

## Evidence Table 5. Patient/Provider Education: Asthma Self-Management Education in Community Settings

Abbreviations used in table:

<b>Bla g 1</b>	cockroach allergen
<b>COPD</b>	chronic obstructive pulmonary disease
<b>ED</b>	emergency department
<b>ETS</b>	environmental tobacco smoke
<b>FEV<sub>1</sub></b>	forced expiratory volume in 1 sec.
<b>FVC</b>	forced vital capacity
<b>HEPA</b>	high-efficiency particulate air
<b>IgE</b>	immunoglobulin E
<b>ITT</b>	intent-to-treat analysis
<b>NAC</b>	Neighborhood Asthma Coalition
<b>OR</b>	odds ratio
<b>PEFR</b>	peak expiratory flow rate
<b>PM<sub>10</sub></b>	particulate matter 10 mcm or smaller
<b>PM<sub>2.5</sub></b>	particulate matter 2.5 mcm or smaller
<b>RR</b>	relative risk
<b>95% CI</b>	95% Confidence Interval

\* indicates primary outcome

## Evidence Table 5. Patient/Provider Education: Asthma Self-Management Education in Community Settings

### A. ASTHMA SELF-MANAGEMENT EDUCATION IN COMMUNITY SETTINGS: PHARMACY-BASED

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Knoell et al. Measurement of outcomes in adults receiving pharmaceutical care in a comprehensive asthma outpatient clinic. <i>Pharmacotherapy</i> 1998;18(6): 1365–1374.	Nonrandomized control group design	To evaluate the effect of structure and process change from a pharmacist-provided comprehensive educational program on economic, clinical, and humanistic outcomes of adults with asthma	100 (100)	<b>Age</b> 12% <25 yr, 78% 25–65 yr, 10% >65 yr	6% intermittent, 15% mild persistent, 66% moderate persistent, 13% severe persistent 56% used inhaled steroid 24% used long-acting beta-agonist 79% used short-acting beta-agonist	<b>Intervention group (E)</b> Pharmacist interacted with physician and patient during clinic visits, introduced an individual self-management plan to the patient in a 30–60 minute session, and met with patient at least once more over 45 days to reinforce plan. (n=45) <b>Control group (C)</b> Usual care (n=55)	45 days after initial clinic visit	E more likely to have an established personal best peak flow value and more likely to have recorded recent readings as compared to C (p<0.004).		No difference in cost savings for E vs. C. No difference in lost productivity, fewer emergency department visits, fewer hospitalizations, and fewer physician visits (p>0.05) although both groups differed from before treatment (p<0.05).	*Both groups had improvement in clinical symptom scores in 45 days. No difference in percentage of E vs. C who experienced a moderate or large change in quality of life (p=0.36). E reported greater improvement in satisfaction with care as compared to C (p<0.05).
Bynum et al. The effect of telepharmacy counseling on metered-dose inhaler technique among adolescents with asthma in rural Arkansas. <i>Telemed J Health</i> 2001;7(3): 207–217.	Randomized controlled trial	To determine the effectiveness of pharmacists using interactive compressed video in teaching MDI technique to a rural, adolescent asthma population in junior high and high schools	49 (36)	<b>Age</b> 43.4% 12–14 yr, 50% 15–17 yr, 6.5% 18–19 yr <b>Gender</b> 31% male, 69% female <b>Ethnicity</b> 91.8% Black/African-American, 2.0% White/Caucasian, 6.2% Unknown	Diagnosis of asthma	<b>Intervention group (E)</b> Telepharmacy instruction (n=24; N=15 completers) <b>Control group (C)</b> Written instructions (n=25; n=21 completers)	2–4 week followup assessments			E vs. C improved more over time on MDI Technique scores (p<0.001). No difference between E and C in satisfaction with instructional sessions (p=0.13).	
Cordina et al. Assessment of a community pharmacy-based program for patients with asthma. <i>Pharmacotherapy</i> 2001;21(10): 1196–1203.	Nonrandomized control group design (pharmacies randomly assigned; patients self-selected pharmacy and were analyzed)	To examine the impact of a community pharmacy-based education and monitoring program for patients with asthma	22 pharmacy sites; 152 patients	<b>Age</b> >14 yr, mean = 43.2 yr <b>Gender</b> 50.6% male, 49.4% female		<b>Intervention group (E)</b> Pharmaceutical care program including education addressing asthma pathology, trigger factors, and use of inhaled drugs and peak flow meters. (n=86; n=64 completers) <b>Control group (C)</b> No pharmaceutical care program (n=66; n=55 completers)	Followup at 4, 8, and 12 months	PEF was not different between E and C over time adjusting for gender and age (p>0.05).		Greater difference in Inhaler technique score from baseline to 12 months in E vs. C (p=0.021). No difference between E and C in compliance with inhalers (p>0.05). No difference between E and C in asthma visits or days lost from work/school (p<0.05). Self-reported hospitalization differed between E and C (0 vs. 8, p=0.002). No difference at 12 months between E and C in wheezing or only nighttime wheezing (p=0.051). C vs. E more likely to rate service provided by pharmacist as poor (81.8% vs. 20.3%, p<0.001).	No difference between E and C in change in SF-36 over time except for vitality dimension (4.29 vs. –8.87, p=0.001), adjusting for age and gender. No difference in Living with Asthma scores over time, adjusting for gender and age.

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Stergachis et al. Improving pediatric asthma outcomes in the community setting: Does pharmaceutical care make a difference? J Am Pharm Assoc (Wash) 2002;42(5):743-752. (Agency for Health Care Research and Quality)	Quasi-experimental design (pharmacies randomized, analysis at individual level)	To assess the effect of a structured program of pharmaceutical care on changes in disease control, functional status, and health services utilization for pediatric and adolescent patients with moderate-to-severe asthma. (Pharmaceutical Care Evaluation of Asthma in Kids (PEAK) Study)	32 pharmacies; 330 children (274 children)	<b>Age</b> Mean = 11.7 yr; 46% 6-11 yr, 54% 12-17 yr <b>Gender</b> 65% male, 36% female <b>Setting</b> 66% HMO, 34% community <b>Household Income</b> 10% <\$20,000; 11% \$20,000-\$29,999; 18% \$30,000-\$39,999; 42% ≥\$40,000	Moderate-to-severe All receiving either oral theophylline daily, oral or inhaled beta <sub>2</sub> -agonists more than twice daily, or inhaled anti-inflammatory agents for asthma daily Duration of asthma, mean = 7.3 yr FEV <sub>1</sub> % pred., mean = 90.4 Over 14-day period, PEF days ≥80%, mean = 0.71; ≥50%, mean = 0.97	<b>Intervention group (E)</b> Integrate the goals of pharmaceutical care and asthma management, emphasizing the areas that have the greatest amount of overlap over the course of 1 year, including assessing the patient for potential or actual drug-related problem, prioritizing and making a plan for resolving each problem, and implementing the plan. (14 pharmacies; n=153) <b>Control group (C)</b> Usual care (18 pharmacies; n=177) Final sample size for both groups combined: 287. Not reported by group.	Interviewed at 3, 6, 9, and 12 months	Both E and C had minimal change in PEF days >80% (0.75 vs. 0.79, p>0.5). Change in FEV <sub>1</sub> did not differ over time between groups.		No difference in functional status questionnaire scores between E and C over time (0.7 vs. 1.4, p=0.275). No difference in school days lost between E and C. No difference in rates of use of medical care services between E and C.	No difference between E and C in change in quality of life over time (-9.4 vs. -7.4, p=0.15).
Barbanel et al. Can a self-management programme delivered by a community pharmacy improve asthma control? A randomized trial. Thorax 2003;58(10): 851-854.	Randomized controlled trial	To test whether a community pharmacist with basic asthma training could improve asthma control with a simple program of self-management advice	24 (23)	<b>Age</b> ≥18 yr, mean = 46 yr <b>Gender</b> 46% male, 54% female <b>Ethnicity</b> 33% minority group <b>Smoking</b> 46% smoker, 33% nonsmoker, 8% exsmoker, 12% passive smoker	All using inhaled corticosteroids	<b>Intervention group (E)</b> Individual self-management education by pharmacist lasting 45-60 minutes including review of inhaler technique and weekly telephone call from pharmacist for 3 months. (n=12) <b>Control group (C)</b> No input from pharmacist (n=12; 11 completers)	Followup 3 months after intervention			*Adjusting for baseline scores, difference in asthma symptom scores at 3 months favored E vs. C (diff. = 7.0, 95% CI 4.4 to 9.5, p<0.001). E symptom scores decreased from 26.3 to 20.3; C scores increased from 27.8 to 28.1.	
McLean et al. The BC community pharmacy asthma study: a study of clinical, economic and holistic outcomes influenced by an asthma care protocol provided by specially trained community pharmacists in British Columbia. Can Respir J 2003;10(4):195-202.	Quasi-experimental design (pharmacies randomly assigned; patients randomly assigned within pharmacies; analysis at individual level)	To demonstrate a significant difference in clinical, economic, and quality of life outcomes in asthma patients who received enhanced pharmaceutical care versus those who received usual care	405 patients (224 patients)	<b>Age</b> 7-84 yr, mean = 48 yr <b>Gender</b> 37% male, 63% female		<b>Intervention group (E)</b> Usual care plus teaching of asthma self-management, appointments about 1 hour in length with pharmacist every 2-3 weeks for at least three appointments, and followup appointments at least every 3 months for remainder of study. (n=191; n=119 completers) <b>Control group (C)</b> Usual care (n=214; n=105 completers)	Followup at 1 year	PEFR 34.0 L/min in E and 7.8 L/min in C (11% diff, p<0.0002).		Greater decrease for E vs. C in symptom scores (-0.55 vs. -0.13, p<.0001) and beta-agonist use (-2.0 vs. -0.69 doses/day, p=0.008), but no difference in corticosteroid doses/day. Change in medical visits in previous month favors E (-0.94 vs. +0.31, p=0.045). No difference in change in days off school/work, hospitalizations, or emergency visits in previous month (p>0.50). Cost per patient was \$150 for E vs. \$351 for C.	Greater increase in knowledge score for E vs. C (10.5 vs. 5.9, p<.0001) and in asthma quality of life scores (0.84 vs. 0.17, p=0.0001).

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Saini et al. Development, implementation, and evaluation of a community pharmacy-based asthma care model. Ann Pharmacother. 2004;38(11): 1954–1960. (Pharmacy Research Trust and Pharmacy Board of New South Wales)	Parallel, controlled design	To measure the impact of a specialized asthma service provided through community pharmacies in terms of objective patients clinical, humanistic, and economic outcomes	102 (102)	<b>Age</b> Mean = 45 yr <b>Gender</b> 31% male, 69% female	Duration of asthma, mean = 21 years Age at diagnosis, mean = 24 years Days affected by asthma in past 6 months, mean = 8.2 days Proportion using preventers, 86% Proportion using relievers, 93% Proportion with written action plan, 14%	<b>Intervention group (E)</b> Pharmacists trained to deliver service element of the model: saw patients on appointment basis, conducted individualized needs analysis and interventions to address needs that emerged, documented interventions delivered and outcomes measured, collaboratively set goals with the patient, monitored patients and collaborated with other healthcare practitioners involved in the asthma care of the patient. (n=52) <b>Comparison group (C)</b> No training to pharmacists in the control area (n=50)	Service delivered and data collected at 1 month, 3 months, and 6 months.	Peak flow (measured only in E) improved from 82.7% to 87.4% (p<0.001).	Reduction in asthma severity score in E vs. C (2.6 to 1.6 vs. 2.3 to 2.4, p<0.001). Difference in proportion of patients on preventer medication (p=0.04), which was 84.0% in C and 97.4% in E. No difference in use of relievers or mean number of reliever medications used.	Improvement in perceived control of asthma and asthma-related knowledge scores in E vs. C (p<0.001).	A specialized asthma care model offers community pharmacists an opportunity to contribute toward improving asthma management in the Australian community.
Basheti et al. Counseling about Turbuhaler technique: needs assessment and effective strategies for community pharmacists. Respir Care 2005;50(5): 617–623.	Randomized trial (pilot study)	To compare the effect of 3 counseling methods provided at the community pharmacy level on Turbuhaler technique	26 (24)	<b>Age</b> 11–76 yr, mean = 42 yr <b>Gender</b> 35% male, 65% female	15% mild, 62% moderate, and 23% severe asthma Medications used by Turbuhaler: 12% budesonide, 35% terbutaline, 19% both	<b>Standard Verbal Counseling (V)</b> Instructions on Turbuhaler technique using the text of 2 standard items of printed material that took approximately 5 minutes (n=8; n=7 completers) <b>Augmented Verbal Counseling (AV)</b> Instructions as above plus reinforcing the 4 essential steps and advising the patients on holding the Turbuhaler that took approximately 5 minutes (n=9; n=9 completers) <b>Augmented Verbal + Physical Counseling (AV+P)</b> Augmented verbal counseling plus physical demonstration by the researcher that took 5–10 minutes. (n=9; n=9 completers)	Patients returned to pharmacy after 2 weeks for reassessment.			Prior to counseling, no patient demonstrated optimal technique and only 23% had satisfactory technique. Difference between the 3 groups in Visit 2 technique score (Kruskal-Wallis, p=0.003) with change in score from baseline greatest in AV+C. Optimal technique was recorded 1 week after counseling by 0/7 patients in V, 2/8 patients in AV, and 7/9 patients in AV+C (Fisher's Exact test for AV vs. AV+C, p=0.006).	Counseling in Turbuhaler use represents an important opportunity for community pharmacists to improve asthma management, but physical demonstration appears to be an important component to effective Turbuhaler training for educating patients toward optimal Turbuhaler technique.

**B. ASTHMA SELF-MANAGEMENT EDUCATION IN COMMUNITY SETTINGS: SCHOOL-BASED**

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Christiansen et al. Evaluation of a school-based asthma education program for inner-city children. J Allergy Clin Immunol 1997;100(5): 613–617. (National Institutes of Health; Scripps Clinic Department of Medicine)	Comparative design	To assess the impact of a school-based education program on asthma outcomes	52? Not clearly stated	<b>Age</b> 9–12 yr, mean = 10.4		<b>Intervention group (E)</b> Five-session asthma education program based on consensus report guidelines published by National Heart, Lung, and Blood Institute. Each lesson presented in 20-minute segments. (n=34?; not clearly stated) <b>Control group (C)</b> No education program (n=18?; not clearly stated)	Sessions over a 5-week period. Assessment monthly during school year.	No difference between E and C in peak flow or percent of predicted peak flow.		After 180 days, symptoms scores for asthma severity were lower in E vs. C (2.87 vs. 4.36, p=0.019). No difference between E and C in school absence, emergency department visits, and hospitalization.	Scores for E improved (p<0.00001) on asthma quiz (9.9 to 13.7), peak flow meter technique (3.9 to 6.4), and inhaler technique (2.3 to 4.3). Scores for C did not change significantly. No direct comparison between E and C.
Evans et al. Can children teach their parents about asthma? Health Educa Behav 2001;28(4): 500–511. (National Heart, Lung, and Blood Institute, NIH; Spunk Fund)	Quasi-experimental design (schools randomly assigned, analysis at individual level)	To test the hypothesis that parents whose children had received the Open Airways for Schools (OAS) program would have increased asthma self-management skills	239 families (127 child-parent pairs)	<b>Child Age</b> Mean = 9.4 yr <b>Grade level</b> 50% third grade, 29% fourth grade, 21% fifth grade <b>Gender</b> 59% male, 41% female <b>Ethnicity</b> 70% Hispanic, 28% African American, 2% non-Hispanic White <b>Mother's Education</b> Mean = 9.7 yr <b>Family Size</b> Mean = 4.3 71% received Medicaid or other public assistance	93% diagnosed with asthma by physician; 7% experienced at least 2 of 3 symptoms (wheeze, persistent cough, shortness of breath) All had at least 3 episodes of symptoms during previous year	<b>Intervention group (E)</b> OAS program delivered in six 60-minute sessions over a 3-week period. Content focused on self-management and included 5 assignments to complete with family members. (number not reported) <b>Control group (C)</b> (number not reported)	1-year followup			Mother's followup asthma self-management score related to baseline asthma self-management score (beta=0.39, p<0.001), log of child's days with symptoms at followup (beta=0.18, p=0.02), child's participation in OAS (beta=.16, p=0.04), general child-parent communication score at followup (beta=0.24, p=0.002), and child-parent school communication at baseline (beta= -0.17, p=0.026). In E, child communication with mother about asthma was more strongly associated with increases in mother followup asthma self-management scores than in C.	

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Shah et al. Effect of peer led programme for asthma education in adolescents: cluster randomized controlled trial. BMJ 2001;322(7286): 583–585. (The Commonwealth Department of Health and Aged Care and Asthma, New South Wales, Australia)	Cluster randomized controlled trial (Schools randomized; analysis adjusted for clustering effect)	To evaluate the effect of the triple A programme on self-reported quality of life and related morbidity in high school students	272 in 6 schools (251)	<b>Age</b> Mean 12.5 yr in Year 7, 15.5 in Year 10 <b>Gender</b> 45% male, 55% female (more females in intervention than control due to 2 schools being single sex)	All reported recent wheeze; 75% had asthma diagnosed by physician; FEV <sub>1</sub> % pred., mean 89.4 FEV % pred., mean 103; 36% taking inhaled corticosteroids, 20% bronchodilator alone, 65% asthma drugs	<b>Intervention group (E)</b> Triple A program, a 3-step approach to educating and empowering students: (1) student volunteers trained as asthma peer leaders during 6-hour workshop; (2) teams of 3–4 peer leaders conducted three 45-minute health lessons for Year 10 students; (3) Year 10 students developed and presented key messages to Year 7 students (n=124; n=113 completers) <b>Control group ©</b> Standard care (n=148; n=138 completers)	Volunteers from Year 11 were trained as asthma peer leaders during a 6-hour workshop; teams of 3–4 peer leaders conducted three 45-minute health lessons for Year 10 students who in turn developed and presented key messages learned to Year 7 students. (analyses adjusted for clustering effect) Assessment 3 months after the intervention was completed.	Overall improvement in lung function in both groups, with no intervention effect.		(analysis adjusted for cluster effect) *Median number of days absent from school decreased in E (8 vs. 5 days), with no difference in C (5.5 vs. 4 days). Proportion reporting asthma attacks at school in Year 10 increased in C (21.2% to 34.8%), with no change in E (24.2% to 25.8%). No difference in school absenteeism and asthma attacks in Year 7 students.	(analysis adjusted for cluster effect) *Quality of life scores improved after adjusting for year and gender in E vs. C (diff .12, 95% CI .05 to .18). Clinical improvement reported by 25% of E vs. 12% of C.
MeGhan (sic) et al. Evaluation of an education program for elementary school children with asthma. J Asthma 2003;40(5):523–533. (Alberta, Canada, Asthma Network; Alberta Lung Association)	Cluster randomized controlled trial (Schools randomized; analysis adjusted for clustering effect)	To determine whether an interactive childhood asthma education program, “Roaring Adventures of Puff” (RAP), based on the principles of Social Cognitive Theory, improved asthma management behaviors, health status, and quality of life in elementary school children	162 in 18 schools (136)	<b>Age</b> 5–7 yr, 25.3%; 8–10 yr, 59.3%; 11–13 yr, 15.4% <b>Gender</b> 59.3% male, 40.7% female <b>Other</b> 77.8% Caucasian; 25.9% regular smoking in the home; 20.4% cat in the home	All diagnosed with asthma Parent rating of severity: 64.8% mild, 28.9% moderate, 6.3% severe Seasonal asthma, 88.1% ED visits in past year, 18.6% Missed school days in past year: none, 26.4%; 1–3 days, 24.5%; 4–7 days, 22.1%; 8–11 days, 16.0%; 12 or more, 11.0%	<b>Intervention group (E)</b> “Roaring Adventures of Puff” (RAP) program based on asthma practice guidelines and the principles of social cognitive theory and self-regulation theory consisting of parent and teacher asthma awareness events, recommendations for school asthma guidelines, and six 60-minute education sessions for the children with asthma taught by nursing and pharmacy students. Each session was interactive. (n=76; n=65 completers) <b>Control group (C)</b> Standard care (n=86; n=71 completers)	Assessed after 9 months Significantly more children in E had previously received some education related to asthma (53% vs. 34%, p=0.016).			E vs. C improved in use of appropriate medication for relief of symptoms (20.6% vs. 17.4%, p<0.001) and in having an action plan after the program (+18.6% vs. –2.8%, p=0.01). Only difference in indicators of control for E vs. C was change in limited kind of play (–12.3% vs. +1.4%, p<0.01).	Parents of E indicated greater improvement in understanding (p<0.001) and ability to control (p<0.01) and cope (p<0.001) with asthma than parents of C.

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Clark et al. Effects of a comprehensive school-based asthma program on symptoms, parent management, grades, and absenteeism. Chest 2004;125(5):1674–1679. (National Health, Lung, and Blood Institute, NIH)	Quasi-experimental design (schools randomly assigned, analysis at individual level)	To evaluate a comprehensive asthma program introduced into elementary schools in high asthma prevalence areas	14 schools; 835 children and their parents	<b>Age</b> Grades 2–5; 93% between 7 and 10 yr <b>Ethnicity</b> 98% African American 45% of families had annual income < \$15,000	28% mild persistent, 15% moderate, 5% severe	<b>Intervention group (E)</b> Education to enhance disease management skills and a series of components aimed at those in the social environment who might enable child to manage better. (n=7 schools with 416 children) <b>Control group (C)</b> Wait list control group (n=7 schools with 419 children)	Followup at 12 and 24 months after intervention			(Results reflect adjusting for baseline values and demographics.) E vs. C had 17% fewer daytime symptoms (p<0.0001) and 40% more nighttime symptoms (p<0.0001). Among those with persistent disease, E vs. C had 14% fewer daytime symptoms (p<0.0001) and 14% fewer nighttime symptoms (p<0.0001). No difference in math or reading grades, but science grades were higher for E vs. C and decline in science grades was less for E than C (–0.27 vs. –0.43, p=0.02). No difference in school absences, but E had 34% fewer absences related to asthma in previous 3 months (p<0.0001) and 8% fewer in previous 12 months (p<0.05).	E vs. C parents had higher scores on disease management index (2.19 higher, p=0.02).
Halterman et al. Benefits of a school-based asthma treatment program in the absence of secondhand smoke exposure. Arch Pediatr Adolesc Med 2004;158(5):460–467. (Halcyon Hill Foundation, Webster, NY; Robert Wood Johnson Foundation’s Generalist Physician Faculty Scholars Program)	Randomized controlled design with assessor blinded to group membership.	(1) To evaluate the impact of school-based provision of inhaled corticosteroids as opposed to the standard of care on asthma symptoms among urban children with mild persistent to severe persistent asthma and (2) analyze the effectiveness of this intervention among children with and without exposure to secondhand smoke in the home	184 (ITT)	<b>Age</b> 54% 3–5 yr, 46% 6–7 yr <b>Gender</b> 63% male, 37% female <b>Ethnicity</b> 12% White, 59% Black, 20% Other 32% Hispanic ethnicity, 75% Medicaid 62% public assistance 44% smoker in the home	Mild persistent to severe persistent Symptom days, mean = 5.0 in previous 2 wks Symptom nights, mean = 4.2 in previous 2 wks Days with rescue inhaler, mean = 4.6 in previous 2 wks 48% had ≥3 acute visits 23% had ≥1 hospitalization	<b>Intervention group (E)</b> School-based care group with school nurse administering 1 dose (2 puffs) of fluticasone propionate, 110 mcg/puff each day child was in school; family administered medication at home on days when child not in school. (n=93; 89 completers) <b>Control group (C)</b> Usual care (n=91; 91 completers)	Duration of school year; monthly telephone contact to assess for 2-week recall.			*E had more symptom-free days in the 2 weeks before each followup interview compared with C (9.2 vs. 7.3, p=0.02) and fewer school absences (6.8 vs. 8.8, p<0.05). Among those exposed to smoke in the home, no difference between E and C in outcomes. Among those with no exposure to smoke in the home, E vs. C had more symptom-free days (11.5 vs. 10.8, p<0.05), fewer days needing rescue medications (1.6 vs. 2.3, p=0.03), and fewer absences (4.0 vs. 7.6, p<0.04), and were less likely to have ≥ 3 acute visits (13% vs. 31%, p<0.05).	E vs. C had greater change in quality of life score (0.63 vs. 0.24, p<0.05). No difference in change in quality of life between E and C among those with no exposure to smoke in the home, but among those with exposure, E vs. C had greater increase in quality of life (0.65 vs. 0.11, p<0.05).

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Shames et al. Effectiveness of a multicomponent self-management program in at-risk, school-aged children with asthma. <i>Ann Allergy Asthma Immunol</i> 2004;92(6):611–618. (The David and Lucile Packard Foundation, Los Altos, CA)	Randomized, controlled trial	To determine the effectiveness of a behavioral, educational, and medical intervention that included the use of an asthma education video game to reduce morbidity among high-risk, school-aged children with asthma	119 (92 completers; ITT)	<b>Age</b> 5–12 yr, mean = 8.1 yr <b>Gender</b> 57.9% male, 42.1% female <b>Ethnicity</b> 57.5% Hispanic, 21.8% African-American, 20.7% Other <b>Family Income</b> 68.6% < \$15,000 <b>Mother's education</b> 56% <12 years	Moderate-to-severe; FEV <sub>1</sub> % pred., mean = 91; PEFr mean = 213.5 L/s; mean = 4.0 asthma attacks and 3.5 asthma visits during 2 months before enrollment; asthma symptoms on average 4.14 times/week; 42% use of asthma care plan; 43% current use of asthma anti-inflammatory medication	<b>Intervention group (E)</b> Assignment to asthma case manager, 3-session curriculum on asthma management based on goals recommended by National Heart, Lung, and Blood Institute, asthma video game, visits to pediatric allergist/immunologist, and access to toll-free hotline (n=59; 43 completers) <b>Control group (C)</b> Usual care (n=60; 49 completers)	Assessments at 8, 32, and 52 weeks after baseline	Adjusting for baseline, no difference between E and C for FEV <sub>1</sub> % predicted or for change in FEV <sub>1</sub> pre- to postbronchodilator.		Adjusting for baseline, no difference between E and C for any outcome: symptom days, wheezing days, number asthma attacks, days using rescue bronchodilator, and urgent care visits.	At 32 and 52 weeks, E compared with C improved in physical domain (p=0.04 and p=0.01) and social activity domain (p=0.02 and p=0.05) of asthma quality of life survey. E vs. C improved in asthma self-management knowledge of children at 8 weeks (p=0.02) and of parents at 32 and 52 weeks (p=0.04 and p=0.004).
Cicutto et al. Breaking the access barrier: evaluating an asthma center's efforts to provide education to children with asthma in schools. <i>Chest</i> 2005;128(4):1928–1935. (The Change Foundation, Credit Valley Hospital, Asthma Society, University of Toronto, Ontario Lung Association)	Cluster randomized controlled trial (Analysis indicated no difference between schools, and data were pooled for analysis)	To evaluate a school-based asthma education program delivered by certified asthma educators from the local asthma center	256 in 26 schools (ITT)	<b>Age</b> Grades 2–5, mean 8.6 yr <b>Gender</b> 58.9% male, 41.1% female	Based on parental report, 68.8% mild, 21.9% moderate, 6.3% severe, 3.0% unknown Duration: 53.1% diagnosed >5 yr before Management: followed by specialist, 12.5%; drug plan, 81.2%; inhaled steroid, 86.7%; anti-leukotriene, 9.7%; inhaled long-acting bronchodilator, 4.6% School absenteeism in past 6 months, mean 2.3 days Visits to physician for asthma, mean 4.1 visits/year ED visit in past year, 50.4%	<b>Intervention group (E)</b> "Roaring Adventures of Puff" (RAP) program based on asthma practice guidelines and the principles of social cognitive theory and self-regulation theory delivered in six 50–60 minute sessions once a week over 6 weeks. Instructors were certified asthma educators who attended a 2-day workshop. (n=132; n=121 completers) <b>Control group (C)</b> Standard care (n=124; n=118 completers)	Data collection for children at 12 months; data collection for parents at 3, 6, 9, and 12 months			At 1 year, E vs. C had fewer urgent health care visits (1.7 vs. 2.5, p<0.01), days of limited activity due to asthma (6.2 vs. 9.1, p<0.01), health care visits (3.2 vs. 4.1, p<0.05), and days of school absenteeism (3.0 vs. 4.3, p<0.05). Proportion who missed ≥1 day of school because of asthma was 58% in E vs. 65% in C. No difference between E and C in parental work absenteeism or scheduled asthma visits.	Children in E vs. C had higher self-efficacy at 2 months (3.8 vs. 3.6, p<0.05) and overall quality of life (5.5 vs. 5.0, p<0.05). Proportion which showed clinical improvement in quality of life was 55% in E vs. 26% in C.

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Halterman et al. A randomized trial of primary care provider prompting to enhance preventive asthma therapy. Arch Pediatr Adolesc Med 2005;159(5):422-427. (Halcyon Hill Foundation, Rochester, NY; the Robert Wood Johnson Foundation Generalist Physician Faculty Scholars Program; the Strong Children's Research Center, Rochester, NY)	Randomized controlled trial (Children identified using school district health forms)	To test the effectiveness of a provider prompt to improve the prescription of preventive medications for children with persistent asthma	151 (150)	<b>Age</b> 3-4 yr, 50%; 5-7 yr, 50% <b>Gender</b> 58% male, 42% female <b>Ethnicity/Race</b> White, 11.3%; Black, 59.3%; Other, 29.3% 24.7% of Hispanic ethnicity <b>Other</b> 33.3% of parents had less than high school education 66.7% Medicaid insurance	Mild persistent to severe persistent according to NHLBI guidelines Diagnosed by physician as having asthma Preventive medication use, 44.7% In past 4 weeks: $\geq 4$ symptom days/week, 26.4%; $\geq$ symptom nights/week, 16.1% In past year: $\geq 3$ acute visits, 31.5%; hospitalization, 5.3%	<b>Intervention group (E)</b> Primary care providers of children sent a letter indicating number of days child experienced daytime and nighttime symptoms during past 4 weeks and number of emergency medical visits for asthma during past 12 months along with a copy of 2002 NHLBI guidelines for asthma management and recommendation to consider medication action based on child's current therapy. (n=74; n=73 completers) <b>Control group (C)</b> Routine care; no primary care provider letter (n=77; n=77 completers)	Telephone interview 3-6 months after randomization Parents in both groups notified of child's asthma severity at baseline and recommendations were made for them to speak with their child's provider about the asthma symptoms.			No difference between E and C for receiving preventive medication action (p=0.57) or other preventive measures (p>0.29). Of children in both groups with no medication changes, 52% were still experiencing persistent symptoms. No difference between E and C in office visits (85.3% vs. 79.2%, p=0.38). No difference for E vs. C in emergency contact for asthma (32.4% vs. 44.4%, p=0.17), office visit for acute asthma (25% vs. 27.8%, p=0.85), or ED visit for asthma (11.8% vs. 19.4%, p=0.25). Based on logistic regression, only $\geq 3$ acute visits in past year (OR 3.10, 95% CI 1.20 to 8.03) and preventive medication use (OR 3.01, 95% CI 1.15 to 7.89) were predictive of preventive medication action.	
Joseph et al. Effect of asthma intervention on children with undiagnosed asthma. J Pediatr 2005;146(1):96-104. (National Heart, Lung, and Blood Institute, NIH)	Comparative secondary analysis using data from a randomized trial	To describe changes in functional status and morbidity for undiagnosed children exposed to an asthma intervention	809 (809) 1,227 met criteria for current asthma or reported no physician diagnosis; 809 completed baseline and at least 1 followup	<b>Age</b> Elementary school age, mean = 8.1 yr <b>Gender</b> 52% male, 48% female <b>Ethnicity</b> 97% Black in population <b>Caregiver Education</b> 88% high school diploma <b>Household Income</b> 50% $\leq$ \$15,000 <b>Household Smokers</b> 58% with $\geq 1$ smoker in household Recruited from 14 Detroit public elementary schools	Based on NAEPP-II classifications, of the diagnosed (n=510), 47.5% were mild-intermittent, 29.4% mild-persistent, 17.1% moderate-persistent, and 5.9% severe-persistent. Among undiagnosed (n=299), 60.5% were mild-intermittent, 24.9% mild-persistent, 11.7% moderate-persistent, and 3.0% severe-persistent.	<b>Intervention group (E):</b> Asthma education in the form of "open airways" <b>Control group (C):</b> Usual care Schools randomly assigned to E vs. C. GEE models used to account for correlation between repeated measurements; generalized linear modeling used to adjust for clustering of children within schools.				Fewer allergies (OR 0.5, 95% CI 0.4 to 0.6), seasonal variation in symptoms (OR 0.4, 95% CI 0.3 to 0.5), and wheeze with exercise (OR 0.2, 95% CI 0.2 to 0.3) for undiagnosed. Among moderate-severe, symptom days (p=0.02), caregiver changed plans (p=0.03), restricted activity (p<0.01), and school absenteeism (p=0.02) were reduced at followup for intervention group, but not for control group. Among those with mild asthma, there were no changes over time for undiagnosed in the intervention group. (Adjusted for age, gender, caregiver education, and household income)	

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Patterson et al. A cluster randomized intervention trial of asthma clubs to improve quality of life in primary school children: the School Care and Asthma Management Project (SCAMP) Arch Dis Child 2005;90(8): 786–791. (South and East Belfast Health and Social Services Trust; the Primary Care and Development Fund; Eastern Health and Social Services Board the Department of Child Health, Queen’s University Belfast, UK)	Cluster randomized controlled trial (Schools randomized from matched pairs; analysis adjusted for clustering effect)	To evaluate the effectiveness of a school-based education program of weekly asthma clubs in improving quality of life for primary school children with asthma	176 children in 22 schools (173)	<b>Age</b> 7–11 yr, mean 9.0 yr <b>Gender</b> 52% male, 48% female <b>Ethnicity</b> Not reported	Diagnosed with asthma Regular reliever, 40%; regular preventer, 57% (verified, 31%); reliever in school, 36% (verified, 21%); self-management plan, 7%; prescribed peak flow meter, 20% FEV <sub>1</sub> % pred., mean 98.9; <80% for 6% FVC % pred., mean 98.6 Inhaler technique: correct, 16%; correct and partially correct, 43%	<b>Intervention group (E)</b> Eight weekly, lunchtime, child-friendly asthma club sessions led by community nurses. (n=83; 81 completers) <b>Control group (C)</b> Delayed intervention after 16-week interval (n=92; 92 completers)	End of club assessments at 7 weeks; followup assessment after another 8 weeks	No difference in change in spirometry for E vs. C (FEV <sub>1</sub> % pred., diff –.4, 95% CI –2.8 to 2.0, p=0.74; FVC % pred., p=0.98). Increased inhaler technique for E vs. C (correct 56% vs. 15%, p<0.001; correct and partially correct, 84% vs. 40%, p<0.001).		No difference in change in quality of life for E vs. C (diff .20, 95% CI –.20 to .61, p=0.32).	
Velsor-Friedrich et al. A practitioner-based asthma intervention program with African American inner-city school children. J Pediatr Health Care 2005;19(3): 163–171. (National Institute of Nursing Research; Loyola University Research Award; the Respironics Corporation)	Intact groups pretest/posttest design (quasi-experimental) (Schools randomly assigned; no adjustment for clustering effect)	To examine the effect of a school-based intervention program, Open Airways; combined with 5 monthly followup visits with a nurse practitioner on selected psychosocial and health outcomes	73 students from 4 schools (52)	<b>Age</b> 8–13 yr, mean 10.1 yr <b>Gender</b> 50% male, 50% female <b>Ethnicity</b> 100% African American	All diagnosed with asthma; 38% mild persistent In previous 2 weeks: 59% no asthma symptoms, 38% symptoms for 1–2 days 94% had acceptable peak flow readings (green zone); 6% had peak flow readings in the warning (yellow) zone	<b>Intervention group (E)</b> Open Airways Program consisting of six 45-minute sessions offered once per week in which small groups of children learn new asthma management skills. Program was followed by 5 monthly visits with the nurse practitioner at the school-based health clinic. (n=?; n=28 completers) <b>Control group (C)</b> Usual care (n=?; n=24 completers)	Data collection at baseline, 2 weeks, 5 months, and 12 months post-intervention	(Repeated measures analysis adjusting for baseline) Both E and C increased peak flow percentage over time (p<0.001) with no differences between groups.		(Repeated measures analysis adjusting for baseline) Increase over time in general self-care practice (p=0.02) and asthma self-care practice (p=0.004) with scores for E vs. C higher (general self-care p=0.02; asthma self-care p=0.01). In regression analysis, only predictor of asthma self-care practice at each time was general self-care ability.	(Repeated measures analysis adjusting for baseline) E vs. C had higher knowledge scores (p=0.03) and higher asthma self-efficacy scores (p=0.01) with no change over time. No difference between groups or over time in self-esteem.

**C. ASTHMA SELF-MANAGEMENT EDUCATION IN COMMUNITY SETTINGS: COMMUNITY-BASED INTERVENTIONS**

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Gallefoss & Bakke. Impact of patient education and self-management on morbidity in asthmatics and patients with chronic obstructive pulmonary disease. <i>Respir Med</i> 2000;94(3):279-287.	Randomized controlled trial (outpatient chest clinic in Norway)	To assess the effects of a standardized education program and a self-management plan on general practitioner visits and absenteeism from work	78 (71) (Sample included patients with asthma or COPD. Only data from patients with asthma are reported here.)	<b>Age</b> Mean = 42 yr <b>Gender</b> 29% male, 71% female <b>Smoking</b> 28% current smokers	Duration of symptoms, median 6.5 yr FEV <sub>1</sub> % pred., ≥80% with mean = 94 FVC % pred., mean = 104 Current use of peak flow meter, 36%	<b>Intervention group (E)</b> Educational intervention consisting of a specially constructed patient brochure, two 2-hour group sessions, and one or two 40-minute individual sessions with a nurse and a physiotherapist; self-management plan. (n=39; n=32 completers) <b>Control group (C)</b> Treatment as usual (n=39; n=39 completers)	12-month followup			C more likely than E to visit general practitioner during 12 months (OR 5.1, 95% CI 1.8 to 14.2). Visits reduced by 73% for E vs. C. During the 12 months, percentage of acute visits due to asthma problems did not differ between E and C. In C, 50% of employed patients reported absenteeism from work due to symptoms vs. 24% of E (p=0.06). Mean reduction in absenteeism for E was 69% vs. C.	
Ochsner et al. Increasing awareness of asthma and asthma resources in communities on the Southwest border. <i>J Amer Acad Nurse Pract</i> 2002;14(5): 225-234.	(1) Descriptive (2) Comparative	To study the effectiveness of a southwest border hospital's in-house asthma educational program	Descriptive: 3,429 (2,411) Comparative: 58 (39)	Descriptive: children in grades 4 and 5 Comparative: <b>Age</b> 8 months-18 yr <b>Gender</b> 78% male, 22% female	Descriptive: Subgroup of 259 either had asthma or had a family member or friend with asthma. Comparative: All children referred had been admitted to hospital or treated in emergency department.	<b>Intervention group (E)</b> Hospital asthma education plus additional education through home visits, telephone calls, and mailings (n=23; n=18 completers) <b>Comparison group (C)</b> Hospital asthma education only (n=35) <b>In-School Education (Descriptive study)</b> 50-minute asthma overview based on Open Airways for Schools curriculum presented in classroom; subgroup volunteered in small group followup sessions (1-3 sessions depending on school) (n=3,429 with n=2,411 paired responses for overview; n=259 with n=248 paired responses for small group sessions)	12-month followup for comparative study			*2 of 23 in E and 1 of 35 in C were readmitted to hospital or emergency department (8.7% vs. 2.9%).	Scores on 5-item test increased from 2.9 to 3.5 (p-level not reported). Scores for a random sample (n=248) of tests including both true/false and completion items increased from 10.3 to 13.1 (p not given).

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Bryant-Stephens and Li. Community asthma education program for parents of urban asthmatic children. J Natl Med Assoc 2004;96(7):954-960.	Single group pre-/posttest design	To demonstrate the effectiveness of community asthma education provided by peers in the urban community	342 adults (267 caregivers of 309 children)	<b>Child Age</b> 19% 2-3 yr, 20% 4-5 yr, 40% 6-10 yr, 17% 11-19 yr, 4% unknown <b>Child Gender</b> 58% male, 42% female <b>Race</b> 100% African American <b>Caregiver Education</b> 5% elementary school, 52% high school graduate, 28% college attendance or completion, 12% post-high school training, 3% unknown	Not reported	<b>Intervention group (E)</b> Five-week community-based class taught by trained parent educators and teen educators. Topics included asthma pathophysiology, triggers of asthma, prevention techniques, medicines and asthma devices, asthma action plan, and school and family issues. (n=267; n=200 at 3 and 6 months; n=134 at 12 months)	5-week session; assessment at beginning and end of classes with followup telephone assessment at 3, 6, and 12 months.				*Asthma knowledge score increased from 81% preinstruction to 94% (p<0.05) immediate post-instruction. Scores decreased slightly at 3 months but at 6 and 12 months did not differ from immediate posttest (p>0.05). Parental perceptions of asthma control and quality of life showed significant improvement at immediate postinstruction (p<0.01) and remained significant at 6 and 12 months (p<0.05).
Fisher et al. Community organization to reduce the need for acute care for asthma among African American children in low-income neighborhoods: the Neighborhood Asthma Coalition. Pediatrics 2004;114(1):116-123. (National Heart, Lung, and Blood Institute; National Institute of Environmental Health Sciences; Key Pharmaceuticals)	Comparative cohort design (4 NAC neighborhoods and 4 control neighborhoods) (identified from medical records)	To determine whether a community-based intervention, NAC, conducted through a well-established neighborhood organization could improve awareness of asthma, change attitudes about its care, improve asthma management practices, and reduce the need for acute care for asthma	306 (249)	<b>Age</b> 5-14 yr, mean = 9.5 yr <b>Gender</b> 58% male, 42% female <b>Other</b> 29% with parents having less than high school diploma; 23% with parents owning own home; 77.5% with health insurance, including Medicaid	Examined in ED or hospitalized for treatment of asthma at a children's hospital In previous year: acute visits, mean = 1.97; admissions, mean = 0.39; ED visits, mean = 1.58	<b>Intervention group (E)</b> Promotional campaigns to increase awareness, asthma management courses in schools and neighborhood settings, involvement of neighborhood residents in planning programs, training of neighborhood residents to implement asthma management classes, recruitment of residents to assist in program activities, and recruitment of residents to provide basic education and support to parents and children. Implemented for 36 months. (n=4 neighborhoods and 140 subjects; n=100 provided utilization data) <b>Control group (C)</b> (n=4 neighborhoods and 166 subjects; n=149 provided utilization data)	Parents interviewed quarterly. Utilization data reflects periods of 36 to 48 months, including the 12 months before program initiation.			Acute care rates decreased for both E and C. Controlling for age and gender of child and educational level of mother, difference between groups was not significant (p=0.35). No effect on acute care rates of length of involvement with the program or the number of telephone evaluation interviews completed. Low-participation E and C did not differ (p=0.46), but high-participation E differed from pooled low-participation E and C groups (p=0.014). Subjects in E increased from 30% to 51% for seeking help at the appropriate point in the escalation of symptoms while subjects in C increased from 47% to 53%. There was no difference between E and C by the end of the intervention period.	Scores on Index of Asthma Attitudes increased in both groups, with no difference between groups, (p=0.35). Contacts with E staff members and attendance at education events were associated with changes toward stronger views that asthma can be managed (partial correlation = 0.27, p=0.03; partial correlation = 0.24, p=0.06, respectively).

**D. ASTHMA SELF-MANAGEMENT EDUCATION IN COMMUNITY-BASED SETTINGS: HOME-BASED**

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Jones et al. Increasing asthma knowledge and changing home environments for Latino families with asthmatic children. Patient Educ Counsel 2001;42(1):67-79. (National Heart, Lung, and Blood Institute, NIH)	Single group pretest/posttest design	To test for change in asthma management knowledge and for indications that participants took action to reduce the prevalence of allergens in child's sleeping area	193 (190)	<b>Age</b> 3-17 yr, mean = 7.2 yr <b>Gender</b> 60% male, 40% female <b>Ethnicity</b> All self-identified as Latino or Hispanic <b>Caregiver</b> Mean age = 33.5 yr 66% married or living with partner	40% rated by caregiver as moderate or severe, 58% as mild or modest, 2% as no symptoms Over 20% hospitalized for respiratory problems in previous year	<b>Intervention group (E)</b> Adapted from "You Can Control Asthma" program; average duration of session was 108 minutes.	Posttest at a minimum of 1 week after intervention		Number of asthma triggers observed in child's bedroom decreased from 2.5 to 1.8 (p<0.001) and number of asthma controllers in bedroom increased from 0.7 to 0.9 (p<0.001).		Average percent correct increased from 38.5% to 50.1% (p<0.001).
Brown et al. Home-based asthma education of low-income children and their families. J Pediatr Psychol 2002;27(8):677-688. (NIR, NIH)	Randomized controlled trial	To test whether families in the home-based asthma education group would demonstrate reduction in the children's asthma morbidity, show improvement in self-reported caregiver quality of life, and report gains in asthma management behaviors	95 (95)	<b>Age</b> 1.3-6.9 yr, mean = 4.3 yr, 48% 3 yr or less <b>Gender</b> 62% male, 38% female <b>Ethnicity</b> 90% African-American <b>Caregiver's age</b> Mean = 31 yr 82% on Medicaid <b>Caregiver's education</b> 28% no high school diploma, 50% high school diploma, 22% some college	19% mild intermittent, 56% mild persistent, 21% moderate persistent, 4% severe persistent	<b>Intervention group (E)</b> Adapted "Wee Wheezers at Home" program to consist of eight 90-minute weekly home sessions. (n=49) <b>Control group (C)</b> Usual care (n=46)	Followup at 3- and 12-month visits		E vs. C reduced bother by asthma symptoms during past week at both 3 and 12 months for children 1-3 but not for those 4-6 (p<0.01). E vs. C increased number of symptom-free days at 12 months for children 1-3 yr (p<0.05) but not for children 4-6 yr. No difference between E and C in number of medical visits.	E vs. C increased caregiver quality of life rating for children 1-3 yr (p<0.01), but not for children 4-6 yr (p>0.05). No difference in caregiver asthma management behavior between E and C.	

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Eggleston et al. Home environmental intervention in inner-city asthma: a randomized controlled clinical trial. <i>Ann Allergy Asthma Immunol</i> 2005;95(6):518–524. (US Environmental Protection Agency; National Institute of Environmental Health Sciences; National Heart, Lung, and Blood Institute; US Environmental Protection Agency's Science to Achieve Results (STAR) program)	Randomized controlled trial	To test the efficacy of a home-based intervention in reducing allergen and particulate exposure	100 (97)	<p><b>Age</b> 6.1–11.9 yr, mean = 8.4 yr</p> <p><b>Gender</b> 66% male, 54% female</p> <p><b>Ethnicity</b> 99% African American 1% Other</p> <p><b>Family Income</b> 39% &lt;\$10,000; 38% \$10,000–20,000; 23% &gt; \$20,000</p> <p><b>Other</b> 69% smoker in home, 39% cat or dog in home, 64% reported cockroach infestation, 80% reported mouse infestation</p>	<p>Physician-diagnosed asthma, 24% with moderate-severe persistent symptoms</p> <p>30% took daily controller medications</p> <p>FEV<sub>1</sub> % pred., 97%</p> <p>In past 3 months: 35% ED visit for asthma, 8% hospitalized</p> <p>Positive skin test results: 30% house-dust mite, 42% cockroach, 9% mouse, 23% cat; 70% ≥1 positive result</p>	<p><b>Intervention group (E)</b> Physical component included a room-sized high-efficiency particulate air filter for child's bedroom fitted to monitor compliance, allergen-proof mattress and pillow encasings, and free professional extermination, for cockroach and mouse, if needed. Behavior component included environmental educator at 3 home visits and a telephone followup during a 5-month period. (n=50)</p> <p><b>Control group (C)</b> No intervention (n=50)</p>	Home environmental evaluation at 6 and 12 months; clinic visit at 12 months. (84% of E received cockroach extermination, and 75% of E used the air cleaner)			<p>*Levels of PM<sub>10</sub> decreased 20% at 6 months and 39% at 12 months in E vs. increases of 8% and 5% in C (p&lt;0.001 at 12 months). Changes in PM<sub>2.5</sub> significant (p&lt;0.001 at 12 months).</p> <p>No difference between E and C in change in Bla g 1 levels in bedroom.</p> <p>E less likely than C to report daytime symptoms during first 9 months (adj. OR 0.55, 95% CI 0.31 to 0.97, p=0.04); mean difference between E and C comparing daytime symptoms across 12 months not significant (OR 0.62, 95% CI 0.36 to 1.05, p=0.07).</p> <p>Other health outcome measures did not differ between groups.</p>	

**E. ASTHMA Education IN COMMUNITY SETTINGS: ALLERGEN-CONTROL INTERVENTIONS**

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Leickly et al. Self-reported adherence, management behavior, and barriers to care after an emergency department visit by inner city children with asthma. Pediatrics 1998;101(5):E8. (National Institute of Allergy and Infectious Disease, National Institutes of Health)	Observational study (chart review and survey) (recruited from EDs and community clinics in 8 major metropolitan inner city areas)	To identify issues reported by families that could adversely affect their adherence to an asthma care program	344	<b>Age</b> 4–9 yr, mean = 6.3 yr <b>Gender</b> 61.6% male, 38.4% female <b>Ethnicity</b> 66.2% African American, 25.0% Hispanic, 8.8% Other <b>Other</b> 54.7% with at least 1 smoker in household; 55.7% family history of asthma; 56.5% family income < \$15,000; 28.4% of caretakers married; 86.6% of respondents were mother, 4.7% father, 8.7% other or unknown	Moderate to severe Recruited while in ED for acute asthma exacerbation During 3 months before baseline, hospitalizations occurred in 22.4% of children Wheezing in the 2 weeks before baseline, mean = 3.23 days At least 1 hospitalization, 22.4%		(Controlled for gender, baseline, foreign-born status, psychological resources, and baseline medication)			Percent of those prescribed at ED who reported the medicine at baseline: beta-agonists, 94.9%; xanthines, 93.3%; steroids, 86.8%; cromolyn, 69.4% Most (85.8%) were able to follow all treatments most of the time; 81.4% used all medicines as prescribed, 78.5% had no problems ensuring child took medicine; 94% had medicines at home to use in event of an attack. Only 6.7% admitted not filling a prescription. Doubts about usefulness of medication was reported by 34% of those adherent vs. 54% of those nonadherent (p=0.002). Probability of making and keeping an appointment is 60%. Most common reason for not making followup appointment was that child was well.	Prevention strategies included keeping child from running or getting excited (62.5%), avoiding known allergies (48.3%), avoiding smoke (37.5%), avoiding bad weather (36.9%), and giving asthma medication (23.5%). Management strategies included giving asthma medicine (81.7%), going to clinic or ED (64.2%), having child rest (48.0%), giving fluids by mouth (15.4%), and call physician (13.4%). Most (72.1%) use medicine or call physician as first or second action.
Carter et al. Home intervention in the treatment of asthma among inner-city children. J Allergy Clin Immunol 2001;108(5): 732–737. (National Institutes of Health)	Single-blinded, randomized controlled trial	To investigate whether implementing low-cost measures for indoor allergen avoidance could reduce the number of sick days and unscheduled visits to health care facilities for asthma	104 (92 and 85)	<b>Age</b> 6–16 yr, mean = 10.9 yr <b>Other</b> Outpatient population is 92% African American, with 80% living in poverty	Being treated for asthma 49% receiving inhaled controller medicine	<b>Intervention group (E)</b> Avoidance measures included allergen-impermeable mattress and pillow covers, effective roach bait, instructions to wash the bedding once/week in hot water, and instructions about cleaning measures to control dust mites and cockroaches (n=35; 30 completers) <b>Placebo group (P)</b> Allergen-permeable mattress and pillow covers, ineffective roach traps, and instructions to continue their normal practice of washing the bedding (n=34; 25 completers) <b>Control group (C)</b> Routine medical care; allergen-control measures in the home were not discussed (n=35; 30 completers)	E and C homes visited at enrollment and at 3, 8, and 12 months. Homes of C visited at 12 months.			*Significant (p<0.001) decrease in acute visits for E (down 30%) and P (down 30%) vs. C (up 6%). Over 70% decrease in allergen concentration in 33% of homes with no difference between E and P. Children allergic to and exposed to mite with a decrease in mite allergen concentration showed a decrease in acute visits (65% vs. 25%, p=0.035). Among those with mite allergy who had a decrease in visits, mean change in mite allergen was –22.4% vs. +30.1% among those without a decrease in visits (p<0.01).	

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Custovic et al. Effect of environmental manipulation in pregnancy and early life on respiratory symptoms and atopy during first year of life: a randomized trial. Lancet 2001; 358(9277):188–193. (The National Asthma Campaign, UK)	Prospective, prenatally randomized, cohort study	To ascertain whether living in a low-allergen environment reduces the risk of asthma and atopic diseases in infants	620 (517)	<b>Gender</b> 54% male, 46% female <b>Delivery</b> 83% normal, 17% Caesarean section <b>Parents (randomized trial)</b> Both atopic, mother sensitized to indoor allergens, and no cat or dog in home <b>Parents (cohorts)</b> (1) Both parents have positive skin test, with a cat and/or dog (2) Both have negative skin test, no history of atopic disorders, and no pets		<b>Intervention group (E)</b> Prenatal intervention included covering the maternal bed with allergen-impermeable bedding; providing of high-filtration vacuum cleaner, vinyl floor in infant room, crib mattress encased in allergen-proof material, and washable soft toy; and applying benzyl benzoate to carpets and soft furnishings. (n=145; n=133 at 1 year) <b>Control group (C)</b> No environmental manipulation (n=146; n=118 at 1 year) <b>Cohort 1</b> High risk with pets followed prospectively (n=161; n=140 at 1 year) <b>Cohort 2</b> Low risk with no pets followed prospectively (n=168; n=126 at year 1)	Assessment at 12 months			Relative risk of E vs. C was 0.44 (95% CI 0.20–1.00) for attacks of severe wheeze, 0.58 (95% CI 0.36–0.95) for prescribed medication for wheeze attacks, and 0.18 (95% CI 0.04–0.79) for wheeze after playing or exertion.	
Woodcock et al. Control of exposure to mite allergen and allergen-impermeable bed covers for adults with asthma. N Engl J Med 2003;349(3): 225–236. (United Kingdom National Health Service Research and Development Programme on Asthma Management)	Randomized, double-blind, placebo-controlled design	To test the hypothesis that allergen-impermeable bed covers improve asthma control	1,150 (965 at 6 months; 882 at 12 months)	<b>Age</b> 18–50 yr, mean = 36.3 yr <b>Gender</b> 36.2% male, 63.8% female <b>Ethnicity</b> 98% White <b>Smoking</b> 48% ever smoked; 24% current smoker 55% cat or dog owner 65% mite sensitive	All regularly taking inhaled corticosteroids: 80% beclomethasone (50–3,200 mcg/day, mean = 500 mcg/day), 9% budesonide, and 11% fluticasone (200–8,000 mcg/day, mean = 1,000 mcg/day) Evening PEF mean = 426.8 l/min	<b>Intervention group (E)</b> (Phase I) Received mattress, pillow, and quilt covers impermeable to D. pteronyssinus 1 (Der p1). (Phase II) After 6 months, corticosteroid dose reduced by 25% to 50% each month. (n=574 in Phase I, n=480 completers; n=369 in Phase II, n=437 completers) <b>Control group (C)</b> (Phase I) Received nonimpermeable polyester-cotton covers. (Phase II) After 6 months, corticosteroid dose reduced by 25% to 50% each month. (n=576 in Phase I, n=485 completers; n=382 in Phase II, n= 445 completers)	Assessment at 6 months and 12 months	*Adjusting for baseline, there was no difference between E and C in PEF (diff. –1.6 l/min, 95% CI –5.9 to 2.7, at 6 months; diff. 3.4, 95% CI –1.7 to 8.4, at 12 months).		Adjusting for baseline, no difference between E and C in daytime use of beta-agonist (p=0.08), nighttime use of beta-agonist (p=0.78), symptom score (p=0.65), exacerbations (p=0.38), or days of work missed at 6 months. At 12 months, no difference between E and C in percentage no longer receiving inhaled corticosteroids (RR of discontinuation 1.02 in all patients; 47% vs. 48% in those entering Phase II).	Adjusting for baseline, no difference between E and C in quality of life (p=0.90) at 6 months.

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Morgan et al. Results of a home-based environmental intervention among urban children with asthma. N Engl J Med 2004;351(11): 1068–1080. (National Institute of Allergy and Infectious Diseases and National Institute of Environmental Health Sciences, NIH; National Center for Research Resources, NIH)	Multisite randomized controlled trial (research centers in 8 cities)	To determine whether an intervention tailored to each child's sensitization and environmental risk profile could improve the symptoms of asthma and decrease the use of health care services	937 (869 at year 1; 821 at year 2)	<b>Age</b> 5–11 yr, mean = 7.6 yr <b>Gender</b> 62.7% male, 37.3% female <b>Ethnicity</b> 39.6% Black, 40.2% Hispanic, 20.2% Other <b>Caregiver</b> 29% of caregivers completed high school Household income: 60% > \$15,000 <b>Environmental exposure</b> 68% with evidence of cockroach allergen and 84% of dust-mite allergen in bedroom 22% with dog living in home; 18% with cat living in home	Moderate-to-severe: 46% on anti-inflammatory agents, 85% on beta-agonists In previous 2 weeks, maximal days with symptoms, mean = 6.0; school days missed, mean = 1.0 FEV <sub>1</sub> % pred., mean = 87.8 FVC % pred., mean = 96.7 PEF in morning, mean = 203.8 l/min	<b>Intervention group (E)</b> Multifaceted, home-based, environmental intervention consisting of 6 education modules, 5 mandatory and 2 optional home visits, and telephone calls to address barriers to implementing the remediation plan. Families given bed covers, vacuum cleaner with HEPA filter, HEPA air purifier, and, if needed, professional pest control. (n=469; n=444 at year 1 and n=407 at year 2) <b>Control group (C)</b> Usual care; visits only for evaluation at 6-month intervals. (n=468; n=425 at year 1 and n=414 at year 2)	Assessment at 6, 12, 18, and 24 months	No difference between E and C in pulmonary function.	E vs. C had greater reduction in levels of cockroach allergen Bla g1 (p>0.001) and dust-mite allergens Der f1 (p<0.001) and Der p1 (p<0.007) in the bed and B1a g1 (p<0.001) and Der f1 (p=0.004) on the bedroom floor. During year 2, reduction in Der f1 in bed and Bla g1 on floor remained greater in E. Cat allergen decreased by 28% in E and increased by 15% in C (p<0.001) in year 1. In year 2, cat allergen decreased by 14% in E and increased by 30% in C (p<0.001).	Number of days with symptoms was lowered in E vs. C by 0.82 days/2-week in year 1 and 0.60 days/2-week in year 2. Greater reduction occurred within 2 months. Visits to ED or clinic were lower for E vs. C (2.2 vs. 2.6, p=0.04) in year 1 but not in year 2. Number of school days missed lower for E vs. C (0.65 vs. 0.82, p=0.003 in year 1; 0.54 vs. 0.71, p=0.009 in year 2). No difference in proportion hospitalized for asthma.	
Klennert et al. Short-term impact of a randomized multifaceted intervention for wheezing infants in low-income families. Arch Pediatr Adolesc Med 2005; 159(1): 75–82. Childhood Asthma Prevention Study (CAPS)	Randomized controlled trial (recruited from pediatric departments of local hospitals and clinics in metropolitan area)	To evaluate the effect of the year-long intervention on targeted variables, including environmental tobacco smoke (ETS) and cockroach, cat, and dog allergens and maternal care giving, including asthma management and emotional care giving	181 (150; ITT)	<b>Child Age</b> 9–24 months, mean = 16.8 months <b>Gender</b> 72% male, 28% female <b>Ethnicity</b> 21% European American, 32% US-born Hispanic, 21% foreign-born Hispanic, 23% African American, 3% other <b>Mother</b> Education, 58% < high school; age, 26% <20 yr; asthma, 28% <b>Other</b> 30% prenatal smoke exposure; 13% infant birth weight <2,500 g; 49% income <\$12,000/yr; 30% infant eczema; 64% cigarette smoker in home	Skin test ≥1, 16% Total serum IgE level, geometric mean = 15 IU/mL Cockroach allergen levels higher than standard cutoff in 12% of homes, cat dander in 31% of homes, and dog dander in 19% of homes. Infant urinary cotinine levels detectable in 56% of families.	<b>Environmental support intervention group (E)</b> Caregivers received educational videotape that described child's risk and received feedback letters regarding allergen and cotinine levels following baseline assessment. Received home visits by nurse, with goal of 18 visits across 12 months. Nurses spent 15% of visit time on allergen and ETS reduction, 37% on health promotion, 14% on parent-child interaction, and 30% on caregiver psychological health. (n=90; n=74 completers) <b>Control group (C)</b> Caregivers received educational videotape that describe child's risk and received feedback letters regarding allergen and cotinine levels following baseline assessment. No home visits by nurse. (n=91; n=76 completers)	Single clinic visit for skin test and blood draw. Caregiver interviewed at home and house dust and infant urine samples collected at 12 months. Medical records obtained. Median number of visits, including telephone calls, was 15, lasting average of 53 minutes.			(Controlled for gender, baseline, foreign-born status, psychological resources, and baseline medication) Cockroach dander was reduced in E vs. C (p<0.03) with no difference for change in cat dander (p=0.25) or dog dander (p=0.07). No difference in number of families with infants with detectable cotinine levels (66% vs. 56%, p=0.28), but levels were lower in E vs. C (p=0.02) with reduction greatest among low-psychological resource families (p=0.01). No difference in occurrence of ED visits (p=0.40) or hospitalizations (p=0.63). Number of corticosteroid steroid bursts during year was higher for E vs. C (p<0.01; Poisson regression).	Families in E had greater asthma knowledge scores than C (5.2 vs. 4.8, p<0.04) and higher collaboration with medical provider scores (6.1 vs. 5.8, p=0.04).

Citation (Sponsor)	Study Design	Purpose/Objective	Study N (Number Evaluable)	Population Characteristics	Asthma Severity at Baseline (if reported)	Treatment	Assessment/Off-Treatment Followup	Lung Function	Environment	Morbidity	Knowledge/Quality of Life
Krieger et al. The Seattle-King county healthy homes project: a randomized, controlled trial of a community health worker intervention to decrease exposure to indoor asthma triggers. Am J Public Health 2005;95(4): 652–659. (National Institute of Environmental Health Sciences; Seattle Partners for Healthy Communities, a Centers for Disease Control and Prevention funded Urban Research Center; the Nesholm Foundation; the Seattle Foundation)	Randomized trial (recruited from community and public health clinics (65%), local hospitals and emergency departments (27%), and referrals from community residents and agencies (8%))	To assess the effectiveness of a community health worker intervention focused on reducing exposure to indoor asthma triggers	274 (214; ITT analysis)	<b>Child</b> <b>Age</b> 4–12 yr, mean = 7.4 yr <b>Gender</b> 58% male, 42% female <b>Caregiver</b> <b>Age</b> Mean = 35.2 yr <b>Ethnicity</b> 16.8% Non-Hispanic White, 29.9% Non-Hispanic African American, 23.8% Vietnamese, 17.6% Hispanic, 11.9% other <b>Education</b> 39.3% less than high school, 26.8% high school graduate or general equivalency diploma, 26.1% some college, 7.8% college graduate <b>Household Income</b> 56.4% <100% poverty, 28.7% 100–149% poverty, 14.9% 150–200% poverty <b>Other</b> 52.6% caregiver employed; 40.9% smoker in home; 23.6% pet in home; 43.6% mold in home; 17.6% roaches in home	Diagnosed with persistent asthma 23.7% mild intermittent, 14.2% mild persistent, 34.0% moderate persistent, 28.1% severe persistent Urgent health use in past 2 months, 23.6% In past 2 weeks: symptom days, mean = 7.8; days with activity limited by asthma, mean = 4.7; days used beta <sub>2</sub> -agonist, mean = 7.2; days used controller medications, mean = 4.9; missed school, 30.2%	<b>Intervention group (E)</b> High-intensity intervention provided by community health workers, including structured home environmental assessment plus 4–8 additional visits to encourage completion of an action plan, provide education and social support, deliver resources to reduce exposures, offer assistance with roach and rodent eradication, and advocate for improved housing conditions. (n=138; n=110 completers) <b>Comparison group (C)</b> Low-intensity intervention, consisting of a single community health worker visit which consisted of the home environmental assessment, an action plan, limited education, and bedding encasements. (n=136; n=104 completers)	1-year followup Community health worker made mean of 7 visits to each participant in E. Fewer than 20% required 9 visits. Mean visit length was 1 hour.			(Analysis used GEE adjusted for baseline across group differences.) *Urgent health services use decreased more in E vs. C (p=–0.26) with decrease of 15% in E and increase of 3.8% in C. Symptom days decreased more in E (–4.7 days) vs. C (+3.9 days), with no difference between groups (p=0.138). Behavior summary score increase in both groups, with no difference between groups (E +1.5, C +0.9; p=0.141). Urgent care costs during 2 months before exit interview were \$6,301 to \$8,856 less in E (\$57 to \$80/child) relative to C.	(Analysis used GEE adjusted for baseline across group differences.) *E provided greater benefit in caregiver quality of life (+1.6 vs. +1.0, p=0.005).
McConnell et al. Educational intervention to control cockroach allergen exposure in the homes of Hispanic children in Los Angeles: results of the La Casa study. Clin Exp Allergy 2005;35(4): 426–433. (National Institute of Environmental Health Sciences; Environmental Protection Agency; Hastings Foundation; Southern California Particle Center and Supersite)	Randomized controlled trial (recruited through school-based asthma clinic or allergy clinic at a university medical center)	To evaluate an educational intervention for cockroach control and cockroach allergen reduction directed to the primary caretaker of inner city, primarily Hispanic children	150 families (139)	<b>Child</b> <b>Age</b> 6–14 yr <b>Gender</b> 67% male, 33% female <b>Caretaker</b> <b>Gender</b> 7% male, 93% female <b>Ethnicity</b> 93% Hispanic, 7% other <b>Education</b> 37% < 7th grade, 34% 7th–11th grade, 29% high school graduate Family income 39% <\$15,000; 32% \$15,000–\$24,999; 29% ≥\$25,000	Positive skin test to mixed cockroach allergen or house-dust mite 54% cockroach allergic 50% previously hospitalized At least 3 visits to mobile asthma clinic or allergy clinic	<b>Intervention group (E)</b> Educational intervention delivered by a peer health educator to the caretaker in the child's home. Intervention focused on conditions in the home and included allergen-impermeable casing on pillows, mattress and box springs of child's bed; providing boric acid, caulking materials, and a list of cockroach control products and prices and store locations. (n=75; n=68 completers) <b>Comparison group (C)</b> Usual care (n=75; n=71 completers)	Followup assessment at 4 months			(Analyses adjusted for baseline and cockroach allergy in child) Geometric mean cockroach number in E at followup was 60% lower than in C (95% CI 14% to 81%). Geometric mean total cockroach allergen from child's bedding was 64% lower in E vs. C (95% CI 12% to 85%).	(Analyses adjusted for baseline and cockroach allergy in child) Knowledge was greater by 0.25 in E vs. C (p=0.10). E more likely to report activities that were primary recommendations (mean increase = 0.67, p=0.01) including use of boric acid (OR 13, 95% CI 4.3 to 41), caulking (OR 2.9, 95% CI 1.2 to 6.9), and use of sticky traps (OR 3.1, 95% CI 1.1 to 9.2).