



Effect of a mobile health, sensor-driven asthma management platform on asthma control



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ABSTRACT

Background: Asthma inflicts a significant health and economic burden in the United States. Self-management approaches to monitoring and treatment can be burdensome for patients.

Objective: To assess the effect of a digital health management program on asthma outcomes.

Methods: Residents of Louisville, Kentucky, with asthma were enrolled in a single-arm pilot study. Participants received electronic inhaler sensors that tracked the time, frequency, and location of short-acting β -agonist (SABA) use. After a 30-day baseline period during which reference medication use was recorded by the sensors, participants received access to a digital health intervention designed to enhance self-management. Changes in outcomes, including mean daily SABA use, symptom-free days, and asthma control status, were compared among the initial 30-day baseline period and all subsequent months of the intervention using mixed-model logistic regressions and χ^2 tests.

Results: The mean number of SABA events per participant per day was 0.44 during the control period and 0.27 after the first month of the intervention, a 39% reduction. The percentage of symptom-free days was 77% during the baseline period and 86% after the first month, a 12% improvement. Improvement was observed throughout the study; each intervention month demonstrated significantly lower SABA use and higher symptom-free days than the baseline month ($P < .001$). Sixty-nine percent had well-controlled asthma during the baseline period, 67% during the first month of the intervention. Each intervention month demonstrated significantly higher percentages than the baseline month ($P < .001$), except for month 1 ($P = .80$).

Conclusion: A digital health asthma management intervention demonstrated significant reductions in SABA use, increased number of symptom-free days, and improvements in asthma control.

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Introduction

Asthma affects 1 in 12 individuals in the United States,¹ disproportionately affecting children, women, African Americans, and those living in poverty.² Despite decades of pharmacologic and clinical progress, disease morbidity has not decreased substantially. Each year in the United States, 1.8 million asthma-related emergency department visits and 439,000 asthma hospitalizations occur,³ with overall costs reaching \$56 billion.⁴

Despite the launch of major strategic initiatives, such as Healthy People 2020 and the National Asthma Education and

Prevention Program (NAEPP),⁵ which emphasize appropriate management and control, most individuals with asthma do not have adequate control^{6–10} of their symptoms.¹¹ Improved monitoring, management and control reduce health care use¹²; however, the absence of real-time data collection has hindered the ability to monitor patients and improve treatment, especially self-management. The National Heart, Lung, and Blood Institute's NAEPP, Global Initiative for Asthma, and American Thoracic Society clinical practice guidelines recommend that physicians monitor patients' frequency of short-acting β -agonist (SABA) use as an important indicator of asthma control and impairment.^{5,13–15} Most patients and caregivers lack objective ways to assess asthma symptoms and often underestimate their frequency and severity.¹⁴ Survey tools, such as the Asthma Control Test (ACT), can assist in assessing level of control¹⁴ but are limited by infrequent administration and recall bias.

Digital health interventions, such as those leveraging short message service, websites, and sensor technology, are being used increasingly in clinical interventions for asthma. Studies have revealed the effectiveness of digital interventions in improving clinical outcomes, including asthma control and adherence; however, these studies largely occurred within a clinical setting with consistent clinical oversight.^{6–10} This pragmatic single-arm pilot study aimed to test whether a digital health intervention could improve specific asthma outcomes in a real-world setting, primarily through participant self-management, without systematic clinical oversight. We hypothesized that a digital health intervention would result in increased frequency of symptom-free days, reduced frequency of SABA use, and improved asthma control.

Methods

The study was reviewed and approved by the Copernicus Group Independent Review Board. The study received written informed consent from all participants, including written consent from guardians on behalf of minors enrolled in the study.

The Sensor and Digital Health Intervention

The electronic inhaler sensor used in the study passively and objectively monitors the use of metered dose inhalers, capturing the date and time of use (Fig 1) (Propeller Health, Madison, Wisconsin). The sensor stores up to 3,900 actuations and transmits the information via Bluetooth to a paired smartphone, which determines the geographic location of the use and communicates the information to secure servers. For those participants without a smartphone, a wireless hub was used for data transmission. Either device automatically downloads new actuations from the sensor whenever it is in range (<25 m) and securely uploads this information to encrypted servers. All protected health information associated with the platform is encrypted at rest and in motion in compliance with the Health Insurance Portability and Accountability Act of 1996 privacy laws. The sensor and data transmission processes are fully described elsewhere.¹⁶

The sensor is a component of a US Food and Drug Administration–cleared digital health platform aimed at promoting self-management and consists of mobile applications, web-based dashboards, and other communication channels, such as short message service and e-mail.¹⁶ Smartphone applications designed for both Android and iOS devices are available in English and Spanish.

These tools aim to promote disease awareness and self-management by enabling the participants to access their own analyzed data, including objective assessments of asthma control, adherence, and potential triggers, and receiving education derived from the national guidelines.⁵ In addition, participants were able to authorize their health care practitioners to view their collected data and summary reports through a web interface, which enabled practitioners to integrate timely information about SABA use into their clinical decision making.

Participant Identification and Enrollment

The pilot study recruited individuals from community asthma activities, clinics, and retail pharmacies. Individuals were eligible if they reported a physician diagnosis of asthma, were 4 years or



Figure 1. Electronic sensor attached to a metered-dose inhaler canister, paired with the smartphone and web applications that present visualized data and trends.

older, and had a current prescription for a SABA. Individuals were excluded if they (1) were younger than 4 years, (2) did not speak English, (3) did not have access to the internet, or (4) had substantial comorbidity that would influence their participation or disease status, such as chronic obstructive pulmonary disease, heart failure, or lung cancer. All interested and eligible residents received a kit that included a sensor with instructions for self-enrollment. A 30-day baseline period served to ensure enrollment of individuals adherent with the study requirements. To be included in the study, the participant had to create an account, activate the sensor, and remain active, as defined by sensor syncing, for the first 30-day baseline period. Recruitment occurred between June 2012 and January 2013, with the last participant exiting the program in January 2014. Electronic surveys administered at intake collected demographic information, including age, sex, and race.

Data Collection

Participants attached the sensor to their SABA medications, which tracked the time and location of SABA use for up to 13 months.¹⁷ The 30-day baseline period assessed baseline asthma control and SABA use. SABA actuations were tracked during this time, but neither participants nor physicians received access to the data. After the baseline period, participants received full access to the digital health intervention for up to 12 months. SABA use data were recorded and presented to study participants via mobile apps, online dashboards, weekly e-mail reports, and text message reminders. This communication provided an ongoing assessment of the participants' asthma control based on the national guidelines criteria, as well as personalized information to encourage and support appropriate self-management.⁵ All participants were invited to share reports with their health care practitioners, but sharing was not required. Participants were included in the analysis if they received at least 30 days of the digital health intervention after the baseline period, meaning that they were enrolled, synced a sensor, and remained syncing a sensor for at least 60 days. Syncs occur at a regular cadence and demonstrate that the sensor is capable of collecting and transmitting data via a smartphone or hub; syncs do not require actuation of the medication. There were no thresholds for inclusion based on amount of SABA use; participants at all levels of SABA use were included as long as the number of syncing days exceeded 60. All available data were included up until the date of their last sensor sync.

Asthma Outcome Measures

Primary outcome measures included mean daily number of SABA actuations, symptom-free days, and asthma control. All 3 measures were assessed using data passively collected by the inhaler sensor. Following American Thoracic Society and European Respiratory Society guidance,¹⁴ SABA actuations occurring within a 2-minute period were considered a single medication use event, although the individual inhalations were retained as discrete records in the database and served as a validation of this measurement. The time, date, and location (when available) of each actuation were recorded. Each 24-hour period without a SABA actuation was counted as a symptom-free day. The proportion of participants with a symptom-free day was calculated for each day of the program, with the denominator including all active participants on that day of the program, defined as those who synced after that date.

Asthma control was evaluated using 2 validated methods. At study intake, the ACT^{18,19} was completed by participants 12 years or older. Children younger than 12 years at study intake took the Childhood ACT (C-ACT).¹⁹ The ACT and C-ACT scores greater than 19 indicate that asthma is well controlled.^{13,14} During the study, asthma control was calculated weekly based on the timing and

frequency of SABA collected by the sensor, as described in the NAEPP guidelines⁵ (eTable 1). For example, asthma is considered not well controlled if more than 2 daytime events requiring SABAs occur twice during the prior 7 days (excluding use before exercise) and/or more than 2 nighttime events requiring SABAs occur during the prior month.

Statistical Analysis

The analyses compared the change in the number of SABA actuations, symptom-free days, and level of asthma control between the initial control period and all subsequent months of the intervention. Mixed-model regressions with a random intercept for each participant were used to account for the repeated observations of each person, with indicator variables for each month of the program. Poisson regression was used for analysis of daily SABA events and logistic regression for analysis of symptom-free days and asthma control. As a sensitivity analysis for the effect of selective attrition, the analyses were rerun after excluding individuals with incomplete follow-up. A *P* value significance threshold of .05 was used in all analyses, which were conducted using R, version 3.01.²⁰

Results

Participant Enrollment, Retention, and Engagement

Participant enrollment (*N* = 120) occurred at community activities (31%), community pharmacies (21%), specialty clinics (20%), community programs (9%), and other locations (19%). Of these participants, 95 completed the 30-day baseline period and received at least 30 days of the intervention and were included in the analyses. Participants ranged from 5 to 67 years of age, with a mean age of 28 years, and 57% were female (Table 1). At enrollment, 54 participants (57%; 44 adults and 10 children) completed an ACT. At intake, the mean adult ACT score was 18.6, with 43% of the participants considered controlled. The mean C-ACT score was 17.8, with 40% of children considered controlled. Participants who successfully completed at least 30 days of the intervention did not differ significantly by race, sex, age, or baseline ACT scores compared with those who did not.

Participants remained active in the program for a mean of 264 days (8.8 months). Fifty-nine percent opted to share their asthma data with their practitioner, a parent, or another family member. All participants younger than 12 years shared access to their data with a parent. Of participants older than 12 years, 30% shared data with their practitioner and 6% shared with a family member. Across all participants who shared their data with their practitioner, 66% were enrolled directly through their practitioner through a private specialty practice.

Asthma Outcomes

The sensors collected and uploaded 25,096 person-days (68.8 years) of data on inhaler use, which included 4,559 SABA events (mean of 1 event every 5 days). Participants recorded a mean of 0.18 SABA events per person per day (range, 0–19), and a mean of 0.33 puffs per person per day (range, 0–104). Across participants, 85% recorded at least one SABA event. SABA use was inversely correlated with ACT scores; participants with initially uncontrolled asthma recorded a mean of 0.73 SABA uses per person per day during the baseline period vs 0.20 for patients with initially controlled asthma.

The mean number of SABA events per participant per day was 0.44 during the control period (*n* = 95) and 0.27 during month one of the intervention (*n* = 95), indicating a 39% reduction in SABA use (Fig 2). Reduction in SABA use was observed throughout the study; each intervention month demonstrated significantly lower SABA use than the baseline month (*P* < .001). At month 12, SABA use had

Table 1
Demographic Characteristics of Analyzed Program Participants and Their Potential Exposures in the Home

Characteristic	Finding ^a
Female (n = 53)	57
Age, mean (SD) [range], y (n = 95)	28 (18.3) [5–67]
Children <12 y (n = 95)	35
ACT score at study intake, mean (SD) [range]	
Adults (≥12 y) (n = 44)	18.6 (4.45) [6–25] (43% controlled)
Children (<12 y) (n = 10)	17.8 (3.74) [13–27] (40% controlled)
Race (n = 53)	
African American	31
White	58
Hispanic	1
Native American	3
Other	8
Shared data (n = 95)	
Any sharing	59
<12 years old and signed up with parent	100
<12 years old and share with practitioner	10
≥12 years old and shared with family member	6
≥12 years old and shared with practitioner	30
Device type (n = 95)	
Smartphone (Android)	52
Smartphone (iOS)	36
No smartphone (Qualcomm Base station)	12
Tobacco exposure (n = 53)	
Current smoker	6
Used to smoke	4
No smoke exposure in home	76
Other people smoke outside home	12
Other people smoke inside home	4
Pet exposure in the home (n = 53)	
>1 pet at home	28
1 pet at home	28
No pets	44

Abbreviation: ACT, Asthma Control Test.

^aData are presented as percentage of participants unless otherwise indicated.

further decreased but among a smaller group of participants (n = 35). To evaluate the effect of selective attrition, a sensitivity analysis was conducted across groups of participants with varying length of follow-up. This analysis demonstrated significant improvements over time in all groups regardless of the maximum follow-up duration.

The percentage of symptom-free person-days was 77% during the baseline period (n = 95) and 86% after the first month of the intervention (n = 95), demonstrating a 12% improvement in the

percentage of symptom-free days (Fig 3). Improvement in symptom-free days was maintained throughout the study; results from the logistic mixed-model regression reveal that symptom-free days during the baseline month were significantly lower than in all subsequent months ($P < .001$). At month 12, among a smaller group of participants (n = 35), the percentage of symptom-free days was 95%, representing a 23% improvement from baseline to study exit.

The percentage of participants with well-controlled asthma, as measured by the control score reflecting SABA use, similarly revealed sustained improvement during the intervention (Fig 4). Sixty-nine percent had well-controlled asthma during the baseline period and 67% during the first month of the intervention (Fig 4). Improvement in the percentage of participants with well-controlled asthma was observed throughout the study; each intervention month had significantly higher percentages than the baseline month ($P < .001$), except month 1 ($P = .80$). Conversely, the percentage whose asthma was poorly controlled decreased during the program.

Discussion

Improvement in Asthma Outcomes and Self-management

The results from this pragmatic pilot study indicate that routine, passive collection of objective SABA use data and the provision of this information to patients, which can help illuminate possible asthma triggers, may improve self-awareness, self-management, and asthma outcomes. Participants experienced significant reductions in the frequency of SABA use, increased frequency of symptom-free days, and improved asthma control. These improvements are noteworthy because they occurred in a real-world setting, even in the absence of consistent clinical supervision.

The results of this program are consistent with evidence from previous studies demonstrating that digital health tools have a positive effect on asthma outcomes when implemented with consistent clinical oversight.^{6–10} Through consistent monitoring, immediate feedback, and treatment advice, digital tools have demonstrated significant improvements in assessing and promoting adherence^{6–8} and improving other asthma outcomes, including symptoms, control, quality of life, lung function, airway responsiveness, symptom-free days, and reducing exacerbations and unscheduled clinic visits.^{21–27} Previous studies of digital health interventions found significant improvements in asthma control and a significant reduction in the frequency of asthma symptoms and SABA use with strong clinical oversight.^{10,28} This is the first

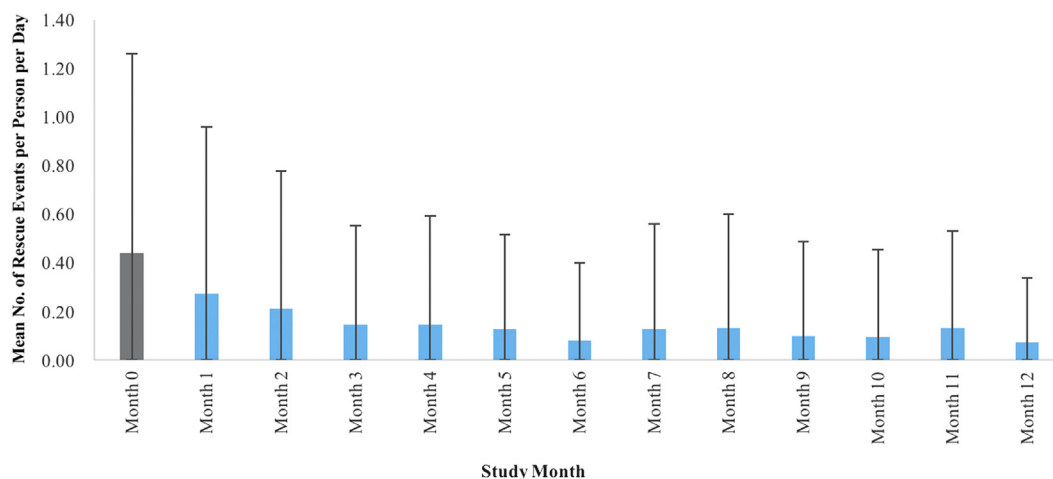


Figure 2. Mean short-acting β -agonist use per active participant per day of the program, aggregated by month, with error bars representing 1 SD.

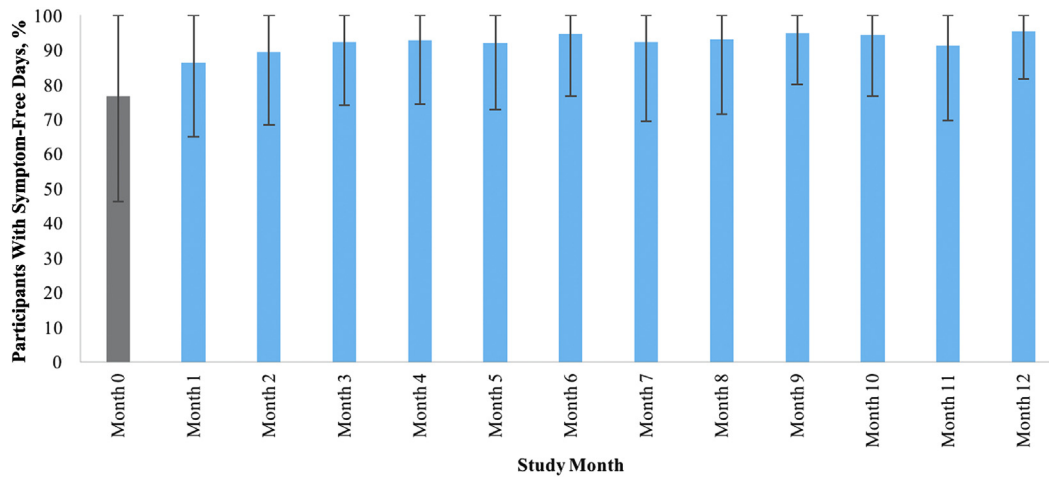


Figure 3. Percentage of active participants with a symptom-free day for each day of the program, aggregated by study month, with error bars representing 1 SD.

study of a digital health intervention to demonstrate that outcomes can improve as a result of self-management.

Potential Mechanisms That Drive Improvement

Several factors may have influenced improvements in asthma outcomes but were not assessed directly in this study. First, the data collected may have promoted improved self-awareness. Clinical guidelines emphasize patient self-awareness through education and self-tracking,⁵ yet many patients incorrectly perceive their level of control.^{11,29} In one recent study, more than 4 of 5 individuals with poorly controlled asthma regarded their disease as well controlled or very well controlled.¹¹ The sensor used in this study permits routine capture of the date, time, and number of SABA actuations, enabling the frequent evaluation of asthma control status as a function of nighttime and daily SABA use and potentially leading to a more accurate perception of control. This passive and objective method of data collection, which requires little additional time or effort from the participant, eliminates the need for self-reporting symptoms and medication use, which is fraught with recall error and is burdensome for the patient. Although not studied in this program, other studies have found that objective monitoring of inhaled corticosteroids and the use of audiovisual reminders can promote adherence to controller therapy.^{6,8} Second, the digital platform collected data on environmental factors, such as temperature, humidity, and air quality levels,

associated with SABA use. The insights from this information may have influenced individuals to avoid or mitigate identified exposures in their home, work, and school environments. Third, objective data may support practitioners in delivering guideline-concordant care. The NAEPP guidelines recommend that at each clinic visit of a patient practitioners assess the following: asthma symptom frequency, control, inhaler technique, adherence, environmental control, patient concerns, and the presence of a written asthma action plan.⁵ Although practitioners should then use this information to make medication adjustments as appropriate, they are often limited by time. Thus, the availability of objective SABA use data may improve adherence to guidelines by increasing the ease and frequency of symptom and control assessments and resulting medication adjustments. These data could also enable the identification of issues with inhaler technique, poor adherence, lack of medication response despite adequate adherence, and the need for behavioral interventions to avoid environmental triggers.

Limitations

The program had several key limitations. First, it was a pragmatic pilot study implemented through a variety of recruitment channels and therefore did not standardize enrollment, clinical integration, or population management. Second, enrollment was achieved through convenience sampling. It is possible that individuals who agreed to participate, and then remained in the program, were interested in self-management and more inclined to be proactive about their asthma, had a stronger connection with their health care practitioner, or went into the study experiencing less severe asthma symptoms. Third, Hawthorne effects, or the potential alteration of a participant's behavior as a consequence of being observed within the program, and regression to the mean may have influenced asthma self-management behavior and outcomes³⁰; however, the single-arm design did not allow us to evaluate these effects. Fourth, the loss of participants who did not receive 30 days of the intervention limited our sample size but does not appear to have biased the sample. The participants who completed the run-in period were not significantly different in race, sex, age, or initial asthma control from those who did not. Fifth, the study experienced significant attrition. We believe these issues were associated with the pragmatic nature of the pilot: the study did not provide any ongoing personal attention, communication, or study clinical visits, so attrition was more likely. Sensitivity analyses did not identify an effect of selective attrition on the

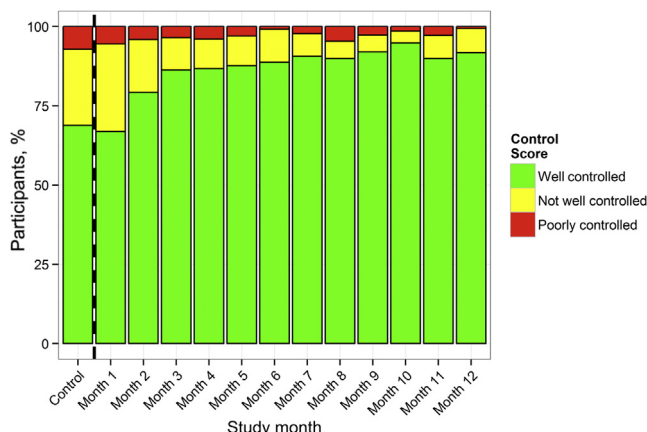


Figure 4. Percentage of participants with well-controlled, not well-controlled, and poorly controlled asthma, aggregated by study month.

results because the findings were consistent across all durations of follow-up. Although there was attrition throughout the study, the effect size for SABA reduction and symptom-free days was demonstrated with the full cohort ($N = 95$) after the first month of the intervention and was maintained across subsequent months, regardless of follow-up duration. A randomized controlled trial was recently completed assessing the effect of this digital health intervention on asthma outcomes at a health system in California ([clinicaltrials.gov](https://clinicaltrials.gov/Identifier/NCT01509183) Identifier: NCT01509183), which addressed many of the limitations described here and demonstrated improvements in SABA use and asthma control while under consistent clinical care.¹⁰

This pragmatic study demonstrated that a digital health intervention that collects objective SABA use data and supports self-management can improve asthma outcomes, such as asthma control, SABA use, and symptom-free days. Additional randomized controlled trials are needed to demonstrate the effectiveness of technologies of this type in different settings and populations.

This type of intervention fits into the broader landscape of health care innovation, where digital health technology, remote patient monitoring, and sensors are emerging as tools to support self-management of chronic disease, promote wellness, improve quality of care, reduce health care cost, and personalize medicine.^{31–33} The literature demonstrates that digitally enhanced monitoring of medications as part of an overall approach to personalized care is rapidly developing,^{34,35} which suggests that connected, digitally enhanced medications may be adopted widely in the coming years. Additional patient data signals, such as home-based lung function testing with Bluetooth-enabled spirometers or peak flow meters, physical activity monitoring, biometric signals (such as heart rate, respiratory rate, and oxygen saturation), and other medications using smart pill bottles, will expand the potential for understanding trends and inflection points in respiratory disease. Ubiquitous sensing of environmental data, such as air pollutants, pollen, and weather conditions, will broaden the field's capability to understand the progression of respiratory disease from early-life exposure to the development of environmental sensitivities. These developments and new tools will trigger the integration of digitally enhanced health care into the standard of care.

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Supplementary Data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.anai.2017.08.002>.

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Supplementary Data

eTable 1
Measure of Asthma Control Calculated Based on the Timing and Frequency of SABA Use Collected by the Sensor, as Described in the NAEPP Guidelines⁵

Age, y	Measurement	Well controlled	Not well controlled	Poorly controlled
<12	Nighttime awakenings ^a (rescue inhaler use at night)	≤1 time per month	≥2 times per month	≥8 per month
	Rescue inhaler use	≤2 days per week	>2 days per week	Every day in previous week
≥12	Nighttime awakenings ^a (rescue inhaler use at night)	≤2 times per month	>2 times per month	≥16 per month
	Rescue inhaler use	≤2 days per week	>2 days per week	Every day in previous week

^aNighttime is defined as 10 pm to 6:59 am local time.