

Test for Respiratory and Asthma Control in Kids (TRACK): Clinically meaningful changes in score

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Background: The Test for Respiratory and Asthma Control in Kids (TRACK) is the first validated questionnaire to assess respiratory and asthma control exclusively in young children. **Objective:** We sought to determine the minimally important difference (MID) for interpreting meaningful changes in individual patients' TRACK scores.

Methods: In this prospective, nonrandomized, longitudinal study conducted at 20 US pediatric sites, TRACK was administered at 2 separate clinic visits (4-6 weeks apart) to caregivers of children aged less than 5 years with symptoms consistent with asthma. Anchor-based methods were used to determine the MID from mean score differences between patients based on multiple criteria measures: physician guidelines-based respiratory control rating, physician-recommended changes to therapy, episodes of symptoms lasting more than 24 hours in the past 3 months, oral corticosteroid use for respiratory tract illnesses in the past year, physician-assessed change in control status at follow-up, and caregiver-reported change in respiratory status. The MID also was determined from distribution-based methods.

Results: TRACK scores were assessed at baseline (426 caregivers) and follow-up (396 caregivers). Mean differences in TRACK scores between patients differing on criteria measures ranged from 3.4 to 16.4 points (mean, 11.1 points). Distribution-based techniques confirmed these findings. Based on logistic regression analyses, scoring 10 or more points less than 80 on TRACK was associated with an approximately 2-fold increased odds of having uncontrolled asthma or respiratory symptoms.

Conclusion: Changes in TRACK scores of 10 or more points represent clinically meaningful changes in respiratory control status in individual young children with respiratory symptoms consistent with asthma and should alert health care providers to re-evaluate asthma management. (J Allergy Clin Immunol 2011;■■■:■■■-■■■.)

Key words: Asthma, asthma control, epidemiologic measurements, questionnaire, pediatric, preschool children, risk, validation studies, wheezing

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Preschool-aged children with frequent recurrent and intermittent wheezing episodes are a major public health concern because they have higher rates of health care use and morbidity than older children.^{1,2} Spirometry is a standard objective test that is used in older children and adults to help evaluate asthma control; however, it cannot be performed routinely in children younger than 5 years.³ Moreover, previous validated asthma control tools were not specific to preschool-aged children.^{4,5} It is recommended that patient-reported outcome measures for patients who cannot respond for themselves, such as very young children, be developed to include only events or behaviors that can be observed.⁶

To address this unmet need, we developed and validated the Test for Respiratory and Asthma Control in Kids (TRACK) in cross-sectional⁷ and longitudinal⁸ cohorts to assess respiratory and asthma control in children younger than 5 years with symptoms consistent with asthma.⁷ TRACK⁹ is a 5-item standardized questionnaire (Fig 1), with 4 questions that address the impairment domain and 1 question that addresses the risk domain of asthma control, as outlined by the National Asthma Education and Prevention Program (NAEPP)'s Expert Panel Report 3 (EPR-3) guidelines.³ Each item is scored from 0 to 20 points on a 5-point Likert-type scale for a total score ranging from 0 to 100. Higher scores indicate better respiratory and asthma control; a score of less than 80 points suggests that a child's breathing problems might not be controlled.⁷

Determining the minimally important difference (MID) of a control tool is important to help practitioners interpret what

Abbreviations used

EPR-3: Expert Panel Report 3
 MID: Minimally important difference
 NAEPP: National Asthma Education and Prevention Program
 TRACK: Test for Respiratory and Asthma Control in Kids

change in score is clinically relevant.¹⁰ The MID represents the smallest difference in a score that patients perceive as clinical improvement^{11,12} or worsening¹² and that would lead a clinician to consider a treatment change. No single statistical approach is optimal for determining MIDs,¹³ and therefore several strategies can be used.

The objective of the present study is to further validate TRACK by determining its MID by using 2 established approaches¹⁴⁻¹⁶: an anchor-based technique using an independent clinical measure (anchor) and a distribution-based technique using statistical distribution around a mean. Herein we report the results of the MID for TRACK determined by using the anchor-based method and confirmed by using distribution-based methods.

METHODS**Study design and patients**

This prospective, longitudinal, nonrandomized, observational TRACK validation study consisted of a convenience sample of English-speaking caregivers and their children aged less than 5 years presenting to 1 of 20 practice sites in the American Academy of Pediatrics' Quality Improvement Innovation Network.¹⁷ One physician from each practice site participated; the number of patients seen at each site varied. TRACK surveys were completed from January 2009 to May 2009. Details of the study have been described previously.⁸ Children were included if they met the following criteria: (1) a history of 2 or more episodes of wheezing, shortness of breath, or coughing lasting more than 24 hours at any time in their lives (with 1 episode having occurred in the past year) and (2) an asthma diagnosis or improvement in respiratory symptoms with a prescription bronchodilator. Children were excluded if they had a respiratory condition other than asthma or were currently involved in another clinical study.⁸ Visits were conducted at baseline during routine pediatric visits and at follow-up during a scheduled study visit. The American Academy of Pediatrics' Institutional Review Board approved the study, and informed consent was obtained from each caregiver.

Data collection

Data collected at baseline and follow-up included the TRACK survey and caregiver and physician questionnaires.⁸ Briefly, caregivers completed the TRACK survey (Fig 1) at the initial physician's office visit (baseline). At baseline, they also answered the following question: "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?" Answers were based on a Likert-type scale, as described previously.⁸ The same caregivers completed the TRACK survey 4 to 6 weeks later at a follow-up visit. On the follow-up visit, caregivers also were asked to characterize the change in respiratory symptom status as "a lot better now," "a little better now," "about the same," "a little worse now," or "a lot worse now."

Physicians blinded to caregiver responses completed a separate survey based on the NAEPP's EPR-3 asthma control table for children aged 0 to 4 years at the initial visit and at the 4- to 6-week follow-up visit.³ These physicians previously completed a 30-minute training course and passed a test on the NAEPP's guidelines⁸; each patient was seen by the same physician at the baseline and follow-up visits. Results from each question were used to score the survey on a 3-point scale of well controlled, not well controlled, and very poorly controlled.

Data analyses

Anchor-based analyses for determination of TRACK MID. The anchor-based analysis was performed in 2 steps. ANOVA was first conducted to evaluate the magnitude and significance of differences in mean TRACK scores among patient subsets differing on each of the following 6 criterion measures (ie, anchors):

1. physician guidelines-based control table rating (well controlled, not well controlled, very poorly controlled)⁷;
2. physician's therapy recommendation (step-up, no change, step-down);
3. frequency over the past 3 months of caregiver-reported episodes or attacks that "lasted more than 24 hours involving coughing, wheezing, or shortness of breath resulting from activity" (not at all, once or twice, once every week, 2 or 3 times a week, ≥ 4 times a week);
4. frequency of times the child used oral corticosteroids to treat episodes of coughing or wheezing in the past 1 year (0-1 times/y, 2-3 times/y, >3 times/y);
5. change in respiratory control status based on physician guidelines-based control table rating (better by 1 level, same, worse by 1 level); and
6. caregiver's report of change in respiratory symptom status (a lot better now, a little better now, about the same, a little worse now, a lot worse now).

The MID was established based on the mean differences in TRACK scores between subsets of patients for each criterion measure. These differences were analyzed for cross-sectional data at baseline, cross-sectional data at follow-up, and longitudinal data at follow-up. The longitudinal analysis included only the subset ($n = 271$) of children whose physicians reported 0- to 1-time use of oral corticosteroids to treat episodes of cough or wheeze in the past year at baseline, enabling examination of the subset of the population for whom changes in risk would be measurable. Additionally, we calculated the effect size to determine the magnitude of the difference in TRACK score in standardized units between patient subsets.¹⁸ For these analyses, effect size was calculated by dividing the mean difference in TRACK score by the SD at baseline.

Distribution-based analyses for determination of TRACK MID.

Distribution-based analyses were based on the distribution of the TRACK scores within the cohort responses at baseline and at the follow-up visit by using 2 recommended approaches: (1) the 0.5 SD method, which defines a moderate effect size as a change in scale scores equal to 0.5 SD¹⁸ and is considered a universal criterion for MID thresholds for disease-specific patient-reported outcomes tools,¹⁰ and (2) the validated 1 SEM method,¹⁶ which identifies intraindividual change by calculating 1 SEM as the SD multiplied by the square root of $(1 - \text{Cronbach } \alpha)$, where Cronbach α is a measure of internal consistency reliability.¹⁹

Logistic regression analyses of TRACK score changes.

Logistic regression analysis was used to investigate the odds of poor respiratory control as a function of differences in TRACK scores less than and equal to or greater than the MID starting at the previously established cut point score of less than 80 to determine the meaningfulness of score differences on TRACK. Odds ratios and 95% CIs were determined for each time period (baseline and follow-up) based on regression coefficients predicting physician guidelines-based respiratory control status. As previously described,⁷ respiratory control was dichotomized as controlled and uncontrolled; children with not well-controlled and very poorly controlled ratings were combined into the uncontrolled subset. A 2-tailed P value of .05 was considered significant.

RESULTS**Demographics**

A total of 438 caregivers enrolled in the study, but some caregivers did not provide complete answers to every question. Because of missing responses to survey items needed for analyses, complete data were available for 426 caregivers at baseline and 396 caregivers at the follow-up visit. Details of the

						Score
1	During the past 4 weeks, how often was your child bothered by breathing problems, such as wheezing, coughing, or shortness of breath?					
	Not at all ☐ 20	Once or twice ☐ 15	Once every week ☐ 10	2 or 3 times a week ☐ 5	4 or more times a week ☐ 0	
2	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?					
	Not at all ☐ 20	Once or twice ☐ 15	Once every week ☐ 10	2 or 3 times a week ☐ 5	4 or more times a week ☐ 0	
3	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?					
	Not at all ☐ 20	Once or twice ☐ 15	Once every week ☐ 10	2 or 3 times a week ☐ 5	4 or more times a week ☐ 0	
4	During the past 3 months, how often did you need to treat your child's breathing problems (wheezing, coughing, shortness of breath) with quick-relief medications (albuterol, Ventolin®, Proventil®, Maxair®, ProAir®, Xopenex®, or Primatene® Mist)?					
	Not at all ☐ 20	Once or twice ☐ 15	Once every week ☐ 10	2 or 3 times a week ☐ 5	4 or more times a week ☐ 0	
5	During the past 12 months, how often did your child need to take oral corticosteroids (prednisone, prednisolone, Orapred®, Prelone®, or Decadron®) for breathing problems not controlled by other medications?					
	Not at all ☐ 20	Once or twice ☐ 15	Once every week ☐ 10	2 or 3 times a week ☐ 5	4 or more times a week ☐ 0	
					Total	

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FIG 1. TRACK questionnaire. TRACK is a trademark of the AstraZeneca group of companies. ©2009 AstraZeneca LP. All rights reserved 278650 5/09. Reprinted with permission from AstraZeneca Pharmaceuticals.

demographic characteristics of the population at baseline have been described previously.⁸ Most caregivers were white (59% [n = 252/425]) women (89% [n = 387/437]) aged 25 to 34 years (51% [n = 222/434]) who had graduated from college or higher (53% [n = 231/433]). Based on the caregiver survey, 71% (n = 306/433) of children had an asthma diagnosis. Based on the physician survey, 47% of children had used albuterol more than 2 days per week or several times per day in the past 4 weeks, and 30% had used oral corticosteroids for respiratory symptoms more than 1 time in the past year (Table I).⁸

Anchor-based MID

The mean differences in TRACK scores among patients differing on each anchor measure of respiratory control ranged from 3.4 to 16.4 points across the 15 comparisons (Table II). For 10 of the 15 measures, the mean difference between subsets was greater than 10. The mean and median TRACK score differences were similar (11.1 and 11.7, respectively), suggesting that the MID for TRACK based on this methodology is 11 points. However, because TRACK is scored in 5-point increments, the actual MID when used for assessing individual patients would need to be 10 or more points.

Effect sizes calculated for the mean differences between each subset for the 15 anchors ranged from 0.22 to 0.78. The mean and median effect sizes computed across all comparisons were similar (0.54 and 0.57, respectively) and considered moderate.¹⁸

Distribution-based MID

The 0.5 SD and 1 SEM distribution-based approaches led to MID mean estimates of 9.6 and 11.1, respectively (Table III), and were similar to the MID determined by using the anchor-based methodology.

Logistic regression analyses of TRACK score changes

The likelihood of poor respiratory control for TRACK scores less than and equal to or greater than the MID are described in Table IV. Scoring 10 or more points less than 80 on TRACK was associated with an approximately 2-fold increased odds of having uncontrolled asthma or respiratory symptoms.

DISCUSSION

The current NAEPP's EPR-3 guidelines recommend monitoring asthma control to determine whether therapy should be maintained or adjusted.³ The TRACK instrument addresses this recommendation for children younger than 5 years who have respiratory symptoms consistent with asthma by assessing the impairment and risk domains of asthma control. The TRACK instrument has been validated in cross-sectional⁷ and longitudinal⁸ settings and has been shown to be responsive to change in respiratory or asthma control in children younger than 5 years.⁷

TABLE I. Clinical characteristics of children based on physicians' responses to the respiratory control survey*

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

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OCS, Oral corticosteroid.

*The survey included 5 specific respiratory control questions based on the NAEPP's asthma control table for children aged 0 to 4 years.

The present prospective, longitudinal, observational study of children younger than 5 years with asthma or respiratory symptoms consistent with asthma further validates and extends the utility of the TRACK control tool by determining the MID needed to suggest a clinically meaningful change over time in respiratory or asthma control status. These results will aid practitioners in the ongoing assessment and clinical care of this patient population. These results also will guide treatment changes because the MID represents a threshold of change that is outside of chance. An improvement in TRACK score reaching the MID suggests that the treatment had a positive effect on controlling the patient's symptoms, whereas a decrease in TRACK score greater than the MID suggests that the practitioner should consider a change in the management plan because the patient's clinical status has deteriorated to a meaningful degree. For investigators who use TRACK in a research setting, determination of the MID informs sample size and enhances the interpretability of treatment response comparisons.¹³ Because no single optimal method has been established for the determination of MID, the present study reports the clinically relevant approach of multiple anchor-based analyses, which was confirmed by the statistical distribution approach.

The mean value is a reasonable and acceptable approach to establish the MID by using the anchor-based method. The results of this study showed a mean MID of 11.3 based on anchor-based analyses (Table II). Moreover, 11 of the 15 anchor-based values were 10 or more points when rounded to the nearest whole number. These findings were supported by the distribution-based analyses, which showed that a mean TRACK score change of 9.6 points corresponded to a moderate effect size (ie, 0.5 SD)

TABLE II. Anchor-based approach to determining the MID for TRACK

	Mean difference in TRACK score (absolute values)	Effect size*†
Cross-sectional comparisons at baseline (n = 426)		
Physicians' control table rating		
Well vs not well controlled	13.3	0.63
Not well vs very poorly controlled	14.7	0.70
Physician-recommended changes to therapy		
No change vs step-up	11.9	0.57
Frequency of respiratory episodes or attacks‡		
None vs once or twice	9.7	0.46
Once or twice vs 1 time/wk	16.0	0.76
1 time/wk vs 2-3 times/wk	7.4	0.35
Frequency of oral corticosteroid use§		
0-1 times/y vs 2-3 times/y	11.1	0.53
2-3 times/y vs >3 times/y	3.4	0.16
Cross-sectional comparisons at follow-up (n = 396)		
Physicians' control table rating		
Well vs not well controlled	11.7	0.56
Not well vs very poorly controlled	14.3	0.69
Physician-recommended changes to therapy		
No change vs step-up	16.4	0.78
Longitudinal comparisons at follow-up (n = 271)¶		
Change in physicians' control table rating		
Better (1 level) vs same	13.4	0.64
Worse (1 level) vs same	5.4	0.26
Caregiver report of change in respiratory symptom status		
Little better vs same	7.7	0.22
Little worse vs same	10.2	0.48
Mean	11.1	0.52
Median	11.7	0.56

*Mean differences in TRACK scores divided by baseline SD (21) of TRACK scores in total sample (n = 426); Effect size = Mean difference in TRACK score/SD_{baseline}.

†Based on definitions by Cohen,¹⁸ a small effect size is defined as a change in scale score of 0.2 SD, a moderate effect is a change of 0.5 SD, and a large effect size is a change of 0.8 SD.

‡Only assessed at baseline based on caregiver's report; episodes lasted more than 24 hours and involved "wheezing, coughing, or shortness of breath resulting from activity."

§Only assessed at baseline based on physician's report of oral corticosteroid use in the previous year.

||Caregiver's answer choices were "a lot better," "a little better," "about the same," "a little worse," or "a lot worse." Comparisons were restricted to same versus little change.

¶Subset of sample whose physicians reported 0- to 1-time use of oral corticosteroids to treat episodes of cough or wheeze in the past year at baseline.

and a mean change of 11.1 approximated the 1 SEM criteria recommended for individual patient classification (Table III). Because TRACK is scored in 5-point increments, score changes of 10 or more points are suggested to assess clinically meaningful changes over time in respiratory control status in individual young children with respiratory symptoms consistent with asthma. Results of logistic regression analysis provide further support for an MID score of 10 or more points because a decrease of the magnitude of the MID (10 points) doubles the odds of symptoms being uncontrolled. A change of 10 or more points provides a signal to the physician to evaluate factors that affect disease control, such as environmental triggers and patient adherence, and determine whether the treatment plan requires adjustment.

TABLE III. Summary of the distribution-based approach to determining the MID for TRACK

Sample	Criterion	
	0.5 SD	1 SEM
Baseline (n = 426)	10.5	11.9
Follow-up (n = 396)	8.7	10.2
MID mean estimate	9.6	11.1

TABLE IV. TRACK scores (physicians' control rating) of less than 80 used to screen patients with uncontrolled asthma or respiratory symptoms

TRACK score	Physicians' control table rating			
	Baseline		Follow-up	
	OR*	95% CI	OR*	95% CI
75 points	1.35	1.33-1.37	1.45	1.43-1.47
70 points	1.82	1.80-1.84	2.10	2.08-2.12
65 points	2.45	2.41-2.49	3.05	3.03-3.07
60 points	3.30	3.26-3.34	4.42	4.40-4.44
55 points	4.46	4.43-4.49	6.41	6.39-6.43
50 points	6.01	5.97-6.05	9.29	9.27-9.31

OR, Odds ratio.

*ORs for each TRACK score are based on a comparison with a TRACK score of 80 and calculated based on the logistic regression coefficients.

The present study is the first to define the MID for a psychometric instrument exclusively for use in children younger than 5 years with recurrent respiratory symptoms consistent with asthma. Previously, an MID has been determined for 2 psychometric instruments that assess asthma control in adults: the Asthma Control Questionnaire²⁰ and the Asthma Control Test.²¹ The MID for the Asthma Control Questionnaire was established by using anchor-based analyses in individual patients studied over time.²² Similar to the present study, the MID for the Asthma Control Test was established by using anchor- and distribution-based analyses to assess meaningful differences in individual patients over time.²¹

The strengths of the present study include the large cohort for analysis (approximately 400 caregivers), the high level of retention during longitudinal follow-up (93%), and the generalizability of the results to similar populations of patients younger than 5 years who are treated by pediatricians.

A possible limitation of the TRACK MID analysis is that it focused on the change in clinical status of individual patients over only 1 time interval of 4 to 6 weeks, and TRACK items 4 and 5 include a longer time frame. This approximately 1-month period of follow-up might not have been of sufficient duration to determine greater changes in asthma control, particularly related to risk. Therefore anchor-based longitudinal comparisons included only those patients whose physicians reported that the child used oral corticosteroids 0 to 1 times in the past year, which was approximately 70% of our population. This methodology enabled us to examine the subset of the population for whom changes in risk would be measurable. Nonetheless, exacerbations in young children are often virus or allergen associated and occur with yearly or seasonal peaks. Therefore, a longer follow-up period might be needed to determine changes in risk, such as exacerbations requiring oral corticosteroids. As such, the MID

established in the present study primarily reflects changes when monitoring impairment. Further studies are recommended to evaluate the MID of TRACK over a longer period of time and to establish an MID for risk. Future studies should focus on children treated by generalists (family practitioners) and asthma specialists and on cohorts with more severe phenotypes and ethnic, educational, and sex diversity to increase the generalizability of the present findings, which were obtained from children during routine visits to a pediatrician.

In conclusion, TRACK is a validated, easy-to-use tool to detect changes over time in respiratory control status in an individual child younger than 5 years with symptoms consistent with asthma. A TRACK score change of 10 or more points represents a clinically meaningful change in respiratory or asthma control and should alert health care providers to re-evaluate the patient's asthma treatment plan in children younger than 5 years with symptoms consistent with asthma.

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Clinical implications: Our study results extend the utility of TRACK by determining the MID needed to suggest a clinically meaningful change over time in respiratory or asthma control status for children aged less than 5 years with symptoms consistent with asthma.

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