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Abbreviations: CAG, community advisory group; CARAT, Child Asthma Risk Assessment Tool; DOHH, Louisiana Department of Health and Hospitals; ED, emergency department; ERAT, Environmental Risk Assessment Tool; HEAL, Head-off Environmental Asthma in Louisiana Study; LOESS, Locally Estimated Scatterplot Smoothing; MSD, maximum symptom days; NCICAS, National Cooperative Inner-City Asthma Study; ICAS, Inner-City Asthma Study; NO, city of New Orleans and surrounding parishes; NOHD, New Orleans Health Department; PFT, pulmonary function testing.

Abstract

BACKGROUND: In the city of New Orleans and surrounding parishes (NO), children with asthma were perilously impacted by Hurricane Katrina from disrupted healthcare, high home mold and allergen levels, and high stress.

OBJECTIVES: The Head-off Environmental Asthma in Louisiana (HEAL) study was conducted to examine relationships between the post-Katrina environment and childhood asthma in NO and assess a novel asthma counselor intervention that provided case management and guidance for reducing home mold and allergen levels.

METHODS: Children (4-12 years old) with moderate-to-severe asthma were recruited from NO schools. Over 1 year, they received 2 clinical evaluations, 3 home environmental evaluations, and the asthma intervention. Quarterly endpoints included symptom days, medication use, and unscheduled ED or clinic visits. A community advisory group was assembled and informed HEAL at all phases.

RESULTS: Children (N=182) were enrolled in HEAL; 67% were African American, and 25% came from households with annual incomes <\$15,000. HEAL children were symptomatic, averaging 6.6 symptom days in the 2 weeks before baseline, and had frequent unscheduled visits to clinics or emergency departments (76% had at least 1 unscheduled visit in the preceding 3 months). In this report, we describe study design and baseline characteristics of HEAL children.

CONCLUSIONS: Despite numerous challenges faced by investigators, study staff, and participants, including destroyed infrastructure, disrupted lives, and lost jobs, HEAL was successful in terms of recruitment and retention, the high quality of data collected that will provide insight into asthma-allergen relationships, and the asthma intervention. This success was due to using an adaptive approach and refining processes as needed.

Introduction

Hurricane Katrina struck the city of New Orleans and surrounding parishes (NO) on August 29, 2005, and was one of the most destructive and costly disasters in US history. Storm surges breached substandard flood walls along outfall canals, and as a result, 80% of Orleans Parish and large tracts of land in neighboring parishes flooded (Kates et al. 2006). Water rose to 20 feet in some locations and remained for weeks, damaging approximately 70% of housing, displacing approximately 1 million residents, and destroying much of the city's infrastructure (Liu et al. 2006). The environmental consequences of the flooding and rain included a copious growth of mold and other microbes and increased levels of asthma triggers. The Centers for Disease Control and Louisiana Department of Health and Hospitals (DOHH) found that 46% of 112 homes examined in the aftermath of Katrina had visible mold, with 17% having heavy mold contamination (Rao et al. 2007; Ratard et al. 2006). The levels of mold by-products (β -D-glucans) found in these homes have been associated with cough, nose/throat irritation, decreased lung function, tiredness, and headache (Rylander and Lin 2000; Rylander et al. 1998). Other homes in the CDC and Louisiana DOHH study had levels of bacterial by-products (endotoxin) that have been associated with decreased pulmonary function (Douwes et al. 2002; Reynolds et al. 2001).

In addition to environmental devastation, Katrina destroyed an already strained healthcare system and its provider base. About 4,500 physicians left the region, leaving 50% of children who previously had a healthcare provider without one. Most of Orleans Parish's hospitals and clinics were closed, including Charity Hospital, where 90% of the poor and uninsured received

medical care (Rudowitz et al. 2006). Numerous pharmacies were destroyed, and residents also had difficulty filling prescriptions because of lost or missing medical records, insurance cards, and Medicaid cards (Kaiser Institute 2007).

In 2006, the Merck Childhood Asthma Network and National Institute of Environmental Health Sciences (NIEHS) formed a public-private partnership that later joined with the National Institute of Minority Health and Health Disparities and local institutions (New Orleans Health Department or NOHD, and Tulane and Louisiana State Universities) to conduct the Head-off Environmental Asthma in Louisiana Study (HEAL). They viewed post-Katrina NO as an unprecedented opportunity to study relationships between environmental triggers and childhood asthma morbidity while simultaneously addressing the high rate of childhood asthma morbidity in this region. Asthma, like most chronic diseases, is influenced by the quality and continuity of healthcare. Ongoing monitoring of symptoms and medication use are crucial in its management. The disruption to healthcare by Katrina put children with asthma at risk, which was exacerbated by prolonged exposures to environmental hazards that affect symptoms (Rao et al. 2007; Ratard et al. 2006; Solomon et al. 2006).

HEAL was an observational study designed to examine relationships between childhood asthma morbidity and the physical (allergens, mold, other exposures) and psychosocial (stress, social support, healthcare barriers) impacts of post-Katrina environments. Another goal was to implement and assess a novel asthma counselor intervention (“asthma intervention”) that provided asthma case management and guidance for environmental remediation. The intervention drew upon the National Cooperative Inner-City Asthma Study (NCICAS) (Evans et al. 1999) and the Inner-City Asthma Study (ICAS) (Crain et al. 2002; Morgan et al. 2004) but

contained some unique aspects. NCICAS was initiated in 1994, conducted in 8 major US inner cities, and encompassed 1033 children with asthma. The children were randomized into 2 groups: a control group that received “usual asthma care,” and an intervention group that received asthma case management for one year in addition to “usual asthma care.” In the intervention group, the children’s caretakers also received education on asthma triggers, environmental controls, asthma physiology, and techniques for better communicating with their children’s physicians. ICAS was initiated in 1998, conducted in 7 major inner cities, and encompassed 937 children with asthma. Similar to NCICAS, the children were randomized into two groups. Both groups received “usual asthma care,” but the children in the intervention group also received home remediation focused on reducing/eliminating exposure to cockroach, dust mite, rodent, pet, and mold allergens in addition to environmental tobacco smoke. In conducting HEAL, we combined aspects from both NCICAS and ICAS into a hybrid intervention with modifications to meet the post-disaster needs of NO families. We believed this approach would result in a field-applicable model for other disaster situations. In this report, we describe the methods, implementation, and study population of HEAL.

Methods

Study design. HEAL was a pre-post interventional study that aimed to: 1) characterize relationships between environmental exposures and childhood asthma morbidity in post-Katrina NO; 2) assess the success of a novel asthma intervention; and 3) collect biological and environmental specimens to support future studies. Children with moderate-to-severe asthma were recruited from NO schools, pre-screened by telephone, and clinically evaluated to confirm

eligibility and collect baseline data. Over 1 year, they received 3 home environment evaluations, asthma counseling, and another clinical evaluation. Asthma morbidity endpoints were collected quarterly (Figure 1). HEAL was approved by the NIEHS, Tulane University, and Louisiana State University Institutional Review Boards.

Population. Children were 4-12 years old, lived in NO, and had moderate-to-severe asthma as defined by the 2007 National Asthma Education and Prevention Program (National Heart Lung and Blood Institute 2007). Caretakers were the children's legal guardians. Children were required to sleep in the intervention home ≥ 5 nights/week. Children were excluded if they had a hypoxic seizure or a life-threatening asthma exacerbation in the past 5 years requiring intubation or mechanical ventilation, they had a serious medical condition other than asthma, or their caretaker planned to move from NO during the year.

Recruitment. During the first 6 months of recruitment (March-August 2007), children in grades pre-K to 6 in public and parochial schools in Orleans Parish were targeted. They were given a 1-page letter to bring home to their caretakers. The letter was on school letterhead signed by the principals and asked caretakers about their children's symptoms and if they were interested in participating in a study about asthma. Children were instructed to return the letters to their teachers, indicating whether caretakers were interested. Some schools conducted recruitment internally utilizing their own staff (trained by HEAL staff). Other schools were inadequately staffed and let HEAL staff distribute the letters. Similar letters were also given to children attending school-sponsored summer camps in 2007. During the second 6 months of HEAL (September 2007-March 2008), recruitment was expanded to schools in 4 other parishes (Jefferson, St. Tammany, St. Bernard, and Plaquemines Parishes). In addition, the procedure for

distributing letters was modified. Instead of distributing letters to all children in the classroom to take home to caretakers, recruitment letters were now written by school nurses and distributed only to children in the classroom with documented asthma to take home to caretakers. Nonresponders received follow-up letters and telephone calls, also from school nurses.

Information about HEAL was also disseminated through local radio and television stations, newspapers, and magazines. Pamphlets and posters were placed in schools, churches, community centers, pharmacies, clinics, emergency departments (EDs), and physician's offices. Community Advisory Group members (described below) attended local events to discuss HEAL and pass out pamphlets.

Pre-screening. Caretakers interested in HEAL were pre-screened with a 15-minute phone survey by trained nurses from Tulane's Clinical and Translational Research Center. They were asked about their children's asthma symptoms, medication usage, ED visits, hospitalizations, and current living conditions. Eligible caretakers and children were invited to the baseline clinical evaluation.

Baseline. At the baseline clinical evaluation, trained research assistants described HEAL to participants and answered their questions. Children were examined by physicians board-certified in Pediatrics and in Allergy and Immunology for atopy and to confirm moderate-to-severe asthma. If final eligibility was met, caretakers were asked for written informed consent. Children were asked for oral (if less than 7 years of age) or written (if 7 years of age or older) assent. Other baseline procedures included taking medical histories (emphasizing respiratory symptoms and medications), pulmonary function testing (PFT) (spirometry on 6-12 year old

children and peak flow on all children), and blood collection (16 mL) by venipuncture. Blood was used for complete blood cell counts and differentials, serum levels of total and allergen- and mold-specific IgE, and archiving for future studies.

Allergen skin testing was performed using a multi-test device (Lincoln Diagnostics, Inc, Multi-Test II) applied to the volar surface of the arms. The panel included dust mites (Der p and Der f mix), cockroach (American and German mix), cat, dog, mouse, rat, Bermuda grass, and molds (*Alternaria*, *Cladosporium*, *Aspergillus fumigatus*, *Penicillium*, and 10 other molds found in high concentrations in NO).

Caretakers completed questionnaires for literacy, quality-of-life, children's behavior, asthma attitudes and knowledge, healthcare access and barriers, life events, and stress. All questionnaires in HEAL were administered to caretakers by trained research assistants, with the exception of one form that was validated as a self-administered questionnaire. Caretakers were also interviewed about their smoking habits and their children's symptoms, unscheduled ED or clinic visits, hospitalizations, medications, adherence, and home environments. Children completed verbal or written questionnaires, depending on age, about asthma attitudes and quality-of-life.

The baseline clinical evaluation took approximately 3 hours to complete. Afterward, the children's primary care physicians (PCPs) were sent letters summarizing the results.

Final clinical evaluation. Another clinical evaluation was conducted approximately 12 months after the baseline examination that consisted of a physical exam, PFT, and blood collection (10 mL) for determining serum levels of total and mold-specific IgE.

The questionnaires used at baseline were re-administered to caretakers by the trained research assistants during the 12 month follow-up. In addition, caretakers were administered a new Post-Katrina Needs Assessment Questionnaire that contained questions from the Kaiser Report (Kaiser Institute 2007) and the Breslau Post-Traumatic Stress Disorder Scale (Breslau et al. 1999) and new questions developed by HEAL investigators based on their post-Katrina experiences. These questionnaires focused on stress and the emotional, psychological, and physical impacts of Katrina, on-going problems, support systems, and needs.

Home environmental evaluations. Homes of HEAL children were evaluated at baseline and at 6 and 12 months by trained technician pairs. If a child moved within 6 months after their baseline evaluation, the baseline evaluation was repeated in their new home. Evaluations focused on environmental hazards and allergens, and they consisted of visual inspections, dust and air sampling, and face-to-face surveys of caretakers. The survey was a modified version of the ICAS survey that was supplemented with questions from the U.S. Department of Housing and Urban Development/NIEHS National Survey of Lead Hazards and Allergens in Housing.

During the indoor inspection, technicians recorded evidence of moisture, water damage, environmental tobacco smoke, pests (cockroaches, rodents), mold, and other hazards. Air samples were collected from the living room, children's sleeping area/bedroom, and outside the home using Air-O-Cell spore traps (Zefon International, Ocala, FL). These samples were analyzed for mold (total fungal spores and over 30 taxa categorizations). Dust samples were collected from the family/living/television room, kitchen, and children's bedroom floor and bed (Gruchalla et al. 2005). Bed dust was analyzed for Der p 1 (dust mite), Bla g 1 (cockroach), Mus

m 1 (mouse), and *Alternaria* allergens. If bed dust samples were insufficient for testing, they were supplemented or replaced with bedroom floor dust. Remaining bed and floor dust was analyzed for endotoxin and 1→3 and 1→6-β-D-glucans (Peter Thorne, University of Iowa) (Blanc et al. 2005). Dust from the family/living/television room was combined with bedroom dust and analyzed by PCR for mold species (Vesper et al. 2007; Vesper et al. 2004).

During one of the home environment evaluations, technicians administered a one-time questionnaire (Home Remediation and Remodeling Questionnaire) to caretakers, which asked about post-Katrina renovations and mold remediation. Additional details about these evaluations are provided in the accompanying article (Grimsley et al. 2012).

Asthma intervention. The goals of the asthma intervention were to empower caretakers to better manage their children's symptoms, improve interactions with primary care providers, reduce home allergen levels, and manage psychosocial issues and stress resulting from Katrina. The intervention combined case management elements from NCICAS (Evans et al. 1999) and environmental remediation measures from ICAS (Crain et al. 2002; Morgan et al. 2004) into a hybrid model that also incorporated modifications to address post-disaster problems. These included helping caretakers identify healthcare centers, identify pharmacies and providers, navigate public services established for post-Katrina victims, and replace lost documents such as insurance and prescription cards. Evidence-based practices incorporated into HEAL included the Child Asthma Risk Assessment Tool (CARAT) (Evans et al. 1999) and Environmental Risk Assessment Tool (ERAT) (Crain et al. 2002). These are computer-generated reports that estimate children's risk levels based on the results of their clinical exams, allergen sensitivities, and environmental exposures.

Most asthma counselors had Master degrees in health-related fields, backgrounds in counseling and public health, and experience working in community programs. They worked in teams with community health workers, who were high school graduates who worked for community-based organizations and were familiar with NO communities. The teams underwent rigorous training and had lighter caseloads compared with NCICAS counterparts. Additional details about the asthma counselor model are provided in the accompanying article (Mitchell et al. 2012).

Compensation and retention. Participating caretakers received gift cards for completing the baseline clinical evaluation (\$50), 12-month clinical evaluation (\$40), home evaluations (\$15 for each), and quarterly phone assessments (\$15 for each). Caretakers received an additional \$40 at the completion of the study.

Measures were taken to facilitate participation and minimize attrition. Caretakers were asked to update their contact information and that for family members and friends who served as back-ups at every point of HEAL contact (by asthma counselors, by home evaluators, by administrators of the quarterly surveys, and every time a HEAL caretaker contacted HEAL staff). Evening and weekend appointments were offered to accommodate caretakers' schedules. Transportation to and from appointments was pre-arranged and subsidized.

Community engagement. A community advisory group (CAG) was assembled to engage local constituents and consisted of 15 members, including parents, individuals representing schools, faith-based and community groups, local businesses, medical clinics, and media. CAG members facilitated communication between communities and investigators, incorporated cultural and

community views into HEAL, helped develop recruitment strategies and resolve problems, and represented HEAL at community events. The CAG met periodically with investigators, received reports on study progress, and disseminated results to local communities.

Health outcomes. Health outcomes data were collected from caretakers at baseline and 3, 6, 9, and 12 months post-baseline using a brief (<5 minute) phone survey. The primary outcome was maximum symptom days (MSD) for asthma. This is determined as the number of days of the asthma symptom with the highest number of occurrences in the past 2 weeks. The different asthma symptoms were defined as: 1) the number of days with wheezing, chest tightness, and cough; 2) the number of nights with disturbed sleep resulting from asthma; or 3) the number of days of disrupted activities because of asthma. Secondary outcomes included the number of unscheduled visits (ED and clinic) due to asthma in the previous 3 months, the number of hospitalizations due to asthma in the previous 3 months, and the number of Prednisone bursts in the previous month. The same outcomes also were assessed during clinical evaluations.

Statistical methods. The characteristics of children from Orleans and Jefferson Parishes were compared using t tests (continuous outcomes) and Fisher's exact (categorical outcomes). Parish-specific seasonal trends for symptoms and mold levels were analyzed using Locally Estimated Scatterplot Smoothing (LOESS) curves with 95% confidence intervals. Analyses were conducted using SAS version 9.2 (Cary, NC) and R version 2.11.1.

Results

Study design and recruitment. HEAL was initially designed as a randomized, controlled trial requiring 450 children to detect a significant reduction in asthma symptoms. Specifically, children with moderate-to-severe asthma were to be recruited from Orleans Parish over a 6-month period (March through August 2007) and randomized to a control group (n=225) that would receive an excellent standard of care or to an intervention group (n=225) that would receive the same standard of care plus the asthma counselor intervention. However, because only 77 children had been enrolled after 6 months, starting in September 2007 we expanded recruitment into 4 other Parishes (Jefferson, St. Bernard, St. Tammany, and Plaquemines Parishes) and extended recruitment for an additional 6 months (September 2007 through February 2008). In addition, instead of distributing recruitment letters to all children in the classroom to bring home to caretakers, recruitment letters were now written by school nurses and distributed only to children with documented asthma to take home to caretakers.

Over the entire 1-year recruitment period, 182 children were recruited into HEAL. A total of 105 children were recruited into HEAL during the second 6 months after the recruitment modifications were implemented. Of these 105 children, 49 came from Orleans Parish, 49 came from Jefferson Parish, 5 came from St. Bernard Parish, and 2 came from St. Tammany Parish. Children enrolled from all parishes were included in the study and overall analyses. In the comparison between parishes (Table 1), we included the 7 children from St. Bernard and St. Tammany Parishes in with the children from Jefferson Parish.

Despite the study modifications implemented above, we still realized after the first 6 months that we would not be able to recruit enough children to support the original randomized, controlled trial study design. Therefore, HEAL was transitioned to the observational study described in the Methods. This new design reduced the number of observations required to analyze study questions with adequate power (< 160 children for most comparisons). At the same time, the original study goals were maintained, the data already collected were utilized, and the impact on enrolled participants was minimized.

Over the 1-year recruitment period, 184 schools participated, including 89 schools in Orleans Parish and 95 in Jefferson and other parishes. Over 36,000 school letters were distributed, and 6,911 were returned. From this response and responses from other recruitment methods (e.g., disseminating study material through local news media outlets, distributing pamphlets and posters, and community engagement), a total of 2,821 children were found eligible for a phone screen. Of these, 1,864 were successfully pre-screened, and 320 children that met pre-screening criteria were invited to the baseline clinical evaluation. Baseline clinical evaluations were completed by 201 children; 193 of these met final eligibility requirements and 182 were enrolled. Most of the enrolled children (89%) were recruited through schools, but some (11%) came from the other recruitment methods described above. The locations of the participating children's homes, along with the areas impacted by post-Katrina flooding, are shown in Figure 2.

Demographics. Children in HEAL were predominantly African American (67%), and about 25% came from households with annual incomes <\$15,000 (Table 1). Demographic characteristics differed by parish. Orleans Parish children were predominantly African American (81%); Jefferson Parish children were predominantly Caucasian (55%). More Orleans Parish children

came from households with annual incomes <\$15,000 (31%) compared with Jefferson Parish (12%). However, in each parish, African Americans were more likely to come from households with annual incomes <\$15,000 compared with Caucasians and other races (including those of Hispanic descent) ($p<0.001$), and within-race income levels were similar for the 2 parishes ($p=0.95$) (data not shown).

Housing. Families moved an average of 3 times since Katrina (Table 1). Most (64%) were living in single-family dwellings; 5% were living in Federal Emergency Management Agency trailers. Most homes (62%) were damaged, with 23% from flooding, 25% from roof leaks, and 14% from both flooding and roof leaks. Mean indoor airborne mold levels (502 spores/m³) were lower than outdoor levels (3958 spores/m³). Mean indoor airborne mold levels were significantly higher in Orleans Parish compared with Jefferson Parish (567 versus 379 spores/m³) ($p=0.05$).

Healthcare access. Most children (85%) had a usual place of asthma care, but parish differences were observed. Only 80% of Orleans Parish children had a usual place of care, compared with 96% Jefferson Parish children ($p<0.01$). Orleans Parish children also used EDs 4 times more often than Jefferson Parish children (15% versus 3%, $p=0.05$) (Table 2).

Baseline asthma morbidity and allergic sensitization. HEAL children were symptomatic, averaging 6.64 MSD; wheeze was the most common symptom, averaging 5.34 days in the previous two weeks (Table 2). Average FEV1 levels were generally normal (91.05 \pm 16.74% predicted), but the average FEV1/FVC ratio (78.22 \pm 10.13) in HEAL children provides evidence for physiologic airway obstruction. Of the 182 children, 19% had an FEV1/FVC ratio below 70%, indicating compromised pulmonary function. For allergic sensitization, 89% of

children skin-tested positive to at least 1 of 22 allergens; 72% tested positive to at least 1 of 14 molds.

Baseline morbidity differed between parishes. Overall, Jefferson Parish children had more MSD (7.70 ± 5.06 versus 6.17 ± 4.71 ; $p=0.05$), days of wheeze (6.52 ± 4.92 versus 4.81 ± 4.27 ; $p=0.02$), and unscheduled ED or clinic visits ($p=0.06$) than Orleans Parish children. However, when we compared these same baseline morbidity variables between Orleans and Jefferson Parishes during the second 6 months of recruitment only (August 2007 to March 2008), when recruitment was occurring concurrently in both parishes, the significant parish differences in MSD, wheeze, and unscheduled ED or clinic visits were eliminated.

Study progress and attrition. Study activities concluded in September 2009. Of the 182 children enrolled, 161 (88%) completed the study; of those who did not, 5 withdrew, 3 moved out of NO, and 13 were lost to follow-up.

Discussion

Katrina caused catastrophic environmental devastation and disrupted the lives of people in NO. Flooding and rain destroyed much of the area's infrastructure, and residents suffered great losses, including homes, jobs, schools, support systems, and sometimes their lives. Concerns included the lack of healthcare and rising mold and allergen levels and their potential effects on children with asthma. HEAL was designed to characterize post-Katrina exposures of children with asthma and address their healthcare management. However, numerous challenges from the devastation

were faced when implementing HEAL. Approximately 1 million residents had evacuated the area, and only about 50% had returned by mid-2007 (Elliot 2009). Vague population estimates made it difficult to develop a study framework and estimate recruitment and statistical power for various study designs. Furthermore, we encountered problems in recruiting children, which resulted in low numbers. This difficulty might have been due to a low number of children with asthma in general (many children with asthma might not have returned to NO after Katrina) or to other reasons. Given the vague population estimates, the reason for low recruitment is unclear. Despite these challenges, however, HEAL was a success in terms of the high quality of data collected, which will provide insight into post-disaster asthma-allergen relationships. This includes data characterizing post-disaster exposures and asthma morbidity, but more importantly, data on effective interventions aimed at reducing post-disaster asthma symptoms. HEAL's success was due to taking an adaptive approach and refining processes as needed, as described below.

An important modification that epitomizes the adaptive approach used in HEAL, and ultimately led to its success, was transitioning HEAL from a clinical trial to a 1-year observational study with post-intervention follow-up. HEAL was initially designed as a randomized, controlled trial, but after 6 months, it became obvious that the recruitment numbers would not support this design. This problem was presented to the Data and Safety Monitoring Board, who worked with the investigators to modify the design to maintain the original study goals. In addition, data collection (morbidity, skin sensitivity, exposures) remained the same, and the quarterly endpoints could still be used to examine relationships between morbidity and exposures and to assess the effectiveness of the asthma intervention.

Another important modification that led to HEAL's success was refined recruitment strategies. These refinements, especially the nurse-based recruitment, were effective and led to increased enrollment during the second 6 months. Nurse-based recruitment allowed us to target children with documented asthma, enabling more focused messaging that resonated more effectively with caretakers. It also supported more efficient eligibility screening as interviewers worked with an asthma-enriched population rather than children with broad respiratory conditions. Other recruitment strategies (media, pamphlets, community engagement) raised public awareness of HEAL but resulted in only a small increase in enrollment (approximately 11%). Thus, active recruiting methods proved more successful in this environment, but passive recruiting helped to increase numbers somewhat. Ultimately, 182 children were enrolled in HEAL. Despite all the post-Katrina challenges faced by NO residents and HEAL scientists, this is one of the largest childhood asthma populations ever recruited from a single geographic location compared with other NIH-funded childhood asthma studies.

Unfortunately, the enrollment expansion introduced parish-related demographic differences. Children from Jefferson Parish were predominantly Caucasian and from higher income households compared with Orleans Parish children. Surprisingly, Jefferson Parish children were more symptomatic (higher MSD and days of wheeze). This is contrary to historical data showing that minority and low income children with asthma are more symptomatic (Boudreaux et al. 2003; Erickson et al. 2007). However, the expansion into Jefferson and other parishes was initiated during the cold and flu season when asthma symptoms are typically elevated (Gergen et al. 2002). We also switched to nurse-based recruitment about the same time. These two modifications might have resulted in recruiting a more symptomatic population during the second 6 months. Furthermore, the statistically significant parish differences in MSD and days

of wheeze were eliminated when only children recruited concurrently from both Orleans and Jefferson Parish (during August 2007-March 2008) were compared ($p=0.53$ for MSD and $p=0.24$ for wheeze) (data not shown). This result suggests that the differences may have been partly due to seasonal variation in asthma symptoms rather than actual differences between the two parishes.

One challenge of HEAL was the many activities required of participants in a post-disaster situation. Participants were required to take part in multiple, time-consuming activities over a short period of time during an otherwise stressful time in their lives. City infrastructure was still in disarray. Key public services (schools, transportation, utilities) were operating at less than half capacity; housing was scarce and expensive; unemployment was high; and federal money had not been distributed to areas most impacted by Katrina (Liu et al. 2006). At the time of HEAL, 32% of NO residents said their lives remained “very disrupted” or “somewhat disrupted;” this value rose to 59% among African Americans (Kaiser Institute 2007). In addition, hiring and maintaining study staff was problematic as potential hires experienced similar problems. We overcame these problems due to a highly dedicated staff and the strong desire of caretakers to alleviate their children’s symptoms, which can be attested to by the high percentage of participants who completed the study.

HEAL children were more symptomatic at baseline (6.64 MSD) compared with children from NCICAS (MSD=5.18) and ICAS (MSD=5.99). HEAL children also had more unscheduled ED or clinic visits in the 3 months prior (76%) compared with NCICAS (30%) and ICAS (51%) children, which was surprising as HEAL children were better off economically. Only 25% of HEAL children came from households with annual incomes $< \$15,000$, while 67% and 60% of

NCICAS and ICAS children, respectively, came from households with annual incomes <\$15,000. The lower economic situations of NCICAS and ICAS children were a result of recruitment strategy; NCICAS and ICAS targeted children living in census tracts where >20% of households had an annual income below the federal poverty line. In HEAL, children were targeted based on residing in an area impacted by Katrina; having a specific annual income was not an eligibility requirement. While the economic differences between the study populations resulted from differing recruitment strategies, the morbidity differences were real and require further examination. The higher morbidity in HEAL, despite the children's better economic circumstances, might be due to living in a post-disaster region with increased environmental exposures, high stress, and adverse psychosocial factors. It is well recognized that such factors have a strong impact on childhood health (Turyk et al. 2008; Wright 2005).

Characterizing post-Katrina exposures and exploring their relationships to asthma was an important focus of HEAL that will be described in future publications. Testing for mold-asthma relationships is problematic due to limitations of mold methodologies and the lack of biomarkers (Brandt et al. 2006). Typically, mold is cultured from air (CFUs/m³), but this procedure does not detect nonviable and unculturable species, resulting in exposure underestimations because nonviable mold also carries mycotoxins that can trigger allergic reactions. Dust has been proposed as a better medium for mold analyses and might represent longer timeframes of potential exposures; when analyzed by PCR, nonviable and unculturable species in dust can be detected. In HEAL, we used a comprehensive, multi-pronged approach to characterize mold and other exposures. Different samples (air, dust, HEPA filter extracts) were collected and examined for many molds, allergens, glucans, and endotoxin. When analyzed in conjunction with specific biomarkers (skin sensitivities, serum IgEs), these data will provide us with important insights

into asthma-allergen-mold relationships. HEAL baseline findings of indoor mold and allergens are described in the accompanying article (Grimsley et al. 2012).

In addition to studying environmental relationships with asthma in a post-disaster setting, another goal of HEAL was to intervene in childhood asthma morbidity using a novel hybrid asthma counselor model that combined traditional case management with education and aid in reducing home exposures. We felt that incorporating allergen reduction measures in the model might increase its effectiveness considering the levels of mold, allergens, and other toxic exposures that were reported following Katrina. We found that HEAL children were highly sensitive to molds compared with children in earlier studies. In ICAS, 100% of children were skin-test positive (children were required to test positive to at least 1 of 9 allergens to be enrolled; 4 of the 9 were molds). In HEAL, 89% of children were skin-test positive (children were not required to be skin-test-positive). Only 50% of ICAS children tested positive for 1 of the 4 mold species (O'Connor et al. 2004), while 67% of the skin-test-positive children in HEAL tested positive for at least 1 of the same 4 species.

Conclusion

HEAL will provide valuable insight into post-disaster asthma-allergen relationships. HEAL was successful despite the extreme challenges faced by investigators in conducting HEAL and by participants in dealing with competing demands. These challenges were overcome by taking an adaptive approach that included refining recruitment processes, being flexible in scheduling, cross-communicating between study teams for the diligent follow-up of participants, and

identifying and subsequently augmenting resources in problem areas. HEAL also underscores the importance of involving community members in the research process. Community advisory group members represented diverse segments of the community, including schools, religious groups, healthcare providers, and parents. They helped to anticipate problems in implementing HEAL and provided insight into research design, recruitment and implementation, psychosocial and socioeconomic issues, and cultural norms.

The success of HEAL is measured in its sustainability. Pilot programs/studies are rarely sustained for multiple reasons, such as problems with buy-in and maintaining funding and the interest of supporters. However, due to its success and support from Merck Childhood Asthma Network, the HEAL hybrid asthma counselor model has been adopted by multiple public health programs, including those administered by Xavier University's Center for Minority Health and Health Disparities Research and Education Program in NO, George Washington's School of Public Health and Health Services, and Rho, Inc., at federally qualified health centers in the US.

Appendix

HEAL was a collaboration of the following institutions, investigators, and staff: Tulane University School of Public Health and Tropical Medicine, Maureen Lichtveld (principal investigator), Faye Grimsley (investigator), LuAnn White (investigator), William Hawkins (program management), Melissa Owsiany (senior program coordinator), Shannon DeGruy, Dorothy Paul, Latasha Barlow, Nicole Bell, Erica Harris (home evaluators); Tulane University Health Sciences Center, Jane El-Dahr (investigator); Tulane University School of Medicine, Maxcie Sikora (physician); Tulane Clinical and Translational Research Center of Tulane and Louisiana State Universities Schools of Medicine, Mary Meyaski-Schluter, Virginia Garrison, Erin Plaia, Annie Stell, Jim Outland, Shanker Japa, Charlotte Marshall (nursing staff); New Orleans Health Department, Kevin Stephens (principal investigator), Mosanda Mvula (investigator), Stacey Denham, Margaret Sanders, Claire Hayes (asthma counselors), Alfreda Porter, Tenaj Hampton, Angela Sarker (community health workers), Mamadou Misbaou Diallo, Shawanda Rogers, David Ali (recruiters), Doryne Sunda-Meya, Ariska Fortenberry (administrative), Florietta M. Stevenson (personnel); Louisiana State University Health Sciences Center School of Nursing, Yvonne Sterling (investigator); Louisiana State University Health Sciences Center, Ken Paris (physician); National Institute of Environmental Health Sciences, Patricia Chulada (health scientist administrator); and National Institute of Child Health and Human Development, William Martin II (principal investigator). Eleanor Thornton (investigator) is employed by Visionary Consulting Partners, LLC, Fairfax, VA. Rich Cohn (investigator) is employed by SRA International, Inc., Durham, NC. Herman Mitchell (principal investigator), Suzanne Kennedy (investigator), John Lim (data manager), Gina Allen (research associate), Jeremy Wildfire, Katy Jaffee, Agustin Calatroni, Becca Zabel, John Schwarz (statisticians), and Theresa Zuccherro Scocca (scientist) are employed by Rho, Inc., Chapel Hill, NC.

Supplies were generously donated or discounted by: Lincoln Diagnostics, Inc., Decatur, IL, donated the Multi-Test II devices; Greer Laboratories, Inc., Lenoir, NC, donated the allergenic extracts used for skin testing; Ives Business Forms, Inc., New Orleans, LA, provided a discount for environmental supplies; Kaz USA, Inc., Southborough, MA, provided a discount on Honeywell 40200 Platinum HEPA Air Purifier units; Allergy Control Products, Inc., Danbury, CT, provided mattress, box spring, and pillow encasings at cost. Additional funding for environmental and administrative supplies and equipment and for patient transportation vouchers was provided by MCAN.

A variety of committees and working groups were formed for study development and implementation. The Community Advisory Group was critical for recruitment and community outreach. Members included: Dr. Corey Hebert, Pediatrician, Children's Medical Clinic (chair); Julia Bland, Executive Director, New Orleans Children's Museum; Mary Croom-Fontenot, All Congregations Together (ACT); Janice Dupuy, Principal, Audubon Montessori Charter School; Stephanie Duplantier, Parent; Andrea Duplechain, Director of Nurses, Algiers Charter Schools Association; Marilyn Hammett, Nurse Supervisor, Recovery School District; Dr. Kathleen Kennedy, Dean, Xavier School of Pharmacy; Dr. Julie Morial, Family Physician; Christy Ross, Assistant Director of Tobacco Free Living; Joe Rossolino, Associate Superintendent, Archdiocese School System; Dr. Diane Russel, Superintendent, Jefferson Parish School Board; Dr. Beverly Wright, Executive Director, Deep South Center for Environmental Justice; and Alida Wyler, Health Services Director, Jefferson Parish School Board.

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Table 1. Baseline demographics and housing characteristics of HEAL children by parish

	All N=182	Orleans Parish N=126 (69%)	Jefferson Parish ^a N=56 (31%)	<i>p</i> -value
Demographics				
Male	54%	56%	48%	0.34
Race/ethnicity				<0.01
African-American	67%	81%	36%	
Hispanic	7%	6%	9%	
Caucasian/Other	26%	13%	55%	
At least one household member employed	91%	90%	95%	0.40
Household income <\$15,000	25%	31%	12%	<0.01
At least one smoker in household	32%	34%	27%	0.39
Total number of people in household				0.73
2-3	29%	31%	25%	
4-5	57%	56%	59%	
≥6	14%	13%	16%	
Caretaker married	54%	45%	75%	<0.01
Caretaker completed high school	88%	88%	89%	0.99
Housing				
Number of times moved since Katrina ^b	3.09±2.03	3.26±2.09	2.71±1.85	0.09
Current housing type				
Single-family detached house	64%	56%	82%	
Multi-family house (duplex/triplex/row house)	23%	30%	7%	
Apartment	8%	8%	9%	
Federal Emergency Management Agency trailer	5%	6%	2%	
Current housing damage				0.09
Flooding only	23%	29%	13%	
Roof leak only	25%	23%	29%	
Flooding and roof leak	14%	14%	12%	
None	38%	34%	46%	
Mold air sampling ^c				
Indoor total	502	567	379	0.05
Outdoor total	3958	4054	3751	0.74

^aIncludes children recruited from Jefferson (49), St. Bernard (5), St. Tammany (2), and Plaquemines (0) parishes.

^bMean +/- standard deviation

^cSpores/m³ reported as geometric means.

Table 2. Baseline access to care and morbidity of HEAL children by parish

	All N=182	Orleans Parish N=126 (69%)	Jefferson Parish ^a N=56 (31%)	<i>p</i> -value
Access to Care				
Usual place for follow-up asthma care for child	85%	80%	96%	<0.01
Pre-Katrina: location of asthma care				<0.01
Emergency Department	13%	17%	2%	
Clinic/office	74%	70%	84%	
Both	13%	13%	13%	
Past 12 months: location of asthma care				0.06
Emergency Department	12%	15%	3%	
Clinic/office	76%	72%	86%	
Both	12%	13%	11%	
Financial/insurance problems affecting asthma meds	12%	14%	9%	0.46
Baseline Morbidity				
Symptoms 2 weeks prior to baseline				
Maximum symptom days ^b	6.64±4.86	6.17±4.71	7.70±5.06	0.05
Days of wheeze	5.34±4.54	4.81±4.27	6.52±4.92	0.02
Days child slowed down/stopped play	3.22±3.93	3.10±3.78	3.48±4.27	0.55
Nights child woke due to asthma	3.29±4.16	3.31±4.14	3.23±4.25	0.91
School days missed due to asthma	24%	23%	27%	0.58
Caretaker ^b				
Nights caretaker woke due to child's asthma	2.99±4.35	3.15±4.46	2.63±4.11	0.45
Days caretaker changed plans	0.88±1.66	0.85±1.59	0.95±1.82	0.72
Lung Function ^b				
Percent predicted FEV ₁	91.05±16.74	92.83±16.25	88.34±17.34	0.21
FEV ₁ /FVC ratio	78.22±10.13	79.50±8.79	76.28±11.75	0.13
Healthcare Utilization ^c				
At least 1 unscheduled visit (ED or clinic)	76%	72%	86%	0.06
At least 1 prednisone burst	19%	17%	23%	-.49
At least 1 hospitalization due to asthma	3%	2%	5%	0.37

^aIncludes children recruited from Jefferson (49), St. Bernard (5), St. Tammany (2), and Plaquemines (0) parishes.

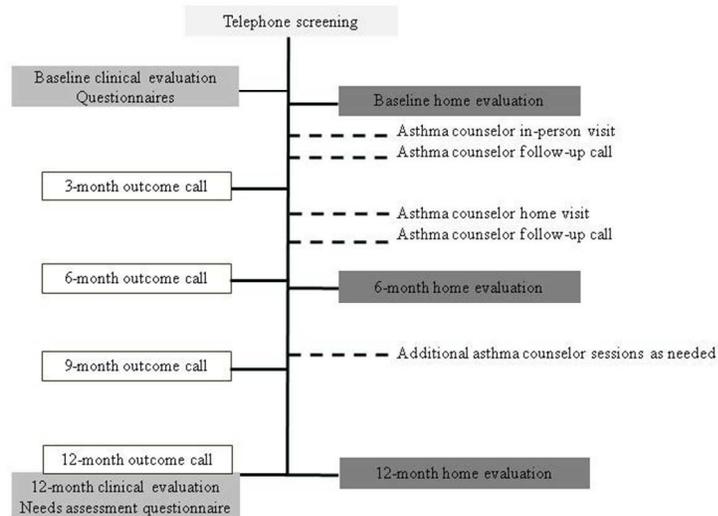
^bMean +/- standard deviation

^cHospitalizations and Unscheduled visits in the last 3 months. Prednisone in the last 1 month.

Figure Legends

Figure 1. Timeline for HEAL study activities. Children were prescreened for eligibility by phone. During the call, caretakers were asked about the children's asthma symptoms and post-Katrina living conditions. Eligible children were invited to have a baseline clinical evaluation, where they received a complete asthma workup to confirm their asthma status, blood work for basic clinical and immunological parameters, and skin sensitivity testing. Children who were enrolled in HEAL received 3 home evaluations and the hybrid asthma counseling intervention over a 1-year period. During each home evaluation, the children's homes were examined visually and air and dust samples were collected. The intervention included two in-person visits, with one of these conducted in the children's homes, and additional asthma counseling sessions as needed. The asthma counselor called the caretaker 2 weeks after each in person session to provide follow-up. To assess changes in the children's asthma morbidity, caretakers were called every 3 months and surveyed about their children's asthma outcomes. At the end of the 1-year study period, the children received a final clinical evaluation.

Figure 2. Geospatial mapping of the children's homes at the time of study enrollment. Red dots represent children's homes in Orleans Parish, and blue dots represent homes in Jefferson and other parishes (St. Bernard and St. Tammany). Flooding overlays were only available for Orleans and St. Bernard Parishes; while areas of Jefferson Parish also flooded, they are not shown on this map.



1

Figure 1. Timeline for HEAL study activities. Children were prescreened for eligibility by phone. During the call, caretakers were asked about the children's asthma symptoms and post-Katrina living conditions. Eligible children were invited to have a baseline clinical evaluation, where they received a complete asthma workup to confirm their asthma status, blood work for basic clinical and immunological parameters, and skin sensitivity testing. Children who were enrolled in HEAL received 3 home evaluations and the hybrid asthma counseling intervention over a 1-year period. During each home evaluation, the children's homes were examined visually and air and dust samples were collected. The intervention included two in-person visits, with one of these conducted in the children's homes, and additional asthma counseling sessions as needed. The asthma counselor called the caretaker 2 weeks after each in person session to provide follow-up. To assess changes in the children's asthma morbidity, caretakers were called every 3 months and surveyed about their children's asthma outcomes. At the end of the 1-year study period, the children received a final clinical evaluation.

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