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A pilot randomized trial of school-based administration of inhaled corticosteroids for at-risk children with asthma

Cherise B. Harrington, PhD, MPH^b, Eric Langhans, MHS, PA-C^a, Deborah Q. Shelef, MPH^a, Molly Savitz, MSN, FNP^a, Colleen Whitmore, MSN, RN, FNP^a, and Stephen J. Teach, MD, MPH^a

^aChildren's National Health System, IMPACT DC/Children's Research Institute, Washington, DC, USA; ^bDepartment of Prevention and Community Health, George Washington University Milken Institute School of Public Health, The George Washington University, Washington, DC, USA

ABSTRACT

Objective: To investigate whether high adherence to inhaled corticosteroids (ICS) among disadvantaged urban public school children on public insurance with persistent asthma is achievable by having school nurses administer morning doses on each day that school is in session. **Design/methods:** This was a pilot prospective randomized clinical trial of home versus school nurse-administered ICS among children on Medicaid enrolled in grades K-8. The primary outcome was the proportion of expected morning doses of ICS given to the intervention group in school over the 60-day treatment period. Secondary outcomes included the relative proportions of expected doses (morning, evening, and total), asthma-related morbidity, quality of life, and health-care utilization. **Results:** A total of 46 patients were enrolled (mean age 8.21 ± 2.45 ; 56.5% male; 91.3% non-Hispanic, African-Americans), and follow-up data were available for 44/46 (95.7%) patients. The groups did not differ in age, gender, race/ethnicity, or asthma severity. The intervention group received 91.7% of expected morning doses of ICS at school over the 60-day treatment period (95% CI [87.7, 95.5]). Intervention patients reported significantly less functional limitation (42.9% vs. 73.9%, $p = 0.04$), adjustment to family life (23.8% vs. 56.5%, $p = 0.03$), and sleep loss (1.7 vs. 4.1 nights in last 2 weeks, $p = 0.035$) than control patients at the end of the 60-days study period. There were no differences in unscheduled health-care utilization by group. **Conclusions:** These pilot data suggest that school-based administration of ICS has the potential to achieve high adherence to morning doses of ICS on school days among urban, disadvantaged, and largely minority children with asthma.

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Introduction

After several years of increasing pediatric asthma prevalence, rates may be decreasing for some patient populations, while plateauing for others, namely non-Hispanic African-American children [1]. Marked disparities in prevalence persist among children of different racial, ethnic, and socioeconomic groups. African-American children, for example, are twice as likely as Caucasian children to have asthma [2], to be hospitalized, and to suffer other adverse health outcomes or even death [3].

Asthma typically responds well to the management guidelines of the National Institute of Health including proper diagnosis, medications, education, monitoring, and avoidance of triggers [4]. Additionally, school-based asthma interventions have been shown to have positive impacts on children's asthma [5–13]. At least five efforts [5,6,8–10] used school-based administration of inhaled corticosteroids (ICS). In a population composed largely of minority children in the Rochester, New York area on Medicaid, Halterman et al. [9] reported 98%

compliance with daily medications. This study highlighted that effective school-based programs require complex collaborations and relationships among multiple agencies [9].

For this formative pilot project, the primary objective was to extend these observations [6,9] by examining whether collaboration among key stakeholders engaged in asthma-related medical care serving urban, disadvantaged, and largely minority children with persistent asthma could be leveraged to promote a school-based asthma-control program. The proposed intervention included providing daily (on school days) ICS for school administration and working with families and school nurses to implement the program. A pilot sample of participating school nurses and families tested the capacity of this approach to improve adherence to morning doses of ICS on school days.

The primary outcome was the proportion of expected morning doses of ICS administered by school nurses in the intervention arm of a pilot randomized trial. We

hypothesized that high adherence (greater than 80%) within this high-risk population was achievable. Secondary outcomes included the relative proportions of expected morning, evening, and total expected doses between the two groups, asthma-related morbidity, quality of life (QOL), and health-care utilization.

Methods

Overview

This project was a pilot prospective randomized clinical trial of home versus school administration of ICS among Washington, DC public and public charter school children in grades K-8 with persistent asthma on public insurance. All patients were recruited through an existing specialty asthma clinic in DC. This clinic delivers a previously validated intervention [14] to >1300 new patients/guardians annually within the Children's National Health System, an urban tertiary care pediatric medical center in Washington, DC. This study was approved by the IRB at Children's National Health System as well as the Government of the District of Columbia Department of Health.

Sample

From August 2013 to October 2013, a sample of children was enrolled who met the following eligibility criteria: current enrollment in grades K-8 at a DC public school (DCPS) or DC Public Charter School (DCPCS), persistent asthma as determined by a physician, a medication plan that included ICS, active public insurance, English speaking, and no medical comorbidities including, but not limited to, other chronic diseases of the cardiorespiratory system. Specific DCPS or DCPCS schools were not identified for participation.

Procedures

Enrollment

In early August 2013 patients/guardians of patients who attended the specialty asthma clinic between January 1, 2013 and August 1, 2013 and who fulfilled preliminary eligibility criteria were contacted by trained research assistants first via mail and then by phone about the study and invited to return to the clinic for an enrollment visit. In addition, new patients seen between August 2013 and October 2013 were approached in clinic by trained research assistants to assess for eligibility. Each child who attended the clinic received individualized care according to the standard curriculum of the program. This included education about asthma and its triggers and the creation

of a tailored Asthma Action Plan. After providing written informed consent, parents/guardians answered a baseline structured questionnaire before randomization.

Intervention

Eligible patients were randomized by block into two groups using shuffled, sealed, sequential, and opaque envelopes. The control group was prescribed daily ICS to be administered at home, morning and evening, every day for the 60-day study period. For the intervention group, the clinician in clinic provided a specific order for the school nurse to administer ICS every day that school was in session, and prescribed ICS for administration at home every evening on school days and every morning and evening on weekends and holidays. The ICS for school was provided directly to the school nurse via a dedicated CSS courier, along with a spacer and an updated Asthma Action Plan. Study staff contacted each school nurse the day after enrollment to confirm receipt of the medication and to review the administration procedure. In addition, study staff contacted the guardians of all participants a week after enrollment to review the parameters of the study and to confirm that they had obtained the prescribed ICS medication for home use.

Measures

Baseline

A baseline questionnaire was administered to guardians that gathered their child's demographic information, asthma care variables, history of health-care utilization for asthma, asthma severity classification based on the existing criteria of the National Institutes of Health [4], Asthma Control Test [15,16], use of controller medications in the last two days, and experience with the school nurse.

Follow-up

Guardians were administered a structured follow-up interview conducted by phone by trained and blinded research assistants approximately 60 days after enrollment. The interview addressed many of the same variables as baseline, but also included detailed questions about their reported use of ICS during the treatment period.

The primary outcome was the total proportion of expected morning doses of ICS administered by the school nurse within the intervention group. This was calculated on the basis of the exact follow-up period in days for each patient in the intervention group, excluding weekends and school holidays. Secondary outcomes included the relative proportions of expected doses of ICS (morning, evening, and total) given over the 60-day treatment period in both groups. Using a school-based

electronic health record, school nurses recorded and reported morning doses of ICS administered at school. Parents reported all other doses for all participants in both groups by structured telephone interview at follow-up. Additional outcomes included asthma-related QOL and health-care utilization. QOL was assessed with the Integrated Therapeutics Group Child Asthma Short Form [17,18]. This eight-item questionnaire assesses disease-specific, parental reported symptoms and disability resulting from pediatric asthma among children aged 5–12 years, which closely approximated the age range expected for children in grades K–8. The eight questions are further grouped into three subscales: daytime symptoms (2 questions), nighttime symptoms (2 questions), and functional limitations (4 questions). Two additional questions were added from the measure's original long form to assess family life adjustment to the child's asthma and interference with the child's life because of medication use.

Analysis

First, we explored primary and secondary outcomes using univariate statistics appropriate for each measure with proportions (including 95% confidence intervals [CI]) and rates. Because exact follow-up periods varied for each participant, proportions of reported expected doses were adjusted to a standardized 60-day treatment period. We then compared the distribution of each baseline and follow-up measure across the two groups using the chi-square test statistic for categorical variables and the *F*-statistic from one-way ANOVA (Analysis of Variance) for continuous variables.

Sample size considerations

We sought to enroll at least 25 patients in each arm of the study. Given that each of the participants in the intervention arm would attend approximately 40 school days during the treatment period, we expected approximately 1000 total morning doses of ICS to be administered during the 60-day trial among participants in the intervention arm. We hypothesized that greater than 80% of these doses would actually be administered. An estimated 1000 morning doses would allow us to estimate the true proportion of total morning doses of ICS administered at school in our population with a 95% confidence interval of approximately $\pm 2.5\%$.

Results

This study enrolled a total of 48 children. One subsequently withdrew and one was declared an enrollment violation, leaving 46 participants from 18 different schools (21 intervention and 25 control [Figure 1]). Their baseline

demographic variables are reported in Table 1. The groups did not differ in demographic characteristics or asthma severity. The overwhelming majority of participants in both groups was African-American, non-Hispanic, and all had active public insurance. Regarding ICS in schools, 19/21 (91%) participants in the intervention group and 23/25 (92%) participants in the control group reported no ICS in their schools at baseline. The majority of participants had mild or moderate persistent asthma at baseline (95 and 96% of participants in the intervention and control groups, respectively). Finally, at baseline, both groups had received similar courses of systemic steroids in the last 12 months.

Follow-up was available at 60 days on all intervention patients and 23/25 (92%) of control patients.

Primary outcome

The adjusted overall proportion of expected total doses of morning ICS administered at school by school nurses in the intervention group was 91.7% (95% CI [87.7, 95.5]). This exceeded our hypothesized rate of 80%.

Secondary outcomes

The number of expected doses of ICS (morning, evening, and total both reported by parents and documented by school nurses) administered over the 60-day treatment period did not differ by group (Table 2). At the 60-day follow-up point, there were no significant differences between the intervention and control groups in the number of patients who reported use of ICS in the last 2 days (81.0% vs. 87.0%, respectively, $p = 0.59$).

In the intervention group, 23.81% of patients missed ≥ 1 school days related to asthma, while 43.5% of those in the control group reported missing ≥ 1 school days ($p = 0.17$).

Additionally a QOL tool was used at the end of the study period to identify limitations using sub-scales for daytime and nighttime symptoms, functional limitations, family adjustments, and medical interference. The intervention and control groups were compared on reporting at least one limitation compared to none (Table 2). Intervention patients reported significantly less functional limitation (42.9% vs. 73.9%, $p = 0.04$) and fewer required adjustments to family life to accommodate asthma-related health (23.8% vs. 56.5%, $p = 0.03$). Additionally, the intervention group reported less sleep loss due to asthma (1.7 vs. 4.1 nights in last 2 weeks, $p = 0.04$) at the end of the 60-day study period.

There were no differences in unscheduled health-care utilization (Emergency Department (ED) visits and hospitalizations) for asthma between the two groups during

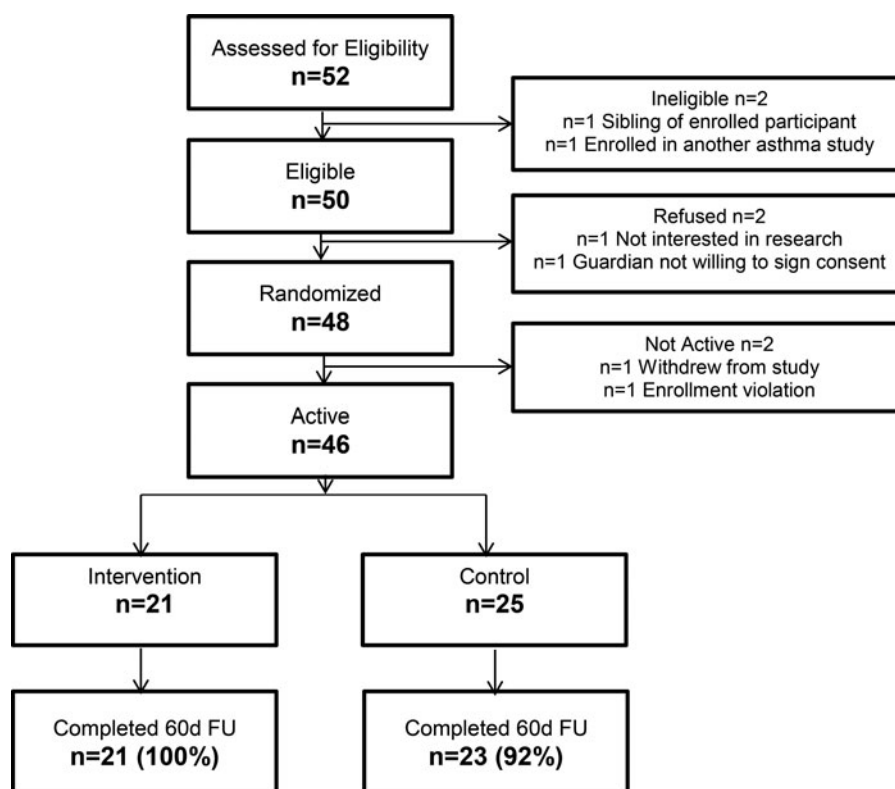


Figure 1. CONSORT diagram.

the outcome period, nor were there in reported differences in systemic steroid courses (Table 3).

Discussion

This pilot work was designed to develop a protocol to examine if high rates of school-based administration of daily ICS on school days by public school nurses were achievable within a population of urban, disadvantaged, and largely minority students with persistent asthma. Over 90% of the expected morning doses were documented as delivered by school nurses across 18 different public and public charter schools in the District of Columbia. These pilot data suggest that school-based administration of ICS has the potential to achieve high rates of administration of morning doses of ICS in similar populations with asthma enrolled in public schools.

Our secondary outcomes are interesting as well. We demonstrated significant improvements in multiple measures of asthma-related QOL. These occurred despite not demonstrating a significant difference in the total number of reported doses of ICS administered (morning, evening, and total between groups, as reported by parents and documented by school nurses). This may be due to over reporting of the administration of ICS at home by parents. Alternatively, parents could be administering the drug with improper technique at home.

As one of the most common childhood conditions, the burden associated with asthma is high [19]. From the perspective of the child, asthma can be severe and debilitating, resulting in deficits in learning, playing, and sleep [19]. Asthma is the most common childhood illness and when moderate to severe (i.e., persistent), results in a considerable number of hospital admissions, physician visits, and school absences [6,11,20,21].

Other programs have been similarly successful in using school-based approaches. Only two reported exact compliance with school-based therapy, and both came from the same group in the same city [9,22]. The first study from Halterman et al. was a school-based intervention for children aged 3–10 in the Rochester City School District with physician-diagnosed asthma [9]. The study population was similar to ours, but included younger children and some with private medical insurance. In addition, all of the participants in our study were recruited from a validated asthma specialty clinic [14], while the Halterman study recruited directly from schools. After randomization, the treatment group in the Halterman study received the intervention that consisted of school nurse-administered daily ICS and an extra canister of medication for use on weekends and holidays. Families with smoke-exposed children were enrolled in an environmental smoke reduction program. The control group was a usual care group. Similar to our study, overall compliance was high (98%). The treatment group had

Table 1. Baseline demographics of study population.*

Variable	Category	Intervention <i>n</i> = 21	Control <i>n</i> = 25
Age (mean and standard deviation)	Mean age	<i>M</i> = 8.43 <i>SD</i> = 2.32	<i>M</i> = 8.03 <i>SD</i> = 2.60
Sex (<i>n</i> (%))	Males	13 (61.9%)	13 (52.0%)
Race (<i>n</i> (%))	African American	20 (95.2%)	22 (88%)
	Asian	0 (0%)	1 (4%)
	Native Hawaiian/Pacific Islander:	1 (4.8%)	0 (0%)
	Other	0 (0%)	2 (8%)
Ethnicity (<i>n</i> (%))	Hispanic	0 (0%)	0 (0%)
	Non-Hispanic	17 (81.0%)	20 (80.0%)
	Other	4 (19.0%)	5 (20.0%)
Insurance (<i>n</i> (%))	Public	21 (100%)	25 (100%)
	Private	0 (0%)	0 (0%)
Home environmental tobacco smoke exposure (<i>n</i> (%))	Daily or often	3 (14.3%)	7 (28.0%)
	Not daily or often	18 (85.7%)	18 (72.0%)
Albuterol available for use at school (<i>n</i> (%))	Yes	11 (52.4%)	15 (60%)
ICS prescribed for use at school (<i>n</i> (%))	Yes	2 (9.5%)	2 (8%)
Parent reports having met the school nurse (<i>n</i> (%))	Yes	19 (95.0%)	20 (87%)
ICS used in last two days (<i>n</i> (%))	Yes	9 (42.9%)	11 (44%)
Albuterol used in last 2 days	Yes	8 (38.1%)	8 (32%)
Asthma control test score (Mean-SD)		<i>N</i> = 19 20.58 (4.15)	<i>N</i> = 25 18.04 (4.97)
Persistent asthma by NIH criteria (<i>n</i> (%))	Mild	12 (57.1%)	18 (72%)
	Moderate	8 (38.1%)	6 (24%)
	Severe	1 (4.8%)	1 (4.0%)
Emergency department visits in last 12 months (<i>n</i> (%))**	0	2 (9.5%)	7 (28%)
	1–2	14 (66.7%)	14 (56%)
	≥3	5 (23.8%)	4 (16%)
Hospital admissions in the last 12 months (<i>n</i> (%))**	0	12 (57.1%)	18 (72.0%)
	1–2	9 (42.9%)	7 (28.0%)
	≥3	0 (0%)	0 (0%)
Courses of systemic steroids in last 12 months (<i>n</i> (%))	0	3 (14.3%)	4 (16.0%)
	1–2	7 (33.3%)	11 (44.0%)
	≥3	11 (54.4%)	10 (40.0%)

Notes. *Differences between the intervention and control group were not significant. **Sum of parent report and chart report for emergency department visits and hospitalizations.

more symptom-free days, fewer nighttime symptoms, and fewer exacerbations. There were also more positive results for the children with smoke exposure. In a follow-up study of largely Medicaid children (70%) in Rochester from the same group, overall compliance was again 98% [10].

Our study had several limitations. First, it was conducted among a largely homogenous population of children in a single city and may not be generalizable to other populations in other urban environments. Second, it was limited to elementary and middle school students and therefore may not be generalizable to preschools or high schools. Third, for all but our primary outcome, outcomes were dependent on parental report, including report of all doses of ICS administered in both groups outside of school. Use of electronic monitoring devices would have potentially improved our measurements of adherence [23]. Fourth, we were unable to account for missed school days in the intervention group. Missed days would have the effect of lowering our overall estimate of school-based adherence. Fifth, our study did not address the issue of costs associated with school-based administration of ICS. A recent study by the Rochester group discussed

above did demonstrate cost-effectiveness of this approach [22]. Finally, the study was short term (conducted over 60 days), and it is unclear if school-based administration of ICS or other positive outcomes could be sustained. On the other hand, a longer study that provides more ICS to children during the school year might demonstrate greater improvements in asthma-related QOL and reduced health-care utilization.

Conclusion/key findings

School nurses across 18 different public and public charter schools in the District of Columbia delivered over 90% of the expected morning doses in a largely homogenous population of urban and minority children with persistent asthma on Medicaid. These pilot data suggest that school-based administration of ICS can achieve high rates of administration of morning doses of ICS on school days in similar populations with asthma in public schools settings. Additionally, we demonstrated significant improvements in multiple secondary outcomes including measures of asthma-related QOL. This pilot program is an essential first step for a randomized clinical

Table 2. Reporting of (a) adjusted doses of ICS over the 60-day follow-up, (b) at least one limitation in the quality of life subscales at 60-day follow-up and (c) symptom days in the last 14 days.

(a) Adjusted ICS doses	Intervention (<i>n</i> = 21)	Control (<i>n</i> = 22)	Significance*
			(<i>t</i> -test)
Morning doses	<i>M</i> = 58.0 <i>SD</i> = 12.6	<i>M</i> = 51.2 <i>SD</i> = 14.8	<i>p</i> = 0.11
Evening doses	<i>M</i> = 54.6 <i>SD</i> = 8.6	<i>M</i> = 50.3 <i>SD</i> = 17.4	<i>p</i> = 0.31
Total doses (at home and at school)	<i>M</i> = 112.7 <i>SD</i> = 12.0	<i>M</i> = 100.1 <i>SD</i> = 27.0	<i>p</i> = 0.06
(b) QOL subscale	Intervention <i>n</i> = 21 <i>N</i> (%)	Control <i>n</i> = 23 <i>N</i> (%)	Significance* (chi square)
Daytime subscale	7 (33.3%)	7 (30.4%)	<i>p</i> = 0.84
None	14 (66.7%)	16 (69.6%)	
At least one			
Nighttime subscale	7 (33.3%)	8 (34.8%)	<i>p</i> = 0.92
None	14 (66.7%)	15 (65.2%)	
At least one			
Functional limitation subscale	12 (57.1%)	6 (26.1%)	<i>p</i> = 0.04
None	9 (42.9%)	17 (73.9%)	
At least one			
Family life adjustment subscale	16 (76.2%)	10 (43.5%)	<i>p</i> = 0.03
None	5 (23.8%)	13 (56.5%)	
At least one			
Medical interference subscale	16 (76.2%)	12 (52.2%)	<i>p</i> = 0.10
None	5 (23.8%)	11 (47.8%)	
At least one			
(c) Symptom days in last 14 days	Intervention <i>n</i> = 21 <i>M</i> (<i>SD</i>)	Control <i>n</i> = 23 <i>M</i> (<i>SD</i>)	Significance* (<i>t</i> -test)
Parent wake up/sleep loss (previous 14 days)	1.71 (1.52)	4.13 (4.87)	<i>p</i> = 0.035
Number of days with symptoms (previous 14 days)	3.10 (3.01)	3.61 (3.62)	<i>p</i> = 0.06
Limited activity (previous 14 days)	3.14 (3.66)	2.70 (2.14)	<i>p</i> = 0.62
Child wake up/sleep loss due to asthma (previous 14 days)	1.71 (1.52)	3.04 (3.59)	<i>p</i> = 0.12

Note. *All comparisons are unadjusted and univariate.

Table 3. Health-care utilization: proportion with one or more of the following events during the 60-day outcome period.

Variable	Intervention <i>n</i> = 21 <i>N</i> (%)	Control <i>n</i> = 23 <i>N</i> (%)	Statistic (chi square)
Emergency department visits (<i>n</i> (%))			
0	19 (90.5%)	20 (87%)	$\chi^2 = 0.135$
>=1	2 (9.5%)	3 (13%)	<i>p</i> = .713
Hospital admissions (<i>n</i> (%))			
0	20 (95.2%)	23 (100.0%)	$\chi^2 = 1.121$
>=1	1 (4.8%)	0 (0%)	<i>p</i> = 0.290
Courses of systemic steroids (<i>n</i> (%))			
0			
1–2	19 (90.5%)	20 (87.0%)	$\chi^2 = 0.135$
≥3	2 (9.5%)	3 (13%)	<i>p</i> = 0.713
	0 (0%)	0 (0%)	

trial of the administration of ICS within a school-based program, demonstrating that school-based administration of ICS in a high-risk urban population of children with persistent asthma is possible.

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Declaration of interest

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

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