

Caregiver's functional status during a young child's asthma exacerbation: A validated instrument

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Background: Few instruments exist to measure caregivers' functional status during a young child's asthma exacerbation. **Objective:** We sought to develop and validate a measure of caregivers' functional status during a preschooler's asthma exacerbation.

Methods: The psychometric properties of the 21-item questionnaire Effects of a Young Child's Asthma Flare-up on the Parents (ECAP) were tested in a randomized placebo-controlled trial of pre-emptive high-dose fluticasone in preschoolers with virus-induced asthma. Caregivers completed the ECAP questionnaire on the last day their child exhibited symptoms of an upper respiratory tract infection or asthma exacerbation (episode). The mean of each item, scored on a scale of 1 (best) to 7 (worst), provided the ECAP score.

Results: Ninety-three preschoolers (2.5 ± 1.0 years old; 62.4% male) experienced 878 episodes. Feasibility (80% questionnaire return rate; 90% completion) and internal consistency (Cronbach $\alpha = 0.97$) were high. Of 628 episodes with a completed ECAP questionnaire, 621 (98.9%) had data on exacerbations, and 609 (97.0%) had data on health care use. The ECAP score was significantly higher for children experiencing an asthma exacerbation versus those who were not (mean difference, 0.8; 95% CI, 0.6-1.0) and for episodes resulting versus not resulting in an emergency visit (mean

difference, 1.2; 95% CI, 1.0-1.4), systemic corticosteroid use (mean difference, 1.4; 95% CI, 1.1-1.7), or hospitalization (mean difference, 1.9; 95% CI, 1.4-2.5). The ECAP score was significantly lower in children treated with fluticasone versus those treated with placebo (mean difference, -0.7; 95% CI, -1.1 to -0.3).

Conclusions: The 21-item ECAP questionnaire, showing high feasibility, internal consistency, discriminative validity, and responsiveness, has the psychometric properties to serve as a validated outcome to measure the burden of preschoolers' asthma exacerbations on their caregivers' functional status. (*J Allergy Clin Immunol* 2015;■■■■:■■■-■■■.)

Key words: Asthma, caregivers, discrimination, preschool child, quality of life, questionnaire design, randomized controlled trial, reliability, validity

The preschool age group accounts for half of all pediatric emergency department presentations attributable to asthma.^{1,2} Although approximately 1 in 4 exacerbations result in an emergency visit,³ the majority of exacerbations in this age group are managed in the home setting.³ Thus in preschoolers the burden of care rests with their parents because asthma symptoms can continue for a number of days or weeks before^{4,5} and even after⁶ seeking medical attention, which can cause considerable disturbance to the caregivers' normal responsibilities and quality of life. Clinical trials that do not measure the burden of home management of an acute exacerbation on caregivers can lead to erroneous conclusions or at least omit an important dimension when exploring the effectiveness of an intervention to reduce the severity of asthma exacerbations.

Several generic questionnaires are available to assess the effect of chronic conditions on the caregiver, family, or both.⁷⁻⁹ However, generic quality-of-life measures might not capture aspects that are unique to a particular condition, such as asthma, and specific to an acute deterioration of the child's condition. A review of 43 randomized controlled trials reporting head-to-head comparisons of generic ($n = 31$) and specific ($n = 84$) health-related quality-of-life instruments concluded that generic instruments were not as responsive to change as disease-specific measures in studies demonstrating a therapeutic effect.¹⁰ The observed lower effect sizes are likely attributable to the content of generic measures because disease-specific instruments include items unique to the condition of interest. A recent systematic review identified only 3 pediatric asthma-specific questionnaires assessing caregiver quality of life¹¹: the Quality of Life of Parents of Asthmatic Children,¹² for which data on its psychometric properties and application are lacking; the Family Impact of Childhood Bronchial Asthma Questionnaire, which is available only in Spanish¹³; and the Pediatric Asthma Caregiver Quality of Life Questionnaire (PACQLQ).¹⁴ Both the Quality of Life of

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Abbreviations used

ECAP: Effects of a Child's Asthma Flare-up on the Parents
 PACQLQ: Pediatric Asthma Caregiver Quality of Life Questionnaire
 URTI: Upper respiratory tract infection

Parents of Asthmatic Children and the PACQLQ target parents of school-aged children; the latter, which is available in several languages and most frequently used, assesses quality of life over the preceding week. Only the Family Impact of Childhood Bronchial Asthma Questionnaire included the preschool age group (2-17 years), but it was designed to assess caregiver burden over the preceding 3 months and not during an exacerbation and has not been tested in the context of a clinical trial. Thus a valid measure of the burden on caregivers of an acutely ill, preschool-aged child with asthma is lacking.

The aims of this study were to develop a functional status instrument to measure the burden of a young child's asthma exacerbation on caregivers and to validate the instrument's psychometric properties in the context of a therapeutic trial by using of a rigorous methodology.

METHODS

Questionnaire development followed the 5 steps proposed by Kirshner and Guyatt¹⁵: (1) item generation, (2) item reduction, (3) item presentation and scaling, (4) pretesting of items for clarity, and (5) subsequent validation of psychometric properties. At each phase, Canadian French and English versions of the instrument were generated by using the back-translation technique.¹⁶ The Institutional Review Board of the Montreal Children's Hospital (Montreal, Quebec, Canada) approved all study phases. The parents or guardians of preschoolers provided informed consent for participation, as well as for access to medical and pharmacy records.

The first 4 steps of the instrument development are described in detail in the **Methods** section in this article's Online Repository at www.jacionline.org. At each step, different caregivers were recruited in the emergency department or short-stay unit during their child's exacerbation. Briefly, a literature review and consultations with experts identified key items serving as "probes" in a semistructured, open-ended item-generation questionnaire, which was administered during a face-to-face interview with 26 caregivers. A second group of 103 caregivers was asked to consider each of the 73 items generated in the first phase, indicating whether they experienced the item (endorsement) and, if so, rating its importance on a Likert scale of 1 to 5. Items were eliminated according to the product of endorsement and importance, correlation coefficients, and principal component analysis. Each of the remaining 21 items was phrased as a question with a scaled response option from 1 (not at all) to 7 (extremely), including a "cannot answer" option. Using cognitive interviews, a third group of 24 caregivers was consulted to assess the clarity of instructions, statement and response options, and scale and layout of the instrument, with iterative revisions until greater than 85% clarity was obtained. The final 21-item version had a reading level (Flesch-Kincaid) between 7th and 8th grade and was called the Effects of a Child's Asthma Flare-up on the Parents (ECAP; see [Fig E1](#) for the English version and [Fig E2](#) for the French version in this article's Online Repository at www.jacionline.org).

Pretesting for psychometric properties

Pretesting of the psychometric properties of the ECAP questionnaire occurred in a subset of children aged 1 to 6 years with virus-induced asthma who were enrolled in a randomized placebo-controlled trial of pre-emptive high-dose fluticasone initiated at the beginning of an upper respiratory tract infection (URTI).³ Caregivers were asked to complete the ECAP questionnaire on the last or 10th day (which ever occurred first) of an episode,

which was defined as a URTI triggering or not triggering an asthma flare-up. Resolution of an episode was defined as no asthma symptoms (cough, wheeze, and shortness of breath). Parents were specifically instructed that an ongoing runny/congested nose without cough was defined as a day with no symptoms. Three days without symptoms must elapse before a new episode was defined. A completed ECAP questionnaire was defined *a priori* as having no more than 1 missing or "cannot answer" item of the 21 items. The total score was the average of all completed items (score range, 1-7). Concomitantly, caregivers rated the global effect of the episode (URTI with or without an asthma exacerbation) on a scale of 1 (not at all) to 7 (extremely), the number of regular activity days missed, and their ability, expressed as a percentage, to perform regular planned activities, and they simultaneously completed the PACQLQ.¹⁴ An asthma exacerbation was defined *a priori* as at least 2 symptomatic days; a symptomatic day required a score of 2 or greater for 2 of the 3 symptoms of cough, wheezing, and dyspnea on a daily diary completed by caregivers during each episode.¹⁷ The cumulative daily score for this diary represented the clinical severity of the episode. Monthly telephone calls served as reminders to complete the questionnaire and were an additional source of documentation of URTIs, exacerbations, and health events. Pharmacy and hospital records verified all reports of emergency visits, rescue systemic corticosteroid use, and hospital admissions.

Statistics

Feasibility was assessed by calculating the following: (1) the return rate of the ECAP questionnaire (ie, the proportion of episodes reported verbally during monthly contact for which an ECAP questionnaire was returned) and (2) the completion rate of the ECAP questionnaire (ie, the proportion of each ECAP item completed in all returned questionnaires). Because children experienced an average of 8 (range, 1-22) URTIs, we randomly selected 1 ECAP questionnaire per child for the following 3 analyses using only ECAP questionnaires with no missing or "cannot answer" items for the first and no more than 1 missing or "cannot answer" item for the last 2 analyses.

First, a factor analysis with a procrustean transformation matrix was performed to validate final items and domains based on the following: factors with an eigenvalue of greater than 1, items with a relevance score of 0.4 or greater, and consideration of clinical effect.¹⁸ Second, internal consistency was assessed by calculating each item, as well as the total Cronbach α value, with missing items imputed by their mean value. Third, spearman correlation coefficients were calculated to examine agreement between the ECAP score and each of the following measures: (1) caregiver's global assessment of the effect of the asthma flare-up or URTI; (2) number of lost productivity days; (3) self-perceived functioning level (0% to 100%); (4) cumulative daily diary score; and (5) total PACQLQ score.

By using all valid questionnaires (ie, with no more than 1 missing or "cannot answer" item), the discriminative validity was evaluated by assessing the mean difference with the 95% CI in ECAP scores between episodes associated or not with the following: (1) asthma exacerbation, (2) emergency department visit, (3) rescue systemic corticosteroid use, or (4) hospital admission, adjusting for language, site, and individual clustering of episodes. By using a general linear model, responsiveness was evaluated by the mean difference (95% CI) in the ECAP score in children treated with high-dose fluticasone versus placebo adjusted for language, site, and individual clustering of episodes. All statistical analyses were carried out with SAS software, version 9.3 (SAS Institute, Cary, NC). Results were considered statistically significant if the *P* value was less than .05.

RESULTS

Because the ECAP questionnaire was added 1 year after trial initiation, data from 93 of the 129 children enrolled in the randomized controlled trial³ were available, providing a total of 699 reported episodes. Questionnaires were completed in French (51.1%) or English (48.9%). The characteristics of the parents (and children) are presented in [Table I](#). The groups were comparable across languages, with the exception of more boys

TABLE I. Characteristics of participants by language version completed of the ECAP questionnaire

Variable	French (n = 50)	English (n = 43)	P value
Child			
Age (y), mean $\pm$ SD	2.7 $\pm$ 1.0	2.4 $\pm$ 0.9	.161
Male sex, no. (%)	37 (74.0)	21 (48.8)	.012
White, no. (%)	46 (92.0)	26 (60.5)	.010
Parents			
Married/common law relationship, no. (%)	44 (88.0)	39 (90.7)	.801
Schooling years, median (range)			
Mother	14 (7-25)	14 (7-20)	.771
Father	13 (6-24)	14 (6-23)	.467
Country of birth, father,* no. (%)	n = 31	n = 33	<.001
Canada	26 (52.0)	14 (32.6)	
Other	5 (10.0)	19 (44.2)	
Country of birth, mother,* no. (%)	n = 31	n = 33	.077
Canada	27 (54.0)	22 (51.2)	
Other	4 (8.0)	11 (25.6)	
Native language, father,* no. (%)	n = 33	n = 33	<.001
French	26 (52.0)	5 (11.6)	
English	3 (6.0)	12 (27.9)	
Other	4 (8.0)	16 (37.2)	
Native language, mother,* no. (%)	n = 31	n = 33	<.001
French	27 (54.0)	3 (7.0)	
English	—	14 (32.6)	
Other	4 (8.0)	16 (37.2)	

*Information is available for only a subset (62% to 66% and 66% of parents completing the French and English versions, respectively).

and a higher number of white children among those completing the French version. Most parents who completed the English version were not Canadian born and identified their native language as “other than French or English.” Ninety-two percent of the ECAP questionnaires were completed by the mother, 7% by the father, and 1% by another caregiver (female).

Feasibility

Of the 878 episodes reported verbally during monthly contacts, 699 (79.6%) questionnaires were returned; of these questionnaires, 92.7% or more of all individual items were completed per episode (Table II). Of the 699 questionnaires, 603 (86.3%) had no missing items, 25 (3.6%) had 1 missing item, and the remaining had 2 or more missing items. Because there was no meaningful difference in the mean ECAP score between questionnaires with no missing items (2.6 ± 1.4) and those with up to 1 missing item (2.7 ± 1.5), we included questionnaires with up to 1 missing or “cannot answer” item; thus 628 (89.8%) of the returned questionnaires were considered for subsequent analyses (Fig 1).¹⁷

Internal validity

On the basis of both factor analysis and clinical relevance,¹⁸ all 21 items were preserved and grouped into 5 domains listed in decreasing order of importance regarding the caregiver’s perception of the following (see Table E1 in this article’s Online Repository at www.jacionline.org): (1) sleep and activity disruption (items 4 and 16-21); (2) emotions (items 1, 2, 3, and 5); (3) concerns about medication and acute care (items 11-13); (4) concerns about losing control (items 6-10); and (5) concerns

TABLE II. Completion rate of the ECAP questionnaire per episode

Questionnaire item	Completion rate per episode (n = 699 episodes),* no. (%)
Emotions	
Sad	686 (98.1)
Stressed	685 (98.0)
Nervous	685 (98.0)
Tired	684 (97.9)
Sorry for my child	682 (97.6)
Concerns	
How severe exacerbation could become	682 (97.6)
Child might lack oxygen	681 (97.4)
Not able to control exacerbation at home	679 (97.1)
Lack of effectiveness of medication	676 (96.7)
Difficulty assessing severity	679 (97.1)
Long stay in emergency clinic or hospital	682 (97.6)
Too much medication	680 (97.3)
Side effects of medication	679 (97.1)
Person caring for child in my absence	652 (93.3)
Person administering medication in my absence	648 (92.7)
Disruption	
Need to change family sleeping arrangements	675 (96.6)
Responsibilities at home	679 (97.1)
Loss of sleep taking care of child	678 (97.0)
Loss of sleep worrying about child	678 (97.0)
Disrupted family activities	677 (96.9)
Decreased time for myself	668 (95.6)
Total diary	
No missing or “cannot answer” items	603 (86.3)
No more than 1 missing or “cannot answer” item	628 (89.8)

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

about leaving the child with another caregiver (items 14 and 15). The standardized Cronbach α value ranged from 0.96 to 0.97 for each item, with an overall value of 0.97 (see Table E2 in this article’s Online Repository at www.jacionline.org).

Discriminative ability

Of the 621 episodes for which there was a complete ECAP questionnaire and a corresponding valid diary set of the child’s symptoms (Fig 1)¹⁷ from which an exacerbation could be determined, 261 (42.0%) episodes met the definition of an exacerbation. The mean ECAP score was significantly higher for episodes associated with an exacerbation compared with those not associated with an exacerbation (mean difference, 3.2 [95% CI, 2.9-3.4] vs 2.4 [95% CI, 2.2-2.6]; Fig 2).¹⁷ Of the 609 episodes for which health care use data were documented, 115 (18.9%) resulted in an emergency department presentation, 67 (11.0%) were treated with rescue systemic corticosteroids, and 15 (2.5%) resulted in a hospital admission. The mean ECAP score was significantly higher for episodes resulting in an emergency department visit (3.7 [95% CI, 3.4-4.0] vs 2.5 [95% CI, 2.3-2.8]), rescue oral corticosteroid use (4.0 [95% CI, 3.6-4.3] vs 2.6 [95% CI, 2.4-2.8]), and hospital admission (4.6 [95% CI, 4.0-5.2] vs 2.7 [95% CI, 2.5-2.9]) compared with those that did not (Fig 2) after adjusting for language, site, and clustering of episodes within subjects. No meaningful difference in the discriminative performance of the ECAP questionnaire was

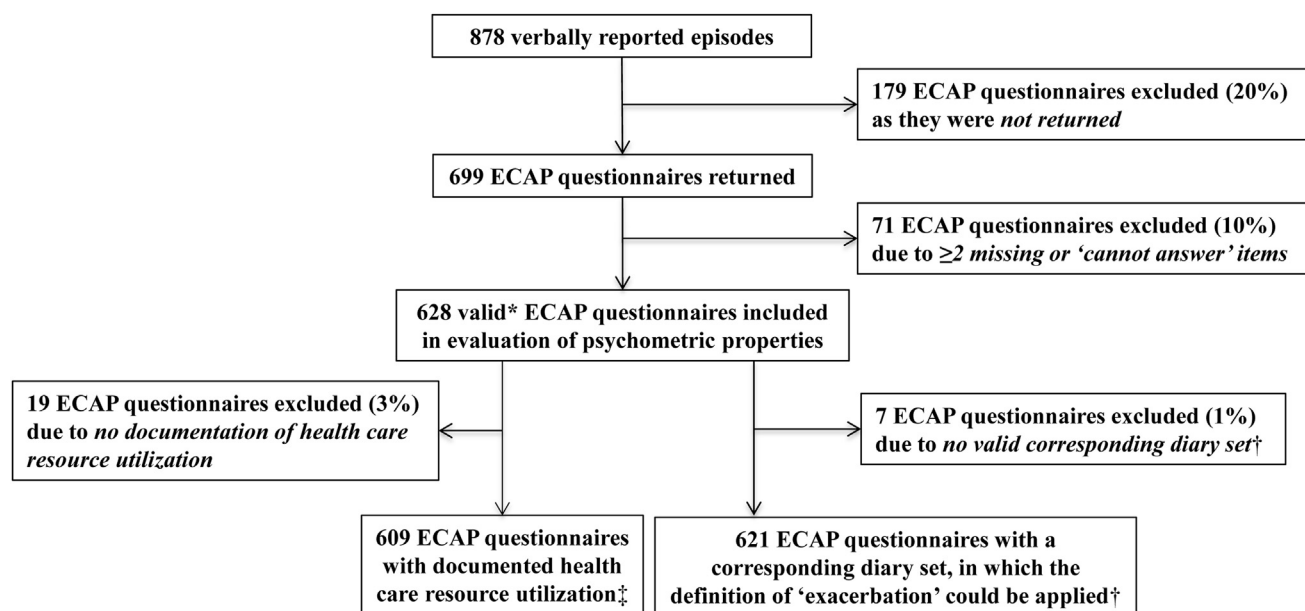


FIG 1. Selection of the ECAP questionnaire for analyses of psychometric properties. The selection of ECAP questionnaires per our *a priori* definitions is presented in the graph. *A valid ECAP questionnaire is defined as containing no more than 1 missing or "cannot answer" item. †The asthma diary is a valid 17-item instrument¹⁷ completed daily during an episode. A valid asthma 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. An asthma exacerbation was defined as at least 2 symptomatic days, with a symptomatic day requiring a score of 2 or greater for 2 of the 3 following symptoms: cough, wheezing, and dyspnea. ‡Oral corticosteroid medication was recorded from pharmacy and medical notes; acute care presentations and hospitalizations were recorded from medical notes.

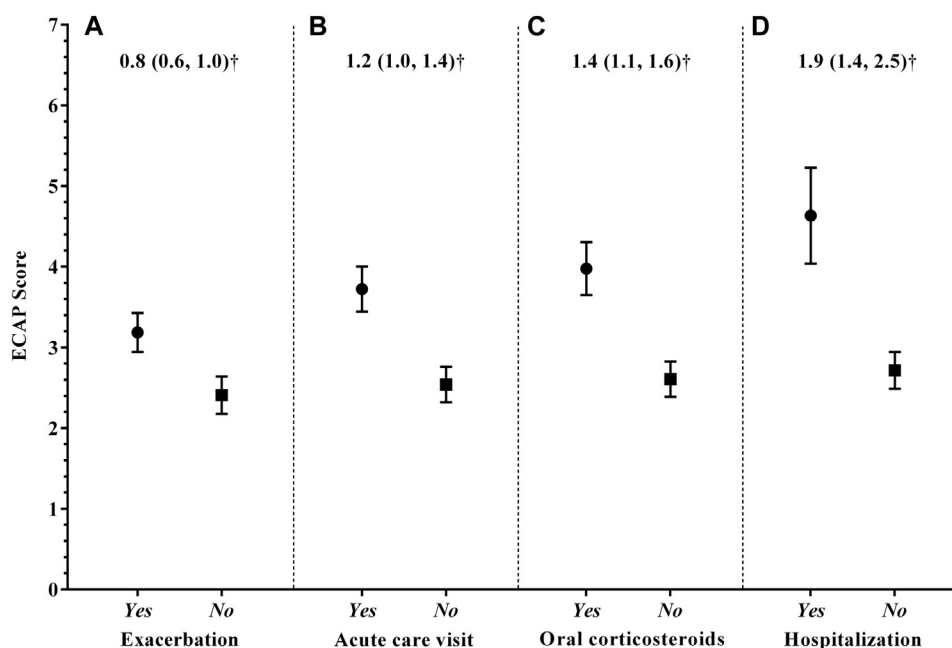


FIG 2. Discriminant validity of the ECAP questionnaire. Mean ECAP scores are displayed on a scale of 1 to 7 for flare-ups that did or did not result in an exacerbation, which was defined as 2 or more symptomatic days in the validated asthma symptom diary set¹⁷ for the index episode (A); an acute care visit (B); use of rescue oral corticosteroids (C); or a hospital admission (D). Error bars represent 95% CIs around mean scores. †The mean group difference (95% CI) is reported at the top of each graph.

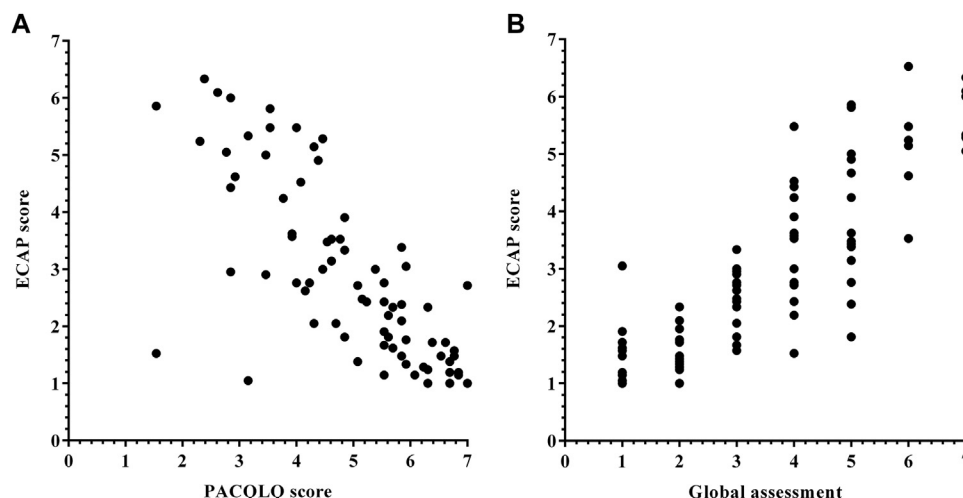


FIG 3. Correlation between the ECAP score and several indicators of caregiver burden. The figure depicts correlations of the ECAP score with the PACQLQ score on a scale of 1 to 7 (**A**) and the caregivers' global assessment of the burden of their child's asthma exacerbation on a scale of 1 to 7 (**B**).

observed when restricting the analyses to questionnaires with no missing items (see [Table E3](#) in this article's Online Repository at www.jacionline.org).

The ECAP score was highly correlated with the global assessment of the effect of exacerbation on the caregiver's functional status ($n = 93$, $r = 0.86$, $P < .001$) and the PACQLQ score ($n = 79$, $r = -0.83$, $P < .001$; [Fig 3](#)), which also showed a significant group mean difference (0.49 [95% CI, 0.10-0.89])³ between the placebo and fluticasone groups. In addition, it was moderately correlated with the number of caregiver days missed from regular activities ($n = 91$, $r = 0.52$, $P < .001$), the extent (as a percentage) that caregivers were able to perform regular activities ($n = 88$, $r = -0.64$, $P < .001$) and the cumulative asthma diary score representing the severity of symptoms during episodes ($n = 93$, $r = 0.33$, $P = .001$).

Responsiveness

The ECAP questionnaire showed a differential response to therapy in a therapeutic trial, with a significantly lower mean score for episodes experienced by the pre-emptive high-dose fluticasone group compared with the placebo group (2.4 [95% CI, 2.1-2.7] vs 3.1 [95% CI, 2.4-3.4]; mean difference, -0.7 [95% CI, -1.1 to -0.3]). There was no difference in effect when restricting to questionnaires with no missing items (see [Table E3](#)). Of note, the median duration of asthma symptoms was 4 (25% to 75%, 2-6.5) and 5 (25% to 75%, 3-8) days, respectively, in the fluticasone and placebo groups, such that the overwhelming majority of episodes were completed before 10 days.

DISCUSSION

The 21-item ECAP questionnaire has the desired psychometric properties to measure the burden of a preschool-aged child's asthma exacerbation on the functional status of his or her caregiver. In a randomized placebo-controlled trial the ECAP questionnaire proved feasible (supported by an item completion rate of >90%) and demonstrated high internal and construct validity with strong correlations with other markers of caregiver

functional impairments and proved discriminative across various severity levels of exacerbations. Moreover, the ECAP questionnaire appears to be a valid evaluative instrument because it was highly responsive in a therapeutic clinical trial, detecting higher functional status in the caregivers of children allocated to the effective intervention compared with the placebo arms.

The ECAP questionnaire was specifically developed to assess the effect of a preschool-aged child's acute exacerbation on the caregivers' overall functional status; thus parents of acutely ill preschoolers with asthma were involved at each questionnaire development phase. All 21 items retained after item generation and reduction were deemed clinically relevant,¹⁸ and their inclusion was supported further by factor analysis and a high Cronbach α value.¹⁹ The final ECAP questionnaire includes 5 important domains pertaining to the disturbance of caregiver sleep and regular activities, emotional effect, and concerns about medication and acute care needs, loss of control, and the ability of another person to care for the child. These domains underline the high dependency of a preschooler on their caregivers, in part because of a lower ability to communicate their health status and partake in their health care, which is in contrast to older children, who can often vocalize their disease status and request care (eg, rescue medication and a health care visit). Such items were not typically included in other instruments used to assess general functional status in caregivers of school-aged children with asthma.^{13,14,20} As requested by parents to better reflect their burden, the rating of each item in the ECAP questionnaire pertains to the intensity rather than the frequency of an item, as often sought in other instruments for caregivers.^{13,14} Designed at a reading level between the 7th and 8th grades (Flesch-Kincaid) and in a simple 1-page layout with "fill-in-the-circle" options,¹⁹ the 90% completion rate supports the feasibility of the instrument. In summary, the ECAP questionnaire demonstrates good internal consistency and content validity, containing items that are of high relevance to the caregivers of preschool-aged children with an asthma exacerbation.

The ECAP score successfully distinguished between URTIs associated with an exacerbation and those that were not. It also discriminated across different levels of increasing asthma

severity, namely those requiring an emergency department visit, rescue systemic corticosteroid, or hospital admission. Moreover, the ECAP score correlated with caregivers' global assessments of impairment, work absenteeism, and productivity, as well as the PACQLQ validated for parents of school-aged children. The ECAP score also correlated with the clinical severity of the child's episode (represented by the cumulative asthma diary score), although with lower correlation; this suggests that the ECAP score provides complementary information on caregiver burden, which is distinct from their assessment of the child's functional status. The ECAP questionnaire adequately identified a significant difference to an effective therapeutic intervention compared with placebo. To our knowledge, of the 3 identified asthma-specific quality-of-life instruments for caregivers of children, only the PACQLQ has also shown responsiveness in clinical trials.^{3,21} Of note, the responsiveness and discriminative properties of the ECAP questionnaire were similar between questionnaires with no missing items and questionnaires with up to 1 missing item, suggesting that 1 missing item does not affect validity. Supported by strong criterion and construct validity for both discrimination and responsiveness, the ECAP questionnaire appears to be a valuable caregiver-centered measure for use in intervention trials for preschool-aged children with asthma or wheezing illness.

The following limitations are recognized. Although parents reported taking only a few minutes, we did not formally document the time to complete the ECAP questionnaire. As for other caregiver-completed instruments,^{7,13,14} the response rate was dominated by that of mothers, and thus the validity of the instrument in fathers and the potential differential effect of the child's illness on fathers versus mothers have yet to be examined. Enrolled children were considered to have asthma on the basis of repeat wheezing episodes and response to asthma therapy, as per Global Initiative for Asthma guidelines²² and supported by the 2015 Canadian Thoracic Society and Canadian Pediatric society position paper²³; we acknowledge that enrolled children might have been referred to as "preschool wheezers" by others. The study was not designed to assess the test-retest reliability and minimally important difference of the ECAP questionnaire; these properties are yet to be determined. In this head-to-head comparison of the ECAP questionnaire with the PACQLQ, the observed strong correlation might suggest that the PACQLQ could also be used in preschool-aged children during an exacerbation. The ECAP questionnaire showed a slightly larger effect size (0.70) than the PACQLQ (0.49) between the fluticasone and placebo groups; however, more data are needed to confirm this observation. Conversely, the ECAP questionnaire might be applicable to school-aged children during an exacerbation, although we recommend validation in this age group before uptake. The choice of functional status instrument should depend on the intended application (context and target group) and the demonstrated psychometric properties of the instrument. Finally, although the ECAP questionnaire has 3 sections, it reflects 5 main domains; whether some domains are more sensitive to specific interventions remains to be explored.

The ECAP questionnaire was elaborated from caregivers of preschoolers with acute asthma; however, we suspect it could also be applicable to caregivers of children with bronchiolitis or other "wheezing" illnesses because of the similarity of caregivers' concerns. Although all iterative versions of the ECAP questionnaire were back translated between French and English,

maximizing the conformity between language versions, language remained a frequently significant covariate, resulting in all analyses being adjusted for language. Given the differences in child ethnicity and native language and country of birth of the parents who completed the ECAP questionnaire in French versus English, we suspect that cultural differences might explain the observed variability in response to a sick child associated with language. The performance of the ECAP questionnaire suggests that the validity of the instrument is robust across cultural differences, as observed in Canada; however, because a large proportion of caregivers did not complete the questionnaire in their native languages, there might be a need to validate the ECAP questionnaire further in different populations with a higher proportion with French or English as their native language.

The 21-item ECAP questionnaire appears to be a feasible, valid, discriminative, and responsive instrument to assess the burden of a preschool-aged child's acute asthma exacerbation on caregiver functional status. Simultaneously developed in the French and English languages, the ECAP questionnaire meets the desired psychometric properties of a good evaluative instrument, bringing a complementary perspective to traditional outcomes in therapeutic trials of acute exacerbations in preschoolers.

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Clinical implications: The ECAP questionnaire is a validated instrument to measure caregivers' functional status during their preschooler's asthma exacerbation, bringing a complementary perspective to traditional outcomes.

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METHODS

Item generation

A list of potentially relevant items were generated from (1) a literature review of generic and disease-specific instruments developed for use in school-aged children, adults, and caregivers using the specific key words of “asthma” and (“school-aged children” or “preschool-aged children” or “infants” or “adolescents” or “adults” or “caregivers”) and (“quality of life” or “functional status” or “symptoms” or “health outcomes”); (2) references of the articles identified above; and (3) expert opinions of collaborators. Identified items served as probes in the semistructured item-generation questionnaire, which contained open-ended questions relating to emotions, ability to function, social life, medical behavior, and personal relationships. This questionnaire was administered by a bilingual research assistant in a face-to-face interview of 26 (11 French- and 15 English-speaking) caregivers recruited in the emergency department or short-stay unit during their child’s acute asthma exacerbation. Recruitment continued over 10 interviews until new items no longer arose. Transcription of taped interviews ensured reporting accuracy and provided interviewer feedback.

Item reduction

The item-reduction questionnaire consisted of 73 items related to emotions, concerns about delegating care, assessment of severity, family relationships, function, social life, and work and medical issues. It was administered to 103 caregivers (51 French- and 52 English-speaking) recruited in the emergency department or short-stay unit at the time of their child’s asthma exacerbation. For each item, caregivers provided endorsement by indicating whether they

had ever experienced an item and rated its importance on a Likert scale of 1 to 5. Items were eliminated if they were endorsed by 20% or less of caregivers ($n = 5$), the product of endorsement and importance was less than 0.40 ($n = 40$) after standardization for the number of participants who endorsed the item, apparently similar variables were highly correlated (≥ 0.8 , $n = 2$), or items that described a similar phenomenon were highlighted in principal component analysis ($n = 9$).

Item presentation and scaling

The final questionnaire was comprised of 21 items categorized according to those that parents considered to be the most useful indicator of the intensity of their feelings, level of concern, and experience during their child’s exacerbation. Each item was formulated as a statement and matched with a scaled response option from 1 (not at all) to 7 (extremely) and a “cannot answer” option.

Pretesting for clarity

Twenty-four caregivers of acutely ill children aged 1 to 6 years were recruited in the emergency department to participate in a cognitive interview. Feedback on the clarity of instructions, statement and response options, scale, and layout was provided immediately after the caregiver read the questionnaire aloud. Caregivers were instructed to provide a response for each item on the instrument, which the interviewer then challenged, to confirm that the question and response option was understood. After continued revision of the instrument, the final version obtained greater than 85% clarity for instructions and item and response options and was called the ECAP questionnaire.

Effects of a young child's asthma flare-up on parents[®]

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<table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 40%; text-align: left; padding: 5px;">During my child's flare-up, I experienced:</th> <th style="width: 10%; text-align: center; padding: 5px;">Not at all</th> <th style="width: 10%; text-align: center; padding: 5px;">1</th> <th style="width: 10%; text-align: center; padding: 5px;">2</th> <th style="width: 10%; text-align: center; padding: 5px;">3</th> <th style="width: 10%; text-align: center; padding: 5px;">Moderately</th> <th style="width: 10%; text-align: center; padding: 5px;">4</th> <th style="width: 10%; text-align: center; padding: 5px;">5</th> <th style="width: 10%; text-align: center; padding: 5px;">Extremely</th> <th style="width: 10%; text-align: center; padding: 5px;">6</th> <th style="width: 10%; text-align: center; padding: 5px;">7</th> <th style="width: 10%; text-align: center; padding: 5px;">Cannot Answer</th> </tr> <tr> <td style="padding: 5px;">The need to change my family's sleeping arrangements</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> </tr> <tr> <td style="padding: 5px;">A decrease in my ability to take care of my responsibilities at home</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> </tr> <tr> <td style="padding: 5px;">A loss of sleep in order to take care of my child</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> </tr> <tr> <td style="padding: 5px;">A loss of sleep because I worried for my child</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> </tr> <tr> <td style="padding: 5px;">A disruption in family activities because of the asthma flare-up</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> </tr> <tr> <td style="padding: 5px;">A decrease in the amount of time that I set aside for my own needs during my child's flare-up</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> <td style="text-align: center;">☐</td> </tr> </table>		During my child's flare-up, I experienced:	Not at all	1	2	3	Moderately	4	5	Extremely	6	7	Cannot Answer	The need to change my family's sleeping arrangements	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	A decrease in my ability to take care of my responsibilities at home	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	A loss of sleep in order to take care of my child	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	A loss of sleep because I worried for my child	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	A disruption in family activities because of the asthma flare-up	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	A decrease in the amount of time that I set aside for my own needs during my child's flare-up	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐																																																
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FIG E1. English version of the 21-item ECAP questionnaire for caregivers of children aged 1 to 6 years during an asthma exacerbation.

Effets d'une crise d'asthme du jeune enfant sur les parents[©]

Date			exemple			Pour l'usage du bureau seulement				
		-				(10-OCT-1999)	ID			Rhume #
S.V.P. remplir ce questionnaire à la fin de la crise d'asthme ou après 10 jours, le premier des deux événements. CECI CONCERNE LA CRISE ACTUELLE DE VOTRE ENFANT. Veuillez noircir un seul cercle pour CHAQUE question. Répondez à CHAQUE question S.V.P.										
Pendant la crise de mon enfant, je me suis senti(e):			Pas du tout		Moyennement		Énormément		Je ne peux répondre	
			1	2	3	4	5	6	7	
Triste			☐	☐	☐	☐	☐	☐	☐	☐
Stressé(e)			☐	☐	☐	☐	☐	☐	☐	☐
Nerveux (se)			☐	☐	☐	☐	☐	☐	☐	☐
Fatigué(e)			☐	☐	☐	☐	☐	☐	☐	☐
Peiné(e) pour mon enfant			☐	☐	☐	☐	☐	☐	☐	☐
Durant la crise de mon enfant, je me suis inquiété(e):			Pas du tout		Moyennement		Énormément		Je ne peux répondre	
			1	2	3	4	5	6	7	
De la gravité possible de la crise d'asthme			☐	☐	☐	☐	☐	☐	☐	☐
Que mon enfant puisse manquer d'oxygène			☐	☐	☐	☐	☐	☐	☐	☐
De ne pas pouvoir contrôler la crise à la maison			☐	☐	☐	☐	☐	☐	☐	☐
Que les médicaments utilisés pour la crise d'asthme ne soient pas assez efficaces			☐	☐	☐	☐	☐	☐	☐	☐
De la difficulté à évaluer la gravité de la crise d'asthme			☐	☐	☐	☐	☐	☐	☐	☐
De la possibilité d'un long séjour à l'urgence / à la clinique / à l'hôpital			☐	☐	☐	☐	☐	☐	☐	☐
Du risque de lui donner trop de médicaments			☐	☐	☐	☐	☐	☐	☐	☐
Des effets indésirables des médicaments donnés pour contrôler la crise			☐	☐	☐	☐	☐	☐	☐	☐
Qu'en mon absence, la personne qui s'occupe de mon enfant ne sache pas quoi faire			☐	☐	☐	☐	☐	☐	☐	☐
Qu'en mon absence, la personne qui s'occupe de mon enfant ne sache pas comment administrer correctement les médicaments			☐	☐	☐	☐	☐	☐	☐	☐
Pendant la crise de mon enfant, j'ai éprouvé:			Pas du tout		Moyennement		Énormément		Je ne peux répondre	
			1	2	3	4	5	6	7	
Le besoin de changer l'organisation de ma famille pour le coucher			☐	☐	☐	☐	☐	☐	☐	☐
Une diminution de ma capacité à assumer mes responsabilités à la maison			☐	☐	☐	☐	☐	☐	☐	☐
Un manque de sommeil parce que j'ai dû prendre soin de mon enfant			☐	☐	☐	☐	☐	☐	☐	☐
Un manque de sommeil parce que je m'inquiétais pour mon enfant			☐	☐	☐	☐	☐	☐	☐	☐
Une perturbation des activités familiales causée par la crise d'asthme			☐	☐	☐	☐	☐	☐	☐	☐
Une diminution du temps que je consacre à mes propres besoins pendant la crise d'asthme			☐	☐	☐	☐	☐	☐	☐	☐

FIG E2. Effets d'une crise d'asthme du jeune enfant sur les parents: French version of the 21-item ECAP questionnaire for caregivers of children aged 1 to 6 years during an asthma exacerbation.

TABLE E1. Profactor analysis of the 21-item ECAP questionnaire

Questionnaire item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Emotions					
1. Sad	4	100*	2	3	1
2. Stressed	11	45*	3	4	3
3. Nervous	11	51*	3	8	3
4. Tired	51*	26	1	1	0
5. Sorry for my child	17	47*	8	8	0
Concerns					
6. How severe the exacerbation could become	2	25	6	35†	6
7. Child might lack oxygen	3	16	3	21‡	0
8. Not able to control exacerbation at home	2	1	4	100*	1
9. Lack of effectiveness of medication	4	10	16	46*	1
10. Difficulty assessing severity	1	6	37	42*	0
11. Long stay in emergency clinic or hospital	2	14	43*	21	0
12. Too much medication	2	0	100*	3	0
13. Side effects of medication	2	6	74*	2	5
14. Person caring for the child in my absence	2	1	0	2	93*
15. Person administering medication in my absence	1	1	1	0	100*
Disruption					
16. Need to change family sleeping arrangements	98*	0	2	2	0
17. Responsibilities at home	98*	4	2	0	0
18. Loss of sleep taking care of child	80*	11	0	1	2
19. Loss of sleep worrying about the child	74*	9	2	1	1
20. Disrupted family activities	100*	0	0	2	0
21. Decreased time for myself	98*	1	0	0	2
Factor eigenvalue¶	61.4	10.3	4.7	4.1	2.3

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

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

†Item was deemed clinically relevant and thus included.

‡The item relevance score was greater than 0.4 in an additional factor 6; however, based on clinical relevance, the item was included in factor 4, and the factors were condensed to 5.

¶Domains were validated if the factor had an eigenvalue of greater than 1.

TABLE E2. Standardized Cronbach α value for individual items and the total score on the ECAP questionnaire

Questionnaire item	Standardized Cronbach α value (n = 93)
Emotions	
Sad	0.967
Stressed	0.966
Nervous	0.966
Tired	0.967
Sorry for my child	0.967
Concerns	
How severe the exacerbation could become	0.966
Child might lack oxygen	0.966
Not able to control exacerbation at home	0.967
Lack of effectiveness of medication	0.966
Difficulty assessing severity	0.968
Long stay in emergency clinic or hospital	0.968
Too much medication	0.967
Side effects of medication	0.967
Person caring for child in my absence	0.968
Person administering medication in my absence	0.969
Disruption	
Need to change family sleeping arrangements	0.968
Responsibilities at home	0.967
Loss of sleep taking care of child	0.966
Loss of sleep worrying about child	0.966
Disrupted family activities	0.967
Decreased time for myself	0.967

TABLE E3. ECAP scores and mean group difference (95% CIs)

Event	No missing values			Up to 1 missing value		
	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	3.2 $\pm$ 1.5	2.2 $\pm$ 1.3	0.8 (0.6-1.0)	3.2 $\pm$ 1.5	2.2 $\pm$ 1.3	0.8 (0.6-1.0)
Acute care visit	3.7 $\pm$ 1.5	2.4 $\pm$ 1.3	1.2 (1.0-1.4)	3.8 $\pm$ 1.5	2.4 $\pm$ 1.3	1.2 (1.0-1.4)
Systemic steroids	4.1 $\pm$ 1.5	2.5 $\pm$ 1.3	1.4 (1.1-1.7)	4.1 $\pm$ 1.5	2.5 $\pm$ 1.4	1.4 (1.1-1.6)
Hospitalization	4.5 $\pm$ 1.5	2.6 $\pm$ 1.4	1.9 (1.3-2.5)	4.6 $\pm$ 1.6	2.6 $\pm$ 1.4	1.9 (1.4-2.5)
Fluticasone	2.3 $\pm$ 1.3	3.0 $\pm$ 1.5	0.7 (0.3-1.2)	2.3 $\pm$ 1.3	3.0 $\pm$ 1.5	0.7 (0.3-1.2)