

Abbreviations used

ADYC: Asthma Flare-up Diary for Young Children
MD: Mean difference
SABA: Short-acting β_2 -agonists
URTI: Upper respiratory tract infection

asthma exacerbation. Therefore a validated measure is needed to assess the severity of asthma exacerbations in preschool-aged children.

With a rigorous methodology, the objectives of this study were (1) to develop a parent-completed functional status instrument to ascertain the severity of an acute asthma exacerbation in children aged 1 to 6 years and (2) to ascertain its psychometric properties in the context of a therapeutic randomized controlled trial.

METHODS

In accordance with Kirshner and Guyatt's approach,¹⁹ the questionnaire development involved 5 sequential tasks: (1) item generation, (2) item reduction, (3) item presentation and scaling, (4) pretesting for clarity, and (5) independent validation of psychometric properties. The institutional review board of the Montreal Children's Hospital (Montreal, Quebec, Canada) approved all phases of the study. Informed consent was obtained from parents or guardians of preschoolers. French and English versions of these instruments were simultaneously developed by using the back-translation technique²⁰ and underwent simultaneous and independent evaluations across each of the development phases.

The development phases are described in detail in the [Methods](#) section in this article's Online Repository at www.jacionline.org. Briefly, item generation involved a literature review to generate items to use as probes in an open-ended questionnaire, which was administered to caregivers of preschool-aged children recruited in the emergency department and short-stay hospitalization unit during an exacerbation. In the item-reduction phase an 84-item questionnaire was administered to a second group of caregivers, who were asked to endorse and rate the perceived importance of each item. Items were then eliminated based on the relevance, the product of endorsement and importance, the correlation coefficients, and principal component analysis. Item presentation and scaling involved grouping the 17 remaining items and formulating them into a statement of frequency or intensity coupled with a scaled response option from 1 (not at all) to 7 (all the time/extremely) with a "cannot answer" option. In pretesting for clarity, cognitive interviews with a third group of caregivers elicited feedback and verified understanding of each question and response option; the final 17-item instrument, called the Asthma Flare-up Diary for Young Children (ADYC), surpassed the requirement for 80% or greater clarity. Available in French and English, it has a sixth-grade reading level (Flesch-Kincaid), with each of the 17 items scored from 1 to 7 and a maximum average daily score of 7 (see [Figs E1 and E2](#) in this article's Online Repository at www.jacionline.org).

Pretesting for psychometric properties

The psychometric properties of the ADYC were pretested in preschoolers enrolled in a multicenter randomized trial of pre-emptive high-dose fluticasone versus placebo initiated at the onset of an upper respiratory tract infection (URTI); as described previously, the intervention reduced by half the number of exacerbations requiring rescue oral corticosteroids (odds ratio, 0.49; 95% CI, 0.3-0.83).⁴ Briefly, 129 participants aged 1 to 6 years with virus-induced asthma who recently required systemic corticosteroids were enrolled in the trial. From the first day of a URTI (ie, symptoms of runny or congested nose, sore throat, earache, and/or fever), parents were asked to initiate use of the study drug and complete the ADYC diary daily in the evening until 2 days without any asthma symptoms (ie, cough, whistling,

or difficulty breathing). On the same page as the ADYC, parents documented their global assessment of the change in their child's status over the past 24 hours, the number of inhalations of rescue SABAs, and administration of rescue oral corticosteroids, if any. At randomization, the research personnel explained how, when, and how long to fill out the ADYC and asked parents to contact them at the first URTI to review the instructions for completion. If asthma symptoms developed, parents were instructed to start salbutamol at a dose of 2 to 4 puffs every 4 hours as needed and explained when to present to the emergency department in the case of a poor response. If asthma symptoms persisted for 10 days or more, parents were to contact the research nurse, who then reviewed the progress and could request a physician's office visit, if needed; such unscheduled medical assessments were not used in the validation process, although any referral to the emergency department, prescription of oral corticosteroids, or hospital admission were considered in the validation. During monthly telephone calls, the research nurse enquired about URTIs and health care resource use and reviewed the instructions for completion of the ADYC.

A priori diary definitions

A complete set of diaries for an episode was defined as 2 or more consecutive days, with no more than 1 missing or "cannot answer" item per day. A symptomatic day required at least 2 of 3 symptoms (cough, difficulty breathing, or wheezing). An asthma exacerbation was defined as 2 or more symptomatic days. The cumulative ADYC score was the sum of the total daily score from the first to last day during an episode.

Statistical methods

The applicability of the ADYC was explored based on the proportion of caregivers who answered each of the 17 items per day and per episode. With an average of 8 (range, 1022) URTI episodes per child,⁴ we randomly selected 1 complete set of diaries (with no missing items) per patient for inclusion in a factor analysis. Using the target matrix for Procrustean transformation, the factor analysis served to validate domains of the ADYC. Final items were selected based on the combination of an eigenvalue of greater than 1 for each factor, a relevance score of greater than or equal to 0.4 for each item, and clinical relevance.²¹ Allowing for no more than 1 missing or "cannot answer" item, the following analyses were conducted. Internal consistency was examined by using the Cronbach α value in 1 randomly selected symptomatic day per subject; missing items were imputed by their means. Randomly selecting 2 consecutive symptomatic days per patient in whom the parents' global assessment of change on the second day was deemed "unchanged" from the previous 24 hours (ie, rated -1, 0, or 1), we examined test-retest reliability using intraclass correlation. Conversely, randomly selecting 2 consecutive symptomatic days per patient in whom the parental global assessment of change on the second day indicated notable deterioration (-2 to -7) or improvement (+2 to +7) in the past 24 hours, we reported the within-subject change in daily score with 95% CIs and documented the responsiveness to change by using the Guyatt responsiveness statistic; that is, the mean change in those who changed divided by the SD of those who did not change.²² The difference (95% CI) in cumulative ADYC scores during episodes was compared between the pre-emptive high-dose fluticasone and placebo groups, adjusting for individual clustering of episodes and sites and using random effects. Discriminative validity was examined by comparing the mean difference (MD; and 95% CI) in the cumulative score for dichotomous episodes that did or did not result in an (1) exacerbation, (2) emergency department visit, (3) rescue systemic corticosteroid use, and (4) hospitalization adjusted for individual clustering of episodes and sites and using random effects. Mean ADYC scores with SDs were also reported. The minimally important change in the daily ADYC score between 2 consecutive days was calculated on all pairs of consecutive days during which a parent's global assessment of change in his or her child's asthma status between the 2 days was rated -2, -3, +2, or +3; this analysis was adjusted for within-subject clustering of episodes. For all above analyses, language was offered as a candidate variable. The analyses were conducted with SAS 9.3 software (SAS Institute, Cary, NC).

TABLE I. Characteristics of participants by language version completed of the ADYC

Variable	French version (n = 69)	English version (n = 52)	P value
Demographic characteristics			
Age (y), mean $\pm$ SD	2.9 $\pm$ 1.2	2.4 $\pm$ 1.0	.02
Male sex, no. (%)	43 (62.3)	29 (55.8)	.47
Ethnicity, no. (%)			<.001
White	64 (92.8)	31 (59.6)	
Black	—	6 (11.5)	
Other	5 (7.2)	15 (28.8)	
Risk factors			
Eczema, no. (%)	28 (40.6)	24 (46.2)	.58
Family history of asthma, no. (%)	32 (46.4)	34 (65.4)	.81
Day care attendance, no. (%)	55 (79.7)	25 (48.1)	<.001
Morbidity in preceding 12 mo			
Episodic virus-induced asthma, no. (%)	69 (100)	52 (100)	.12
Short courses of oral cortico- steroids, mean $\pm$ SD	1.8 $\pm$ 0.5	1.8 $\pm$ 0.4	.11
One or more hospital admis- sions, no. (%)	32 (46.4)	27 (51.9)	.53
Allocated intervention in a randomized trial			
High-dose pre-emptive fluticasone, no. (%)	35 (50.7)	22 (42.3)	.46
Placebo, no. (%)	34 (49.3)	30 (57.7)	

RESULTS

Pretesting for psychometric properties

Of the 129 children with virus-induced asthma enrolled in the trial testing high-dose fluticasone at the beginning of a URTI,⁴ 8 subjects were excluded from the current analysis because the ADYC was either not returned (n = 6) or returned without a minimum of 2 consecutive days recorded per episode (n = 2). Fifty-nine percent of diaries were completed in French, and the remainder were completed in English. The characteristics of the 121 included children randomized to high-dose fluticasone (n = 57) or placebo (n = 64) are presented by language of ADYC completion in Table I. Language groups were similar, with the exception of a higher number of white subjects and day care attendance in the French group. Enrolled children had high prior morbidity, with about 50% having been hospitalized and mean use of almost 2 short courses of oral corticosteroids in the past 12 months. The ADYC was completed primarily by mothers (90.4%), followed by fathers (7.7%) and then other caregivers (1.9%).

Feasibility

Of 963 episodes recorded by verbal report, 895 (93%) sets of diaries were returned, totaling 7239 days. The completion rate of each of the 17 items was high, exceeding 90% per day and 80% per episode of the 895 episodes; the lowest filled items (76% to 81%) pertained to the response to SABAs (Table II). Of the 895 diary sets, 670 (75%) have no missing items on any days, 201 (22.5%) episodes had 1 or more days with 1 missing item, and 64 episodes had 1 or more days with 2 or more missing items. Because there was no meaningful difference in the ADYC average daily score (1.9 $\pm$ 0.8 vs 1.9 $\pm$ 0.8) or the cumulative ADYC score during episodes (11.9 $\pm$ 9.5 vs 12.6 $\pm$ 9.7) between

TABLE II. Completion rate of each of the 17 items of the ADYC per day and per episode*

Questionnaire item	Completion rate per day (n = 7239 d), no. (%)	Completion rate per episode (n = 895 episodes),* no. (%)
Frequency		
Coughing	7104 (98.1)	825 (92.2)
Wheezing	7040 (97.3)	801 (89.5)
Loud breathing	7048 (97.4)	807 (90.2)
Fast breathing	7046 (97.3)	803 (89.8)
Gasping for air	7037 (97.2)	796 (88.9)
Stomach pushing out	6988 (96.5)	790 (88.3)
Skin pulling	6924 (95.7)	754 (84.3)
Intensity		
Coughing	7099 (98.1)	819 (91.5)
Sleep disturbed	7063 (97.6)	795 (88.8)
Decrease energy	7072 (97.7)	811 (90.6)
Unwilling to move	7065 (97.6)	809 (90.4)
Loss of appetite	7069 (97.7)	811 (90.6)
Requesting more attention	7073 (97.7)	811 (90.6)
Irritable/cranky	7054 (97.4)	798 (89.2)
Response to SABAs†		
Does not respond as well as usual	6790 (93.8)	726 (81.1)
Does not respond as rapidly as usual	6776 (93.6)	726 (81.1)
Effect does not last as long as usual	6687 (92.4)	682 (76.2)
Total diary		
No missing items	6335 (87.5)	670 (76.4)
No more than 1 missing item per day	6640 (91.7)	871 (97.3)

*Parents reported asthma flare-ups or suspected URTIs based on symptoms of runny or congested nose, sore throat, earache, and/or fever.

†Items were recoded as “1” (not a problem at all) for days during which no dose of SABA was administered, and the items were coded “cannot answer” by the caregiver.

diaries with no compared with those with up to 1 missing item per day, we accepted diaries with no more than 1 missing or “cannot answer” item per day; thus 871 (97.3%) were deemed valid diary sets for subsequent analyses (Fig 1). Of note, the overwhelming majority (92.9% [n = 809]) of included diary sets had no more than 1 missing item throughout the whole episode.

Internal validity and reliability

Based on statistical and clinical relevance,²¹ all 17 initial items were retained and grouped into one of 4 factors (see Table E1 in this article's Online Repository at www.jacionline.org): general functional status (questions 9-14), breathing difficulties (questions 2-7), response to SABAs (questions 15-17), and coughing (questions 1 and 8). The overall standardized Cronbach α value of the ADYC was 0.97 (range, 0.96-0.97 for each item; see Table E2 in this article's Online Repository at www.jacionline.org). The intraclass correlation between 2 consecutive days with no clinically important change in status was 0.71 (95% CI, 0.59-0.80; n = 93 pairs); the change in ADYC score between these 2 days was statistically significant (-0.19 ; 95% CI, -0.34 to -0.04) yet modest.

Responsiveness

For patients in whom parents perceived a significant improvement (+2 to +7, n = 92) or deterioration (-2 to -7 , n = 88)

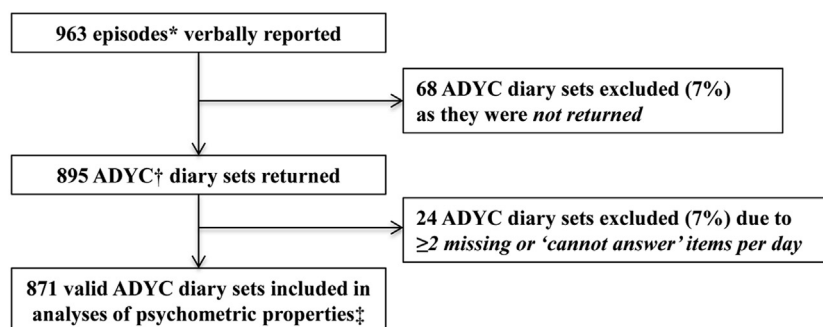


FIG 1. Selection of ADYC diaries for analyses of psychometric properties. Selection of ADYC diary sets, as per our *a priori* definitions, is presented in the graph. *Parents reported asthma flare-ups or suspected URTIs based on symptoms of runny or congested nose, sore throat, earache, and/or fever. †ADYC, Asthma Flare-up Diary for Young Children. ‡A valid ADYC diary set is defined as containing at least 2 consecutive days and no more than 1 missing or “cannot answer” item per day per episode.

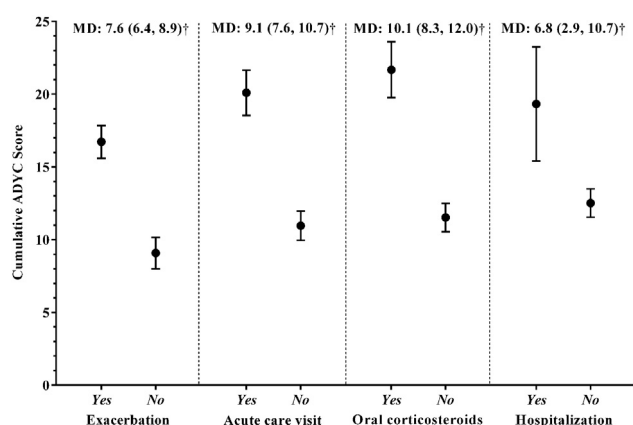


FIG 2. Discriminant validity of the ADYC. The mean cumulative scores on the 17-item ADYC (ie, the sum of each daily score [each item on a scale of 1-7]) throughout the duration of the episode are displayed with 95% CIs (error bars) for those that did or did not result in (1) an exacerbation, which was defined as 2 or more days with a minimum of 2 of 3 symptoms (cough, wheeze, and dyspnea) with a score of 2 or more on the 7-point scale, as recorded on the ADYC; (2) an acute care visit; (3) use of rescue oral corticosteroids; or (4) a hospital admission. Error bars represent 95% CIs around mean cumulative scores. †The group MD and 95% CI are reported at the top of each graph.

between 2 consecutive symptomatic days, the average daily score changed by 0.55 (95% CI, 0.41-0.70). The Guyatt responsiveness index was 0.79. Patients treated with high-dose fluticasone experienced exacerbations with a statistically significantly lower cumulative ADYC score versus placebo (mean $\pm$ SD, 14.8 ± 9.4 vs 19.7 ± 14.7 ; MD, 5.1; 95% CI, 1.8-8.3) per episode, a finding similar to that previously reported by using different metrics.⁴

Discriminative abilities

Of the 871 episodes with valid ADYC sets, 389 (44.7%) met our definition of an exacerbation, 18.0% resulted in an emergency department visit, 11.0% resulted in rescue systemic corticosteroid use, and 2.5% resulted in a hospital admission. The cumulative ADYC score was significantly higher during an exacerbation compared with scores in those with no exacerbation (16.8 ± 10.9 vs 9.2 ± 6.9 ; MD, 7.6; 95% CI, 6.4-8.9) and was higher in those requiring an acute-care visit versus no visit (20.0 ± 14.4 vs 11.0 ± 7.3 ; MD, 9.1; 95% CI, 7.6-10.7), rescue oral corticosteroids versus none (21.9 ± 15.2 vs 11.4 ± 8.0 ; MD, 10.1; 95% CI,

8.3-12.0), or a hospitalization versus no hospitalization (20.1 ± 10.8 vs 12.4 ± 9.6 ; MD, 6.8; 95% CI, 2.9-10.7; Fig 2). We conducted the analyses with diaries with no missing items and repeated them in diaries with no more than 1 missing value per day; no meaningful difference was observed in the discriminative performance of the ADYC, although some differences in magnitude were noted (see Table E3 in this article's Online Repository at www.jacionline.org). The minimally important change in the daily score was 0.22 (95% CI, 0.27-0.18) based on 850 diary pairs in which the global assessment of change was ± 2 or 3 on the second day.

DISCUSSION

The caregiver-completed 17-item ADYC, which was developed by using a rigorous 5-step process, demonstrates the desired psychometric properties to capture the functional status of preschool-aged children during an asthma exacerbation. Tested in the context of a therapeutic clinical trial, the ADYC proved applicable, as evidenced by the high completion rate of each item; showed solid test-retest reproducibility; was discriminative across various exacerbation severities; and was responsive to day-to-day change in status. Importantly, the cumulative ADYC score during an episode was highly responsive to identifying an overall reduction in the severity of episodes between an active intervention (high-dose fluticasone) and placebo in the context of the randomized clinical trial.

The ADYC was specifically developed to be a functional status instrument by incorporating not only symptom assessment (importance and frequency) and the quality of the response to SABAs, when used, but also general status (eg, child wanting to be carried and requesting more attention). The factor analysis and high internal reliability of the ADYC²³ both supported the inclusion of all 17 items in this construct. Breathing difficulty, cough, the quality of the response to rescue SABAs, and functional limitations are important indicators of asthma control, particularly in young children who cannot perform lung function testing. Contrary to instruments in school-aged children,^{24,25} parents did not volunteer any specific age-related activities and tasks to be included in the functional status instrument, perhaps because of their low relevance in the preschool age group and/or during an exacerbation, and thus none were included in the ADYC. The ADYC does not include rescue oral corticosteroid and health care use, as seen in other instruments.^{10,14,17,18} Instead, concomitant documentation of these

outcomes has provided solid construct validation of the ADYC, which is offered as a complementary outcome.

A high completion rate is an important characteristic of any evaluative instrument to ensure the target outcome is measured in the majority of participants; such acceptance hinges on relevance, format, and language. Based on strong parental input throughout the multiple development phases, the final questions and response options for the ADYC were selected for their relevance to and endorsement by parents of preschoolers with asthma. With a sixth-grade reading level and fill-in-the-circle answers, the ADYC was presented in a 1 page per day format to be completed only during URTIs, asthma flare-ups, or both. More than 80% of caregivers identified the 17-item ADYC as clear and relevant, and they adequately completed the ADYC, with no more than 1 missing or “cannot answer” item per day throughout the episode in 97% of returned diaries. Parents received monthly telephone calls to remind them in part to complete the ADYC when indicated, which might have improved completion rates. Relevance, readability, easy-to-use format, completion of the ADYC only during episodes, and monthly reminders probably explain the high completion rate in the context of our clinical trial.

Because children's symptoms deteriorate and improve rapidly during an exacerbation,^{11,26} a functional status measure that can detect rapid changes in impairment occurring day to day or over the short duration of an exacerbation is desirable. Although statistically significant, the change in ADYC score, a fifth of a point, appeared clinically trivial during consecutive days in which parents identified no clinically important change compared with the almost 3-fold higher value observed when a clinically important change was noted by parents. Between-days reliability was also demonstrated for the Childhood Asthma Control Test²⁷ and a subscale of the Pediatric Asthma Caregiver Diary.¹¹ The ADYC score was responsive to day-to-day change in the child's status, with a mean change of 0.55 on a scale of 1 to 7 as indicative of a clinically important improvement or deterioration within 2 consecutive days. Importantly, the cumulative ADYC score during episodes was significantly lower in the intervention group compared with the placebo group, which is indicative of a lower severity of exacerbations; this finding is in line with the primary outcome of our placebo-controlled trial reporting significantly lower odds of rescue oral corticosteroids in the intervention group.⁴ Only 2 other pediatric instruments that included preschoolers have demonstrated responsiveness in randomized controlled trials^{16,28}; in most instruments changes in clinical status were explored in the context of observational studies.^{11,12,17,29} The Pediatric Asthma Caregiver Diary is the only other parent-reported questionnaire developed as a daily diary for use in preschoolers; with a recall period of 12 hours, it contains 10 items, including 3 questions specific to nighttime symptoms, is available in English only, and is intended for overall asthma monitoring, as opposed to uniquely targeting an acute deterioration. To our knowledge, the ADYC appears as the first validated functional status instrument specifically designed to evaluate the severity of exacerbations in preschoolers: tested in a therapeutic clinical trial, it has the desired psychometric properties to be used as a responsive outcome variable.

The ADYC was highly discriminative, distinguishing between exacerbations and URTIs and between exacerbations requiring health care resource use and those that did not. Of note, the mean cumulative ADYC score for exacerbations requiring health care use was consistently around 20, irrespective of whether the patient required an acute care visit, rescue oral corticosteroids, or a

hospital admission, whereas it was less than 10 in those with only URTIs. Furthermore, a similar discriminative performance of the ADYC was observed for distinguishing between exacerbations of different severities and, in response to an effective therapy, when restricting the analyses to questionnaires with no missing items, confirming our proposed approach to accept up to 1 missing item per day. The ADYC compares favorably with other asthma-specific instruments^{12,30} in its ability to discriminate across URTIs, exacerbations managed exclusively at home, and exacerbations requiring health care resource use in preschool-aged children with asthma.

The ADYC was specifically developed as an evaluative tool to assess the functional status of the preschool-aged child exclusively managed at home or not during an asthma exacerbation. A strength of the ADYC is the development and validation rigor, including independent validation of the instrument in a different sample than those in which it was developed and in the context of a therapeutic randomized controlled trial. Potential overrepresentation of children with repeated episodes was addressed by either randomly selecting 1 episode per child or by adjusting for individual clustering of episodes. Of importance, the psychometric properties of the ADYC were documented in a randomized controlled trial (ie, the expected context of its projected application).

However, we recognize the following limitations. Although functional status is best provided directly by the subjects themselves,³¹ in the case of preschoolers, we sought proxy report by the caregiver, as authors of previous instruments have done.³² We acknowledge that the scores can be affected by the caregiver (ie, mother, father, and other) completing the questionnaire because of their perception of the frequency and severity of the symptoms experienced by the child, as well as the amount of time spent with the child, the latter possibly being further reduced as the child recovers and returns to day care. Similar to other instruments targeted at preschoolers,¹⁰ 90% of the diaries were completed by mothers. Because of the large imbalance between the proportion of diaries filled out by the mother, father, or other caregivers, we were not able to explore a potential difference in response nor was the study designed to assess differences in caregiver perception. Seven (5%) parents did not return valid diaries, either because of the absence of episodes or poor adherence. Our already high adherence could potentially be further improved by using different methods, such as offering an online version and electronic reminders instead of or in addition to monthly telephone contacts. Because we did not compare the ADYC with other preschool-specific instruments, selection must be based on the users' preference, objectives, and published psychometric properties rather than on head-to-head comparisons. We would now encourage comparisons of the ADYC with other instruments to assess their relative strengths and weaknesses.

With regard to generalizability, the ADYC was tested in a largely white population of children with virus-induced exacerbations, which might limit its applicability to other ethnic groups or preschoolers with different asthma triggers. However, language was not an important covariate in analysis of psychometric properties, suggesting some robustness to cultural differences. The large number of episodes of varying severity, ranging from simple URTIs to exacerbations requiring hospital admission, suggests that the ADYC performs well across the whole severity spectrum of episodes expected in preschoolers. We used the Global Initiative for Asthma definition of asthma³³ based on repeated episodes of wheezing or clear response to asthma therapy, recognizing that many authors would have labeled these

children “preschool wheezers.” Finally, because the ADYC has not been tested in children 7 years of age or older or in children with bronchiolitis or other “wheezing” illnesses, we advise caution regarding its use in these groups.

The rigorously designed ADYC is a simple 17-item questionnaire easily completed by parents of preschool-aged children with asthma during exacerbations. Available in French and English, the ADYC has demonstrated feasibility, reliability, discrimination, and responsiveness in the context of a clinical trial. The ADYC is offered as an asthma-specific research instrument to monitor change in functional status occurring day to day or over the short duration of an exacerbation in preschool-aged asthmatic children.

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Clinical implications: The ADYC can be used to ascertain the burden of disease in trials testing an intervention to prevent or treat asthma exacerbations in preschoolers.

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METHODS

Item generation

We conducted a literature review of generic and disease-specific instruments using the following key words: “asthma” AND “school-aged children” or “preschool-aged” or “infants” or “adolescents” or “adults” or “caregivers” AND “quality of life” or “functional status” or “symptoms” or “health outcomes.” Identified items of interest were used as probes in the item-generation questionnaire. The open-ended questionnaire consisted of probes to encourage respondents to focus specifically on symptoms and function and a section in which caregivers volunteered specific areas of difficulty. A research assistant trained by a psychologist specialized in child-caregiver interactions (M.J.M.) administered this questionnaire in a face-to-face interview in 25 caregivers. Recruitment of caregivers took place in the emergency department and in the short-stay hospitalization unit until no new items had been generated over 10 consecutive interviews. All interviews were taped and transcribed to ensure accuracy of reporting and provide feedback to the interviewer.

Item reduction

The item-reduction questionnaire, containing 84 symptoms and behaviors elicited in the item-generation phase, was submitted to 104 caregivers (54 French and 50 English speakers) recruited in the emergency department or the short-stay unit during their child's acute asthma exacerbation. Caregivers indicated whether their preschool-aged child ever experienced these items (endorsement) and rated the perceived importance of each item to assess the severity of an asthma flare-up on a Likert scale of 1 to 5. The items were eliminated because of (1) low relevance, if not endorsed by more than 20% of respondents ($n = 15$ items); (2) low product of endorsement and importance value (<0.40) standardized on the number of participants endorsing a given

item ($n = 38$ items); (3) high correlation coefficient (≥ 0.8) across seemingly similar variables ($n = 0$ item); and (4) principle component analysis that identified signs and symptoms describing a similar phenomenon ($n = 14$ items eliminated).

Item presentation and scaling

The selected items were then grouped into those in which the frequency and those in which the intensity of symptoms was considered by parents as the most useful gauge of severity. Question and response options were formulated accordingly. Each item phrased as a statement of frequency or intensity was matched with a response option scaled from 1 (not at all) to 7 (all the time or extremely), with an option for “cannot answer.” The final questionnaire consisted of 17 items, each scored from 1 to 7, that were averaged for a daily score on a scale of 1 (best) to 7 (worst).

Pretesting for clarity

Feedback was obtained by means of cognitive interview, in which 24 caregivers of acutely ill children aged 1 to 6 years recruited in the emergency department were asked to read aloud the questionnaire and provided feedback on the clarity of instructions, questions, items, response options, scale, and layout. Caregivers completed the questionnaire, rating their child's status over the preceding 24 hours. Each chosen response was then challenged by the interviewer to verify understanding of the question and the response option. The instruments were revised in an iterative fashion until 80% or more clarity was reached for instructions, questions, items, and response options. The third and final version tested in 10 participants surpassed the requirement for 80% or more clarity, had a sixth-grade reading level (Flesch-Kincaid), and was called the ADYC.

Asthma flare-up diary for young children®

Date 	e.g. (10-OCT-1999)	For Office use Only ID	URTI #
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Instructions: Please use this diary to record any asthma symptoms your child has experienced during the past 24 hours. **Complete this diary EVERY EVENING from the FIRST SIGN OF A COLD, such as a runny nose, congested nose, sore throat, ear ache, and/or fever UNTIL 2 DAYS WITH NO COUGH, WHISTLING, OR DIFFICULTY BREATHING.** While symptoms may get better or worse rapidly, please answer EACH question by DARKENING only the circle that you feel BEST DESCRIBES what you have OBSERVED in your child over the past 24 hours.

Please state HOW OFTEN your child has experienced each of the following symptoms in the last 24 hours:

	Not at all			Half of the time				All of the time	
	1	2	3	4	5	6	7	8	Cannot Answer
Coughing_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Wheezing/whistling in the chest_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Loud breathing_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Fast breathing_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Gasping for air_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Stomach pushing out with each breath_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Skin pulling in the neck/throat_____	☐	☐	☐	☐	☐	☐	☐	☐	☐

Please state the DEGREE to which each symptom has been a PROBLEM observed in your child in the last 24 hours

	Not at all			Moderately				Extremely	
	1	2	3	4	5	6	7	8	Cannot Answer
Coughing_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Sleep disturbed by cough, wheeze or difficulty breathing_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Decrease in energy level_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Unwilling to move around (e.g. wants to be carried)_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Loss of appetite_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Requesting more attention and/or extra care_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Irritable/ cranky/ fussy _____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Does not respond as well to Ventolin as usual_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
Does not respond as rapidly to Ventolin as usual_____	☐	☐	☐	☐	☐	☐	☐	☐	☐
The effect of Ventolin does not last as long as usual_____	☐	☐	☐	☐	☐	☐	☐	☐	☐

FIG E1. The ADYC. The English version of the 17-item caregiver-completed ADYC questionnaire for children 1 to 6 years of age during an asthma exacerbation.

Journal d'une crise d'asthme chez le jeune enfant[®]

DATE	exemple 10-OCT-1999	Pour l'usage du bureau seulement						
- -	ID	Rhume #						
Instructions : S.V.P. Utilisez ce journal afin d'inscrire les symptômes d'asthme observés chez votre enfant au cours des dernières 24 heures. Remplir le journal CHAQUE SOIR dès le PREMIER SYMPTÔME D'UN RHUME c.-à-d. nez qui coule ou congestionné, mal de gorge ou d'oreille ou fièvre et ce, JUSQU'À CE QUE VOTRE ENFANT AIT EU DEUX JOURS SANS TOUX, SIFFLEMENT OU DIFFICULTÉ À RESPIRER. Bien que les symptômes peuvent varier au cours de la journée, S.V.P. répondre à CHAQUE question en NOIRCISSANT uniquement le cercle CORRESPONDANT LE MIEUX à ce que vous avez OBSERVÉ CHEZ votre enfant au cours des dernières 24 heures.								
Veuillez indiquer À QUELLE FRÉQUENCE votre enfant a expérimenté chacun des symptômes suivants au cours des dernières 24 heures:								
	Jamais	La moitié du temps					Tout le Temps	<i>Ne peut Répondre</i>
	1	2	3	4	5	6	7	
Toux _____	☐	☐	☐	☐	☐	☐	☐	☐
Sifflement/Respiration sifflante _____	☐	☐	☐	☐	☐	☐	☐	☐
Respiration bruyante _____	☐	☐	☐	☐	☐	☐	☐	☐
Respiration rapide _____	☐	☐	☐	☐	☐	☐	☐	☐
Cherche son souffle _____	☐	☐	☐	☐	☐	☐	☐	☐
Ventre qui ressort à chaque respiration _____	☐	☐	☐	☐	☐	☐	☐	☐
Peau qui tire dans le cou/la gorge _____	☐	☐	☐	☐	☐	☐	☐	☐
Veuillez indiquer À QUEL POINT chacun des symptômes suivants ont été un PROBLÈME que vous avez observé chez votre enfant au cours des dernières 24 heures?								
	Pas du tout	Moyennement				Énormément	<i>Ne Peut répondre</i>	
	1	2	3	4	5	6	7	
Toux _____	☐	☐	☐	☐	☐	☐	☐	
Sommeil perturbé par la toux, le sifflement, ou la difficulté à respirer _____	☐	☐	☐	☐	☐	☐	☐	
Diminution de son niveau d'énergie _____	☐	☐	☐	☐	☐	☐	☐	
Refuse de se déplacer (c.-à-d. veut se faire prendre) _____	☐	☐	☐	☐	☐	☐	☐	
Perte d'appétit _____	☐	☐	☐	☐	☐	☐	☐	
Demande plus d'attention et/ou de soins _____	☐	☐	☐	☐	☐	☐	☐	
Est irritable/de mauvaise humeur/difficile _____	☐	☐	☐	☐	☐	☐	☐	
Répond moins bien que d'habitude au Ventolin _____	☐	☐	☐	☐	☐	☐	☐	
Répond moins vite que d'habitude au Ventolin _____	☐	☐	☐	☐	☐	☐	☐	
Le Ventolin agit moins longtemps que d'habitude _____	☐	☐	☐	☐	☐	☐	☐	

FIG E2. Le Journal d'une crise d'asthme chez l'enfant. The French version of the 17-item caregiver-completed ADYC questionnaire for children 1 to 6 years of age during an asthma exacerbation.

TABLE E1. Factor analysis of the 17-item ADYC

Questionnaire item	Factor 1	Factor 2	Factor 3	Factor 4
Frequency				
1. Coughing	4	2	1	100*
2. Wheezing	6	59*	0	12
3. Loud breathing	8	56*	1	9
4. Fast breathing	9	67*	1	4
5. Gasping for air	2	92*	3	1
6. Stomach pushing out	1	84*	2	0
7. Skin pulling	2	100*	1	0
Intensity				
8. Coughing	7	1	2	88*
9. Sleep disturbed	37†	6	1	32
10. Decreased energy	100*	3	0	1
11. Unwilling to move	84*	4	3	1
12. Loss of appetite	85*	2	2	4
13. Requesting more attention	92*	1	0	4
14. Irritable/cranky	100*	2	0	1
Response to SABAs				
15. Does not respond as well as usual	1	2	97*	1
16. Does not respond as rapidly as usual	1	2	97*	1
17. Effect does not last as long as usual	2	1	100*	0
Factor eigenvalue‡	248.0	40.6	15.9	7.2

Values are multiplied by 100 and rounded to the nearest integer.

*Values with a relevance score greater than or equal to 0.4.

†Item deemed clinically relevant and thus included.

‡Domains validated if factor has eigenvalue greater than 1.

TABLE E2. Standardized Cronbach α values for individual items and total daily scores on the ADYC

Questionnaire item	Standardized Cronbach α (n = 121)
Frequency	
Coughing	0.966
Wheezing	0.964
Loud breathing	0.964
Fast breathing	0.964
Gasping for air	0.965
Stomach pushing out	0.964
Skin pulling	0.964
Intensity	
Coughing	0.966
Sleep disturbed	0.965
Decrease energy	0.965
Unwilling to move	0.965
Loss of appetite	0.966
Requesting more attention	0.965
Irritable/ cranky	0.966
Response to SABAs	
Does not respond as well as usual	0.965
Does not respond as rapidly as usual	0.967
Effect does not last as long as usual	0.966
Overall questionnaire	0.967

TABLE E3. ADYC cumulative scores and mean group difference (95% CI)

Event	No missing items per questionnaire			Up to 1 missing item per day per questionnaire		
	Yes (mean $\pm$ SD)	No (mean $\pm$ SD)	Mean group difference (95% CI)	Yes (mean $\pm$ SD)	No (mean $\pm$ SD)	Mean group difference (95% CI)
Exacerbation	16.5 $\pm$ 10.9	8.5 $\pm$ 6.4	8.0 (6.6-9.4)	16.8 $\pm$ 10.9	9.2 $\pm$ 6.9	7.6 (6.4-8.9)
Acute care visit	19.6 $\pm$ 14.8	10.3 $\pm$ 7.1	8.8 (7.1-10.5)	20.0 $\pm$ 14.4	11.0 $\pm$ 7.3	9.1 (7.6-10.7)
Systemic steroids	22.4 $\pm$ 16.1	10.7 $\pm$ 7.6	11.3 (9.1-13.5)	21.9 $\pm$ 15.2	11.4 $\pm$ 8.0	10.1 (8.3-12.0)
Hospitalization	22.1 $\pm$ 11.6	11.7 $\pm$ 9.3	9.1 (4.2-14.0)	20.1 $\pm$ 10.8	12.4 $\pm$ 9.6	6.8 (2.9-10.7)
Fluticasone vs placebo	10.2 $\pm$ 7.2	13.5 $\pm$ 11.0	2.7 (0.6-4.9)	14.8 $\pm$ 9.4	19.7 $\pm$ 14.7	5.1 (1.8-8.3)