Improved Asthma Outcomes in a High-Morbidity Pediatric Population

Results of an Emergency Department–Based Randomized Clinical Trial

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Objective: To determine if an emergency department–based asthma follow-up clinic could improve outcomes within a high-morbidity pediatric population.

Design: Prospective, randomized clinical trial with 6 months of follow-up.

Setting: Emergency department of an urban pediatric medical center.

Participants: Convenience sample of 488 patients aged 12 months to 17 years, inclusive, with prior physician-diagnosed asthma and 1 or more other unscheduled visits in the previous 6 months and/or 1 or more hospitalizations in the prior 12 months.

Intervention: Single follow-up clinic visit focusing on 3 domains: asthma self-monitoring and management, environmental modification and trigger control, and linkages and referrals to ongoing care.

Main Outcome Measures: The primary outcome measure was unscheduled visits for acute asthma care. Secondary outcomes included compliance with a medical plan and asthma quality of life. Analysis was by intention to treat with adjustment for baseline differences.

Results: Of those randomized to the clinic visit, 172 (70.5%) of 244 attended. The intervention group had significantly fewer mean unscheduled visits for asthma care during follow-up (1.39 vs 2.34; relative risk [RR] = 0.60 [95% confidence interval (CI), 0.46-0.77]). At 6 months, significantly more patients in the intervention group reported use of inhaled corticosteroids in the prior 2 days (49.3% vs 26.5%; RR = 2.03 [95% CI, 1.57-2.62]), no limitation in daytime quality of life (43.8% vs 34.4%; RR = 1.36 [95% CI, 1.06-1.73]), and no functional limitations in quality of life (49.8% vs 40.8%; RR = 1.33 [95% CI, 1.08-1.63]).

Conclusion: Attendance in the follow-up clinic was high. The intervention decreased subsequent unscheduled health care use while improving compliance and quality of life.

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known as Improving Pediatric Asthma Care in the District of Columbia (IMPACT DC), targeted frequent users of an urban pediatric ED. It consisted of a single visit scheduled for 2 to 15 days after ED discharge to a specialized asthma clinic located in the ED. The clinic provided education and clinical care, focusing on 3 distinct domains: asthma self-monitoring and management, environmental modification and trigger control, and linkages and referrals to ongoing primary care.

Our primary hypothesis was that this intervention would decrease subsequent unscheduled visits (to both EDs and other sources of urgent care) for acute asthma care during a 6-month follow-up period. We further hypothesized that the intervention would decrease hospitalizations for asthma, improve compliance with an individualized medical plan and with trigger control, increase scheduled primary care practitioner (PCP) visits for routine asthma care, and decrease asthma symptoms while improving asthma quality of life (QOL).

METHODS

We enrolled patients in a prospective, randomized clinical trial in the ED at Children’s National Medical Center in Washington, DC, from April 2002 until January 2004. Children’s National Medical Center is an urban tertiary care pediatric medical center with an ED volume of 72,778 visits in 2003. Of these visits, 4482 (6.1%) included a primary discharge diagnosis of asthma among patients aged 12 months to 17 years, inclusive. Trained research assistants recruited subjects among those with respiratory complaints. Inclusion criteria included: (1) age between 12 months and 17 years, inclusive; (2) prior physician-diagnosed asthma; (3) 1 or more other unscheduled visits for acute asthma care (to an ED or other health care source) in the previous 6 months and/or 1 or more hospitalizations for asthma in the prior 12 months; (4) a parent or guardian available for interview; (5) residence in Washington, DC, or a contiguous Maryland county; and (6) requirement for 3 or more doses of nebulized albuterol in the ED at the time of enrollment.

Exclusion criteria included: (1) significant medical comorbidities affecting the cardiorespiratory system; (2) a visit to an allergist or a pulmonologist in the prior 6 months; (3) 2 or more of the following: a current written asthma medical action plan, current use of more than 1 controller medication, or a scheduled visit for asthma care with their PCP in the prior 2 weeks; (4) enrollment in another asthma research study; (5) unavailability for telephone follow-up; or (6) primary language other than English or Spanish.

Acute asthma therapy while the patient was in the ED at the enrollment visit was at the discretion of the treating ED physicians. This care was largely guided by an existing clinical pathway for acute asthma exacerbation that suggested a 3-day course of oral prednisolone or prednisone be initiated in the ED.

BASELINE DATA COLLECTION AND RANDOMIZATION

After obtaining informed consent and assent and while the patient was still in the ED, the research assistants obtained baseline data from the parent or guardian that assessed demographics, asthma history, medication use, asthma classification by the criteria of the National Heart, Lung, and Blood Institute (NHLBI),1 asthma symptoms and QOL, linkages to primary and specialty sources of care, and triggers in the home. Race and ethnicity were self-described by parents and guardians and were collected because they are independent predictors of asthma severity.20 Symptom questions were drawn from the National Cooperative Inner-City Asthma Study (NCICAS).21,22 Quality of life was assessed through the use of a measure developed and validated for pediatric asthma.23,24

Randomization was then accomplished in blocks of 30 participants. To accomplish this, the project director prepared batches of 30 opaque, sealed envelopes, 15 containing a folded slip of paper specifying randomization to the control group and 15 specifying randomization to the intervention group. Each batch of 30 envelopes was then exhaustively shuffled and numbered with participant identification numbers. During enrollment, the research assistants opened each sequential envelope after informed consent and assent was obtained and after the baseline interview was conducted.

The intervention consisted of a single visit to the IMPACT DC asthma clinic where each family met with an asthma educator and a physician. This clinic was physically located in the ED, using space available on weekday mornings. The control group received an asthma educational booklet but no specialized follow-up.

INTERVENTION

All clinical activities of the intervention were based on a shared dialogue with the families and development of a tailored treatment plan. In common with the NCICAS,21 these family-centered principles were theoretically grounded in the Health Belief Model and promotion of self-efficacy.24 Following a fully specified protocol requiring 60 to 90 minutes, education and care were provided in 3 domains.

Asthma Self-monitoring and Management

Educators first reviewed the basic physiology of asthma with emphasis on its chronicity. After evaluating asthma severity and treatment history, the physician completed an individualized medical action plan and provided any necessary device teaching (metered-dose inhaler, spacer, diskus, compressor, nebulizer). Controller medications were prescribed for a total of 3 months. Self-monitoring was taught by symptoms and/or by peak flow measurement.

Environmental Modification and Trigger Control

After evaluation of potential environmental triggers in the home, each family was educated on their control. The protocol emphasized an “asthma-safe sleep zone” for the child. Each child was provided hypoallergenic bed encasings.

Linkages and Referrals to Ongoing Primary Care

Clinic staff stressed the importance of longitudinal asthma care by a PCP. A full report of the clinic visit, together with a digital photograph of the child and a copy of the medical action plan, was mailed to each child’s PCP, insurance asthma case manager, and school nurse. In addition, the asthma educator scheduled a follow-up appointment with the PCP within 4 weeks. Any child with severe, persistent asthma was instructed to pursue further ongoing care with an asthma specialist.

FOLLOW-UP

Research assistants blinded to randomization status performed follow-up telephone interviews with each child’s parent or guardian at 1, 3, and 6 months after enrollment. The pri-
mary outcome measure was the rate of unscheduled visits (to EDs and other sources of urgent care) for acute asthma care during the 6-month period following randomization. Other utilization outcomes included hospital admissions for acute asthma and routine (scheduled > 24 hours in advance) PCP visits for nonacute asthma care. Other secondary outcomes included asthma medication and device use, efforts to control asthma triggers in the home, linkages to care providers (PCPs, asthma specialists, asthma case managers, and school nurses), asthma classification by NHLBI criteria, current asthma symptoms, and asthma QOL.

VALIDATION STUDY
To validate parental recall of ED visits, a random subset of 30 participants each from the intervention and control groups were recontacted after completion of the 6-month interview and asked to recall visits made to the ED at Children's National Medical Center during the prior 2 months. Their responses were compared with hospital records.

STATISTICAL CONSIDERATIONS
All outcomes were analyzed among those completing follow-up for the relevant period using an intention-to-treat paradigm. Initially, baseline sociodemographic and clinical characteristics in the intervention and control groups were compared using means and frequencies. All subsequent estimates of relative risk (RR) were adjusted for age, sex, race/ethnicity, insurance type, household income, environmental tobacco smoke exposure, and the corresponding baseline variable. All estimates of RR are reported with 95% confidence intervals (CIs).

All models included a specific dependent variable and a binary indicator of the randomly assigned study group. Process measures (elements of medical management, environmental modification, and care coordination) were compared between groups at the 1-month follow-up using multiple logistic regression models. For the primary outcome measure (unscheduled visits for asthma care) and for other measures of health care use, the analysis compared adjusted 6-month rates and RRs. Depending on the degree of dispersion in the rates, these models were based on either Poisson or negative binomial regression models. The latter were used whenever the degree of dispersion exceeded that accommodated by the Poisson model. Similar to the approach used with the process measures, multiple logistic regression models were also used to compare symptom and QOL measures between the 2 study groups at the 1-, 3-, and 6-month follow-ups. Finally, a Cox proportional hazards time-to-event model was developed to estimate and compare the cumulative probability of 1 or more ED visits during the 6-month follow-up period. All analyses were conducted using procedures in STATA version 8 and SAS version 9.

HUMAN SUBJECTS
The institutional review board at Children's National Medical Center approved this study. Legal guardians provided written informed consent. Participants 6 years and older provided written assent.

RESULTS
The research assistants screened 2791 patients during the 22-month enrollment period (Figure 1). Of these, 2270 (81.3%) were ineligible. The main reasons for ineligibility were no prior physician-diagnosed asthma (30.8%), no other unscheduled visits for asthma in prior 6 months and no hospitalization in prior 12 months (19.3%), acute asthma exacerbation not the primary reason for ED visit (18.6%), and significant medical comorbidities (8.6%). Of the 521 eligible patients identified, 490 (94.0%) were enrolled and randomized. Two were subsequently excluded because of enrollment violations, leaving 488 participants available for analysis. Follow-up through 6 months was available for 437 (89.5%) of these participants.

Baseline demographics of all participants are described in Table 1. The intervention and control groups were similar except for the proportions of each reporting environmental tobacco smoke exposure in the home and in the distribution of hospital admissions for asthma and scheduled asthma care visits in the prior 12 months.

Of those randomized to the intervention, 172 (70.5%) of 244 attended. The intervention was implemented with high uniformity. All patients left the clinic with a completed medical action plan, a mattress pad and pillow cover, and a spacer (if prescribed inhaled medicines). Of the 172 patients attending the clinic, 167 (97.1%) were prescribed inhaled corticosteroids (via inhaler or nebulizer), and 69 (40.1%) were prescribed leukotriene antagonists.

Process measures at 1 month after enrollment are reported in Table 2. There were significantly more families in the intervention group reporting use of a written medical action plan, use of inhaled corticosteroids and leukotriene antagonists in the prior 2 days, and use of a spacer whenever using metered-dose inhalers. In addition, significantly more families in the intervention group reported use of bed encasings and no daily smoking within the home. There were no significant differences between the groups in the proportion of families who identified the PCP as their usual source of asthma care, had contact with the school nurse regarding asthma care, or had contact with an asthma case manager from their insurance company.

Improvements in certain process measures continued for the full 6 months of follow-up. Reported use of inhaled corticosteroids in the prior 2 days was significantly greater in the intervention group compared with the con-
control group at both 3 months (54.3% vs 25.6%; adjusted RR=2.37 [95% CI, 1.83-3.04]) and 6 months (49.3% vs 26.5%; adjusted RR=2.03 [95% CI, 1.57-2.62]).

Utilization outcomes during the 6-month follow-up period are reported in Table 3. There were significantly fewer total mean unscheduled visits among children randomized to the intervention (1.39 vs 2.34; RR=0.60 [95% CI, 0.46-0.77]). This benefit of the intervention was also observed when ED visits and other unscheduled visits were considered separately. In addition, as depicted in Figure 2, there was a significantly higher cumulative risk in the control group of making 1 or more ED visits during the 6-month follow-up period (RR=1.74 [95% CI, 1.31-2.31]). There were no significant differences in the number of hospital admissions or scheduled PCP visits between the 2 groups. Of the 219 intervention patients with a complete 6-month follow-up, 32 (14.6%) had 1 or more visits to an asthma specialist outside of our intervention compared with 38 (17.4%) of 218 control patients (P = .42).

As presented in Table 4, data reporting asthma symptoms, NHLBI classification, and QOL during the follow-up period are skewed, with large proportions reporting being symptom free. We therefore analyzed them...
as the proportions in each group reporting no symp-
toms, no persistent asthma criteria, and no compromise
in QOL. The intervention improved asthma symptoms
and QOL in the first month after randomization, with se-
pected improvements persisting to the 6-month follow-
up. Significantly more children in the intervention group,
for example, were free of both diurnal and nocturnal
symptoms and sleep disturbance at 1 month after enroll-
ment. Similarly, persistent asthma symptoms were less
common at 1 month among those randomized to the in-
tervention, and QOL was significantly improved, whether
assessed with respect to daytime, nighttime, or func-
tional limitations. At 3 and 6 months, diminished but still
significant benefits in QOL remained.

Validation of 1 of the primary outcomes (ED use)
showed good agreement (unweighted \( \kappa = 0.67 \)) between
caregiver report and hospital records for 2-month recall
of ED visits. In addition, there was no difference be-
tween the intervention and control groups in the pro-
portion of caregivers with accurate 2-month recall of ED
visits (27 [90.0%] of 30 in both groups; \( P > .99 \)).

Using a rigorous randomized design with blinded inter-
views and intention-to-treat analysis, we demonstrated
that a single comprehensive follow-up visit after ED dis-
charge improved asthma care and outcomes in a high-
morbidity population of urban, largely disadvantaged, and
minority children. The intervention was unique in at least
3 important respects. First, it was an entirely ED-based
effort that did not rely on facilitated follow-up with either
primary care services or a specialized asthma center. Sec-
ond, it achieved rates of follow-up after ED care for asthma
far in excess of those reported in similar urban pediatric
populations.12-16 Finally, unlike prior ED-based efforts,
the intervention improved multiple measures of asthma
1 or more emergency department visits during the 6-month follow-
treatment adherence, symptom control, QOL, and health
period, adjusted for age, sex, race/ethnicity, insurance type, household
care use. Perhaps most importantly, it decreased the rate
income, environmental tobacco smoke exposure, and corresponding
of unscheduled visits for asthma during the entire 6-month follow-
baseline variable.

Table 3. Rates of Health Care Use During 6-Month
Follow-up Period, Adjusted for Covariates*  

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 219)</th>
<th>Control (n = 218)</th>
<th>Adjusted Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total unscheduled visits for asthma (ED and elsewhere)</td>
<td>1.39</td>
<td>2.34</td>
<td>0.60 (0.46-0.77)</td>
</tr>
<tr>
<td>ED visits for asthma</td>
<td>0.64</td>
<td>1.19</td>
<td>0.54 (0.40-0.72)</td>
</tr>
<tr>
<td>Unscheduled visits for asthma to source other than ED</td>
<td>0.68</td>
<td>1.13</td>
<td>0.60 (0.44-0.84)</td>
</tr>
<tr>
<td>Hospital admissions for asthma</td>
<td>0.10</td>
<td>0.18</td>
<td>0.56 (0.33-1.08)</td>
</tr>
<tr>
<td>Scheduled visits with PCP for asthma</td>
<td>2.05</td>
<td>2.04</td>
<td>1.00 (0.85-1.18)</td>
</tr>
</tbody>
</table>

*Adjustments made for age, sex, race/ethnicity, insurance type, household income, environmental tobacco smoke exposure, and corresponding baseline variable.

Figure 2. Cox proportional hazards regression of cumulative risk of having 1 or more emergency department visits during the 6-month follow-up period, adjusted for age, sex, race/ethnicity, insurance type, household income, environmental tobacco smoke exposure, and reported emergency department visits at baseline. There were 219 patients in the intervention group and 218 in the control group. Adjusted relative risk=1.74 (95% confidence interval, 1.31-2.31).

in part by these guidelines, prior ED-based interventions
have focused on improving rates of primary care
follow-up. Zorc et al12 and Smith et al13 have recently re-
ported randomized trials of facilitated follow-up after acute
ED visits for pediatric asthma care. Although these in-
terventions successfully increased follow-up visits, they
did not reduce subsequent ED visits or hospital admis-
sions. Other evidence outside of randomized trials also
suggests that primary care follow-up after acute exacer-
bations is not associated with a decrease in subsequent
ED visits.14

There are several factors that may explain the success
of the intervention described herein. First, it was des-
ign to exploit the “teachable moment,” an approach
documented to improve outcomes in injury prevention, drug and alcohol abuse, smoking, and weight loss. The high rate of clinic attendance (70.5% of those randomized to the intervention) suggests that participants were highly motivated under these circumstances to seek education and improved care. Second, the intervention was comprehensive, addressing environmental change, medical care, and care coordination, and it was highly family- and patient-centered. Several studies have identified this individualized approach to asthma care as especially important to inner-city families. Third, we obtained very high levels of self-reported adherence with inhaled corticosteroids, use of which has been independently associated with improved asthma outcomes. Finally, we provided access to follow-up care within the familiar context of the ED. Based on their prior pattern of frequent ED use for asthma, it may not be surprising that families were comfortable returning to the ED. We do not know whether this comprehensive intervention would be as successful if applied in venues other than the ED.

The intervention was also designed to strengthen each family’s relationship to their child’s PCP, but it did not achieve this objective. It is possible that the intervention might even have negatively impacted the role of the PCPs by establishing an effective ED-based system for short-term asthma management. In any case, the intervention did not increase PCP contact for scheduled asthma care, and this may be an important limitation to its sustained effect. Despite its successes, the intervention has other limitations. First, participants were recruited in a single large, urban pediatric ED, and results may not be generalizable to other geographic areas. Emergency departments with populations similar to the one studied herein clearly exist in other cities; however, and as noted earlier, patients and families see them as important sources of their asthma care. Second, participants were deliberately selected based on high prior rates of health care use for asthma, and the effect of the intervention on patients with less frequent prior ED visits is uncertain. Previous work has shown, however, that a relatively small group of inner-city children contributes disproportionately to overall pediatric ED visits for asthma. Data from Pittsburgh, Pa, and Milwaukee, Wis, for example, demonstrated that 16% to 20% of ED patients with asthma made 36% to 50% of all ED visits. Third, all of the outcomes were based on caregiver recall for periods of 1 to 3 months, and they are therefore subject to recall bias. However, numerous other studies have relied on the same methods, including the NCICAS, which asked participants to recall use during the prior 2 to 3 months. We also validated one of the most important outcomes, ED use, and we found no evidence of selectively biased recall between the 2 study groups. Fourth, we only followed up participants for 6 months after enrollment. It is possible that the effect of the intervention diminished thereafter. Fifth, we performed no cost-benefit analysis of the intervention.
tervention. This was beyond the budgeted scope of the project. Finally, a single physician provided all the medical care for the intervention, and therefore, the results may be due in part to a practitioner effect.

In conclusion, we found that a single follow-up visit to a comprehensive ED-based asthma clinic resulted in significant and clinically relevant improvements in care and outcomes in a high-morbidity pediatric population. We believe that this finding may have implications for the future role of the urban ED in asthma care and potentially in other chronic pediatric conditions with acute exacerbations. At the least, these methods may serve as a useful model in similar urban EDs with a high volume of inner-city children with asthma.

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