6	81.8
Area under ROC curve	0.88	0.88