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# Impaired patient-reported outcomes predict poor school functioning and daytime sleepiness: the PROMIS® Pediatric Asthma Study

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# Abstract

**Objectives**—Poor asthma control in children is related to impaired patient-reported outcomes (PROs; e.g., fatigue, depressive symptoms, anxiety), but less well studied is the impact of PROs on children's school performance and sleep outcomes. This study investigated whether the consistency status of PROs over time impacted school functioning and daytime sleepiness in children with asthma.

**Methods**—Of the 238 children with asthma enrolled in the Patient-Reported Outcomes Measurement Information System® (PROMIS®) Pediatric Asthma Study, 169 children who provided survey data for all four time points were used in analysis. The child's PROs, school functioning, and daytime sleepiness were measured four times within a 15-months period. PROs domains included asthma impact, pain interference, fatigue, depressive symptoms, anxiety, and mobility. Each child was classified as having poor/fair vs. good PROs per meaningful cut-points. The consistency status of each domain was classified as consistently poor/fair if poor/fair status was present for at least three time points; otherwise, the status was classified as consistently good. Seemingly unrelated regression was performed to test if consistently poor/fair PROs predict impaired school functioning and daytime sleepiness at the fourth time point.

#### **CONFLICTS OF INTEREST:**

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At the time this study was conducted, Dr. Darren DeWalt was an unpaid member of the Board of Directors for the PROMIS Health Organization. Dr. DeWalt is also an author of some of the items in the PROMIS instruments and owns the copyright for these items. Dr. DeWalt has given an unlimited free license for the use of the materials to the PROMIS Health Organization. All other co-authors declare no conflicts of interest. No conflicts of interest to other co-authors. No honorarium and other form of payment was given to anyone to produce the manuscript.

**Results**—Consistently poor/fair in all PROs domains was significantly associated with impaired school functioning and excessive daytime sleepiness (p's <0.01) after controlling for the influence of the child's age, sex, and race/ethnicity.

**Conclusions**—Children with asthma with consistently poor/fair PROs are at risk of poor school functioning and daytime sleepiness. Developing child-friendly PROs assessment systems to track PROs can inform potential problems in the school setting.

#### Keywords

Asthma; Children; Daytime Sleepiness; Patient-Reported Outcomes; School Functioning

# INTRODUCTION

Asthma is the most prevalent chronic condition in children, with approximately 6.3 million American children (8.6%) carrying the diagnosis of asthma in 2014.<sup>1</sup> Children with inadequate asthma control status are more likely to experience impaired patient-reported outcomes (PROs), including worse respiratory symptoms, emotional disturbance, fatigue, and activity limitations than those with adequate asthma control status.<sup>2, 3</sup> Children with inadequate asthma control are also more likely to have increased health service use (i.e. asthma-related physician visits and emergency department visits) than those with adequate asthma control.<sup>4</sup>

Our review of literature revealed that the impact of PROs on school performance and daytime sleepiness in children with asthma is less well studied. Few studies have reported that children with asthma have an increased number of missed school days<sup>5</sup> and deficits of cognitive performance.<sup>4, 6</sup> Impaired cognitive performance may be partially explained by sleep disruption since children with asthma are likely to have nighttime sleep problems, which lead to excessive daytime sleepiness and poor academic performance.<sup>6</sup> Children with asthma from low-income families are especially vulnerable to poor health outcomes.<sup>7</sup> However, few studies have examined the associations for the consistency of PROs with school functioning and daytime sleepiness in children with asthma.

The main aim of this study was to examine longitudinal associations of PROs consistency status with school functioning and daytime sleepiness in children with asthma. We hypothesized that a child with asthma with consistently poor/fair PROs will have poor school functioning and excessive daytime sleepiness compared to those with consistently good PROs.

#### METHODS

#### Study Sample

Data used were obtained from the PROMIS Pediatric Asthma Study (PAS), which was funded by the U.S. National Institutes of Health. PROMIS PAS is a retrospective cohort study initially designed to evaluate responsiveness of the PROMIS Pediatric measures.<sup>8</sup> Between 2010 and 2011, a sample of 238 children was recruited from public insurance programs, the Florida Medicaid and State Children's Health Insurance Program (SCHIP). To

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be eligible, participants were between ages 8 and 17.9; had an asthma diagnosis (ICD-9-CM 493.1, 493.2, or 493.x); had at least two medical events caused by asthma in the last year; and had uninterrupted enrollment in the Florida Medicaid or SCHIP for the previous six months. Those who could not read and speak English and did not have Internet access in the past six months were excluded. Informed consent was received from parents/legal guardians during the enrollment phone calls. Subsequently, parents/legal guardians and children gave consent and assent, respectively, on the survey website prior to study participation. University of Florida Institutional Review Board approved the protocol.

#### **Data Collection**

Our previous publications have detailed the methods for data collection.<sup>8, 9</sup> The PROMIS PAS collected data from children with asthma via telephone interviews over two 13-week time periods. In each period, asthma control was evaluated weekly and PROs were collected from two time points (denoted T1 and T2 in the first period and T3 and T4 in the second period). Given the initial design was to test responsiveness of the PROMIS Pediatric measures, PROs were collected at T1 and T3 during the first of the 13 weeks (baselines), and at T2 and T4 whenever the asthma control status changed (better or worse). If asthma control remained the same compared with each baseline, PROs were collected at week 13 of each period. Two cohorts of participants were used to account for the influence of seasonality effects on asthma control status. The fall cohort had data collected between September and December in 2010 for T1 and T2 and in 2011 for T3 and T4. The spring cohort had data collected between February and May in 2011 for T1 and T2 and in 2012 for T3 and T4.

#### Measures

The PROMIS Pediatric Short Forms (SFs; see Online Supplement) were used to measure six PROs domains: asthma impact (8 item),<sup>10</sup> pain interferences (8 items),<sup>11</sup> fatigue (10 items),<sup>12</sup> depressive symptoms (8 items),<sup>13</sup> anxiety (8 items),<sup>13</sup> and mobility (8 items).<sup>14</sup> Domain scores were summed and transformed to a T-metric with a mean of 50 and a SD of 10.15 Lower scores on the mobility domain signified worse PROs.14 Otherwise, higher scores signified worse PROs.<sup>10-13</sup> For each time point, a child's PROs domain was classified as meaningfully poor/fair if the score differed by 5 points of 50 on the T-metric (i.e., 0.5 SD from the norm as a clinically meaningful difference).<sup>16</sup> Specifically, a child with scores >45 on asthma impact, pain interference, fatigue, depressive symptoms, and anxiety domains was considered as poor/fair PROs. A child with scores <55 on the mobility domain was considered as poor/fair PROs. Given that the ultimate goal of asthma therapy is to maintain a patient's PROs in a normal range, this is a useful approach because it compares each patient's PROs scores to the norm. For analyzing consistency status of PROs, children with poor/fair PROs at three or more time points were defined as having consistently poor/fair PROs; otherwise, they were defined as having consistently good PROs. Due to a small sample size, children who were poor/fair in the first two time points and then good in the other two time points or vice versa were collapsed into a single consistently poor/fair PROs category. Therefore, PROs status was categorized as consistently poor/fair or consistently good for statistical analysis.

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School functioning was measured using the PedsQL Core v4 (5 items), a tool created to measure PROs in physical, emotional, social, and school functioning domains using a 5-point Likert scale (see Online Supplement).<sup>17</sup> This study only focused on the school functioning domain as one of the outcome variables with higher scores denoting better school functioning. Daytime sleepiness, defined as the inability to maintain wakefulness throughout the day, was measured by the Pediatric Daytime Sleepiness Scale (8 items) using a 5-point Likert scale with higher scores denoting more daytime sleepiness. Item response categories ranged from 'always getting sleepy' to 'never getting sleepy.'<sup>18</sup>

#### Statistical Analysis

Seemingly unrelated regression (SUR) was performed to test associations of PROs consistency status (T1 through T4) in each domain with school functioning and daytime sleepiness at T4 by adjusting for important covariates (participant's age, sex, and race/ ethnicity).<sup>19</sup> Separate analyses were also performed on the fall and spring cohorts to test the influence of seasonality on asthma control status. SUR is a linear regression model that evaluates multiple linear regression equations simultaneously in the analysis, and each regression equation contains its own dependent variable (school functioning and daytime sleepiness in this study). SUR is used because the two dependent variables are related to one another. Technically, SUR accounts for this issue by correlating the error terms of individual linear regression models; otherwise, the estimation of regression coefficients would be biased.

# RESULTS

#### Participant Characteristics (Table 1)

Of the 238 children who enrolled in the PROMIS PAS, 169 children who provided survey data for all four time points, including school functioning and daytime sleepiness, were included in statistical analyses. Among children, the mean age was 12.0 (SD 2.4) years old, 57.4% were male, and most were non-white (65.1%). Among parents, the majority had a household income under 35K (63.9%) and were married (52.1%). Consistently poor/fair PROs across four time points were found on asthma impact in 59.8% of children, pain interference (58.6%), fatigue (63.9%), depressive symptoms (66.5%), anxiety (55.6%), and mobility domains (83.5%).

# Multivariable Associations of Consistently Poor/Fair PROs with School Functioning and Daytime Sleepiness (Table 2)

Children who had consistently poor/fair PROs on asthma impact, pain interference, fatigue, depressive symptoms, anxiety, and mobility domains experienced more impaired school functioning at T4 than those who had consistently good PROs (betas: -14.6, p<0.001; -21.7, p<0.001; -15.7, p<0.001; -13.4, p<0.001; -14.1, p<0.001; -13.2, p<0.01). Additionally, Children who had consistently poor/fair PROs on asthma impact, pain interference, fatigue, depressive symptoms, anxiety, and mobility domains experienced more daytime sleepiness at T4 than those who had consistently good PROs (betas: 2.4, 2.9, 2.9, 2.1, 1.9, and 2.8, all p's <0.01). The magnitudes for associations in fall cohort were slightly larger than the spring cohort, except for depressive symptoms/anxiety associated with school functioning.

# DISCUSSION

This study found PROs that were consistently poor/fair in all domains were significantly associated with impaired school functioning and excessive daytime sleepiness. Our<sup>8, 9</sup> and other<sup>20</sup> previous studies have reported that poor asthma control status leads to decremented PROs in a longitudinal design; however, those studies did not examine whether consistently poor PROs impact school functioning and daytime sleepiness. From a design viewpoint, the consistency status approach differs from traditional longitudinal analytic approaches (e.g., generalized estimating equation). Traditional approaches focus on the averaged associations between the predictors and outcomes by accounting for clustering effects of repeated outcomes within an individual.<sup>21</sup> In comparison, the consistency status of PROs provides a perspective on an individual's PROs over time and accentuates their unique situation. Measuring PROs consistently allows clinicians to discern which participants experience truly poor/fair PROs and which occasionally experience poor/fair PROs. It is important to design interventions for outcome improvement if children are identified with consistently impaired PROs.

Previous studies have reported that children with asthma suffer from suboptimal school performance and daytime sleepiness.<sup>5, 6</sup> This study further suggests that the consistently poor/fair PROs in different domains indicate problems with school functioning and daytime sleepiness. Notably, we found that consistently poor/fair mobility predicted impaired school functioning and excessive daytime sleepiness. Evidence reveals that an increase in physical functioning is associated with improved executive functioning and restorative sleep.<sup>22, 23</sup> Therefore, maintaining consistently good mobility can lead to good school functioning and less daytime sleepiness.

Our findings provide implications for clinical practice and research. First, it is important to collect PROs data from children with asthma on a regular basis to monitor the consistency status. PROs data have been frequently measured in hospitals or clinics, yet to collect PROs consistently, PROs must be measured from school and home settings. As the integration of patient health information into electronic medical records becomes commonplace, there has been a push to include psychosocial measurements performed by children in the home environment.<sup>24</sup> Second, successful implementation of routine PROs assessment will require a user-friendly, low-cost platform to collect data from children with asthma. A commitment to a dynamic approach (e.g., computerized adaptive tests and mobile technology) could offer an efficient route to collect PROs data longitudinally.<sup>25</sup> Proactive assessment of PROs will allow clinicians and parents to monitor problematic school functioning and daytime sleepiness. Future studies are encouraged to investigate appropriate frequency and intervals that PROs assessment should be performed.

This study has several limitations. First, the cohort was obtained using enrollees of a public health insurance program. Since children from low-income families have high incidence of asthma,<sup>7</sup> our results might not be generalized to other populations. However, low-income populations are vulnerable to poor health outcomes and deserve specific attention. Second, participants were recruited solely from Florida; therefore, our results may not be generalizable to other populations. Third, PROMIS PAS did not collect academic

performance (e.g., report cards) and sleepiness-related objective outcomes (e.g., inflammation biomarkers) from participants. However, this study provides an important foundation for future studies to link PROs consistency status with objective academic performance and clinical-based sleepiness outcomes to identify psycho-behavioral pathology. Fourth, additional variables (e.g., housing availability and food insecurity) that may confound the association of PROs with school functioning and daytime sleepiness were not collected in the PROMIS PAS. These variables should be tested in future studies. Fifth, given a small sample size, individuals were classified into only two subgroups (i.e., three or more time points of poor/fair PROs as consistently poor/fair PROs; otherwise, consistently good PROs) although different consistency statuses exist (e.g., two time points with poor/fair PROs as intermediate patterns between consistently poor/fair and good). Using a larger sample, more subgroups would have been categorized.

# CONCLUSION

With the significant associations of consistently poor/fair PROs with poor school functioning and daytime sleepiness, this study supports the notion that long-term and consistent monitoring of PROs can help identify children with asthma at risk of poor school functioning and daytime sleepiness. Collecting accurate and complete information of PROs will help design future interventions for high risk populations.

#### Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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# WHAT'S NEW?

This is the first study analyzing longitudinal consistency status of PROs in children with asthma to determine the impact on school functioning and daytime sleepiness. Children with poor/fair longitudinal PROs had significantly impaired school functioning and daytime sleepiness.

#### Table 1

# Participant Characteristics (N=169)

	Mean +/- SD
Child's Age	12.01 +/- 2.41
	Frequency (%)
Child's Sex	
Male	97 (57.4%)
Child's Race	
Non-Hispanic White	59 (34.9%)
Non-Hispanic Black	48 (28.4%)
Hispanic	44 (26.0%)
Other (American Indian/Alaskan, Asian, Native Hawaiian/Pacific Islander, or Other)	18 (10.7%)
Mother's Education	
High School or Below	53 (31.7%)
College Degree or Some College	104 (62.3%)
Advanced Degree	10 (5.9%)
Household Income	
<15K	32 (18.9%)
15K-35K	76 (45.0%)
35K-55K	45 (26.6%)
>55K	16 (9.5%)
Parent Marital Status	
Married	88 (52.1%)
Other (Never Married, Living with Partner, Separated, Divorced, or Widowed)	81 (47.9%)
Consistently Poor/Fair PROs	
Asthma Impact	98 (59.8%)
Pain Interference	95 (58.6%)
Fatigue	106 (63.9%)
Depressive Symptoms	109 (66.5%)
Anxiety	90 (55.6%)
Mobility	137 (83.5%)

#### Table 2

Multivariable associations of consistently poor/fair PROs with school functioning and daytime sleepiness<sup>i</sup>, <sup> $\ddagger$ </sup>

	School Functioning (T4)	Daytime Sleepiness (T4)
Consistently Poor/Fair PROs (T1 through T4)	Regression Coefficient (95% CI)	Regression Coefficient (95% CI)
Overall: Fall and Spring Cohorts		
Asthma Impact	-14.59 (-20.87, -8.33) ***	2.42 (0.64, 4.21)**
Pain Interference	-21.67 (-27.76, -15.58) ***	2.93 (1.10, 4.77) **
Fatigue	-15.69 (-22.41, -8.98)***	2.85 (0.84, 4.86) **
Depressive Symptoms	-13.37 (-20.11, -6.64)***	2.12 (0.17, 4.06) **
Anxiety	-14.05 (-20.28, -7.81)****	1.94 (0.14, 3.77) **
Mobility	-13.18 (-21.50, -4.87)***	2.84 (0.47, 5.21) **
Fall Cohort Only		
Asthma Impact	-17.78 (-25.60, -9.95)***	2.14 (-0.17, 4.46)
Pain Interference	-22.15 (-30.13, -14.16)***	2.99 (0.54, 5.43) *
Fatigue	-14.26 (-22.78, -5.75) ****	3.52 (0.81, 6.24) *
Depressive Symptoms	-10.49 (-19.21, -1.77)*	1.62 (-0.95, 4.20)
Anxiety	-8.90 (-17.25, -0.56)*	1.83 (-0.57, 4.23)
Mobility	-15.33 (-25.52, -5.15)***	3.82 (0.84, 6.79)*
Spring Cohort Only		
Asthma Impact	-11.47 (-22.32, -0.61)*	2.94 (0.23, 5.65)*
Pain Interference	-21.74 (-31.62, -11.86) ***	3.09 (0.44, 5.74) *
Fatigue	-19.16 (-30.05, -8.28)***	2.38 (-0.44, 5.20)
Depressive Symptoms	-19.49 (-30.03, -8.94)***	3.27 (0.43, 6.11)*
Anxiety	-21.64 (-30.99, -12.29)****	2.34 (-0.33, 5.02)
Mobility	-10.63 (-25.12, -3.87)*	0.77 (-3.02, 4.55)

\* P<0.05;

> \*\* P<0.01;

\*\*\*\* P<0.001

 $^{\not\!\!\!\!\!\!\!\!\!\!\!\!}^{} Adjusting for a child's age, sex, and race/ethnicity$ 

<sup>‡</sup>Higher scores for better outcomes on school functioning and worse outcomes on daytime sleepiness