

Improving Asthma Outcomes for Children: Many Paths to Progress

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Background: Asthma continues to be a significant public health issue for children. The extent to which tailored evidence-based interventions address the needs of children at varied levels of risk in the community is unclear.

Objective: Using data from five impoverished communities with high levels of pediatric asthma morbidity, this study assessed morbidity outcomes associated with tailored evidence-based interventions after stratifying children for risk based on two variables that reflect control, severity, and behavior: hospitalizations and daily use of a controller medication.

Methods: A pre/post evaluation ($n = 721$) was used to categorize and analyze change in outcomes for four groups of patients: patients with one or more hospitalizations in the past 12 months with or without a baseline controller medication use, and no hospitalizations in the past 12 months with or without baseline controller medication use.

Results: Patients with one or more hospitalizations in the past 12 months and no baseline controller use made the biggest gains in several areas, including the largest percent increase in daily controller medication usage and asthma action plans, and the largest decrease in days and nights of symptoms. However, other groups made larger gains in reducing school days missed and emergency department visits and increasing parent confidence, consistent with the notion that community-based interventions can help a diverse set of patients make progress.

Conclusion: Practitioners in low-income communities where there are varying levels of resources and disease severity can tailor interventions to each child's needs and make substantial gains in outcomes across a range of risk profiles.

Introduction

DESPITE THE AVAILABILITY of numerous effective therapies and evidence-based interventions (EBIs), asthma continues to be a significant public health issue for children. Asthma is a leading cause of hospitalization and emergency department visits among children in the United States.¹ In addition, exacerbation of symptoms results in significant limitations on activities and quality of life, missed school days, and work absenteeism for caregivers. Asthma severity may fluctuate over time, is often difficult to classify, and cannot always be monitored by objective measures such as lung function tests.² Theoretical models of asthma care emphasize the diverse set of circumstances that affect a particular child's success in controlling symptoms and improving quality of life.^{3,4} In addition, neither underlying severity nor control are always predictive of asthma fatalities² or other adverse outcomes.⁵ Overall, the literature attests to the difficulty in defining and measuring good predictive variables for asthma control and severity.

Although EBIs have individually been proven effective in clinical trials, moving beyond a controlled setting into the community requires a multi-pronged approach that is contextually appropriate. The lack of simple, predictive measures confounds efforts to categorize children at highest risk easily and identify the most productive strategies to reduce the high burden of asthma morbidity. The literature on asthma interventions suggests that, on average, the sickest children (i.e., the children with the most symptoms at baseline) make the greatest improvements in outcome measures.^{6–8} Based on this observation, one strategy is to focus intervention resources on the “sickest children” and use a measure of symptom severity to define “sickest.” However, patients with fewer symptoms also often make improvements. Community-based organizations choosing to expand beyond support of a single EBI for children with the worst symptoms to supporting multiple interventions to address children with different levels of need often face a dilemma as to how to direct resources. This study attempts to address this question in the real-world context of EBI implementation.

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Methods and Materials

Patients

The data come from the results of intervention studies supported by the Merck Childhood Asthma Network, Inc. (MCAN).⁹ Over a 4-year period, MCAN supported implementation trials in five impoverished communities in Chicago, Los Angeles, New York, Philadelphia, and San Juan, Puerto Rico, to adapt EBIs for pediatric asthma.^{3,10} The implementation sites served heterogeneous patient populations representing a wide range of circumstances and baseline levels of severity, control, medication use, and trigger reduction behaviors.

Study design

Outcomes and patterns of behavior were assessed before and after intervention from a set of community-based interventions. The sample was stratified for risk based on two variables that reflect control, severity, and behavior more broadly than typical symptom-based measures: hospitalizations and daily use of a controller medication.

Interventions

Each MCAN site adapted a variety of EBIs to meet the needs of the community and resources available.^{9,10} The interventions and adaptations varied across sites and were drawn from a variety of resources, including Yes We Can,¹¹ the Inner City Asthma Study (ICAS) environmental intervention,¹² and the National Collaborative Inner-City Asthma Study (NCICAS).⁷ Investigators at the sites assessed the families' needs and provided different levels of tailored support based on these assessed needs. Although methods of collecting data on families' needs differed among sites, the data uniformly assessed the child's home environment and the caregiver's or child's knowledge about asthma management. Each site provided the children and their caregivers with material support (e.g., hypoallergenic mattress covers), asthma education, care coordination, and emotional support.

Variables for baseline categorization

Baseline symptoms are commonly used in national guidelines, such as the National Asthma Education and Prevention Program (NAEPP) guidelines,¹³ to classify the severity status of asthma patients. Rather than categorizing children by baseline symptoms, for this analysis the children were categorized using prior hospitalizations and use of a daily controller medication, which encompass information on baseline healthcare utilization and disease management behavior.

A survey instrument, the Common Data Elements Survey, was created specifically for the MCAN-funded sites to gather data on a common set of outcomes pre- and post-intervention.⁸ The sites also collected a common set of demographic data. RTI International and the sites obtained IRB approval.^a

From the set of variables in the Common Data Elements Survey, hospitalizations in the last 12 months and daily use of

a controller medication at baseline were selected to categorize the children. Hospitalizations reflect both control and severity, while daily use of a controller medication is one important component of guideline-based treatment for children with persistent symptoms.¹³ These variables are correlated with symptom-based measures; additionally they provide information on the family's interaction with the healthcare system and the need for more or less intensive interventions.

Specifically, hospitalizations result from intense exacerbation of symptoms and can reflect severe asthma and poor control. An overnight hospitalization implies a serious exacerbation of asthma symptoms, making it a more objective measure of severity than a visit to an emergency department. Hospitalizations may also reflect the inability of the family to control the child's asthma through medication and remediation of asthma triggers in the environment.

Self-reported information about medications and frequency of use serves as a proxy for the extent to which a family had access to medications and was adhering to a guideline-based treatment regimen for their child's asthma. Children taking medication(s) classified as daily controller medications are normally under some level of supervision by a healthcare provider, and proper use of the medication demonstrates a basic level of adherence in managing the child's asthma. However, not all children need a daily controller. While it is not possible to identify those children who did not need a daily controller, combining the information about hospitalizations and use of a daily controller medication helps identify children who might need a daily controller (children who have been hospitalized in the last year) with children who might not (children who have not been hospitalized in the last year).

The interaction of these two dichotomous variables produces four categories. Table 1 summarizes the four categories and the hypotheses regarding the likelihood that children in each category will show improvement during the intervention. The predictions are based on the assumption that the "sickest" children benefit the most from EBIs (supported by previous studies^{7,14}) and the expectation of improvement if children followed a guideline-based treatment plan.

In general, if the interventions benefit the population, then all the groups should improve after receiving tailored education and materials. Children who had been hospitalized in the last year may be the best candidates for interventions because, theoretically, they are the "sickest" (categories "hospitalized/on-controller" and "hospitalized/no-controller"). The category "hospitalized/no-controller" is anticipated to make the most progress of all categories following intervention, since these children have symptoms severe enough to have required hospitalization and were not taking a daily controller at baseline. The children in the category "not-hospitalized/no-controller" should have more potential for improvement than those in the category "not-hospitalized/controller," given that the children in the category "not-hospitalized/no-controller" may not be following all the effective guideline-based actions they could be taking.

Study endpoints

The Common Data Elements Survey instrument queried caregivers about a variety of topics, including medication use, disease management, and quality of life indicators. The sites administered the survey at baseline, during intervention

^aThe Los Angeles Unified School District did not have to get IRB approval because they were conducting an evaluation of their own program.

TABLE 1. CATEGORIES BASED ON BASELINE VARIABLES AND HYPOTHESES FOR INTERVENTION SUCCESS

	<i>Used a daily controller medication</i>	<i>Did not use daily controller medication</i>
One or more hospitalizations in the past 12 months	Hospitalized/controller: Good potential to make improvements because asthma may be poorly controlled, but improvement might be limited because family reports adherence to an evidence-based regimen for controller medication use so hospitalizations may signal inherently severe disease.	Hospitalized/no-controller: Best potential to make improvements because asthma may be poorly controlled and family reports non-adherence to an evidence-based regimen for controller medication use.
No hospitalizations in the past 12 months	Not-hospitalized/controller: Least potential for improvement because disease not severe enough to cause hospitalization and family reports adherence to an evidence-based regimen for controller medication use.	Not-hospitalized/no-controller: Lower potential for improvement because while there are no hospitalizations, family reports non-adherence to an evidence-based regimen of controller medication

enrollment, and again after 6 and 12 months (this study focuses on the baseline and 12-month follow-up data). The outcome variables for this study are: quick-relief medication use in the last 14 days, receipt of an asthma action plan (AAP), taking steps to reduce asthma triggers in the home, frequency of day and nighttime symptoms in the last 14 days, caregiver confidence in managing the child's asthma, school absences due to asthma in the last 12 months, and emergency department utilization in the last 12 months. To create the medication variables, the self-reported data on the names of the medications and frequency of use were used. For each medication a caregiver reported, the caregiver was asked if the child took the medication "daily" or "as needed." Each medication was categorized as a long-term controller medication, a quick-relief or short-term rescue medication, or as a non-asthma medication. Trigger reduction activities were analyzed as a binary variable, with "1" indicating that the family reported taking steps to reduce asthma triggers in the home, and "0" indicating that they reported taking no action. To measure caregiver confidence, the survey asked for the level of agreement with the statement "I have control over [child's name] asthma." The variable was coded ranging from 1 = "strongly agree" to 4 = "strongly disagree."

Statistical analysis

For each category, the change from baseline to the 12-month follow-up survey for the outcomes within a category and differences across categories was examined. The significance of the change from baseline to 12-month follow-up was assessed using a paired *t*-test and the McNemar test, depending on whether the variable was a count or a percent. The study measured whether the outcome levels from the four categories were statistically equivalent at baseline and at 12-month follow-up using the Kruskal–Wallis or Fisher's exact test for counts and percentages, respectively. The Wilcoxon signed-rank test was used to assess the significance of the change in mean parental confidence, an ordinal ranking variable.

Results

Table 2 provides the demographic characteristics for the four categories, which underscore the heterogeneity of the patients encountered in community-based settings and

the generally low socioeconomic status of the populations recruited by the MCAN intervention study sites. Table 3 provides the mean values at baseline and at the 12-month follow-up for the outcome measures. All the changes between baseline and the 12-month follow-up were significant for each outcome variable for each category of children, except for days of school missed for the category "hospitalized/no-controller" ($p < 0.05$). The study tested whether the distribution of values was different across all categories at baseline and again at the 12-month follow-up. The outcome levels were significantly different from each other across the four groups at both times, despite improvements by all groups over time ($p < 0.05$).

Children who had been hospitalized in the 12 months prior to baseline had more symptom days and nighttime awakenings and more days of school missed at baseline than children who had not been hospitalized did ($p < 0.01$). At 12-month follow-up, children in all categories made significant improvements for all three outcomes, except for days of school missed for the category "hospitalized/no-controller." The means at the 12-month follow-up were still significantly different from each other across the four categories, with the children who had not been hospitalized experiencing fewer symptoms days and nights and fewer missed school days.

Children who had been hospitalized reported using their quick-relief medication more days than the children did in categories who had been not been hospitalized at baseline and 12-months. By the 12-month follow-up, 42% and 22% of groups "hospitalized/no-controller" and "not-hospitalized/no-controller," respectively, were reported to be using a daily controller, while there were declines of 6% and 20% in daily controller use by groups "hospitalized/controller" and "not-hospitalized/controller," respectively.

Table 3 addresses variables related to asthma management and shows the percent of caregivers who reported that they had an AAP and had taken steps to reduce asthma triggers for the child. The families of children on a daily controller were much more likely to have an AAP than families of children not on daily controller. On the other hand, they were less likely than the families of children not on daily controller to report trigger reduction activities at baseline. Parents of children with no hospitalizations in previous 12 months had higher confidence in their ability to

TABLE 2. BASELINE DEMOGRAPHIC CHARACTERISTICS BY CATEGORY (NUMBER OF OBSERVATIONS)

	<i>Category hospitalized/ controller Mean/percent (n)</i>	<i>Category hospitalized/ no-controller Mean/percent (n)</i>	<i>Category not- hospitalized/ controller Mean/percent (n)</i>	<i>Category not-hospitalized/ no-controller Mean/percent (n)</i>
Total number of people in household	4.6 (n = 113)	4.8 (n = 70)	5.0 (n = 267)	5.2 (n = 271)
Number of children in household	2.6 (n = 113)	2.9 (n = 70)	3.0 (n = 267)	3.1 (n = 271)
Number of years lived at current residence ^a	2.9 (n = 108)	2.9 (n = 68)	3.0 (n = 262)	2.8 (n = 268)
Age of patient in years at baseline	7.0 (n = 111)	6.0 (n = 69)	8.6 (n = 267)	8.7 (n = 270)
Race or ethnicity	(n = 104)	(n = 67)	(n = 232)	(n = 251)
African American ^b	57.7%	14.9%	69.8%	45.4%
White	1.0%	1.5%	1.7%	2.0%
Puerto Rican	14.4%	59.7%	2.6%	24.7%
Dominican	10.6%	10.5%	7.3%	4.8%
Mexican	7.7%	13.4%	11.6%	17.1%
Hispanic, other	5.8%	0.0%	4.7%	5.6%
Other, not Hispanic	2.9%	0.0%	2.2%	0.4%
Male	49.6% (n = 113)	68.6% (n = 70)	61.0% (n = 267)	63.5% (n = 271)
Language primary caregiver speaks at home	(n = 113)	(n = 70)	(n = 267)	(n = 271)
English	62.8%	18.6%	65.5%	48.0%
Spanish	28.3%	78.6%	29.6%	50.6%
Other	8.0%	2.9%	4.5%	1.5%
Child has health or medical insurance ^c	97.3% (n = 113)	98.6% (n = 70)	97.4% (n = 265)	94.5% (n = 271)
Household monthly income less than \$1,667	29.6% (n = 71)	9.8% (n = 51)	33.9% (n = 118)	16.1% (n = 112)
Caregiver's highest level of education	(n = 107)	(n = 68)	(n = 250)	(n = 251)
High school graduate	67.3%	48.5%	66.4%	59.4%
Some college experience, but no degree	35.5%	32.4%	40.8%	35.5%
College degree	18.7%	14.7%	20.4%	16.7%
Percent from Chicago, IL	8.0%	10.5%	23.9%	36.0%
Percent from Los Angeles, CA	15.0%	17.9%	29.5%	34.8%
Percent from New York, NY	18.6%	10.5%	8.6%	5.2%
Percent from Philadelphia, PA	48.7%	1.5%	36.2%	0.8%
Percent from San Juan, PR	9.7%	59.7%	1.9%	23.2%

Note: Percents may not sum due to rounding.

^a < 1 year = 1; 1–2 years = 2; 3–5 years = 3; > 5 years = 4.

^b Chicago did not collect data on race. Based on the site's report, Chicago's 180 baseline observations are coded as African American.

^c While the overwhelming majority of caregivers reported that their child had some type of health insurance, separate interviews with the sites and with families found wide variation in the level of access to quality medical care and many children did not have a primary care physician who provided routine asthma care.

control their child's asthma at baseline. Children in all the categories showed significant improvement at the 12-month follow-up ($p < 0.05$). Although outcomes in the four categories are still significantly different from each other, after 12 months, >70% of children in each category reported having an AAP. This change represents significant improvements for children not on daily controller at baseline. Children on daily controller at baseline, who started with a lower percent reporting taking actions to reduce triggers, caught up after 12 months with children who had been on a daily controller at baseline. Parent confidence increased in all categories as well. Days of quick-relief medication use and the number of trips to the emergency room in the last 12 months decreased on average for all four categories at follow-up, which may suggest better overall management.

Figure 1 displays the change in selected outcome variables between baseline and the 12-month follow-up, while Figure 2 displays change in the percent of caregivers reporting that they had an AAP and that they took some action to reduce triggers. The mean values and percent changes showed significant improvements for all the measured outcomes ($p < 0.05$, except for days of school missed for the category "hospitalized/no-controller"). Improvements were spread across the categories.

For example, the category "hospitalized/no-controller" experienced the largest change in day and nighttime symptoms, and the largest increase in the percent of children with an AAP. The category "hospitalized/controller" showed the largest decrease in emergency department visits and the largest increase in the percent of parents who reported taking action to reduce triggers. Children not experiencing a hospitalization in the past 12 months experienced the greatest reduction in school absences, which was striking because these children already missed less school on average. The category "not-hospitalized/no-controller" had the second highest increase in the percent of children with an AAP. Looking at the variables used to define the four categories, use of a daily controller medication and hospitalizations in the prior 12 months, the category "not-hospitalized/no-controller" experienced the largest increase in the percent of children reporting that they were on a daily controller^b and the largest decrease in hospitalizations.

^b Some children who were not taking a long-term controller daily at baseline may not have needed one, and others who stopped using a daily controller at the 12-month assessment may no longer have needed it.

TABLE 3. OUTCOMES: MEANS AND PERCENT FOR OUTCOME VARIABLES AT BASELINE AND 12-MONTH FOLLOW-UP BY CATEGORY

	<i>Hospitalized/ controller</i>		<i>Hospitalized/ no-controller</i>		<i>Not-hospitalized/ controller</i>		<i>Not-hospitalized/ no-controller</i>	
	<i>Baseline</i>	<i>12-month follow-up</i>	<i>Baseline</i>	<i>12-month follow-up</i>	<i>Baseline</i>	<i>12-month follow-up</i>	<i>Baseline</i>	<i>12-month follow-up</i>
<i>Medication use</i>								
Number of days in the last 14 days child used quick-relief medication for asthma, wheezing, tightness in chest, or cough	5.3	3.2	5.5	3.8	3.6	2.1	3.6	1.4
<i>Management</i>								
A doctor or other healthcare provider has given child or child's parent/caregiver/guardian an asthma management plan	46%	93%	6%	76%	39%	87%	10%	71%
Caregiver reported taking any steps to reduce asthma triggers	66%	96%	79%	97%	67%	96%	75%	89%
Caregiver confidence: Caregiver agreement with "I have control over child's asthma" (1 = "strongly agree" to 4 = "strongly disagree")	2.4	1.7	2.4	1.9	2.1	1.6	2.0	1.6
<i>Symptoms and healthcare utilization</i>								
Number of days in the last 14 days child experienced wheezing, tightness in chest, or cough	5.1	2.6	5.6	2.3	3.6	1.9	3.9	1.2
Number of nights in the last 14 nights child woke up because of asthma, wheezing, tightness in chest, or cough	3.8	2.2	4.2	1.9	2.8	1.3	2.4	0.8
Number of days in the past 12 months child missed school due to asthma	9.6	6.0	8.2	5.0	6.7	2.8	6.8	2.1
Number of times in the last 12 months child was treated in emergency room (ER) for asthma	3.4	1.4	2.7	1.2	1.3	0.6	1.6	0.4
Number of times in the past 12 months child had to stay overnight in the hospital for asthma	1.9	1.1	2.0	0.3	0.0	0.1	0.0	0.1

ER, emergency room.

Discussion

Successful community-based interventions for pediatric asthma must accommodate the circumstances of a variety of children and their families, offering a choice of paths to better management and health. The results from the MCAN initiative to implement EBIs in a community setting provide lessons learned and insights for clinics and community-based organizations that are considering approaches to manage better children's asthma. While the context of each site may differ, the experiences at the MCAN implementation sites provide insight into patterns of change that might be seen in children who start with different risk profiles.

The findings suggest that children in low-income communities with varying levels of resources and disease severity at baseline can make substantial gains in asthma management through community-based interventions. Each MCAN site adapted EBIs that were appropriate for the local community. Using individualized treatment plans and care coordination, MCAN attempted to tailor the intervention to each family's needs.⁹ All categories of children enrolled in the MCAN sites showed improvements in the outcome measures. Based on the hypotheses in Table 1, as expected, children hospitalized in the previous year and not taking controller medications made the biggest gains in several areas, including the largest percent increase in usage of daily

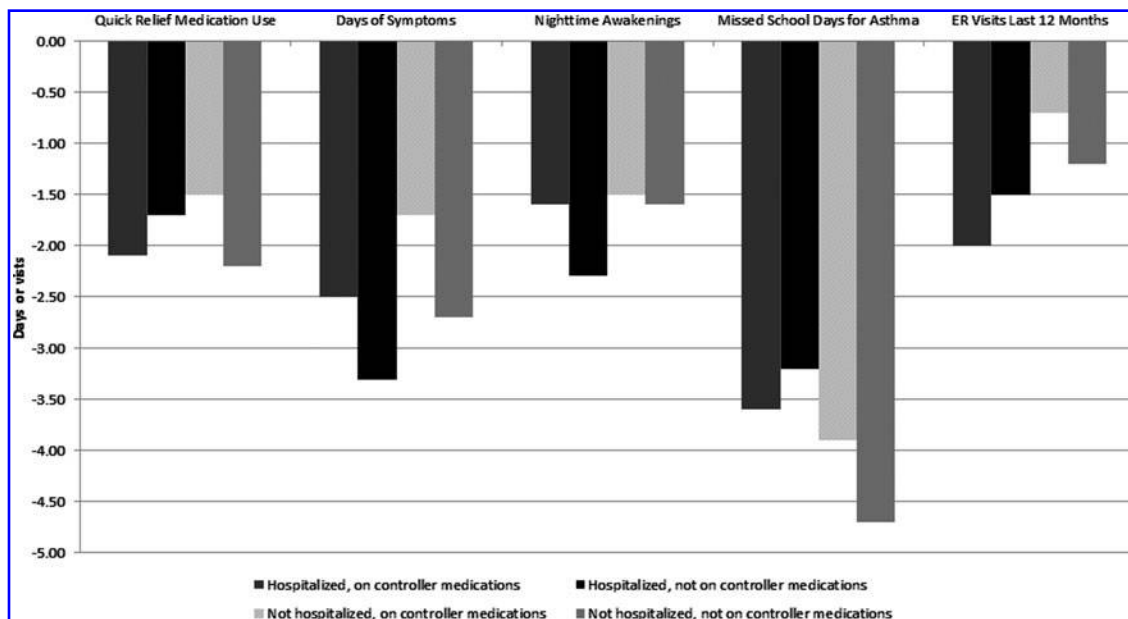


FIG. 1. Change in outcome between baseline and 12-month follow-up by category.

controller medication and AAPs, as well as the largest decrease in symptom days and nights.

However, other groups made larger gains in reducing school days missed and emergency department visits and increasing parent confidence. Reducing missed school days and emergency department visits are important outcomes for children, their families, and the healthcare system. A program focusing only on the “sickest” children, as defined by day and nighttime symptom frequency, would have missed some of these gains. One key limitation to this study is the lack of a control group. It is possible that the symptom improvements reflect regression to the mean or the improvements in management activities such as proper medication use, AAPs, or trigger reduction were caused by another, unmeasured influence.

The study relied on self-reported data. The MCAN interventions were managed by experienced asthma researchers

who are aware of the problems with self-reported data. Efforts were made at each site to collect accurate self-reported data, including careful interviewing and building trust with the children and families. However, self-reported data on medication use can be inaccurate, while reports of symptoms and events such as hospitalizations can be subject to recall bias and other problems. Some studies suggest that patients over-report that they are correctly using prescribed medication.^{15,16} Building trust with the family, using carefully designed questions, and attempting to confirm self-reports during home visits or appointments will improve the accuracy of the data. The possibility of inaccurate reporting also emphasizes the importance of providing ongoing education even to families who report good compliance.

Categorizing children by variables such as prior hospitalizations and medication use, which are related to asthma management behavior and asthma severity, can highlight

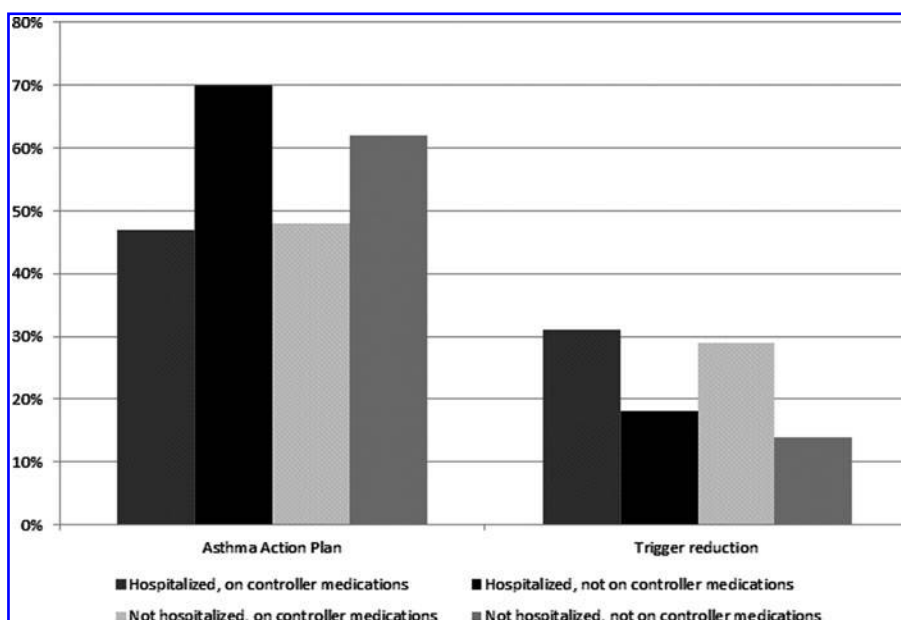


FIG. 2. Percent change in asthma action plan and trigger reduction activities between baseline and 12-month follow-up by category.

social and demographic differences that may contribute to differences in management and control. The demographic differences combined with the differences in use of a daily controller medication, hospitalizations, and baseline asthma severity and control reinforce the notion that a flexible approach involving a suite of interventions may have the best chance for success. Hospitalizations and use of a daily controller medication were selected to classify children for this analysis. However, other variables may be more suitable in other settings taking into account the type of intervention and the available data, including both self-reported data and medical records. In addition, survey instruments have been developed to score asthma control based on a collection of variables that could be used, as well.

Asthma management requires multicomponent interventions to address multifactorial triggers, but these interventions require tailoring for individual patients and their families. Resource-limited practice settings, however, may experience staff time and resource limitations in collecting data to tailor interventions. By selecting a few key variables such as past hospitalization and prior controller use to categorize patients by risk at the start of the intervention, they may still be able to tailor interventions. More highly trained staff such as certified asthma educators could be assigned to patients likely to need more medical advice and counseling.

A key issue in translational research is the degree to which the protocols from EBIs are (or can be) adapted to local circumstances and the impact that this tailoring has on the effectiveness of the EBI. This study is limited by the lack of a control group. However, the results suggest a promising avenue for follow-up studies of community-based interventions attempting to balance fidelity to preset protocols with adaptation based on individual needs.

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Author Disclosure Statement

No competing financial interests exist.

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