Sensor-Based Electronic Monitoring for Asthma: A Randomized Controlled Trial

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BACKGROUND: Although sensor-based monitoring of daily inhaled corticosteroids (ICSs) and short-acting β-agonist medications may improve asthma outcomes, the effectiveness of these interventions in diverse pediatric populations remains unclear.

METHODS: Caregiver and child dyads were randomly assigned to receive inhaler sensors that allowed for caregiver and clinician electronic monitoring of medications. End points included Asthma Control Test scores (>19 indicated asthma control) and asthma health care use. Caregiver quality of life (QoL) and child ICS adherence were also assessed. Multilevel models were used to estimate adjusted changes from baseline.

RESULTS: Dyads were assigned to the control (n = 127) or intervention (n = 125) arms. At the end line, the mean Asthma Control Test score increased from 19.1 (SE = 0.3) to 21.8 (SE = 0.4) among the intervention and from 19.4 (SE = 0.3) to 19.9 (SE = 0.4) among the control ($\Delta_{intervention-control} = 2.2$; SE = 0.6; P < .01). Adjusted rates of emergency department visits and hospitalizations among the intervention were significantly greater (incidence rate ratio_{emergency department} = 2.2; SE = 0.5; P < .01; incidence rate ratio_{hospital} = 3.4; SE = 1.4; P < .01) at endline than the control. Caregiver QoL was greater among the intervention at the endline ($\Delta_{intervention-control} = 0.3$; SE = 0.2; P = .1) than the control.

CONCLUSIONS: Findings suggest that sensor-based inhaler monitoring with clinical feedback may improve asthma control and caregiver QoL within diverse populations. Higher health care use was observed among the intervention participants relative to the control, indicating further refinement is warranted.

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WHAT'S KNOWN ON THIS SUBJECT: Sensor-based mobile asthma management platforms are designed to support patient adherence to inhaled corticosteroids and help providers monitor short-acting β -agonist use. However, their effectiveness in improving medication adherence and asthma outcomes among socioeconomically diverse pediatric populations remains unclear.

WHAT THIS STUDY ADDS: Study findings indicate that sensor-based inhaler monitoring with clinical feedback may improve asthma symptom control and caregiver quality of life among a racially and socioeconomically diverse pediatric population. However, further platform refinement may be necessary to improve health care use.

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Dr Gupta conceptualized and designed the study and coordinated the acquisitions, analysis and interpretation of data; Drs Vojta and Kan and Mrs Boon, Ms Kanaley, and Ms Bozen conceptualized and designed the study, coordinated and supervised data collection, and designed data collection instruments; Drs Fierstein and Warren coordinated the statistical analysis and interpretation of data; and all authors drafted the initial manuscript, reviewed and revised the manuscript critically for important intellectual content, approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.

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Asthma affects nearly 10% of schoolaged children in the United States and costs ~\$82 billion annually because of missed work and/or school days and asthma-related health care use.^{1–3} For many patients, asthma symptom control requires consistent use of preventive medications such as daily inhaled corticosteroids (ICSs). In contrast to recommendations by national asthma management guidelines, daily ICS adherence is often poor among children and among urban-dwelling African American and Hispanic populations.^{4–8} Research suggests that ~ 1 in 4 asthma exacerbations and more than one-half of asthmarelated hospitalizations are attributable to ICS nonadherence,9 leaving children at a higher risk for exacerbations and poor asthma control.¹⁰

The need to improve ICS adherence among children with asthma has spurred the development of sensorbased inhaler monitoring interventions. Although electronic monitoring has been used in asthma research since 1983,¹¹ advances in sensor technology have recently made it possible for clinicians to assess and intervene on the basis of real-time adherence and use data. Furthermore, the integration of sensor-based inhaler monitoring with mobile applications may reduce asthma-related health care use by assisting asthma patients between health care provider visits.¹² Although these interventions may hold promise for reducing asthma burden among urban, minority populations disproportionately affected by this disease,¹³ the effectiveness of sensor-based inhaler monitoring in improving asthma outcomes among such populations is unknown.¹⁴ Consequently, the Improving Technology-Assisted Recording of Asthma Control in Children (iTRACC) trial was aimed to determine the effectiveness of a clinically integrated, sensor-based

inhaler monitoring intervention on improving asthma symptom control and asthma-related outcomes among a diverse sample of children with moderate-to-severe asthma. Our study was focused on children with moderate-to-severe persistent asthma to examine intervention effects on the highest risk patients. We hypothesized that exposure to a sensor-based inhaler intervention over 12 months would lead to significantly greater improvements in asthma symptom control and caregiver quality of life (QoL) as well as reductions in asthma-related health care use rates among the intervention group versus controls.

METHODS

Trial Oversight

iTRACC was a multisite, unblinded, preregistered (NCT02994238), institutional review board-approved randomized controlled trial conducted from 2016 to 2018, supported by funding from UnitedHealth Group, a Minnesotabased managed health care company.

Participants

Recruitment of caregiver and child dyads occurred from November 2016 to December 2017 within 5 Chicago medical clinics (3 primary care, 1 allergy, and 1 pulmonary). Children were eligible for the trial if the following criteria, ascertained by caregiver report and verified by electronic health record (EHR), were met: (1) an age from 4 to 17 years, (2) moderate-to-severe persistent asthma¹⁵; (3) a prescription for daily ICS for ≥ 1 year before enrollment per medical record or parent report; and (4) \geq 1 exacerbation requiring oral corticosteroids (OCSs) the year before trial enrollment. Children were excluded if they did not speak English, were currently participating in other asthma research, and/or had EHR-documented respiratory conditions that would interfere with

the assessment of asthma symptoms (eg, chronic lung disease, cystic fibrosis, and tracheostomy).

Trial Procedures

Within each clinic, caregiver and child dyads were randomly assigned in a 1: 1 ratio by using a permuted block design of 1 to 20 caregiver and child dyads each and stratified by child age (4-11 or 12-17 years), sex (male or female), and insurance type (private or public). Site-specific participant allocation sequences were developed by an independent statistician before participant recruitment was initiated. Study personnel screened potentially eligible parent and child dyads via telephone for eligibility and scheduled an intake visit. Central randomization concealed allocation until assignment of intervention or control condition.

During intake visits, each dyad (n = 252) met with the research team to complete their consent forms and intake surveys through Research Electronic Data Capture and, then, received comprehensive asthma education. Electronic surveys were administered to both the intervention and control arms at 1, 3, 6, 9, and 12 months postintake.

The intervention group (n = 125)received Propeller Health's US Food and Drug Administration-cleared inhaler sensors for ICS and shortacting β -agonists (SABAs) medications that allowed caregivers (through a mobile application) and clinicians involved in the trial (through a provider Web portal) to track the child's SABA and daily ICS use, including the ICS-long-acting β-agonist Advair, throughout the study (Supplemental Figures 7-9). The app also included features such as personalized insights, educational content, encouragement, surveys, and care team services. Sensors monitored inhaled medication use, capturing the date, time, and number of uses, and transmitted this information via Bluetooth to a paired smartphone and the provider portal in real-time. Providers from the 5 clinics received alerts via the Web portal to contact participants by telephone if they: (1) missed ICS doses for 4 continuous days and/or (2) used >4 SABA doses per day. Participant-provider contact via phone call was initiated to help guide asthma management, which could include provider consultation, followup appointment scheduling, refilling medications, and/or addressing technical difficulties with the sensor. Once patients were reached and their problem was addressed, providers resolved the flag in the online portal.

End Points

Primary study end points were changes in asthma symptom control and asthma-related health care use across the study period. Changes in asthma symptom control were measured by the Asthma Control Test (ACT), a validated, 5-item questionnaire administered at baseline, 1, 3, 6, 9, and 12 months among both trial arms.¹⁶ ACT scores ranged from 5 (poorly controlled asthma) to 25 (well-controlled asthma).¹⁷ Children aged 4 to 11 years were evaluated by using the Childhood Asthma Control Test (c-ACT), a 7 item validated questionnaire,¹⁸ with scores ranging from 0 (poor asthma control) to 27 (well-controlled asthma). Scoring ≤ 19 on the c-ACT or ACT scale indicated uncontrolled asthma.¹⁷ Health care use rates of asthma-related emergency department (ED) visits, hospitalizations, and OCS prescriptions during the 12-month trial were gleaned via caregiver report and EHR data extraction.

Daily ICS adherence data were evaluated as a secondary end point, which was manually entered for 12.8% of respondents. No differences in adherence were observed between manually entered versus sensorbased ICS adherence. Information from the Propeller sensors was used as a proxy for engagement with the technology over the course of the intervention. For ICS adherence detection to occur, caregivers affix the inhaler sensor, sync the sensor, and ensure that the sensor remains operable. If caregivers did not complete these all of these steps, they were unlikely to have been correctly using the intervention for its intended purpose. Additionally, asthma caregiver QoL was measured by the Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ), a 13item scale with mean scores ranging from 1 (severely impaired QoL) to 7 (unimpaired and/or not at all limited 0oL).¹⁹

Statistical Analysis

With descriptive analyses, we summarized demographic characteristics and study end points; group differences were assessed via mixed modeling. Among the intervention arm, ICS adherence data were collected from Propeller sensors to calculate mean daily adherence scores ranging from 0 to 1 by dividing the number of ICS doses taken by the number of ICS doses prescribed. For the continuous primary asthma control end point and continuous secondary psychosocial end point (ie, PACQLQ), linear mixed models were used to estimate changes in the adjusted mean scores between the baseline and 1, 3, 6, 9, and 12 months of follow-up. Random subject- and household-level effects accounted for repeated measurements and varying effects of the intervention between households. Fixed effects included trial arm, time point, and the cross product of trial arm by time point. All models adjusted for baseline measurements, child race and ethnicity, sex, insurance type, and clinic. Cross products were used to test for effect modification by subgroup.

To evaluate the effects of intervention assignment on asthma-related health care use during the 12-month trial (ie, 12-month trial rate of asthma-related ED visits, hospitalizations, and OCS prescriptions), intention-to-treat analyses were performed by using negative binomial mixed models fitted with logarithmic link functions and maximal random effects structures. Additional covariates included atopic comorbidities (ie, atopic dermatitis and allergic rhinitis) and asthma-related health care use rates during the year before trial enrollment.

Given that asthma-related health care use rates were sourced from both the EHR and caregiver report, the highest estimate was selected for inclusion into the multivariable analyses whenever sources did not match. For example, if caregivers reported an asthma-related hospitalization unnoted in the child's EHR, the child was considered to have experienced an asthma-related hospitalization. Significance tests were 2-sided, with α = .05. Analyses were performed with Stata 15.1 (Stata Corp, College Station, TX).

By using power calculations assuming a 20% patient drop-out rate, 2-sided α of .05, and population SD of change of 4.5 ACT points in the intervention and 4.6 ACT points in the control, it was determined that 250 patients (randomly assigned 1:1) were needed for the power of 90% to detect a \geq 3 point difference in ACT scores (ie, a clinically important difference)²⁰ between intervention and control groups.

RESULTS

Among 1432 caregiver and child dyads screened, 17.6% were identified as eligible to participate, and 82.4% were excluded because of ineligibility (48.5%), declining interest (11.1%), or inability to verify eligibility (22.8%). In turn, 252 caregiver and child dyads were enrolled and randomly assigned to the control (n = 127) or intervention (n = 125) (Supplemental Fig 4). There

were no withdrawals or adverse events.

Child Characteristics

No significant baseline differences in child characteristics were found between trial arms (Table 1). Overall, the sample was one-third female (33.7%), and the mean age was 9.3 years (SD: 3.4). Among controls, 28.4% of participants identified as Hispanic, and 33.1% identified as non-Hispanic Black; among the intervention, 40.0% of participants identified as Hispanic, and 23.2% identified as non-Hispanic Black. Nearly 60% (57.9%) reported Medicaid insurance.

Primary End Points

As seen in Fig 1, the adjusted mean ACT scores significantly increased from 19.1 (n = 123; SE = 0.3) to 21.8 (n = 102; SE = 0.4) among the intervention group and from 19.4 (n = 126; SE = 0.3) to 19.9 (n = 118; SE = 0.4) among the control group at 12 months postbaseline. The change in adjusted mean ACT scores from baseline was significantly greater in the intervention group than in controls at all time points (P < .01 for

TABLE 1 Child Participant Characteristics at Baseline

	Intervention	Control
	(n = 125)	(n = 127)
Age in y, unadjusted mean (SD)	9.3 (3.2)	9.2 (3.5)
Age in y, %		
4—11	80.0	78.7
12–17	20.0	21.3
Sex, female, %	30.7	36.8
Race and/or ethnicity, %		
Non-Hispanic white	24.0	23.6
Non-Hispanic Black	23.2	33.1
Hispanic	40.0	28.4
Other race and ethnicity	7.2	7.8
No data	5.6	7.1
Insurance, %		
Private	40.8	43.3
Public	59.2	56.7
Asthma symptom control, unadjusted mean (SD)		
ACT, overall ^a	18.8 (4.5)	19.6 (3.8)
ACT, ≥ 12 y of age	18.9 (4.6)	18.6 (3.7)
c-ACT, 4—11 y of age	18.8 (4.6)	19.9 (3.8)
Caregiver asthma-related QoL, unadjusted mean (SD)		
PACQLQ, unadjusted mean (SD)	5.7 (1.3)	5.8 (1.1)

There were no significant between-arm differences in child baseline characteristics (P > .05 for all intergroup comparisons).

^a ACT scores are missing from 1.6% of the intervention group and 0.8% of the control group.

all comparisons). Both groups demonstrated the greatest improvement in scores at the 9month follow-up ($\Delta_{intervention} = 2.8$; SE = 0.4; P < .01; $\Delta_{control} = 0.9$; SE = 0.4; P < .01), and the intergroup difference was the greatest at 12 months ($\Delta_{intervention-control} = 2.2$;



FIGURE 1

Asthma symptom control during the iTRACC trial. We illustrate the change from baseline in the adjusted mean ACT score at each study time point among caregiver-child dyads of the intervention and control groups. Error bars represent 95% confidence intervals.

SE = 0.6; P < .01). In addition to a significant time by intervention interaction (P < .01), effect modification was observed at 6 months by race and ethnicity and insurance (P < .05 for both). Specifically, at this time point, the change in adjusted mean ACT scores from baseline among intervention relative to control was significantly greater in non-Hispanic white participants, relative to Hispanic participants, and those with private insurance, relative to public (Supplemental Figs 5 and 6). Intervention effects were invariant across other sociodemographic strata and clinic.

During the year before the trial, there were no significant intergroup differences between the 12-month unadjusted rate of EHR-documented asthma-related ED visits, hospitalizations, or OCS prescriptions. After 12 months of trial follow-up (Table 2), the adjusted rate of asthma-related ED visits and hospitalizations among the intervention was significantly greater, relative to the control (incidence ratio

TABLE 2 Asthma-Related Health care Use Rates During iTRACC Trial

	Intervention			Control		
	n	Unadjusted 12-Month Rate ± SE	Adjusted ^a 12-Month Rate \pm SE	n	Unadjusted 12- Month Rate ± SE	Adjusted ^a 12 Month Rate ± SE
Asthma-related ED visits						
Among all children	125	1.0 ± 0.1^{b}	$1.2 \pm 0.3^{\circ}$	127	0.6 ± 0.1	0.6 ± 0.1
Among children with at least 1 ED visit	49	2.4 ± 0.3	_	39	1.8 ± 0.2	_
Asthma-related hospitalizations						
Among all children	125	0.4 ± 0.1	$0.5 \pm 0.1^{\circ}$	127	0.1 ± 0.06	0.1 ± 0.05
Among children with at least 1 hospitalization	24	2.0 ± 0.3	_	12	1.6 ± 0.4	—
OCS prescriptions						
Among all children	125	1.3 ± 0.2	1.4 ± 0.3	127	0.9 ± 0.2	0.9 ± 0.2
Among children with at least 1 prescription	46	3.5 ± 0.4	—	46	2.6 ± 0.4	—

Rate was defined as mean number of asthma-related ED visits, hospitalizations, or OCS prescriptions over the 12-month trial period. Rates were derived from the highest estimate between caregiver report and EHR documentation. —, not applicable.

^a Adjusted for household-level random effects and fixed effects of child race and ethnicity and sex, insurance type, and recruitment clinic. Adjusted rates in subsamples are not shown because of power restrictions.

^b Significant difference relative to control, P < .05.

 $^{\circ}$ Significant difference relative to control, P < .01.

ratio_{ED} = 2.2; SE = 0.5; P < .01; incidence rate ratio_{hospital} = 3.4; SE = 1.4; P < .01).

Secondary End Points

As indicated in Fig 2, caregivers had comparable adjusted mean PACQLQ scores at baseline ($\Delta_{intervention-control} =$ -0.1; SE = 0.1; *P* = .5). At 1 month into the trial, caregivers in the intervention group reported significantly improved PACQLQ mean scores ($\Delta_{intervention-control} = 0.3$; SE = 0.1; *P* = .04). The difference was slightly attenuated at months 3, 6, and 9 but reemerged at 12 months ($\Delta_{intervention-control} = 0.3$; SE = 0.2; *P* = .1). No effect modification was observed by sociodemographics or clinic.

As seen in Fig 3, the number of intervention participants with actively transmitting sensors decreased from 102 at baseline to 56 at 12 months. The mean daily ICS adherence increased from 44.9% at 3 months of follow-up to 52.5% at 12 months of follow-up among intervention participants with actively transmitting sensors.

With respect to caregiver-reported end points at 12 months, no significant differences were observed between intervention and control groups with respect to the frequency of asthma attacks, missed school days, physician in-office treatment of asthma attacks, and steroid prescriptions in the ED and/or hospital context (P > .05 for all; Supplemental Table 3). However, a significant difference was observed in the frequency of caregiver-reported asthma attacks over the course of the 12-month trial in which steroids were prescribed by a medical office (72.5% intervention versus 34.6% control; P < .01).

DISCUSSION

In this randomized, sensor-based inhaler monitoring intervention, participants experienced improvements in asthma control and caregiver QoL relative to controls. Asthma-related health care use rates over the course of the study, however, were significantly higher among the intervention arm in comparison with the control.

These data build on previous work suggesting that sensor-based ICS and SABA monitoring, combined with mobile phone-based feedback and health education, improves asthma control. For example, the 2.8 point increase in ACT scores observed among intervention participants in the current trial is equivalent to 4-month improvements observed in a sample of 29 adults who used the same sensorbased monitoring system.²¹ In a larger, year-long randomized controlled trial of the effectiveness of a similar platform, researchers reported a 1.6 point increase in ACT scores among adult intervention participants with poorly controlled asthma relative to adult controls receiving usual care.²² Remarkably in the same trial, greater improvements in ACT scores (>4.5 points) were observed among children in the control, relative to children in the intervention.²² However, in contrast to the current study, rescue inhaler use was monitored among both control and intervention participants via Bluetooth sensors, so it is likely that the Hawthorne effect (ie, behavior change from awareness of observation) was operating among controls. In our study, significant improvements in ACT scores (>2 points) were observed among intervention participants relative to controls, which suggests that sensor-based inhaler monitoring may lead to improvements in asthma control among children



FIGURE 2

Pediatric asthma caregiver QoL during the iTRACC trial. We illustrate the change from baseline in the adjusted mean PACQLQ score at each study time point among caregiver-child dyads of the intervention and control groups. Error bars represent 95% confidence intervals.

with moderate-to-severe asthma, above and beyond routine care.

We observed effect modification by race, with the greatest improvements in asthma control observed among non-Hispanic Black participants. This population generally suffers from higher rates of asthma-related morbidity and mortality^{23,24} and reports lower rates of medication adherence^{25–27} than non-Hispanic white children. In other studies, researchers indicate that sensorbased interventions designed to increase medication adherence are perceived favorably by high-using minority patients,^{13,14,28} which suggests that such approaches hold promise to reduce asthma burden in these highly affected populations.

Caring for a child with moderate-tosevere asthma can impose psychosocial burdens on caregivers and impair QoL.²⁹ As hypothesized, caregivers of intervention participants reported significantly improved PACQLQ scores relative to caregivers of control participants after 1 month of follow-up; improvements were sustained at 12 months of follow-up, although they did not reach statistical significance. These findings are consistent with previous research identifying positive associations between child asthma control and caregiver asthma-related QoL.³⁰

Similar to the findings of other technology-based asthma trials,³¹ in the current study, we improved asthma symptom control but did not reduce health care use. In fact, the intervention group of the current trial experienced significantly higher 12month rates of asthma-related hospitalizations and ED visits, in comparison with the control group. This phenomenon has been observed in other studies^{32,33} and may be explained by several mechanisms. First, intervention participants had increased access to providers because of alerts that triggered provider calls when children had >4 SABA uses per day. Caregivers and children may have

been underdetecting asthma symptoms before the trial, but the alerts enabled providers to detect asthma exacerbation virtually and refer for clinically appropriate care that included directing children to the ED. Second, increased asthma awareness and knowledge with enhanced self-management support by the sensor and app might have led to increased vigilance of clinically concerning asthma symptoms among intervention caregivers and subsequent ED visits. In prospective study of recently hospitalized children with asthma, researchers found that having greater asthma knowledge was associated with increased health care use, highlighting how education might also empower caregivers to use health care.³⁴ Furthermore, because the intervention was unblinded, intervention caregivers assigned to the sensors (which may serve as salient indicators that a child's asthma is sufficiently severe to warrant experimental intervention) might have perceived that their children with asthma had greater clinical needs and sought additional asthma care, including in the ED. Finally, after randomization, there was some baseline imbalance in ACT scores, with the unadjusted mean score in the intervention group meeting criteria for poorly controlled asthma (18.6), compared with the unadjusted mean score of 19.6 among controls, which did not. This may have contributed to the observed differential rates of intergroup health care use.

Next Steps

Previous studies indicate that heterogeneity of participant engagement with sensor-based electronic inhaler monitoring may influence outcomes.³⁵ Similarly, in previous research, researchers have reported nonadherence to intervention protocols.²² Such deviations in participant adherence and/or engagement highlight the importance of future per-protocol analyses, which may identify the type



FIGURE 3

Mean daily ICS adherence during the iTRACC trial. We illustrate the mean daily ICS adherence of participants with actively transmitting sensors at each trial time point. The left hand axis, indicated in blue, reveals the number of actively transmitting sensors. The right hand axis, indicated in black, reveals the mean daily adherence of ICS, ranging from 0% to 100%. A mean daily ICS adherence of 0% indicates nonadherence to a daily ICS medication regimen, whereas 100% indicates complete adherence to a daily ICS medication regimen.

of participants for whom these interventions hold the most promise.

Within an ancillary qualitative component of the current trial, we conducted semistructured interviews among parents of children with at least 9 months of successfully transmitted sensor data. With the interviews, we aimed to identify child subgroups within which the intervention worked best, by determining the technology's compatibility with participant lifestyle, utility, and impact on asthma management and asthma-related health outcomes. Interviews are currently being conducted with participating physicians and nurses to contextualize their experiences and engagement with the intervention. With this information, we will inform future iterations of this intervention to better target participants and improve parent and clinician engagement. Although our study was focused on children with moderate-to-severe persistent asthma, in future studies, researchers should consider including children with mild-persistent asthma.

Limitations

Despite its methodologic strengths, this trial has notable limitations. Some inhalers were incompatible with the sensor, requiring manual data entry, in which participants were prompted to open the app and select the number of daily puffs administered. Moreover, only intervention participants received sensors, precluding intergroup comparison of ICS medication adherence or SABA use. Although efforts were made to comprehensively capture health care use via both EHR data extraction and parent report, it is possible that some events were uncaptured; however, we anticipate such bias would be nondifferential. The generalizability of these findings to non-English-speakers may be limited because they were excluded because of a lack of a non-Englishlanguage app. Finally, because this was a longitudinal study, there were missing data because of incomplete or missing survey responses as well as sensor failure over time. However, we believe further work is warranted as

these devices and their monitoring platforms are optimized, translated, and battery life and reliability improves.

CONCLUSIONS

In this randomized controlled trial, we show that sensor-based inhaler monitoring can improve asthma control and caregiver QoL over a 12month period among a diverse sample of child participants with moderate or severe persistent asthma. Although health care use rates were significantly higher among the intervention group then controls, further intervention refinement may yield reductions in the future.

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ABBREVIATIONS

ACT: Asthma Control Test c-ACT: Childhood Asthma **Control Test** ED: emergency department EHR: electronic health record ICS: inhaled corticosteroid iTRACC: Improving Technology-Assisted Recording of Asthma Control in Children OCS: oral corticosteroid PACQLQ: Pediatric Asthma Caregiver's Quality of Life Questionnaire QoL: quality of life SABA: short-acting β-agonist

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