The School-Based Preventive Asthma Care Trial: Results of a Pilot Study

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Objective To test the feasibility and preliminary effectiveness of the School-Based Preventive Asthma Care Technology (SB-PACT) program, which includes directly observed therapy of preventive asthma medications in school facilitated by Web-based technology for systematic symptom screening, electronic report generation, and medication authorization from providers.

Study design We conducted a pilot randomized trial of SB-PACT versus usual care with 100 children (aged 3-10 years) from 19 inner-city schools in Rochester, New York. Outcomes were assessed longitudinally by blinded interviewers. Analyses included bivariate statistics and linear regression models, adjusting for baseline symptoms.

Results There were data for 99 subjects for analysis. We screened all children using the Web-based system, and 44 of 49 treatment group children received directly observed therapy as authorized by their providers. Treatment group children received preventive medications 98% of the time they were in school. Over the school year, children in the treatment group experienced nearly 1 additional symptom-free day over 2 weeks versus the usual care group (11.33 vs 10.40, $P = .13$). Treatment children also experienced fewer nights with symptoms (1.68 vs 2.20, $P = .02$), days requiring rescue medications (1.66 vs 2.44, $P = .01$), and days absent from school due to asthma (0.37 vs 0.85, $P = .03$) compared with usual care. Further, treatment children had a greater decrease in exhaled nitric oxide (-9.62 vs -0.39, $P = .03$), suggesting reduction in airway inflammation.

Conclusion The SB-PACT intervention demonstrated feasibility and improved outcomes across multiple measures in this pilot study. Future work will focus on further integration of preventive care delivery across community and primary care systems. *(J Pediatr 2012;161:1109-15)*.

Asthma is a chronic disease characterized by inflammation in the airways. Inhaled corticosteroids are the most effective long-term treatment for patients with persistent asthma, and the National Heart, Lung, and Blood Institute (NHLBI) Expert Panel guidelines recommend that all patients with persistent asthma receive daily inhaled corticosteroid therapy.[1] These medications reduce asthma symptoms, improve pulmonary function, and prevent exacerbations leading to hospitalizations[2] when used as recommended. In addition, once medications are prescribed, the guidelines recommend follow-up assessments in 4-6 weeks, with adjustments in therapy as needed, to ensure the goals of therapy are met.[1]

Despite these clear and well-developed guidelines for care, little has been done to ensure implementation of the guidelines. Many children in the United States with persistent asthma symptoms do not receive preventive medications.[3-5] In addition, many children who are prescribed a preventive medication do not achieve optimal control, at least in part due to poor adherence and lack of appropriate follow-up care.[6] Importantly, the greatest underuse of preventive medications and lack of appropriate asthma care occur among poor children living in inner cities.[7]

We developed a unique program of school-based asthma care designed to improve adherence to preventive asthma care guidelines and reduce morbidity for poor and minority children with persistent symptoms.[8,9] Our previous intervention, the School-Based Asthma Therapy Trial (2006-2009), included directly observed administration of preventive asthma medications in school, with guideline-based medication dose adjustments for children who continued to have poor control. This program was successful in reducing asthma morbidity[10]; however, in its original form, the intervention required substantial hands-on participation by the study team to screen children for persistent symptoms and to ensure appropriate medications were authorized, prescribed, and delivered to schools for directly observed therapy.

We subsequently developed the School-Based Preventive Asthma Care Technology (SB-PACT) trial, which uses a Web-based program to overcome key barriers to sustainability identified in the original study. Our goal was to develop a novel mechanism for the implementation of sustainable school-based asthma care in a real-world setting.

This report presents the primary outcomes of the SB-PACT pilot study, focusing on the feasibility and preliminary effectiveness of the intervention on asthma

ACC	Asthma care coordinator
NHLBI	National Heart, Lung, and Blood Institute
PCP	Primary care provider
SB-PACT	School-Based Preventive Asthma Care Technology

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Funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health (RC1HL099432). The authors declare no conflicts of interest.

Registered at ClinicalTrials.gov: NCT01175434.

 http://dx.doi.org/10.1016/j.jpeds.2012.05.059

morbidity, including symptom-free days, quality of life, absenteeism, and urgent health care use.

Methods

The University of Rochester Institutional Review Board approved all study procedures. At the beginning of the 2009-2010 school year, children aged 3-10 years attending school in the Rochester (NY) City School District were screened for eligibility. All schools in the Rochester City School District (N = 39) agreed to participate. We recruited a convenience sample of 100 children into the study from 19 schools (on average, 5 children in each school). Children were identified by school medical-alert forms, which are available to school health staff at the start of the school year and include a list of children with an asthma diagnosis. The school nurse or school health aide (with assistance from the study team, as needed) conducted a brief survey with the child's caregivers using a secure Web-based platform to assess the child's eligibility.

Eligible children had physician-diagnosed asthma with persistent symptoms based on the NHLBI guidelines.[1] Children were excluded if their caregiver was unable to speak and understand English, if they had no access to a working phone for follow-up surveys, if they were planning to leave the school district within <6 months, or if the child had any other significant medical conditions, including congenital heart disease, cystic fibrosis, or other chronic lung disease, that could interfere with the assessment of asthma-related measures.

Once a child was deemed eligible, the study team scheduled a baseline home visit with the family to obtain written informed consent from the parent and assent from children ≥7 years old. The baseline evaluation included an assessment of asthma symptoms, standard family and health history variables, and exposure to secondhand smoke. An asthma symptom diary, developed using the school calendar, was given to the caregiver for tracking of asthma symptoms throughout the school year. We also obtained a saliva sample from each child for cotinine concentration to measure secondhand smoke exposure. Last, we obtained exhaled nitric oxide measurements from each child using a portable NIOX MINO (Aerocrine, New Providence, New Jersey) machine to objectively measure airway inflammation. Enrollment occurred in a rolling fashion, beginning in October of the school year.

Following completion of the baseline assessment, each child was randomly assigned to either the SB-PACT group or the usual care group. Randomization was stratified by the use of a preventive asthma medication at baseline. A permutated block design was used to assure an equal balance of children in each group over time. The randomization scheme was independently developed by the Biostatistics Center; the interviewer called the study coordinator, who provided the subject's ID number and treatment assignment.

SB-PACT Group

Program Overview. The SB-PACT intervention includes several key steps: (1) systematic Web-based screening to assess children's asthma using guideline-based symptom questions along with an algorithm to compute an NHLBI severity or control classification; (2) report generation and electronic communication with primary care providers (PCPs) for authorization of directly observed therapy of preventive asthma medications through school; (3) prescription of guideline-based preventive medications, which are purchased through the child's health insurance and delivered to schools and children's homes by a local pharmacy; (4) directly observed administration of medications at school by a school nurse or health aide; and (5) systematic reassessment of symptoms using the same system, with guideline-based adjustments in therapy as needed. We also incorporated 0.3 full-time equivalent support from an asthma care coordinator (ACC) to facilitate communication between school health staff, healthcare providers, and caregivers. The ACC is a registered nurse with additional training in childhood asthma. Further details of the program are presented elsewhere.[11]

Study Processes. The ACC reviewed the screening data and transmitted an electronic asthma report to the PCP that included a recommendation for directly observed therapy at school. The PCP was then prompted to approve a prescription for a preventive asthma medication that was ordered through one of a number of pharmacies that provide delivery services and to agree to monitor the child for potential side effects. One canister of preventive medication, with a spacer and mask (if indicated), was delivered to the family at home. The family used this inhaler for medication doses on weekend days and other days in which the child did not attend school. A second medication canister with a spacer and mask was delivered to the child's school for use on school days. School health staff administered 1 dose of medication to the child during the school day. The school nurse showed children how to use medications properly and instructed them to rinse their mouth with water after each dose. We also provided written instructions on inhaler technique to families, with demonstration when requested. Even though adherence to medication administration was ensured by school health staff on the days the child attended school, adherence was encouraged but not ensured on days the child did not attend school.

All children in the study had persistent asthma symptoms and/or poor asthma control upon enrollment and thus warranted the use of a daily preventive asthma medication according to the NHLBI guidelines. The starting medication administered through the study varied depending on the child's baseline asthma therapy; some children began a new preventive medication, and others continued with a previously prescribed medication or were stepped-up in their therapy. The ACC reviewed all caregiver-reported preventive medications (if any) prior to the start of the study and made a recommendation to the PCP. The PCP then authorized the recommended medication (or could provide authorization for an alternate medication) to be administered as directly observed therapy through school. Most children received once-daily dosing because it is effective[12] and allows for