


ORIGINAL ARTICLE: ASTHMA

Telehealth delivery of adherence and medication management system improves outcomes in inner-city children with asthma

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Abstract

Healthcare disparities exist in pediatric asthma in the United States. Children from minority, low-income families in inner-city areas encounter barriers to healthcare, leading to greater rates of poorly controlled asthma and healthcare utilization. Finding an effective way to deliver high-quality healthcare to this underserved population to improve outcomes, reduce morbidity and mortality, and reduce healthcare utilization is of the utmost importance. The purpose of this study was to assess the feasibility and efficacy of a novel school-based care delivery model that incorporates video-based telehealth (VBT) medical and self-management visits with electronic inhaler monitoring to improve asthma outcomes. Over a 6-month period, children from inner-city, low-income schools with uncontrolled asthma completed seven scheduled medical visits with an asthma specialist and five self-management visits with an adherence psychologist at school using VBT. Composite Asthma Severity Index (CASI) scores and electronic inhaler monitor data were recorded and analyzed. A total of 21 patients were enrolled in the study. Study subjects with higher baseline severity (CASI ≥ 4 at visit 1) demonstrated a greater reduction in their score than those with lower baseline severity (CASI < 4 at visit 1). The CASI domains showed improvement in daytime symptoms, nighttime symptoms, and exacerbations. Adherence results demonstrated a significant improvement in adherence from baseline to postintervention. Study retention was 100%. This study demonstrates that a multi-component medical and behavioral interventional program delivered by VBT to a school-based setting is feasible and can significantly improve asthma outcomes and care in a challenging population.

KEYWORDS

adherence, asthma, asthma outcomes, children, electronic inhaler monitor, inner-city, telehealth

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1 | INTRODUCTION

Tremendous disparities exist in pediatric asthma outcomes in the United States, with children from minority, low-income families having greater rates of poorly controlled asthma. Medicaid-insured children in central urban, economically disadvantaged neighborhoods demonstrate 15 times greater healthcare utilization rates than children from more prosperous neighborhoods.¹ These children often encounter significant barriers to healthcare and have risk factors that contribute to poor asthma control which traditional models of healthcare have not been able to adequately address.² Thus, there is a need for effective interventions to be implemented and disseminated broadly in these communities. One solution to overcome healthcare access barriers for pediatric asthma is to use technology-enhanced medical care such as video-based telehealth (VBT) and electronic monitoring devices to deliver optimal asthma care directly to the patient's school. Previous studies have demonstrated improved asthma control and self-management using VBT, electronic monitoring devices, and behavioral interventions separately, but no studies have combined these interventions in a way that is easily accessible to patients while also improving asthma control and self-management.³⁻⁵

Through a formal needs assessment regarding asthma care and management with key stakeholders and community partners (eg, patients, parents, school nurses, and pediatricians), we identified and characterized the needs and barriers to medical care for children attending inner-city, low-income schools. Semistructured interviews with patients, families, and focus groups with school nurses were conducted. Participants answered open-ended questions and results were tallied. Based on the results of the needs assessment, we designed an intervention that combines the use of VBT and electronic monitoring devices to deliver medical and behavioral management from an asthma specialist and adherence psychologist to promote improved medical asthma care and self-management skills.

The objective of this study was to determine the feasibility and efficacy of this novel school-based healthcare delivery model in improving asthma control, Composite Asthma Severity Index (CASI), and controller adherence rates in children from urban, economically disadvantaged neighborhoods.

2 | METHODS

2.1 | Study population

Children aged 10 to 17 years old with physician-diagnosed asthma and evidence of uncontrolled asthma in the previous 12 months were identified from three inner-city, economically disadvantaged schools in Cincinnati, Ohio, between February 2016 and November 2017. All schools performed annual Asthma Control Test (ACT) score screening of all students with asthma as part of participation in ongoing asthma outcome quality improvement initiatives. The students who screened positive for uncontrolled asthma were invited to participate

in this study by sending home study flyers to parents as well as follow-up calls from the study nurse.

A total of 55 eligible students were screened by the school nurse, and 21 participants were enrolled. Inclusion criteria for the study included: (a) physician-diagnosed asthma based on the National Asthma Education and Prevention Program guidelines, and (b) evidence of uncontrolled asthma in the past 12 months.⁶ Uncontrolled asthma was defined by two ACT scores less than 20,⁷ one or more asthma-related emergency department (ED) visits or hospitalizations, or two or more asthma-related corticosteroid bursts. Participants were excluded for active chronic disease other than asthma/allergic disease, difficulties in contacting legal guardians for consent, or plans to change schools.

2.2 | Study procedures

The study was reviewed and approved by the Cincinnati Children's Hospital Medical Center Institutional Review Board (IRB), the Cincinnati Health Department IRB, and the Cincinnati Public Schools Department of Performance and Accountability. Written consent was obtained from a parent or legal guardian at the initial visit.

During the 6-month study period, participants attended seven scheduled VBT medical visits conducted by an asthma specialist (pediatric pulmonologist or allergist) and five VBT school-based self-management visits with an adherence psychologist. Subjects completed all scheduled study visits in a private conference room at school on a laptop using Health Insurance Portability and Accountability Act-compliant video-conferencing software (Cisco Jabber, San Jose, CA) with the assistance of a student nurse or study coordinator. Baseline asthma control characteristics were collected by the initial study survey completed at the first visit. The participant's use of both daily controller and bronchodilator medications was monitored using the Propeller Health System (Propeller Health, Madison, WI)⁴ inhaler cap. The Propeller Health inhaler cap is an FDA-approved electronic medication sensor that monitors inhaler usage by a Bluetooth adaptor paired to either mobile phone-based software or electronic hub. Smartphones with data plans preloaded with the Propeller Health application were provided to study participants.

Medical visits were scheduled monthly and included a physical exam and assessment of asthma control using the ACT score, Asthma TreatSmart program (a computer-based decision support tool), and modified CASI, a composite score of key asthma-related outcomes such as ED visits, oral corticosteroid use, and symptoms.^{8,9} An asthma specialist physically located at Cincinnati Children's Hospital Medical Center performed a physical exam with an electronic stethoscope, reviewed Asthma TreatSmart data and recommendations, and made a final decision regarding level of asthma control and level of medication needed via telehealth. Medications were adjusted based on Asthma TreatSmart results and clinical recommendations if adherence was greater than 50% based on data obtained from the Propeller Health System device. A visit note was written in the

participant's electronic medical record and communication were sent to the primary care physician.

In total, five self-management visits were scheduled once every 2 weeks following a 4-week baseline assessment period. During self-management visits, the adherence specialist reviewed Propeller Health adherence data with the participant, identified and discussed barriers to adherence, discussed the link between medication adherence and asthma control, engaged in problem-solving to select strategies to improve adherence, and provided customized supportive text messages and reminders. The study team, subject, and family were blinded to the inhaler use data for the first month, but the data was made available to both parties during remaining study visits to facilitate self-management visits with real-time data. A visit note was written in the participant's electronic medical record and shared with the participant's primary care physician.

2.3 | Outcome measures

The primary outcome of this study was the change in the CASI score. The CASI score is designed to be tracked longitudinally, with a lower score indicating improved asthma control. CASI score was stratified by asthma severity using a cutoff of 4 as per previous studies²; CASI ≥ 4 was defined as severe asthma and CASI < 4 as mild/moderate asthma. In this study, the CASI score was modified to not include lung function since spirometry testing was not readily available in school-based clinics.

Secondary outcomes, such as school absence rates and asthma-related healthcare utilization were obtained by study questionnaires completed by the student. Historical ACT scores were obtained from annual screening results at the beginning of the school year from an ongoing quality improvement initiative by school nurses at each of the participating schools.

Medication adherence data were tracked in real time by the Propeller Health and collected from the Propeller Health web platform at each study visit. Adherence to controller inhalers was calculated based on actual doses taken divided by prescribed doses and was capped at 100%. Bronchodilator use was calculated based on the number of puffs per day. Baseline controller and bronchodilator use were calculated based on the data from the first month from the Propeller Health system. Intervention adherence was calculated for the time of self-management sessions (approximately 10 weeks) and follow-up adherence was calculated for the time period after the self-management intervention (approximately 8 weeks).

2.4 | Data analysis

All data analyses were completed *a priori*. Linear mixed-effect models, with a random effect for participant, were used to model CASI scores over time. Baseline severity (CASI ≥ 4 or CASI < 4) was evaluated as a moderator in the mixed-effect model with additional adjustments based on allergy history, season of enrollment, and patient's age.

Paired *t*-tests were used to compare controller inhaler adherence and rescue inhaler use before and after the intervention. Statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

3 | RESULTS

3.1 | Population demographics and baseline asthma characteristics

Participants enrolled in the study had an average age of 13.7 years and 74% self-reported as African-American (Table 1). The enrolled cohort had poor baseline asthma control (Table 1). Baseline demographics confirmed that our participants were children from economically disadvantaged neighborhoods. Economically disadvantaged was defined as those families who are below the Federal Poverty Line per reported family size based on the 2016 Income and Poverty in the United States report released by the US Census Bureau¹⁰ (Table 1).

3.2 | Asthma control outcomes

Eighty one percent of the participants had a step-up in controller therapy during the course of the study. There was no significant

TABLE 1 Baseline study population and asthma characteristics^a

Baseline study population characteristics ^b	
Variable	Mean (SD) or %
Age, y	13.67 (2.46)
Sex (% males)	57.14%
Race (%) n = 19	
Black/African-American	73.68%
Caucasian	21.05%
Other	5.26%
Family at or below federal poverty line ^c (%) n = 17	64.71%
Medicaid insured (%)	85.71%
Single parent home (%)	76.19%
Current reported home exposure to mold/moisture, cockroach, rodent, or tobacco smoke (%)	71.43%
Use inhaled corticosteroids in past year	90.48%
History of allergic rhinitis	85.71%
History of two or more oral steroid requiring asthma exacerbations in past year (%)	71.43%
History of asthma-related emergency room visit or hospitalization in the past year (%)	38.10%
Two or more ACT scores < 20 in the past year (%)	80.95%
Asthma-related school absences per patient in last 3 mo (d)	1.88 (2.15)

^aDemographic data were summarized using means and standard deviations for continuous measures and proportions for discrete measures.

^bNumber of subjects (n) is 21 unless specified.

^cBased on 2016 Federal Poverty Line per reported family size.

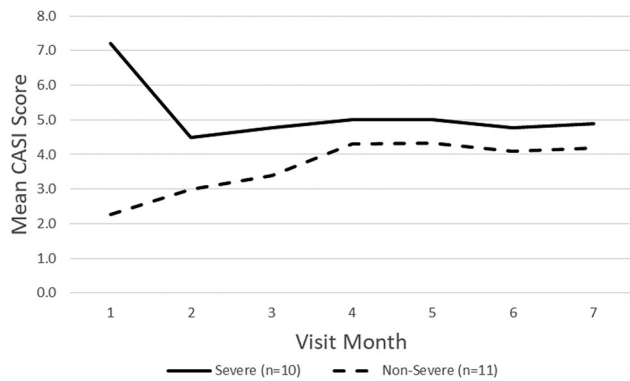


FIGURE 1 Change in mean CASI scores (visits 1-7): the severe group (CASI ≥ 4 at visit 1) demonstrated a greater reduction in CASI than the nonsevere group (CASI < 4 at visit 1). The CASI was significantly different between the severe and nonsevere group at visit 1 ($P < .0001$), but not the following visits. CASI, Composite Asthma Severity Index

change of the mean CASI score of all participants from baseline to postintervention (4.6 vs 4.5). The CASI was significantly different between the severe asthma (CASI ≥ 4 at visit 1) and nonsevere asthma group (CASI < 4 at visit 1) at visit 1 (7.2 vs 2.3, $P < .0001$), but not the subsequent visits. The severe asthma group demonstrated a greater reduction in CASI, from 7.2 to 4.9, than the nonsevere group (CASI < 4 at visit 1) (Figure 1).

A mixed-effect model indicated significantly different trajectories of the CASI between the groups after adjustments ($P < .0001$). The severe group had a sharp decrease in CASI between visit 1 and visit 2 (8.02 vs 5.42, $P < .0001$). CASI was significantly higher in children with a history of allergy than in children with no atopic history (6.76 vs 4.19, $P = .0338$). The CASI domains showed significant improvement in daytime symptoms, nighttime symptoms, and exacerbations (Table 2).

During the study period, there were no asthma-related ED visits or hospitalizations, which was a significant improvement from baseline. At enrollment, 68% of participants had a history of two or more oral steroid requiring asthma exacerbations in the preceding year, whereas during the study period 9.5% of participants required

one course of oral steroids and none required ≥ 2 courses. ACT scores were improved following the intervention. Before the study, 81% of participants had two or more ACT scores less than 20 in the preceding year, compared with 43% during the study period. In the 3 months before the study, the rate of asthma-related school absences per person was 1.9 days; during the study period, the rate of asthma-related school absences per person was 1.4 days. The rate of asthma-related school absences per person during each visit month (Table 2), and demonstrates a significant trend of decline over the study period ($P = .0003$).

3.3 | Adherence outcomes

Eighty six percent of the participants had complete adherence data. Adherence results demonstrated a significant 8% improvement in controller adherence ($t = 1.93$, $P = .03$) from baseline to intervention (Table 3). Specifically, participants demonstrated increase in adherence up to 46% with eight participants demonstrating an adherence increase of greater than 20% as a result of the adherence intervention. A significant difference in controller adherence was not found when comparing baseline with follow-up. The use of albuterol was not significantly reduced during intervention, but was significantly reduced to 0.10 puffs per day during the follow-up as compared with baseline ($t = 2.01$, $P = .03$) (Table 3). Adherence specialists received responses 86% of the time to text messages sent to participants, which facilitated adherence and behavioral plans over the course of the study intervention months.

3.4 | Study feasibility

Participants completed 92% of medical visits, 100% of self-management visits, and study retention was 100%. Fourteen percent of the participants required a replacement smartphone and 57% of participants required at least one replacement inhaler cap, with a mean of 3 caps per participant distributed. At the conclusion of the

TABLE 2 CASI scores and asthma outcomes

Outcome	Baseline (1 y before enrollment)	1-mo follow-up	3-mo follow-up	6-mo follow-up	P
CASI total	4.67	3.79	4.75	4.52	.3522
CASI daytime symptoms	0.48	0.10	0.25	0.10	.0233
CASI nighttime symptoms	0.67	0.19	0.64	0.10	.0017
CASI exacerbations	0.67	0.10	0.11	0.10	.0001
CASI controller treatment	2.86	3.41	3.75	4.24	<.0001
Any exacerbations (%)	90.48%	0.00%	0.00%	9.5% ^a	<.0001
Oral corticosteroid-requiring (%)	90.48% ^b	0.00%	5.26%	0.00% ^a	<.0001
ED/urgent care visit or hospitalization (%)	38.10%	0.00%	0.00%	0.00%	<.0001
ACT score (mean)	17.80	20.28	19.95	20.52	.0001
School absences (number of days per month)	1.88 ^c	1.27	0.00	0.05	.0003

Abbreviations: ACT, Asthma Control Test; CASI, Composite Asthma Severity Index; ED, emergency department.

^aPercent with 1 or more oral corticosteroid bursts during study.

^bPercent reporting 2 or more oral corticosteroid bursts in the previous 12 months at visit 1.

^cBased on parental recall of previous 3 months at visit 1.

TABLE 3 Adherence outcomes

	Baseline (medical 1 to SM 1)	Intervention (SM 1 to SM 5)	Baseline to intervention <i>P</i> -value	Follow-up (after SM 5 to medical 7)	Baseline to follow-up <i>P</i> -value
Albuterol use ^a	0.22	0.21	.24	0.10	.03
Adherence (controller) ^b	40.00	48.62	.03	39.34	.16

Abbreviation: SM, self-management intervention.

^aAlbuterol use calculated based on puffs per day using Propeller Health data consistent with adherence intervention time points.

^bAdherence to controller was calculated based on (actual doses taken)/(prescribed doses) using Propeller Health data consistent with adherence intervention time points. Adherence was capped at 100%.

study, 100% of the participants and parents reported satisfaction of VBT visits and rated study experience as “good to excellent” based on the poststudy survey. Hundred percent of parents and 95% of subjects agreed that telehealth visits were as helpful as in-person visits. Hundred percent of both parents and subjects reported being satisfied with the telehealth medical visits, and 100% of parents and 92% of subjects would recommend the study to others.

3.5 | Feedback from schools

The medical and behavioral management sessions were delivered over lunch hours, noncore class, and free periods during the subjects' days to minimize disruption to their school schedules. The school principals were supportive as they were included in the design and implementation of the study and provided letters of support providing permission for the study to be conducted at their school.

4 | DISCUSSION

This is the first study to our knowledge that utilizes a multi-component medical and behavioral interventional program delivered by VBT in a school-based setting to improve asthma care in a challenging, economically disadvantaged population. This study demonstrated that such an intervention is feasible and improves asthma control outcomes, particularly for children with severe asthma.

Many children with asthma from disadvantaged areas continue to have uncontrolled asthma due to poor self-management. The most important components of effective management include adhering to prescribed medications and attending medical appointments, both of which are significant challenges for children with asthma.¹¹ Previous studies have shown children with asthma in the United States only take 30% to 70% of their prescribed medication.^{12–14} Recent data from our institution have demonstrated 60% to 70% of missed outpatient visits are due to transportation barriers and parental resource constraints leading to uncontrolled symptoms and health-care utilization.^{15–20} In particular, adolescents are at higher risk for nonadherence and poor health outcomes as key lifelong patterns of health behaviors and self-management skills are established during this developmental period.^{21–26} Therefore, interventions such as the one tested in this study may improve long-term asthma control.

Many behavioral self-management interventions exist for adolescents with asthma. A recent review of research included studies utilizing newer technologies to improve asthma adherence and although these studies demonstrated feasibility and acceptance, they did not result in improvements in adherence.²⁷ Furthermore, two recent meta-analyses have demonstrated no differences in asthma outcomes between telemedicine and face-to-face visits for asthma in children and adults.^{28,29} The meta-analyses included very few studies that utilized the integrated approach demonstrated in this study with VBT medical and self-management visits and electronic inhaler monitoring in adolescents living in economically disadvantaged neighborhoods and the majority of studies were conducted in rural or remote settings or enrolled young children.^{30–34}

4.1 | CASI score

The CASI score in the severe group and asthma outcomes such as daytime symptoms, nighttime symptoms, and exacerbations were significantly improved after intervention. The improvement in CASI scores amongst those with higher baseline CASI and more severe asthma is impressive, and is likely driven by reduction in symptoms and exacerbations with an expected increase in treatment burden as was seen in previous asthma studies.³⁵ Notably, the overall CASI score was not significantly different when analyzing the subjects as a whole group, which we attribute to the random patient selection for enrollment. A proportion of children enrolled had low baseline CASI scores, suggesting they have milder disease and may have less potential for improvement after intervention. Thus, stratification by baseline CASI score demonstrated a significant effect of the intervention only in children with a higher baseline CASI score (more severe asthma). The CASI trajectories suggest that interventions are most effective in improving asthma control in the initial three visits and less frequent visits may maximize study cost-efficiency.

4.2 | Adherence

Adherence results were encouraging for this challenging population, with significant improvements in medication adherence during the self-management behavioral intervention period. In addition to the significant increase in adherence in this small sample size, eight

participants demonstrated an adherence increase of greater than 20%. Although the literature regarding the impact of adherence on asthma outcomes or the linearity of this relationship is underdeveloped, a 20% increase in medication adherence may translate to a patient having medication coverage of an additional day each week (eg, a child prescribed once daily medication) or taking twice as many doses per week than they were previously taking (eg, a child prescribed two puffs twice a day may go from taking zero [0%] doses to three doses [21%]), which may have the potential to impact asthma outcomes if maintained over time. The rates of nonadherence during baseline and the return to baseline rates of adherence when behavioral self-management intervention ceased in this study are consistent with findings in the literature.^{12-14,36} Future studies should employ booster self-management behavioral sessions to maintain adherence improvements and assess the impact of sustained improved adherence over time.

4.3 | Innovation

This study is innovative for several reasons. First, we increased the access to care at the community level and reduced disparity for children from disadvantaged neighborhoods who have poor health outcomes by leveraging the use of technology that is engaging and utilizes participants' mobile devices.³⁷ We also reduced disparities for these adolescents by providing care using standardized, evidence-based guideline assessment of asthma severity, control, and treatment.^{38,39} Second, we used real-time adherence assessment and feedback as part of the intervention, enabling us to personalize treatment and address the adherence barriers and risk factors that are most relevant and most significantly impact health outcomes. We believe that technology solutions such as VBT visits and electronic inhaler monitoring systems will be widely adopted as the healthcare system transitions to a pay-for-performance healthcare model, and this adoption may substantially reduce health disparities.^{40,41}

4.4 | Limitations

Limitations of this study include the small sample size and lack of control group. Given the small sample size, the impact of individual components of the intervention could not be assessed. Although speculative, improvement in asthma severity may be largely due to step-up of medications as a part of the intervention resulting in consistent adherence rates of more appropriate medication at the end of the study. Eighty one percent of the participants had an increase in their dose of controller medications during the study as a result of the medical visits, which means that at the end of the study, participants were taking 40% of appropriately dose strength medications over a 3-month timeframe. In addition, we utilized a modified CASI since spirometry was not available in school-based clinics. The investigators in the Inner-City Asthma Consortium who developed the CASI score have determined that the contribution of lung function to the overall

CASI score is minimal (Kercsmar CM, personal communication)^{9,42} as the majority of children with asthma have high baseline lung function.⁴³ Last, since many of the subjects did not receive their asthma care from Cincinnati Children's Hospital, we did not have access to their historical medical records and questionnaires were used for tracking healthcare utilization. Monthly questionnaires at each study visit were utilized to minimize recall difficulties.

4.5 | Considerations for future study designs

Feasibility data were encouraging for this challenging population, with significant improvements in medication adherence following intervention, lower than anticipated rates of lost equipment, very few missed visits, and no study dropouts. Important lessons can be learned from this study that may improve and expedite the clinical application of VBT to deliver multicomponent interventions. Importantly, as the study showed the greatest improvement in children with higher CASI baselines, future studies should enroll children who are at higher risk. In addition, we showed that children had few changes between monthly visits and therefore less frequent visits every 3 to 4 months may be reasonable. Also, as adherence was observed to decline over time without reinforcement, booster sessions for adherence may be considered.

There were several challenges faced while implementing this study, including poor wireless Internet service in the schools and difficulty in synchronizing and downloading the electronic inhaler monitor data as the children often did not leave the monitoring application open on their smartphones. We resolved this by providing an improved Internet hotspot at the school and having study coordinators manually assist the children with synchronizing the data to our servers at each study visit. For this initial pilot study, we provided mobile devices to ensure that the patient's experience with the Propeller Health devices was consistent, but future studies should examine the generalizability of this type of study when using participants' own smartphones as operating systems, phone models, and data plans can vary. Previous national and local surveys of a similar cohort of children in the Cincinnati inner-city area showed 95% of these children have access to their own smartphones.^{44,45} Although automated, passive data collection from electronic inhaler monitors without requiring an open application on a smart device would be the preferred method, there is no current technology available commercially with that capability.

Although there is an associated cost for equipment for adherence monitoring, personnel costs for all medical providers, and telehealth visit equipment costs, the potential benefits for cost reduction from decreasing travel time for the family and child, decreasing the need to miss school, reduction in unplanned healthcare costs due to poorly controlled asthma, and improving regular follow-up can be quite significant. Studies in the future can be designed to use different electronic inhaler monitor technologies depending on the availability and cost of the device. Although cost-effectiveness was not within the scope of this study, we believe there is potential for an economic benefit of VBT in the management of asthma.

The advantages of remote monitoring and delivering multi-component interventions via VBT improve our ability to disseminate evidence-based interventions broadly to populations with limited access to healthcare. Future studies should include implementing similar models of care with larger sample size, in other community settings such as the child's home, and with both intervention and control groups.

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