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# A Multisite Randomized Trial of the Effects of Physician Education and Organizational Change in Chronic-Asthma Care

## Health Outcomes of the Pediatric Asthma Care Patient Outcomes Research Team II Study

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**Background:** Traditional primary care practice change approaches have not led to full implementation of national asthma guidelines.

**Objective:** To evaluate the effectiveness of 2 asthma care improvement strategies in primary care.

**Design:** Two-year randomized controlled clinical trial.

**Setting:** Forty-two primary care pediatric practices affiliated with 4 managed care organizations.

**Participants:** Children aged 3 to 17 years with mild to moderate persistent asthma enrolled in primary care practices affiliated with managed care organizations.

**Interventions:** Peer leader education consisted of training 1 physician per practice in asthma guidelines and peer teaching methods. Planned care combined the peer leader program with nurse-mediated organizational change through planned visits with assessments, care planning, and self-management support, in collaboration with physicians. Analyses compared each intervention with usual care.

**Main Outcome Measures:** Annualized asthma symptom days, asthma-specific functional health status (Children's Health Survey for Asthma), and frequency of brief oral steroid courses (bursts).

**Results:** Six hundred thirty-eight children completed baseline evaluations, representing 64% of those screened and eligible. Mean  $\pm$  SD age was  $9.4 \pm 3.5$  years; 60% were boys. Three hundred fifty (55%) were taking controller medication. Mean  $\pm$  SD annualized asthma symptom days was  $107.4 \pm 122$  days. Children in the peer leader arm had 6.5 fewer symptom days per year (95% confidence interval [CI], -16.9 to 3.6), a nonsignificant difference, but had a 36% (95% CI, 11% to 54%) lower oral steroid burst rate per year compared with children receiving usual care. Children in the planned care arm had 13.3 (95% CI, -24.7 to -2.1) fewer symptom days annually (-12% from baseline;  $P = .02$ ) and a 39% (95% CI, 11% to 58%) lower oral steroid burst rate per year relative to usual care. Both interventions showed small, statistically significant effects for 2 of 5 Children's Health Survey for Asthma scales. Planned care subjects had greater controller adherence (parent report) compared with usual care subjects (rate ratio, 1.05 [95% CI, 1.00 to 1.09]).

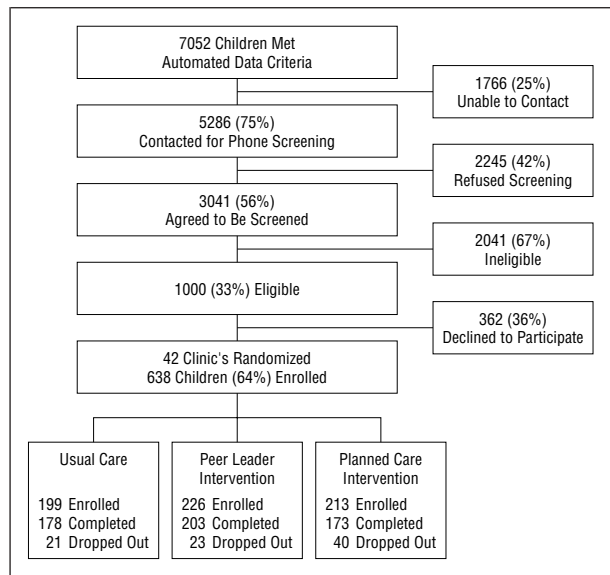
**Conclusions:** Planned care (nurse-mediated organizational change plus peer leader education) is an effective model for improving asthma care in the primary care setting. Peer leader education on its own may also serve as a useful model for improving asthma care, although it is less comprehensive and the treatment effect less pronounced.

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**T**HE NATIONAL ASTHMA EDUCATION and Prevention Program guidelines<sup>1,2</sup> provide evidence-based recommendations for severity assessment, pharmacotherapy, monitoring, environmental control, and promoting patient-physician partnerships. Inhaled anti-inflammatory medications (controllers) form the basis of pharmacotherapy for persistent disease. Current practice falls

short of guidelines, and inadequate asthma control is prevalent. One quarter to one half of high-risk children prescribed controllers take them daily.<sup>3-7</sup> This gap between ideal and actual asthma care must be considered in the context of chronic-illness care and the Institute of Medicine's call for "fundamental changes . . . in the organization and delivery of health care in the United States," with a focus on chronic-illness care.<sup>8(p23)</sup>

Author affiliations are given at the end of the article.



**Figure 1.** Participant screening and enrollment. Overall participant rate,<sup>27</sup> assuming cases of unknown eligibility (those not contacted or who refused to participate) to have the same likelihood of eligibility as those screened, was estimated to be 27%. A total of 554 subjects (87% of those enrolled) was available at the end of the study and analyzed for primary outcome. Eighty-two of the 84 subjects who dropped out contributed at least 1 periodic telephone survey to the outcome data. Among all dropouts, the mean  $\pm$  SD number of periodic telephone surveys completed was  $5.1 \pm 3.2$ .

Approaches to improve chronic-illness care delivery include physician-directed and multilevel interventions. Although effective physician-directed interventions have been developed for other conditions,<sup>9,10</sup> most published trials of such programs in asthma have yielded largely null or weakly positive results.<sup>11-15</sup> Multilevel interventions attempt changes at the level of the clinic or health care organization environment and target patients as well as physicians. While several randomized trials of multilevel interventions for asthma have found positive effects,<sup>16-25</sup> many of the more effective programs have used a referral model, in which higher-risk patients are referred to a specialized asthma clinic or case management program<sup>21-23</sup> rather than a model based in primary care.

The Pediatric Asthma Care Patient Outcomes Research Team II<sup>26</sup> Study was a randomized controlled clinical trial that compared 2 National Asthma Education and Prevention Program guideline-based strategies to improve asthma care for children in the primary care setting against usual care. The first, a provider-oriented strategy (providers included physicians, nurse practitioners, and physician assistants), used targeted physician education through an on-site “peer leader.” The other was a multilevel approach that combined that same physician education program with a nurse-run intervention to better organize chronic-asthma care in the primary care practice. We evaluated the effectiveness of these interventions in children with mild to moderate persistent asthma enrolled in primary care practices affiliated with managed care organizations (MCOs). Our primary hypothesis was that these interventions would reduce asthma symptom days as compared with usual care. In addition, we evaluated the effects on asthma-specific func-

tional health status and rate of brief oral steroid courses (bursts).

## METHODS

The full details of methods are provided elsewhere.<sup>26</sup>

### DESIGN

The Pediatric Asthma Care Patient Outcomes Research Team II Study was a 3-arm cluster randomized controlled clinical trial, with 2 years’ follow-up, designed to evaluate the effectiveness of (1) a peer leader education intervention and (2) a planned care intervention incorporating organizational change along with a peer leader vs (3) no intervention beyond guideline dissemination and printed patient education material (usual care). These approaches were chosen to emulate what might be reasonable strategies for quality improvement efforts in health plans. Because this is a study of effectiveness, not efficacy, efforts to ensure protocol compliance were consistent with a reasonable and practical primary care-based intervention that would likely be used in a real-world managed care environment.

### SETTING AND STUDY POPULATION

The trial was conducted in 42 primary care practices in 3 locales and targeted 3- to 17-year-old children with mild to moderate persistent asthma enrolled in practices affiliated with MCOs. Potential subjects were recruited through managed care plans of which they were members. The 15 practices in Seattle, Wash, were clinics of Group Health Cooperative, a group model health maintenance organization. The 11 Chicago, Ill, area practices were part of the staff model or network model divisions of Rush Prudential Health Plan. Two practices did not yield any subjects. In eastern Massachusetts, 16 practices were recruited, each affiliated with several insurers, including Harvard Pilgrim Health Care and Blue Cross Blue Shield of Massachusetts. Patients enrolled in either plan were eligible. Families received gifts and gift certificates totaling less than \$100 in value across the course of the study. Approval was obtained from the institutional review board at each study site. Parents provided informed consent; children aged 8 years or older provided assent.

Potential subjects were identified by searching automated claims and pharmacy data for children aged 3 to 15 years with any asthma-related use in 1 year, including hospitalization, emergency department visit, or ambulatory encounter. If the only asthma claim was for an ambulatory encounter, we also required 2 or more asthma medications during the same period. This algorithm identified 7052 children (**Figure 1**). We succeeded in contacting the parents of 5286 (75%) of these children by telephone for screening. The telephone screen identified children who used daily medications for at least 2 months during a 1-year period as eligible for the trial but excluded those with severe asthma or another major illness. The goal was to identify children with mild persistent or moderate persistent asthma without serious comorbid conditions. Of those contacted, 2245 (42%) refused to undergo telephone screening, 2062 (38%) were found to be ineligible, and 1000 (33%) were eligible. Six hundred thirty-eight children and their parents completed baseline interviews, representing 64% of all those screened and deemed eligible (Figure 1). Using standard methods,<sup>27</sup> we calculated an overall participation rate assuming cases of unknown eligibility (those not contacted or refused) to have the same likelihood of eligibility as those screened. Among the 7052 subjects initially identified for contact, the overall participation rate was estimated to be 27%.

## INTERVENTIONS

We randomized practices within each geographic site (accounting for practice size and steroid prescription rate at baseline) to 3 arms: 2 intervention arms and usual care. We did not blind participants, parents, or physicians to group assignment.

### Peer Leader Education Intervention

The peer leader education intervention consisted of training 1 physician in each practice site to serve as an asthma “champion,” sharing guidelines and other information with colleagues and encouraging their implementation. Peer leaders received training in asthma pharmacotherapy and physician behavior change strategies and were given ongoing support in their role as change agents. The intervention included 2 workshops, central support by an educational coordinator, and an ongoing learning network for peer leaders via national and local teleconferences. Each peer leader received a physician tool kit containing a variety of materials including the 1997 National Asthma Education and Prevention Program guidelines (Expert Panel Report 2<sup>2</sup> [EPR2]), 1-page evidence-based summaries of key targets for physician behavior change (academic detailing sheets), reference articles supporting the recommendations, and laminated pocket cards summarizing the EPR2 approach to diagnosis and treatment. Academic detailing sheets on prescribing, trigger control, and specialty referral were based on models for effective academic detailing materials.<sup>28</sup> A tool kit of patient education materials was also provided to each practice. The educational coordinator (a nurse with extensive asthma experience) attempted contact with each peer leader every 1 to 2 months to provide ideas, materials, and support; identify and resolve barriers to change; and encourage less active peer leaders. Peer leaders received physician-specific feedback on anti-inflammatory prescribing by their colleagues (with peer comparison), based on data from participating MCOs.

### Planned Care Intervention

The planned care intervention organized chronic-illness care based on the Chronic Care Model.<sup>29,30</sup> In contrast to the physician-level intervention, the planned care intervention represents a comprehensive approach that focuses on changing various attributes of the system of care. Planned asthma care (PAC) visits with a trained asthma nurse constitute the core of this intervention. Asthma nurses were trained in EPR2 and in self-management support techniques. In addition to reading the intervention manual and other written materials, the nurses attended a full-day training session to learn motivational enhancement and problem-solving techniques and met weekly or every other week for 10 weeks for 1-hour conference calls to review written materials with 1 of the investigators (P.L.). The asthma nurse attempted to proactively schedule 4 to 5 PAC visits during the 2 years of the study in conjunction with visits to the primary care physician.

At each visit the asthma nurse aimed to:

1. Conduct a standardized assessment of asthma symptoms, medication use, environmental control, and self-management skills (and share a computer-generated report of findings with the child's physician).
2. Support and participate in care planning (including medication and environmental measures) in conjunction with the primary care physician, using the EPR2, with emphasis on the use of controllers for persistent disease.
3. Provide self-management support to families (regarding medication adherence, technical skills, and environmental triggers) using problem-solving and motivational techniques.

In between PAC visits, asthma nurses provided proactive standardized telephone follow-up. When patients or parents expressed reluctance to attend PAC visits, the asthma nurse would negotiate a callback interval after which she would again attempt to schedule a visit. Other asthma nurse activities included reviewing quarterly registry-based asthma panel reports (on medication use and emergency department visits) with physicians and, in some cases, arranging for allergists to visit the primary care site for case discussions. Asthma nurses stored encounter data on laptop computers. All practices randomized to planned care also received the peer leader education intervention.

### Usual Care

Practices randomized to this arm received a copy of the EPR2 and a tool kit of patient education materials 1 year into the study.

## DATA COLLECTION AND INSTRUMENTS

Baseline data were collected from August 1997 through October 1998 by in-person interviews and self-administered questionnaires. Interviews ascertained medication use, possession of written care plans, asthma symptom days in the past 14 days (ASD-14), and oral steroid bursts. Self-administered questionnaires contained the Children's Health Survey for Asthma<sup>31</sup> (CHSA), an asthma-specific functional status measure, as well as demographics. Outcomes, including ASD-14 and oral steroid bursts, were gathered by telephone survey every 8 weeks throughout the intervention period. The CHSA was administered by telephone at the end of the study. Phone and in-person interviews were conducted by research assistants blinded to group assignment.

## VARIABLES

Parental recall was used to obtain the number of days with any asthma symptoms (including cough, wheeze, limitation in activity, or night wakening) in the 14 days preceding contact (ASD-14).<sup>32,33</sup> The average of ASD-14 measurements was converted to annualized asthma symptom days by multiplying by 26. We analyzed symptom days both as continuous (annualized asthma symptom days) and dichotomized ( $ASD-14 \leq$  or  $> 9$ ) variables. Asthma-specific functional health status was measured using the 5 scales of the CHSA.<sup>31</sup>

For each medication class (controllers and relievers), parents were asked if the child took medications in this class and, if so, how frequently they had taken them in the past 4 weeks. Current use was defined as  $\geq 1$  time per week in the past 4 weeks. Controllers included cromolyn, nedocromil, inhaled steroids, long-acting bronchodilators, and theophylline. Leukotriene modifiers were uncommon during this period and were not included among controllers. Relievers included only short-acting inhaled bronchodilators.

## INTERVENTION IMPLEMENTATION DATA

The peer leader education coordinator documented peer leader reports of asthma-related activities through telephone contacts attempted every 1 to 2 months. Asthma nurses tracked PAC visits and telephone calls on the laptop database.

## ANALYSIS

This study provides hierarchically structured data with 3 levels: subjects, practices, and MCOs. We regard MCO as a potential fixed effect. Practice-level clustering in outcomes of interest proved to be small and strongly dominated by subject-

level clustering on repeated measures. Consequently, all multivariate models of repeatedly measured responses used generalized estimating equations accommodating clustering at the subject level<sup>34</sup> (PROC GENMOD; SAS Institute Inc, Cary, NC). Practice level clustering was ignored. Generalized estimating equations were used to model intervention effects on ASD-14 (mean ASD-14 and odds of ASD-14 >10), log rate of oral steroid bursts per year, emergency department visits, asthma hospitalizations, and health status (mean change from baseline). Oral steroid rate was modeled using overdispersed Poisson regression; all other outcomes were analyzed semiparametrically using generalized estimating equations to model means, regression slopes, and logits of response probabilities.

Each model was evaluated in 2 stages. First, a simple model was fit to estimate the main effects of treatment and time, treatment by time interaction (for some models), quarter of enrollment (to account for season of recruitment), geographic site, and practice size. Second, a refined model was fit to include baseline variables for which imbalance was suggested: current reliever use, presence of written care plan, current cromolyn use, current inhaled steroid use, the interaction of cromolyn and inhaled steroid use, and ASD-14. In the refined model for repeated ASD-14 outcomes, the baseline measurement of ASD-14 was treated as a covariate. Primary effects of intervention on ASD-14 and oral steroid bursts used the repeated measures of these outcomes. Parameters represent change in mean symptom days (or change in oral steroid rate) subsequent to an intervention. Usual care estimates are interpreted as reflecting the secular trend. Recall period was normalized to years so that treatment effect had interpretation as effect on rate per year. Simple and refined models revealed similar results; therefore, results are shown only for refined models.

The  $\chi^2$  test and analysis of variance were used to test for imbalances among arms in baseline characteristics.

## POWER CONSIDERATIONS

The target sample size was 240 individuals per arm, yielding 80% power to detect a 30% reduction in proportion of days with symptoms, using a 2-sided test based on a logit transformation of proportions. The achieved sample size of N=638, and in the longitudinal analysis, led to post hoc power of 40% to detect an odds ratio (OR) of 0.75, 69% power to detect an OR of 0.66, and 98% power to detect an OR of 0.50 using a 2-sided test.

## RESULTS

### SAMPLE DEMOGRAPHICS, RETENTION, AND MISSING DATA

Among the 638 subjects, mean  $\pm$  SD age was 9.4  $\pm$  3.5 years; 383 (60%) were boys (**Table 1**). Based on parent report, there were 421 white subjects (66%), 108 African American subjects (17%), and 108 subjects (17%) of other race. Two hundred eighty (44%) reported a yearly household income of \$30 000 to \$60 000, with 83 (13%) falling below this bracket. Mean  $\pm$  SD ASD-14 was 4.13  $\pm$  4.68, the median was 2.0, and mean  $\pm$  SD annualized asthma symptom days (annualized ASD-14) was 107.4  $\pm$  121.8. Table 1 demonstrates the non-normal "bathtub-shaped" distribution of ASD-14. About one fifth (134 [21%]) of parents reported receiving a written care plan in the past year, about half (306 [48%]) owned a peak flow meter, and three quarters (466 [73%]) owned a

spacer. Eighty-nine (14%) had seen a specialist for asthma in the prior 6 months.

Study arms were comparable at baseline with some exceptions: greater reported use of reliever medications in usual care subjects and higher parental education and greater reported use of cromolyn in planned care subjects (Table 1). Study arms were slightly imbalanced with respect to geographic site ( $P=.04$ ; Table 1).

Of the initial sample, 554 (87%) remained with the study at exit (2 years), with 384 (60%) completing all 13 periodic telephone surveys. Among the 170 (27%) subjects who completed exit interviews but missed at least 1 periodic telephone survey, the mean  $\pm$  SD number of periodic telephone surveys completed was 12  $\pm$  1. Eighty-four subjects (13%) dropped out of the study (11%, 10%, and 19% in the usual care, peer leader, and planned care arms, respectively). Dropouts completed a mean  $\pm$  SD of 5  $\pm$  3 periodic surveys.

Kaplan-Meier plots and proportional hazards regression identified several baseline variables associated with earlier drop out: lower maternal age, lower income, ever hospitalized, emergency department visit (ever and in the past year), lower rating of primary care physician, lower rating of all asthma care, smoke exposure, and higher baseline ASD-14. A formal test for informative missingness<sup>35,36</sup> showed that ASD-14 values among those about to drop out of the study were not different from ASD-14 values among those who remained.

### PARTICIPATION IN INTERVENTIONS

All 28 peer leaders attended the first workshop and 24 (86%) attended the second. Peer leaders performed a mean  $\pm$  SD of 9.5  $\pm$  6.9 (range, 2-27) group sessions in their practices in 2 years. Planned care intervention subjects had a mean  $\pm$  SD of 3.0  $\pm$  1.6 PAC visits and 4.7  $\pm$  3.2 telephone follow-up calls by the asthma nurse. In 81 cases (12%), the PAC visit was conducted by telephone because of scheduling difficulties. Most (408 [64%]) planned care subjects had their first PAC visit within 6 months of study entry, while 64 (10%) had no PAC visits during the study period (because of refusal, changing health plans, or dropping out of the study). Planned asthma care visits averaged 65 minutes (including the physician visit), and telephone sessions averaged 20 minutes.

### ASTHMA SYMPTOM DAYS

We observed a secular trend (usual care intervention) toward a decrease in asthma symptom days during the study period of 14.8 (95% confidence interval [CI] -22.4 to -7.28) fewer asthma symptom days per year of intervention. Children in the planned care arm experienced an additional reduction of 13.3 (95% CI, -24.7 to -2.1) fewer ASD-14 per year of intervention ( $P=.02$ ) relative to children in usual care (**Figure 2**). This decrease attributable to the planned care intervention represented a 12% reduction (95% CI, 2% to 23%) from the baseline of 107.5 days per year. Children in the peer leader arm experienced 6.5 (95% CI, -16.9 to 3.6) fewer asthma symptom days per year as compared with children in usual care, but this decrease did not attain statistical significance (Figure 2).

**Table 1. Selected Baseline Characteristics of Planned Asthma Care Patient Outcomes Research Team Study Participants\***

	Usual Care	Peer Leader Intervention	Planned Care Intervention	Total	P Value†
Sample size	199	226	213	638	
Age, mean, y	9.6	9.3	9.4	9.4	.58
Boys	60	57	62	60	.51
Race					
Black/African American	13	22	18	17	.10
White	70	58	69	66	
Hispanic	6	6	4	5	
Other	11	14	9	11	
Maximum household education					
≤High school	10	16	9	12	.01
Some college	43	37	31	37	
College graduate	47	47	60	52	
Forced expiratory volume in 1 s, % predicted, mean‡					
0-80	10	9	13	11	.34
81-90	16	12	14	14	
≥91	48	53	46	49	
Current asthma medications					
Cromolyn/nedocromil	27	20	37	28	.001
Inhaled steroid	31	38	33	34	.37
Any inhaled anti-inflammatory	51	54	60	55	.57
Inhaled anti-inflammatory use ≥5 d/wk	36	34	40	36	.53
Reliever	80	68	76	74	.01
Asthma symptom days in past 14 d					
0	26.3	35.4	25.4	29.2	.22
1	8.6	11.5	8.9	9.7	
2	14.1	11.5	12.2	12.6	
3	10.6	9.3	8.0	9.3	
4	6.1	4.9	7.5	6.1	
5	4.5	7.5	6.1	6.1	
6-7	6.1	7.1	6.1	6.4	
8-9	4.0	3.1	3.3	3.4	
10-12	4.5	2.2	5.6	4.1	
13-14	15.2	7.5	16.9	13.0	
Oral steroid burst in past 2 mo	33	37	38	36	.44
Hospitalized for asthma, past year	4	5	2	4	.26
Emergency department visit for asthma, past year	22	22	24	23	.81

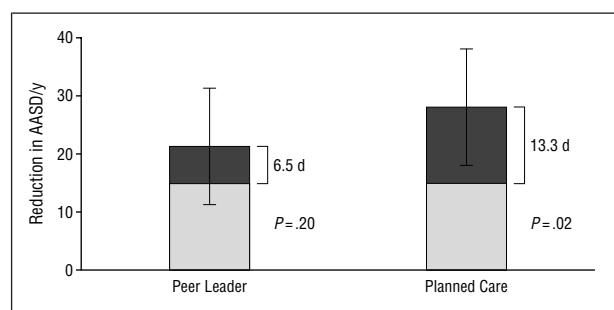
\*Values are expressed as percentages unless otherwise indicated.

†Analysis of variance or  $\chi^2$  test.

‡Data were available for at least 95% of subjects for all variables except forced expiratory volume in 1 second, percentage predicted (74% complete).

Stratified analyses demonstrated trends toward decreased ASD-14 across 2 years for both interventions relative to usual care in children with low ( $\leq 4$ ), moderate (5-9), and high ( $\geq 10$ ) baseline ASD-14. None of these comparisons achieved statistical significance. The greatest absolute difference between interventions and usual care was seen in the high-baseline ASD-14 group ( $n=109$ ) in which children in the planned care and peer leader arms experienced respective decreases of 62.4 and 46.8 annualized symptom days relative to usual care ( $P=.06$  for the planned care arm).

We also examined the effect of interventions on the likelihood of experiencing at least 1 period of frequent symptoms. We modeled the odds of reporting an ASD-14 of 10 days or more at least once during the study period, a cut-off chosen to approximate the National Asthma Education and Prevention Program definition of moderate persistent asthma and which represented 17% of the population at baseline. Children in usual care experienced a significant trend toward decreased events across time (OR, 0.71 [95% CI, 0.57 to 0.89]). For children in planned care, each



**Figure 2.** Marginal effect of interventions on annualized asthma symptom days (AASD) as compared with usual care. Intervention effects (dark bars) are shown as incremental to usual care (light bars). P values compare interventions with usual care in the multivariate model.

year in the study corresponded to an OR of 0.69 (95% CI, 0.50 to 0.96) relative to baseline for reporting an ASD-14 of 10 or more, compared with usual care. There was no significant effect of the peer leader intervention over usual care for this outcome (OR, 1.15 [95% CI, 0.86 to 1.55]).

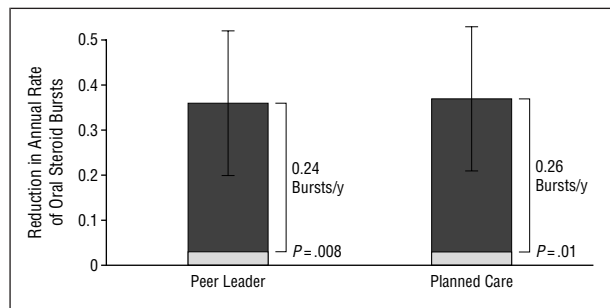
**Table 2. Marginal Effect of Interventions on Asthma-Specific Functional Status: Change in Score Between Baseline and End of Study Compared With Usual Care\***

CHSA Scale	Baseline		End of Study Change From Baseline (95% CI)	
	Mean	P Value†	Peer Leader Intervention	Planned Care Intervention
Physical Health	83.7	.03	3.29 (-1.39 to 7.97)	3.68 (0.06 to 7.30)
Child Activity	90.2	.27	3.89 (0.29 to 7.50)	2.90 (-0.57 to 6.37)
Family Activity	95.0	.90	1.58 (-1.31 to 4.48)	0.12 (-2.52 to 2.75)
Child Emotional	79.2	.41	6.47 (0.72 to 12.22)	6.42 (0.80 to 12.04)
Family Emotional	75.8	.67	0.36 (-1.86 to 2.58)	1.02 (-1.34 to 3.39)

Abbreviations: ANOVA, analysis of variance; CHSA, Children's Health Survey for Asthma; CI, confidence interval; GEE, generalized estimating equations.

\*Linear GEE regression with practice-level clustering. Exit data were available for 523 subjects (82%) for all scales except Physical Health, which was available for 479 (75%).

†P value shown is for ANOVA test comparing means across the 3 study arms at baseline.



**Figure 3.** Marginal effect of interventions on oral steroid burst rate as compared with usual care. Intervention effects (dark bars) are shown as incremental to usual care (light bars). P values compare interventions with usual care in the multivariate model. Relative to the baseline rate of 0.66 oral steroid burst per year, these effects represent 36% and 39% reductions attributable to the peer leader and planned care interventions, respectively.

### ASTHMA-SPECIFIC FUNCTIONAL STATUS

All 5 dimensions of the CHSA demonstrated positive increases for both interventions (**Table 2**). Significant (or nearly significant) incremental differences were noted in 2 CHSA scores for each intervention as compared with usual care. Subjects in the peer leader intervention had a 3.89-point increase in the Child Activity scale score ( $P=.03$ ), and those in planned care had a 3.68-point increase in the Physical Health scale score ( $P=.05$ ) from baseline relative to usual care. The Child Emotional scale scores improved for children in both intervention arms relative to usual care: 6.47 points for the peer leader intervention ( $P=.03$ ) and 6.42 points for the planned care intervention ( $P=.02$ ). No statistically significant differences were seen in the 2 scales pertaining to family domains of health status. Minimally important differences have not been established for 4 of the 5 CHSA scales. However, preliminary studies of Physical Health scale scores estimate a minimally important difference with a range from 0.83 (SD, 0.39) to 1.24 (SD, 1.32) (L. Asmussen, American Academy of Pediatrics, written communication, October 2003).

### ORAL STEROID BURSTS

The baseline rate of oral steroid bursts in the usual care group was 0.66 burst per year. Children in both intervention arms experienced significant decreases in the number of oral ste-

roid bursts per year as compared with the usual care group (**Figure 3**): a 36% decrease for the peer leader arm (95% CI, 11% to 54%) and 39% for the planned care arm (95% CI, 11% to 58%). These effects correspond to oral steroid burst rate reductions of 0.24 and 0.26 burst per year for the peer leader and planned care interventions, respectively.

### CONTROLLER USE

We explored controller use as a possible mediating factor for the observed effects of the interventions on health outcomes. Parents reported regular use (defined as 5-7 days per week) of controller medications at 40% of all follow-up phone surveys (36.5%, 46.7%, and 37.2% in the peer leader, planned care, and usual care arms, respectively). In multivariate models adjusting for regular controller use at baseline, planned care subjects had a greater frequency of parental report of regular controller use during the follow-up period compared with usual care subjects (rate ratio, 1.05 [95% CI, 1.00 to 1.09]). No effect of the peer leader intervention on controller use was detected.

### COMMENT

#### MAIN FINDINGS

We implemented 2 interventions across a 2-year period in real-world primary care practices in rapidly changing health systems.<sup>37</sup> We have demonstrated that an organized approach to pediatric asthma care that includes the services of a nurse plus peer leader education (planned care intervention) can significantly reduce asthma symptom days by 12%, or an average of 13 days per year. The less-costly physician behavior change intervention may also have had a more modest effect on symptom days. Both the planned care and peer leader interventions reduced the rate of oral steroid bursts by about one third per year. The interventions had positive effects on 3 of 5 domains of the functional health status questionnaire. The planned care effect may have been mediated at least in part by increased adherence to controller medication.

#### CONTEXT

Most successful asthma programs have used a referral model, based either in a specialty clinic, hospital, or case

### What This Study Adds

Children with mild to moderate persistent asthma represent a large proportion of asthma morbidity, and their care remains below the standard set by the EPR2. Referral-based programs are inefficient for children on the mild end of the spectrum. Few primary care-based interventions for pediatric asthma have been proven effective in real-world settings. This effectiveness study in 3 managed care settings implemented and evaluated 2 primary care-based strategies for improving care for children with mild to moderate persistent asthma, a physician education strategy (peer leader) and a more resource-intensive, nurse-mediated organizational change intervention plus physician education (planned care).

Both interventions led to some improvements in patient-centered health outcomes. The effect of planned care on asthma symptom days appears to have been mediated at least in part by increasing patient adherence to controller medications. The interventions we implemented, particularly planned care, may provide fruitful models for developing population-based chronic-illness care programs.

management service. Because of asthma's prevalence and the necessary role of the primary care physician in caring for children and teens with asthma, it is incumbent on health systems to explore asthma quality improvement based in primary care.

We evaluated 2 interventions differing greatly in intensity and cost. Peer leader education, which incorporates features of physician-directed interventions previously shown to be effective, such as educational outreach, opinion leaders, and feedback,<sup>9,10</sup> depends largely on modifying the role of existing physicians. Peer leader activities consist of brief training followed by informal interactions between peer leaders and their colleagues supported by a full-time peer leader coordinator. Not surprisingly, the reduction in annualized asthma symptom days estimated for the peer leader intervention (−6.5 days or 6%) was small (and not statistically significant). This less-resource intensive intervention did not target asthma management at the patient level. A priori, we had expected peer leaders to have a lower magnitude effect on health outcomes but at much lower costs.

In contrast, planned care, a multilevel intervention based on the Chronic Care Model,<sup>29,30</sup> requires the services of an asthma nurse (designated by hiring or reallocation). This more intense and costly intervention stipulates proactive planned asthma care visits conducted by the asthma nurse and physician. It incorporates key elements of chronic-illness care, including care planning, feedback reports for physicians, guideline-based decision support delivered by the asthma nurse, and self-management support rooted in techniques to promote patient behavior change.<sup>30</sup> Planned care is an example of a systems-oriented improvement strategy that is being increasingly used for a variety of conditions in diverse health care organizations.<sup>38-42</sup> While more costly than some alternatives, this approach appears to be demonstrating its

fruitfulness across settings.<sup>38-42</sup> The treatment effect seen for the planned care intervention is comparable to effects seen for other successful asthma interventions in managed care<sup>21</sup> and inner city<sup>33</sup> environments. A comprehensive health economic analysis of the planned care intervention is in progress.

Limitations of the Planned Asthma Care Patient Outcomes Research Team II Study relate both to implementation and assessment of the treatment effects and are similar to those seen in similar studies.<sup>43</sup> Various obstacles hindered the real-world implementation of the interventions<sup>37</sup> and resulted in reducing the dose of intervention and raising its cost. Both interventions required a substantial commitment on the part of the primary care practice, more so for the planned care intervention. Peer leaders and asthma nurses often encountered skepticism from physicians, nurses, and staff. Peer leaders expressed reluctance to teach and advise their peers, citing time constraints as well as an environment of limited discussion of clinical decision making among colleagues. In the planned care arm, parents who perceived their child's asthma as quiescent were reluctant to schedule planned care visits.

Study practices comprised a large geographic area, sometimes requiring the asthma nurse to spend several hours driving between sites. This highlights the inefficiencies of the single-condition nurse (a requirement of this research study). Organizations attempting to replicate the planned care intervention may find that developing a multicondition case manager would permit economies of scale and scope.

There was considerable variation in implementation across geographic sites, which appeared to be related to the type of MCO. Some physicians and clinic staff viewed the asthma nurse as an outsider in their practice, a phenomenon that was accentuated in the network practices (where the asthma nurse was employed by the affiliated MCO, not the practice) compared with the group/staff model settings. We sought site diversity to enhance the applicability of our findings to the current health care environment.

Our main outcome, ASD-14, demonstrates great within-person variability, diminishing our power to detect treatment effects. The threshold for use of oral steroids in exacerbations varies by physician and may have changed across time and thus only serves as a rough proxy for exacerbations. Response bias could have resulted from patients perceiving intervention physicians as providing better care. Ascertainment bias may have occurred for patients in the planned care arm if contact with the asthma nurse increased parental perception of the child's asthma symptoms. Frequent telephone surveys could conceivably have influenced parent practices, which would bias results toward the null. Although many subjects had some missing data, the risk of bias from this appears to be negligible. Finally, trial enrollees may differ from the broader population of children with asthma in these practices. We are currently undertaking a separate analysis of Planned Asthma Care Patient Outcomes Research Team II activities on all asthma patients using automated claims data.



Despite these limitations, the Planned Asthma Care Patient Outcomes Research Team II Study compared 2 approaches that are akin to asthma improvement strategies currently used in managed care environments,<sup>44</sup> using patient-centered measures to demonstrate treatment effect in this large, multisite effectiveness trial. By following asthma symptom days across a 2-week period every 8 weeks, we were able to assess 25% of time on study and thus were able to measure the effect of the interventions on long-term health status and daily life. Evaluating oral steroid bursts allows us to detect exacerbations that may not result in an emergency department visit or any health care encounter.

## IMPLICATIONS

Planned care (nurse-mediated organizational change plus peer leader education) may provide an effective model for improving asthma care in the primary care setting. Peer leader education on its own may also serve as a useful model for improving asthma care, although it is a less comprehensive intervention and therefore the treatment effect appears less pronounced.

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#### About the Cover

**Omission in About the Cover Box.** For the Cover Art article titled "Otto Dix (1891-1969): *Frau mit Kind* (1921)," published in the August issue of the ARCHIVES (2004;158:717), the About the Cover box in the Table of Contents should have indicated that the painting was reprinted with permission from Gemaeldegalerie Neue Meister in Dresden, Germany. The ARCHIVES regrets the error. This correction was made previously to online versions of this article.