



Evaluation of the PROMIS pediatric global health scale (PGH-7) in children with asthma

Christopher B. Forrest, Joseph J. Zorc, JeanHee Moon, Ramya Pratiwadi, Brandon D. Becker, Mitchell G. Maltenfort & James P. Guevara

To cite this article: Christopher B. Forrest, Joseph J. Zorc, JeanHee Moon, Ramya Pratiwadi, Brandon D. Becker, Mitchell G. Maltenfort & James P. Guevara (2018): Evaluation of the PROMIS pediatric global health scale (PGH-7) in children with asthma, Journal of Asthma, DOI: 10.1080/02770903.2018.1471701

To link to this article: <https://doi.org/10.1080/02770903.2018.1471701>



Accepted author version posted online: 01 May 2018.
Published online: 05 Jun 2018.



Submit your article to this journal [↗](#)



Article views: 35



View related articles [↗](#)



View Crossmark data [↗](#)



Evaluation of the PROMIS pediatric global health scale (PGH-7) in children with asthma

Christopher B. Forrest, MD, PhD^{a,b}, Joseph J. Zorc, MD, MSCE^{a,c}, JeanHee Moon, PhD^{a,b}, Ramya Pratiwadi, MS^{a,b}, Brandon D. Becker, PhD^{a,b}, Mitchell G. Maltenfort, PhD^{a,b}, and James P. Guevara, MD, MPH^{a,b}

^aDepartment of Pediatrics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, USA; ^bDivision of General Pediatrics, Children's Hospital of Philadelphia, Philadelphia, PA, USA; ^cDivision of Emergency Medicine, Children's Hospital of Philadelphia, Philadelphia, PA, USA

ABSTRACT

Objective: To evaluate the reliability and validity of the PROMIS Pediatric Global Health scale, a 7-item measure of perceived physical, mental, and social health, in children with asthma. **Methods:** From February 2014 to February 2015, convenience samples of 8–17 year-old children ($n = 182$) and parents of 5–17 year-old children ($n = 328$) visiting an emergency department for treatment of asthma were enrolled. The Asthma Control Test was used to characterize children as controlled versus not controlled, and the PROMIS Asthma Impact Scale was used to assess asthma symptoms' impact on functional status. We conducted longitudinal analyses among 92 children and 218 parents at 3 weeks, and 74 children and 171 parents at 8 weeks after enrollment. **Results:** The PGH-7 reliability ranged from 0.66 to 0.81 for child-report and 0.76 to 0.82 for parent-proxy. In cross-sectional analyses, children with controlled asthma had PGH-7 scores 0.40–0.95 standard deviation units higher than those who were uncontrolled. The PGH-7 was responsive to changes in overall general health between time points, with moderate effect sizes (0.5–0.6 standard deviation units). In longitudinal analyses, PGH-7 scores were no different between those who stayed uncontrolled versus became controlled at 3 weeks of follow-up; however, by 8 weeks of follow-up, the differences between these groups were 0.7–0.8 standard deviation units, indicative of large effects. **Conclusions:** The PGH-7 is a reliable and valid patient-reported outcome for assessing general health among children with asthma. It is a useful complement to other asthma-specific outcome measures.

ARTICLE HISTORY

Received 11 September 2017
Revised 15 April 2018
Accepted 28 April 2018

KEYWORDS

Patient-reported outcome;
Quality of life; Health status;
Asthma; Child; PROMIS;
PGH-7

Introduction

Patient-reported outcomes are joining laboratory and radiographic studies, biomarkers, and clinical exams in the repertoire of tools that clinicians deploy to evaluate treatment effectiveness. They evaluate a person's views on how they feel physically or emotionally (i.e., symptom status), how well they can execute actions or participate in desired activities (i.e., functional status), or how they evaluate their health (i.e., general health perceptions) (1). For children with asthma, there are several measures of asthma symptoms (e.g., the Asthma Control Test (2–4)), and the impact of asthma symptoms on functional status (e.g., the PROMIS Asthma Impact Scale (5)) that are in widespread use.

A missing piece in the asthma patient reported outcome profile is a tool for assessing general health. This lacuna could be filled by the PROMIS Pediatric Global Health (PGH-7) scale, which assesses children's perceived general, physical, mental, and social health (6). The PGH-7 comprises 7 items and in general populations of children

has excellent reliability, and demonstrated convergent and discriminant validity with multiple measures of children's health status (7). The PGH-7 was designed to be used in any pediatric population, regardless of health condition, to describe and evaluate changes in global health. Cross-sectionally, differences in the PGH-7 between children with chronic and neurodevelopmental conditions range from effects of 0.5 to >1 standard deviation units (7). Although these results suggest that the PGH-7 can characterize the impact of health conditions on children's perceived health, its use specifically for children with asthma has not been studied.

This purpose of this manuscript is to evaluate the reliability and validity of the PGH-7 in children with asthma. To obtain a sample of children with a wide range of asthma illness severity, we recruited children presenting to a pediatric emergency department (ED) for asthma treatment. We evaluated the measure's reliability and validity at baseline (cross-sectional analysis) and 3 and 8 weeks after enrollment. For the longitudinal portion of this study,

we hypothesized that as the pathophysiological perturbations of asthma subsided with medical treatment, and over time, asthma symptoms and their impact on functional status would change first, and global health would improve more slowly, as all dimensions of a child's health improved.

Methods

The study involved cross-sectional and longitudinal assessments of convenience samples of children with asthma and their parents recruited from the ED at the Children's Hospital of Philadelphia. Research coordinators identified English-speaking children 5–17 years-old visiting the ED for treatment of asthma. Those triaged as critically ill (i.e., requiring airway intervention or actively resuscitated) and 8–17 year-old children who were unable to self-report about their health were ineligible. Parents only were enrolled if the child was 5–7 years-old, assuming all other inclusion criteria were satisfied, and the parent could provide proxy responses about their child's health; self-report and parent-proxy report were obtained for children 8–17 years-old. The Institutional Review Board of the Children's Hospital of Philadelphia approved the study protocol (IRB #13-010598). Parents gave informed consent, and children provided assent for the study.

Data were collected at 3 time points from February 2014 to February 2015. Time 1 data collection (February 2014 to December 2014) occurred in the ED. Time 2 data were collected from March 2014 to January 2015, a median of 20 days after baseline (range 14–32 days); and, Time 3 data were collected from May 2014 to February 2015, a median of 56 days after baseline (range 42–88 days).

Data collection

All data for this study were obtained via parent-proxy or child self-reported questionnaires. The Time 1 data were collected in the ED using tablet computers, which presented questions, one per screen. At Times 2 and 3, children and parents were contacted by a research survey firm (Temple University Institute for Survey Research (ISR)). E-mail reminders were sent every 3 days with a follow-up telephone call occurring daily after the e-mail reminder was sent. The timing of the telephone calls cycled through 3 different times during the day (morning, afternoon, and evening). Contact attempts continued until the follow-up period expired (4 weeks for Time 2 and 12 weeks for Time 3). Mailed letters were sent to participants' home addresses once if contact by e-mail or telephone call was unsuccessful. Participants were provided 2 options for

survey completion: (1) a web link and (2) a toll free number from which a computer-assisted telephone interview (CATI) was conducted.

Variables and measures

A variety of socio-demographic indicators and outcome measures were assessed at each of the time points (see Table 1). To assess financial strain, we measured food insecurity using a 2-item measure (8) and housing insecurity with a single item (9).

Two PROMIS measures were administered at each time point. The PROMIS PGH-7 was used to assess children's global health. This 7-item scale includes items that evaluate physical, mental, and social health (6). It has excellent concurrent validity with a variety of measures of physical, mental, or social health, as well as summary measures of health-related quality of life (7). An 8-item version of the PROMIS Asthma Impact Scale was used to assess the impact of asthma symptoms on functional status (5). Items use a 7-day recall period and address the effects of asthma on affect, sleep, and physical functioning. Both measures are scored on the PROMIS T-scale with a mean of 50 and standard deviation of 10, and they are scored in the direction of their name. Thus, improving health status would be associated with higher scores on the PGH-7 (better general health) and lower scores on the Asthma Impact Scale (fewer asthma symptoms).

A representative sample of US children was used to center the PGH-7 mean and establish its standard deviation while a sample of children with asthma were used for centering the Asthma Impact Scale. These T-scores can be converted into percentile ranks, which allow one to contrast a given score for an individual or group with the reference samples. Thus, a PGH-7 score of 45 (0.5 standard deviation units below the reference sample's mean) has a percentile rank of 31, which indicates that 69% of the 8–17 year-old children from the general US population had a higher score.

To examine change in PGH-7 score associated with a perceptible change in general health as rated by the child or the parent using an independent measure, we modified the subjective significance questionnaire developed by Osaba and colleagues (10). During the Time 2 survey, children and their parents were asked if their (or their child's) "health in general is better, the same, or worse" since they enrolled in the study. The same question was asked again at Time 3, but the question was indexed to completion of date of "the child's second survey."

We used 2 versions of the asthma control test. For children 5–11 years-old the childhood asthma control test (C-ACT) was used, which is a 7-item scale that includes 4

Table 1. Variables and measures by time point.

Variable name	Categories/definition	Time 1		Time 2		Time 3	
		Child survey	Parent survey	Child survey	Parent survey	Child survey	Parent survey
Sociodemographics							
Age	5–7 y; 8–12 y; 13–17 y	X	X	X	X	X	X
Gender	Male; female	X	X	X	X	X	X
Ethnicity	Hispanic/Latino; non-Hispanic/Latino	X	X				
Race	White; Black/African-American; Asian/Pacific Islander; other	X	X				
Parent/caregiver relationship to child	Mother; father; other		X				
Parent/caregiver educational attainment	Less than high school; high school and some college; college graduate or higher		X				
Food insecurity	Affirmative response to: in the past 12 months we worried whether our food would run out OR the food we bought just did not last		X				
Housing insecurity	Difficulty paying household gas, oil, or electricity bills in past 12 months; yes/no		X				
Outcomes							
Asthma Control Test (ACT)	Asthma symptoms, medication use, and impact of asthma on daily activities: 5–7 years-old: 7 items, parent reported 8–11 years-old: 4 self-reported items, 3 parent-reported items 12–17 years-old: 5 items, youth reported The ACT was dichotomized at 19 and below to form “not well controlled” and 20 and above “well controlled” categories.	X	X	X	X	X	X
PROMIS Pediatric Asthma Impact Scale	Asthma symptoms and the impact of asthma on functional status (8-item scale)	X	X		X	X	X
PROMIS Pediatric Global Health Scale (PGH-7)	Health overall across physical, mental, and social dimensions (7-item scale)	X	X		X	X	X
Change in general health status	Change in general health between 2 time points rated as better, same, or worse.				X	X	X

Table 2. Sample socio-demographic characteristics and PGH-7 scores at Time 1.

Socio-demographic Characteristic	Child, <i>n</i> (%)	Parent, <i>n</i> (%)	Child-Reported PGH-7		Parent-Proxy PGH-7	
			Mean (SD)	<i>p</i> -value	Mean	<i>p</i> -value
Total Sample	182 (100%)	328 (100%)	43.8 (7.9)	n/a	43.2 (9.0)	n/a
Age-Gender Groups						
Males						
5-7 years-old	n/a	102 (31)	n/a		44.4 (9.4)	
8-12 years-old	81 (44)	76 (23)	45.0 (8.0)		43.5 (9.4)	
13-17 years-old	23 (13)	23 (7)	45.2 (7.0)		40.9 (9.1)	
Females						
5-7 years-old	n/a	53 (16)	n/a		43.9 (9.4)	
8-12 years-old	45 (25)	40 (12)	44.0 (7.9)		40.8 (7.6)	
13-17 years-old	33 (18)	34 (11)	39.6 (7.0)	0.006	42.3 (8.4)	0.230
Race						
White	7 (4)	3 (1)	47.0 (7.1)		50.7 (13.9)	
Black or African-American	141 (80)	274 (84)	44.3 (8.1)		43.1 (9.2)	
Asian	2 (1)	1 (<1)	38.7 (4.5)		33.6 (n/a)	
Other	27 (15)	47 (15)	40.5 (7.3)	0.062	43.8 (7.7)	0.338
Ethnicity						
Hispanic or Latino	18 (10)	19 (6)	43.0 (8.2)		41.7 (8.0)	
Non-Hispanic	162 (90)	297 (94)	43.9 (8.0)	0.647	43.3 (9.0)	0.426
Worried food would run out or food did not last, past 12 months						
Yes	59 (36)	117 (36)	43.1 (7.9)		41.0 (8.0)	
No	123 (64)	211 (64)	44.3 (7.8)	0.327	44.4 (9.3)	<0.001
Did not pay full utility bill, past 12 months						
Yes	88 (54)	153 (47)	44.1 (6.8)		42.3 (8.3)	
No	94 (46)	175 (53)	43.6 (8.9)	0.682	44.0 (9.6)	0.108
Parental Age						
Less than 35 years	73 (45)	177 (55)	45.1 (8.7)		43.3 (9.7)	
35-44 years	58 (36)	102 (31)	44.0 (7.0)		43.2 (7.6)	
45+ years	31 (19)	46 (14)	41.1 (6.8)	0.059	43.0 (9.4)	0.973
Parental Educational Attainment						
Some high school	10 (6)	31 (10)	43.8 (8.3)		39.7 (10.6)	
High school or GED	44 (27)	92 (27)	44.7 (7.1)		42.6 (9.4)	
Some college/Technical degree/Associate	77 (47)	143 (44)	42.7 (7.8)		43.4 (8.7)	
College degree or higher	33 (20)	62 (19)	45.6 (8.6)	0.311	45.6 (7.8)	0.024

child-report (8–11 year-old children) and 3 parent-report items (2). Parents of children ages 5–7 years-old completed all 7 items. Child-report items have no recall period and address overall assessments of asthma control, interference with exercise, cough, and nighttime awakenings, while parent-report items use a 4-week recall period and cover daytime asthma symptoms, wheezing, and nighttime awakenings. The range of measure scores is 0 (poorest asthma control) to 27 (best asthma control). Scores from 0–19 indicate uncontrolled asthma and 20 and above controlled asthma (2, 11, 12). The asthma control test (ACT) was used for youth 12–17 years-old. It has 5 items, each with a 4-week recall period, that measure shortness of breath, nighttime awakenings, limitations of daily activities, rescue medication use, and rating of asthma control (3). Similar to the C-ACT, a score of ≤ 19 indicates uncontrolled asthma and 20 and above controlled asthma (3, 4, 13).

Statistical analysis

We compared the socio-demographic characteristics of the samples at each time point using the chi-square statistic. At Time 1, we contrasted PGH-7 scores by

socio-demographic characteristics using analysis of variance. A critical value of 0.05 was chosen to indicate statistical significance.

In cross-sectional analyses, we contrasted asthma impact and global health by asthma control status. Effect sizes were reported as Cohen's *d* (14), computed as the difference in means divided by the pooled standard deviation of the 2 samples. We considered Cohen's *d* values of 0.2 to <0.5 to be small effects, 0.5 to <0.8 moderately sized, and 0.8 and above large effects. We used the R package *effsize* (<https://cran.r-project.org/web/packages/effsize/index.html>) to compute the 95% confidence limits for effect sizes. Internal consistency was determined using Cronbach's alpha, estimated with a confidence interval using the *psych* package for R (<https://cran.r-project.org/web/packages/psych/index.html>). We also evaluated the effect of CATI versus self-administered mode of administrations at Times 2 and 3 by regressing PGH-7, Asthma Impact Scale, and ACT scores on an indicator for mode of administration, age, sex, and financial strain. Because there were a large number of contrasts, we used a critical value of 0.01 for statistical significance.

We examined responsiveness of the PGH-7 to changes in subjective assessments of change in general health overall between time points by combining those whose general health stayed the same or worsened into a single category and contrasting them with improvers. In addition, we assessed responsiveness of both the Asthma Impact Scale and the PGH-7 to changes over time in asthma control status among those who had uncontrolled asthma at Time 1 and either stayed the same (remained uncontrolled) or improved (developed controlled asthma). Our goal with this latter analysis was to estimate how much change in the PGH-7 occurs when there is a clinically meaningful change in asthma symptom status. The effect size estimate was obtained using a difference-in-difference approach in which the outcome was regressed on an indicator for group, an indicator for time point of assessment, and the interaction of group*time point. The interaction effect was reported as the estimate of responsiveness, which can be interpreted as the amount of change on the T-scale in the outcome associated with controlled versus uncontrolled asthma, while adjusting for each individual's baseline outcome score. Thus, these difference-in-difference estimates provide the average change over time in the outcomes by comparing the average change for children who improve with the average change for those who remain uncontrolled.

Results

We enrolled 182 children and 328 parents at Time 1. A greater number of parents than children were enrolled, because a large share of eligible children was 5–7 years-old, too young to administer the child self-report questionnaire. At Time 2, we followed up 312 participants (61% participation rate), including 92 children (51% participation rate) and 220 parents (67% participation rate), of which 50 children (54%) and 130 parents (59%) completed the survey via CATI. At Time 3, we followed up 252 participants (49% participation rate), including 74 children (41% participation rate) and 178 (54%) parents, of which 32 children (43%) and 97 parents (51%) completed the survey via CATI. There were no significant differences in PGH-7, Asthma Impact Scale, or ACT scores by mode of administration.

The mean age of children who participated in the child self-report Time 1 survey was 11.2 years (SD 2.6), and the mean age of children about whom the parent-proxy responded was 8.7 years (SD 3.4). The sample was predominantly African-American; less than 5% reported white race (Table 2). Parents also reported high levels of food insecurity and housing insecurity. We found no statistically significant differences across the 3 time points in any of the socio-demographic characteristics shown in

Table 3. PGH-7 by asthma control status and time point: cross-sectional analyses.

	Time 1			Time 2			Time 3		
	Controlled		Effect size ¹ (95% CI)	Controlled		Effect size (95% CI)	Controlled		Effect size (95% CI)
	Yes	No		Yes	No		Yes	No	
Child sample size, N (%)	36 (22%)	128 (78%)		42 (47%)	48 (53%)		42 (58%)	31 (42%)	
Parent sample size, N (%)	63 (20%)	255 (80%)		94 (44%)	120 (56%)		99 (57%)	76 (43%)	
Measure (respondent)									
PGH-7 (Child-report) mean (SD)	47.0 (8.1)	43.0 (7.5)	0.53 (0.15, 0.90)	47.6 (7.3)	44.6 (7.6)	0.40 (−0.02, 0.83)	49.0 (9.6)	41.4 (9.2)	0.81 (0.31, 1.30)
PGH-7 (Parent-proxy) mean (SD)	47.4 (9.1)	42.3 (8.7)	0.58 (0.30, 0.86)	46.4 (7.2)	40.3 (8.0)	0.79 (0.50, 1.07)	47.7 (8.9)	39.5 (8.3)	0.95 (0.63, 1.27)

¹Effect sizes were computed as the difference in means divided by the pooled standard deviation between the two groups. The 95% confidence intervals for bolded effect sizes do not cross zero.

Table 4. Responsiveness of PGH-7 to child- and parent-proxy reported change in general health.

	Time 2 versus Time 1			Time 3 versus Time 2		
	Improved	Same or worsened	Effect size ¹ (95% CI)	Improved	Same or worsened	Effect size (95% CI)
Child-reported change in global health						
Sample size, N (%)	74 (80%)	18 (20%)		46 (62%)	28 (38%)	
Measure (respondent)						
Global health (child) mean (SD)	46.9 (7.5)	42.1 (6.9)	0.64 (0.11, 1.17)	48.0 (9.4)	41.8 (10.4)	0.63 (0.14, 1.12)
Global health (parent-Proxy) mean (SD)	42.6 (8.0)	40.6 (7.6)	0.24 (−0.29, 0.77)	43.5 (8.8)	40.0 (9.4)	0.38 (−0.10, 0.86)
Parent-Proxy Reported Change in Global Health						
Child sample size, N (%)	72 (78%)	20 (22%)		41 (62%)	33 (38%)	
Parent sample size, N (%)	165 (75%)	55 (25%)		101 (57%)	77 (43%)	
Global health (child) mean (SD)	46.8 (7.6)	42.8 (6.7)	0.54 (0.03, 1.05)	45.9 (10.2)	45.3 (10.3)	0.06 (−0.41, 0.52)
Global health (parent-Proxy) mean (SD)	44.2 (8.0)	39.1 (8.0)	0.64 (0.32, 0.95)	46.5 (8.5)	40.8 (9.9)	0.63 (0.32, 0.94)

¹Effect sizes were computed as the difference in means divided by the pooled standard deviation between the two groups. The 95% confidence intervals for bolded effect sizes do not cross zero.

Table 2. We also contrasted those participants who completed all 3 waves of data collection with those involved in the baseline data collection only, and found no statistically significant differences in ACT, PROMIS Asthma Impact Scale, or PGH-7 scores.

Reliability

The reliability of the PGH-7 across the 3 time points was very good to excellent, ranging from 0.66 to 0.81 for child-report and 0.76 to 0.82 for parent-proxy. Across the 3 time points, the internal consistency reliabilities for the ACT were 0.80–0.85 for the 7 parent-reported asthma control items for 5–7 year-olds, 0.71–0.80 for the combination of 3 parent- and 4 child-reported items for 8–11 year-olds, and 0.67–0.80 for the 5 child-reported items among 12–17 year-olds.

Validity: Cross-sectional analyses

The average PGH-7 score for children treated in the ED for asthma was 43.8 (child-report) and 43.2 (parent-report), which is at the 27th and 25th percentiles, respectively. These values indicate that when in acutely ill, the global health experiences of children with asthma are poorer than about 75% of the US population of 5–17 year-old children. Child-reported global health declined with age for girls but not boys (Table 2). Parent-proxy reported global health was lower for children whose families reported food or housing insecurity and those with parents with less educational attainment.

We contrasted cross-sectional differences in mean scores for each time point by asthma control status and found similar effect sizes for child- and parent-proxy reported PGH-7, in the range of 0.50–0.95, indicative of moderate to large effects (Table 3). The effect sizes were substantially larger for the Asthma Impact Scale, from −0.85 to −1.72 for child-report and −1.02 to −1.58 for

parent-proxy report. The magnitude of the effect sizes increased from Time 1 to Time 3 for both outcomes.

Validity: Longitudinal analyses

At Times 2 and 3, both children and parents reported whether the child's general health overall (i.e., their global health) had improved or stayed the same/worsened since the last time point (Table 4). For child-reported changes in general health overall, the effect sizes were 0.6 for child-reported PGH-7, and 0.6 for parent-proxy PGH-7 in association with parent-reported change in children's general health.

We identified children who at baseline were characterized by the asthma control test as uncontrolled and then contrasted at Times 2 and 3 those who became controlled versus those who remain uncontrolled and computed the difference in either the Asthma Impact Scale or PGH-7 scores adjusted for differences between the two groups and change over time (Table 5). We detected sizeable decreases in the Asthma Impact Scale between Times 2 and 1 with drops of 8 and 6 points for child-report and parent-proxy report, respectively, and drops between Times 3 and 1 of 13 and 10 points in the PROMIS T-scores. On the other hand, we found no significant change in global health between Times 2 and 1, while there were significant differences (change in T-scores of 8 for child-reported and 5 for parent-reported in global health) when the contrast was done between Times 3 and 1.

Discussion

The PGH-7 provides an efficient, precise, and valid measure of children's overall health across a wide range of the latent variable and inclusive of their physical, mental, and social health (6, 7). This study, which enrolled children and their parents in a pediatric ED, adds to the PGH-7

Table 5. Responsiveness of the Asthma Impact Scale and PGH-7 to changes in asthma control by time point.¹

	Child-reported asthma impact Time 1 versus Time 2			Parent-reported asthma impact Time 1 versus Time 2		
	Uncontrolled -> Controlled	Uncontrolled -> Uncontrolled	Adjusted difference (95% CI)	Uncontrolled -> Controlled	Uncontrolled -> Uncontrolled	Adjusted difference (95% CI)
	Time 1 versus Time 3			Time 1 versus Time 3		
Number	28	39	- 8.5 (-13.8, -3.2)	59	107	- 6.3 (-10.3, -2.4)
Mean change (SD)	- 15.0 (9.7)	- 6.6 (9.5)		- 15.6 (11.2)	- 9.2 (11.7)	
Child-reported global health Time 1 versus Time 2						
Number	28	26	- 12.8 (-18.0, -7.5)	68	68	- 9.5 (-13.6, -5.4)
Mean change (SD)	- 16.6 (9.3)	- 3.8 (7.6)		- 16.2 (10.5)	- 6.7 (12.1)	
Parent-reported global health Time 1 versus Time 2						
Number	28	39	1.30 (-3.9, 6.5)	59	107	- 0.5 (-4.1, 3.1)
Mean change (SD)	2.8 (10.3)	1.6 (7.5)		- 1.1 (6.6)	- 0.6 (6.6)	
Child-reported global health Time 1 versus Time 3						
Number	28	26	8.0 (1.6, 14.4)	68	68	5.2 (0.9, 9.4)
Mean Change (SD)	5.7 (11.0)	- 2.3 (9.2)		2.5 (7.0)	- 2.6 (7.8)	

¹The adjusted difference is from a multivariable linear regression analysis that regressed the PGH-7 from the two time points on an indicator for asthma control, an indicator for time period, and the interaction between asthma control group and time period. The interaction term is reported as the adjusted difference.

evidence base by demonstrating that it is reliable, valid, and responsive to improvements in asthma control over an 8-week interval. In cross-sectional analyses, differences in PGH-7 between children whose asthma was controlled versus uncontrolled ranged from 0.5 to 0.9 standard deviation units. The PGH-7 was responsive to retrospective evaluations of changes in general health between time points, with effect sizes between around 0.6 standard deviation units.

In longitudinal analyses that followed children classified at Time 1 as having uncontrolled asthma, PGH-7 scores were no different between those who stayed uncontrolled versus became controlled at 3 weeks of follow-up; however, by 8 weeks of follow-up, the differences between these groups were about 0.7–0.8 standard deviation units, indicative of large effects. This slow change in PGH-7 in response to improvements in asthma control contrasts with the rapid change in the Asthma Impact Scale, which showed moderate to large effects by 3 weeks of follow-up and increasing effect sizes by 8 weeks. These findings support our hypothesis that clinical changes in a health condition, such as asthma, first affect symptoms, and their impact on functional status (i.e., Asthma Impact Scale), with slower change seen in general health perceptions, like global health (i.e., PGH-7). They also point out how the addition of the PGH-7 to a profile of asthma-specific symptom and functional status measures enhances the comprehensiveness of outcome assessment from the points of view of children and their parents.

Although this study provides evidence in support of the clinical validity of the PGH-7, responsiveness of a measure like the PGH-7, which is applicable to all children and all health conditions, is not demonstrated by a single investigation. Additional studies are needed to better characterize responsiveness among children whose asthma control changes from good to poor (our study evaluated improvements rather than worsening). More research also should be done to assess the validity of the PGH-7 among samples with socio-demographic diversity, a variety of health conditions, and objective measures of clinical change (e.g., lung function testing for asthma).

At each of the 3 time points, the PGH-7 score for children with controlled asthma was <50 on the PROMIS T-scale, indicative of lower than average global health, while the Asthma Impact Scale score dropped to <50 for those with controlled asthma, indicative of fewer symptoms and less impact on functional status than the asthma reference sample. Data from the National Survey of Children's Health demonstrated lower global health for children with asthma in the US (15). One explanation for this overall lower global health among children with asthma is the persistent nature of this health condition and resultant long-term effects on children's general

health perceptions, even when asthma symptoms are well controlled. Alternatively, our findings may be a result of the socio-demographic characteristics of sample population enrolled in this study.

Conclusions/key findings

This study provides empirical support for use of the PGH-7 to measure global health perceptions in children with asthma. Findings from this study also highlight the temporal effects on change in patient outcomes. Among individuals with asthma, there are both rapidly and slowly changing outcomes: lung function will be most rapidly responsive to medical intervention, followed by an individual's subjective assessment of their asthma symptoms, the impact of asthma symptoms on functional status, and finally global health. The availability of lung function testing, measures of asthma symptom and functional status (e.g., PROMIS Asthma Impact Scale), and the PGH-7 allow for a comprehensive characterization of an asthma episode of illness in both clinical research and clinical practice applications. Future research may benefit from combining these biological and self-reported measures into a profile of asthma health. Across both cross-sectional and longitudinal analyses from this study, we found that a change of approximately 0.5 standard deviation units, or a difference in the PGH-7 T-score of 4–5, is clinically meaningful in children with asthma.

Acknowledgements

We thank Allison Mak and Jason Marshall who provided excellent coordination of patient recruitment in the Children's Hospital of Philadelphia's emergency department.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

Funding

Supported by the Agency for Healthcare Research and Quality (grant number U18HS020508).

References

1. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. *JAMA*. 1995;273(1):59–65.
2. Liu AH, Zeiger R, Sorkness C, Mahr T, Ostrom N, Burgess S, et al. Development and cross-sectional validation of the Childhood Asthma Control Test. *J Allergy Clin Immunol*. 2007;119(4):817–825. doi:10.1016/j.jaci.2006.12.662. PMID: 17353040.

3. Nathan RA, Sorkness CA, Kosinski M, Schatz M, Li JT, Marcus P, et al. Development of the asthma control test: a survey for assessing asthma control. *J Allergy Clin Immunol.* 2004;113(1):59–65. doi:10.1016/j.jaci.2003.09.008. PMID: 14713908.
4. Schatz M, Sorkness CA, Li JT, Marcus P, Murray JJ, Nathan RA, et al. Asthma control test: reliability, validity, and responsiveness in patients not previously followed by asthma specialists. *J Allergy Clin Immunol.* 2006;117(3):549–556. doi:10.1016/j.jaci.2006.01.011. PMID: 16522452.
5. Yeatts KB, Stucky B, Thissen D, Irwin D, Varni JW, Dewitt EM, et al. Construction of the Pediatric Asthma Impact Scale (PAIS) for the Patient-Reported Outcomes Measurement Information System (PROMIS). *J Asthma.* 2010;47(3):295–302. doi:10.3109/02770900903426997. PMID: 20394514.
6. Forrest CB, Bevans KB, Pratiwadi R, Moon J, Teneralli RE, Minton JM, et al. Development of the PROMIS (R) pediatric global health (PGH-7) measure. *Qual Life Res.* 2014;23(4):1221–1231. doi:10.1007/s11136-013-0581-8. PMID: 24264804.
7. Forrest CB, Tucker CA, Ravens-Sieberer U, Pratiwadi R, Moon J, Teneralli RE, et al. Concurrent validity of the PROMIS(R) pediatric global health measure. *Qual Life Res.* 2016;25(3):739–751. doi:10.1007/s11136-015-1111-7. PMID: 26310283.
8. Hager ER, Quigg AM, Black MM, Coleman SM, Heeren T, Rose-Jacobs R, et al. Development and validity of a 2-item screen to identify families at risk for food insecurity. *Pediatrics.* 2010;126(1):e26–e32. doi:10.1542/peds.2009-3146. PMID: 20595453.
9. Kushel MB, Gupta R, Gee L, Haas JS. Housing instability and food insecurity as barriers to health care among low-income Americans. *J Gen Intern Med.* 2006;21(1):71–77. doi:10.1111/j.1525-1497.2005.00278.x. PMID: 16423128.
10. Osoba D, Rodrigues G, Myles J, Zee B, Pater J. Interpreting the significance of changes in health-related quality-of-life scores. *J Clin Oncol.* 1998;16(1):139–144. doi:10.1200/JCO.1998.16.1.139. PMID: 9440735.
11. Liu AH, Zeiger RS, Sorkness CA, Ostrom NK, Chipps BE, Rosa K, et al. The Childhood Asthma Control Test: retrospective determination and clinical validation of a cut point to identify children with very poorly controlled asthma. *J Allergy Clin Immunol.* 2010;126(2):267–273. doi:10.1016/j.jaci.2010.05.031.
12. Voorend-van Bergen S, Vaessen-Verberne AA, Landstra AM, Brackel HJ, van den Berg NJ, Caudri D, et al. Monitoring childhood asthma: web-based diaries and the asthma control test. *J Allergy Clin Immunol.* 2014;133(6):1599–1605.e2. doi:10.1016/j.jaci.2013.10.005. PMID: 24290276.
13. Schatz M, Mosen DM, Kosinski M, Vollmer WM, Magid DJ, O'Connor E, et al. Validity of the Asthma Control Test completed at home. *Am J Manag Care.* 2007;13(12):661–667. PMID: 18069909.
14. Cohen J. Statistical power analysis for the behavioral sciences. London, England: Routledge; 1988.
15. Simon AE, Chan KS, Forrest CB. Assessment of children's health-related quality of life in the United States with a multidimensional index. *Pediatrics.* 2008;121(1):e118–e126. doi:10.1542/peds.2007-0480. PMID: 18056290.