RETENTION FACTORS FOR PARTICIPANTS OF AN INNER-CITY COMMUNITY-BASED ASTHMA INTERVENTION STUDY

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Participant retention is a significant challenge for asthma field trials examining the effectiveness of prevention strategies in inner-city communities. Here, the authors evaluate factors associated with participant retention in an inner-city, pediatric, asthma intervention trial in Atlanta, Georgia, during 1998–2000. Demographic, clinical, residential, personnel, and logistical variables were analyzed by chi-square and Wilcoxon rank sum nonparametric tests to compare children who remained in the asthma study with those who were dropped. Of the 489 participants, 486 (99%) were African-American, 467 (96%) were non-Hispanic, 281 (57%) were male, and 142 (29%) remained in the study. Of the 347 dropouts, 149 (43%) were dropped because of missing study visits. Retention rates were significantly higher ($P<.05$) for participants enrolled in the second year of the study (2nd yr=43%, 1st yr=19%), for those who lived longer at the same residence (≥3 yrs=36%, 2–3 yrs=26%, 1–<2 yr=22%), and for those enrolled during a face-to-face follow-up home visit, rather than at the emergency department (ED) (follow-up=38%, ED=27%). Neither sex nor enrollment season were associated with retention. These findings underscore the importance of performing a comprehensive pilot study and considering a home residency period for participant enrollment eligibility, along with alternative study methods that take into account the challenges of retaining participants. (*Ethn Dis*. 2003;13: 118–125)

Key Words: Asthma, Community-based, Intervention, Pediatric, Retention

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INTRODUCTION

Participant retention in longitudinal asthma research studies based in minority inner-city communities is of pivotal importance to investigators, due to the combination of the issues involved in asthma treatment and prevention, in addition to the complexities faced by families living in urban environments.[1,2] The fact that only limited data exist on study participation among inner-city communities for asthma and other disease conditions suggests that prevention may be a lower priority among residents, that means of contact and location information may be nonexistent or continually changing, and that research may be viewed with suspicion by the residents.[1,3,4]

Both living with asthma and in an urban environment contribute to the challenge of retention in a study such as this. Asthma is the most prevalent chronic illness of childhood in the United States, affecting approximately 5 million children.[5] Children living in inner-city settings are disproportionately affected by asthma, resulting in increased emergency department (ED) visits, hospitalizations, and activity limitation.[6,7] Poverty, under-utilization of services, lack of access to continuous care, and environmental and psycho-social stressors are among the potential risk factors associated with the excess asthma morbidity among urban minority populations.[8,9] The complexities of asthma in urban areas challenge investigators' abilities to execute clinical, environmental, and educational strategies proposed to reduce the burden of asthma.

Low participant retention threatens the validity of a research study and its ability to generalize findings from clinical and epidemiologic research studies that evaluate the effectiveness of new and existing therapies (ie, drug treatments, educational initiatives, and disease prevention strategies).[2] Moser et al report that retention in clinical trials has varied from 15% to 40%.[10] Some of the reasons identified as factors contributing to patient attrition include socioeconomic status, educational level, participant perception of personal benefit, social support from staff, being of younger age, and perceived severity of disease.[7,11] Research findings about retention in asthma studies also have direct relevance for asthma programs, especially in the planning and implementation phase, because the findings may highlight the necessity for innovative approaches to reach people living in urban communities who need the services.

The purpose of this paper is to identify factors that differentiate participants who dropped out of one specific asthma intervention study, and those who either completed the study or were still in the study at the time it was terminated. These factors might be considered in the design of future inner-city community asthma intervention studies.

MATERIALS AND METHODS

Enrollment of Study Population

The recruitment of study participants into this asthma study has been described previously.[12] In brief, all chil-

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dren aged 5–12 years with asthma presenting to the pediatric ED of a major public hospital in Atlanta, Georgia, were eligible for enrollment in the study. Trained community health workers (CHWs) enrolled the children if their accompanying parents or guardians were willing, and if the children's diagnoses in the ED were asthma or "reactive airway disease." Additionally, participants must have resided in specific zip codes within or adjacent to the Atlanta Empowerment Zone (AEZ). The AEZ is so designated because of high poverty rates. A previous study identified asthma as a health problem for residents living within or around the AEZ.[13] For patients who attended the ED when a CHW was not on duty, the parents or legal guardians were later contacted by telephone or mail to assess their eligibility and willingness to participate. A face-to-face follow-up visit was then scheduled to obtain written informed consent. Potential enrollees were excluded from participation if: 1) other household members were currently enrolled in the asthma intervention study, or had been enrolled in any other asthma intervention studies requiring home visits, within the prior 12 months; 2) no one older than 13 years was in the home who was able to speak English fluently; and 3) they had not resided at the same address for at least 6 months.

Human Subject Approval

The study was approved by a special community Institutional Review Board convened at the Centers for Disease Control and Prevention and included members from the community where the study was conducted. All adult caregivers gave written informed consent, and children 7 years and older gave assent before the collection of any information or clinical specimens.

Baseline Evaluations

Participants completed 3 baseline evaluation activities during the first 2 months of the study: a telephone interview, a home visit, and an outpatient clinic visit. A local academic institution conducted the telephone interview with a standardized questionnaire collecting information about health status related to the functional severity of the child's asthma; quality of life; healthcare utilization; caregiver's knowledge, practices, and beliefs about asthma; and the socioeconomic burden of having a child with asthma. Dust samples were collected during the baseline home visits to determine the presence and levels of indoor allergens and pollutants. At the outpatient clinic visits, lung function was measured by spirometry, or peak flow measurements for interval lung function monitoring, and blood samples were collected. Blood was analyzed for cotinine to assess exposure to environmental tobacco smoke, and the radioallergosorben test method was used to determine the IgE levels specific to house dust mite, cockroach, cat, dog, Alternaria mold, and mixed tree and mixed grass pollen allergens. Participants were dropped from the study for failure to complete the 3 baseline activities within a specified 2-month time from initial enrollment.

Randomization into the Intervention and Control Group

Patients were randomly placed in an intervention or control group after completion of the baseline activities. The intervention group received house dust mite covers for the surfaces where the child slept; roach abatement measures that included traps, bait, and gels; customized asthma health information, and a professional house cleaning. After this initial visit, which had to be completed within 2 months of enrollment, 4 additional intervention home visits were scheduled to check the dust mite covers, to replace, if necessary, roach-abatement measures, and to reinforce health messages on topics such as smoking cessation. For ethical reasons, and to obtain community acceptance, creating a strict control group was not possible. The designated comparison group was a delayed intervention group that would also receive the home cleaning, dust mite covers, and roach-abatement interventions, but not until the end of the study period.

Follow-up Evaluations and Criteria for Dropping from Study

The 3 activities (telephone interview, home visit, and clinic visit) formed a recurring triad for monitoring enrollees throughout the study. We required both the control and intervention groups to complete the 3 evaluation activities (a telephone interview, a home visit, and an outpatient clinic visit) every 4 months. Participants who failed to complete any of the follow-up activities within 14 days after the specified period were dropped from the study (designated as dropouts). In all cases, great efforts were made to have the clients complete the activity in the required time. All terminated participants were notified if they did not complete a required activity within the time frame, and were offered an opportunity to participate in the community support arm of the project.

Protocol Revision

After a year of enrollment in the study, participant retention (50%) was substantially lower than projected (80%), with most of the enrollee dropouts occurring during the baseline period of the protocol, and these

dropouts generally were due to the enrollees missing their home and clinic visits. To improve participant retention, modest incentives were approved to be given to participants after completion of the 3 evaluation activities. In addition, we intensified efforts to identify and monitor clients at risk for leaving the study by reviewing weekly each of the Community Health Workers' (CHWs') client files for participants close to the 14-day requirement for completion of a required protocol activity, and to see what other measures could be taken to assist the client in completing the activity. Eighteen months after study initiation, retention remained low (36%), despite these changes. In an effort to salvage the study, we revised the protocol from a 22-month controlled field trial to a 14-month single group pre- vs post-intervention study. The latter design entailed converting all the control group participants to the intervention group, and following all enrollees for a total of 12 months after assignment to the intervention group. Despite these modifications, the study was discontinued prematurely (26 months after enrollment began) because of continued low retention (30%) and lack of funding for research activities beyond the original projected study period.

Statistical Analysis

Data were abstracted from the intake and enrollment forms completed in the ED and from end-of-participation data forms that were completed for all enrollees in the study. Participants who either had completed the protocol, or were still enrolled at the time of study termination (including the baseline up to any activity time point), were considered retainers. Dropouts were participants who initially enrolled, then left the study at any time point. Demographic, clinical, residential, personnel, and logistical variables were analyzed using the Statistical Analysis System (SAS).[14] Chi-square tests were used to compare the difference in the percentages of the categories between the retainers and dropouts. For the variable *length of time at residence,* which was not normally distributed, we performed a Wilcoxon rank-sum nonparametric test.[15] In addition, we used logistic regression modeling to assess the contribution of each significant variable as a predictor of retention, using backward elimination.[16] Retention rates were calculated comparing the percentage retained to the percentage dropped. The level of significance was reported at $P<.05$.

Because the study had a rolling enrollment period of over 24 months, but a fixed termination date, comparisons of retainers to dropouts may be affected by differing lengths of time spent in the study. Factors that significantly affected whether a subject completed the study were further evaluated by Kaplan-Meier methods, with a 2-sided log rank test used to compare dropouts and retainers.[14]

RESULTS

Demographics

Of 981 eligible children, 489 (50%) were enrolled over the 24-month period. Of those children enrolled, 281 (57%) were male; 480 (99%) were African-American, and 20 (4%) were Hispanic; and the median age was 7 years (Table 1). Of the 489 participants, 142 (29%) were retainers, and 347 (71%) were dropouts.

Table 1. Baseline demographic characteristics of children in asthma study, Atlanta, Georgia, 1998–2000 (*N*=489)

Characteristic	N	%
Age (median)	7 years	—
Sex		
Male	281	57
Female	208	43
Race*		
African-American	480	99
Other	7	1
Ethnicity*		
Hispanic	20	4
Non-Hispanic	467	96

* Information missing from 2 respondents.

Reasons for Dropout

Reasons listed on the end-of-participation forms explained why enrollees left the study; 88.5% of these (307) were categorized as involuntary. Missing visits (43%), and inability to be contacted (25%) constituted the most frequent reasons for involuntary dropout. Details were not collected on the specific reasons for the missed visits, but anecdotally, these reasons were issues and commitments that clients had to prioritize over their continued participation in study activities (eg, caring for other children, work/employer responsibilities, etc). The most common reasons for voluntary dropouts were invasion of privacy (3.5%) and unwillingness to answer study questions (2.6%) (Table 2).

Retainer-Dropout Differences

Of factors evaluated for differences between retainers and dropouts, 4 were significant (Table 3). First was the duration of the CHWs' employment. During the study time period, six CHWs left the study for a variety of reasons. We categorized CHWs by the year to which their employment extended, because some were hired at the beginning of the study, and some during the study, to replace those who left the study during the first and second years. CHWs leaving in the first year were classified in the first-year category; those leaving during the second year, in the second-year category; and those who remained until the study ended, in the third-year category. Participant retention among these 3 groups of CHWs differed significantly: 35% for the third-year group, 20% for the second-year group, and 6% for the first-year group. Using the first-year CHW group

Table 2. Categories and reasons for dropout from asthma study in Atlanta, Georgia, 1998–2000 (*N*=347)*

Reason	*N*	%
Voluntary		
Invasion of privacy	12	3.5
Unwillingness to answer questions	9	2.6
Unwillingness to provide samples	6	1.7
Too much time involved	7	2.0
Other†	6	1.7
Subtotal	40	11.5
Involuntary		
Missed visit	149	42.9
Inability to contact	87	25.1
Inability to complete survey	15	4.3
Relocation	40	11.5
Other‡	16	4.7
Subtotal	307	88.5
Total	347	100

* One hundred forty-two children were retained in the study at the time of termination.
† Voluntary other category: parent unwilling to participate (5 children) and child was having surgery (1).
‡ Involuntary other category: professional cleaning not done (10), involved child subsequently found to not have asthma (3), child unable to provide samples (2), and CHW inadvertently performed intervention on control client (1).

as referent, the retention ratio for the third-year CHW group (ie, protection against dropping out by having a third-year CHW) is 5.36 (95% confidence interval [CI]=2.56–11.22); and for the second-year CHW group, the ratio is 3.14 (95% CI=1.18–8.33).

The second significant factor associated with retention was year of enrollment. Being enrolled during the second year was significantly associated with retention: 43%, compared with 19% retention for those enrolled during the first year. The retention ratio for the second vs the first year was 2.20 (95% CI=1.69–2.89). Even though retention was higher among participants with shorter follow-up periods, survival analysis discussed below indicated that the effect of year of enrollment was not artifactual but was associated with retention.

To indirectly assess whether the increased experience of the CHW over time led to improved retention (a learning curve effect), we compared the retention rates between the second- and first-year enrollees for the CHWs who worked throughout the 3 years of the study. Six CHWs in the third-year group had enrollees in both the first and second years. Among these CHWs, the change in retention varied from a decrease of 2.7% to an increase of 47.0% from the first to the second year of enrollment. For this small group of CHWs, the rise in the retention ratio was not significant (paired *t* test, *P*=.06), implying that the increased experience of these long-term CHWs may not be the primary contributor to improved retention.

Duration of the enrolled child's residence at the current address was also associated with retention. For children living 3 or more years at the same address, the retention rate was 36%, compared with 26% for enrollees living 1–2 years at the same address, and 22% for enrollees residing at their addresses for less than a year. Using residence of less than 2 years at the same address as the referent group, retention ratios for remaining in the study are 1.7 (95% CI=1.2–2.3) for children living 3 or more years at the same address, and 1.2 (95% CI=0.8–1.9) for children living at the same address for 1–2 years. Comparison of the years of residence between the retainers and dropouts indicates that the retainers had resided significantly longer at their address (median=3 years), compared to dropouts (median=2 years) (Table 3).

The location in which the child was initially enrolled in the study was the final factor associated with retention. For 383 (78%) of the enrollees, enrollment was completed during the child's visit to the ED. For the other 106 (22%) children, the enrollment process was completed during a face-to-face follow-up visit where informed consent was obtained. Retention was significantly higher (38%) for those enrolled at a follow-up home visit compared to those enrolled at the ED (27%). The retention ratio was 1.42 (95% CI=1.04–1.93). No significant differences existed between retainers and dropouts for sex, race and ethnicity, or season of enrollment.

The factors discussed above were entered into a logistic regression model. Only year of enrollment, living 3 or more years at the same residence, and enrollment completed during a follow-up visit, were factors in predicting retention in the final model (Table 4). CHW employment duration was internally correlated with the year of enrollment and was not included in the final model for predicting retention. The year of enrollment had the greatest impact on retention, with an odds ratio of 3.4 of retaining a child if the child was enrolled in the second year vs the first year of the study. Completing enrollment at a follow-up home visit and residing at the current residence for 3 or more years each had an odds ratio of almost 2 vs completing enrollment at the ED and residing at current residence for less than 2 years, respectively.

The following factors were analyzed by Kaplan-Meier methods: year enrolled (first vs second year of study), length of

Table 3. Retention factors and ratio of participants remaining compared to drop-outs from asthma study in Atlanta, Georgia, 1998–2000*

Risk Factor	# Retained (%)	Retention Ratio	95% CI
Race			
African-American	140 (29%)	2.04	0.4, 10.37
Other	1 (14%)	1.00	Reference
Sex			
Male	81 (29%)	1.01	0.90, 1.13
Female	61 (29%)	1.00	Reference
Ethnicity			
Hispanic	7 (35%)	1.21	0.64, 2.29
Non-hispanic	135 (29%)	1.00	Reference
Season of enrollment			
Spring	40 (32%)	—	
Summer	26 (31%)	—	
Fall	53 (33%)	—	
Winter	23 (19%)	—	
CHW employed until the:			
3rd year	124 (35%)	5.36	2.56, 11.22
2nd year	14 (20%)	3.14	1.18, 8.33
1st year	4 (6%)	—	Reference
Year of enrollment†			
2nd year	87 (43%)	2.20	1.69, 2.89
1st year	55 (19%)	1.00	Reference
Period of residence‡			
≥3 years	78 (36%)	1.7	1.20, 2.28
2–3 years	22 (26%)	1.14	0.76, 1.90
1–2 years	38 (22%)	1.00	Reference
Site of enrollment completion§			
Face-to-face follow-up visit	40 (38%)	1.2	1.04, 1.93
ED visit	102 (27%)	1.00	Reference
Total	138–142 (29%)	—	—

Note: CI = confidence interval; CHW = community health worker; ED = emergency department.
* The percentage dropped = (100–percent retained).
† $P<.001$.
‡ $P<.0$, variable data not available for 2 children.
§ $P<.05$.

residence at the time of enrollment (≥3 years vs <3 years), and location of enrollment (at a follow-up visit vs at the ED). The proportional hazards model was appropriate for each factor. The log-rank test indicated significantly different survival functions (Figure 1) between levels of each factor ($P<.005$). We found the same pattern for survival by year enrolled and location of enrollment. Median survival times for the factors revealed that each factor not only affected completion of the study, but also affected the length of time the child remained in the study (Table 5).

Table 4. Model of factors affecting retention in asthma study in Atlanta, Georgia, 1998–2000

Risk Factor	Odds Ratio	95% Confidence Interval
Year of enrollment	3.4	2.3–5.2
Enrollment completed at follow-up visit	2.1	1.3–3.4
Reside 3 years at current residence	2.2	1.4–3.4

DISCUSSION

Four significant factors were associated with retention in this 2-year inner-city asthma intervention study. The participants most likely to remain enrolled in this study had resided 3 or more years at the same address, and were enrolled in a face-to-face follow-up home visit in the second year of the study by a CHW employed for longer than 3 years. Of these 4 factors, year of enrollment had the greatest effect on retention of study enrollees when combined in a logistic regression model. Because the analysis was conducted for the total enrolled population (though only 30% of the enrollees were eventually retained), this study provided an opportunity to retrospectively pinpoint the key characteristics associated with retention.

We were not surprised to find an association between duration at residence and study participation. Although enrollees had lived at the same residence for 6 months or longer at the survey baseline, few participants moved out of the predefined study area. Moving within the prior years before enrollment also disrupted continued study participation. Although the move occurred before the study, duration of residence at a single location may indicate contact reliability and ease of participation and follow-up. Having a fixed address may also indicate, among other factors, financial and family stability, and possibly having a consistent source of medical care; all these factors may allow for continued involvement in a long-term study. Having a stable housing arrangement is especially relevant for longitudinal asthma studies examining environmental interventions for household allergens, since the residence is a primary reservoir for allergen exposure. To optimize study

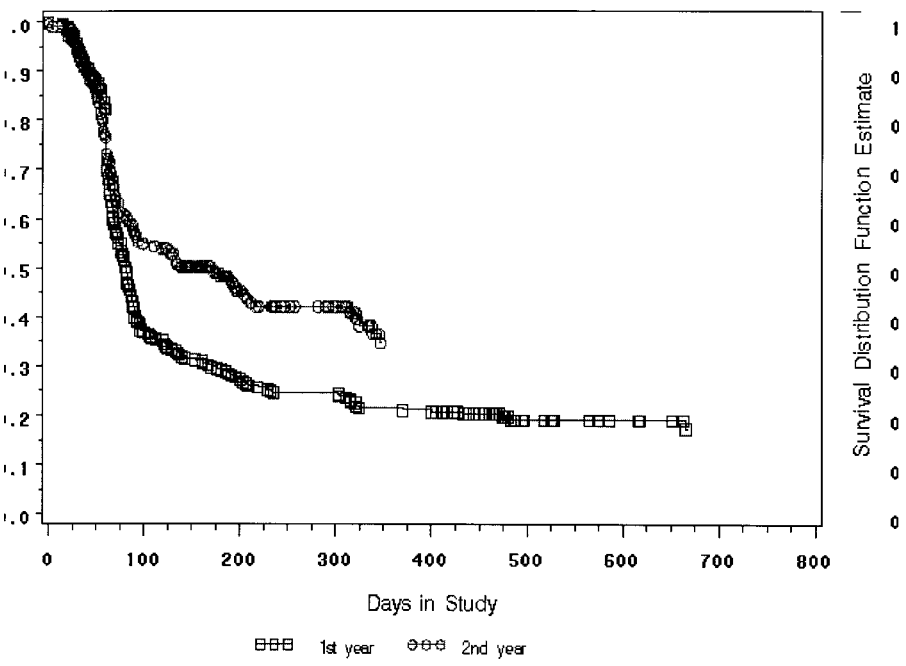

Fig 1. Kaplan-Meier curves of participant study survival by year enrolled in asthma study in Atlanta, Georgia, 1998–2000

Table 5. Median survival times for retention factors in asthma study in Atlanta, Georgia, 1998–2000

Factor	Days
Year enrolled	
2nd	172
1st	82
Length of residence	
3 years	102
<3 years	83
Where enrollment completed	
Follow-up visit	162
ED* visit	80

* ED=emergence department.

participation, residential longevity of various intervals could be used as a screening eligibility factor based on the type and duration of the longitudinal asthma studies.

Face-to-face follow-up visits at participants' homes positively affected patient retention. Children enrolled during follow-up home visits were 42% more likely to remain in the study than those enrolled during an ED visit (even though the ED enrollment rate was more than twice the home enrollment rate). Face-to-face follow-up enrollment may have allowed families more time to discuss the pros and cons of participating in a research study, and perhaps decreased the pressure the family may have felt to enroll in the ED because their child was having an asthma exacerbation. Furthermore, follow-up enrollment may have resulted in a more thoughtful consideration by the caregivers as to whether they and their children would benefit from enrolling in the asthma study, so that once they agreed to enroll, they would remain throughout the study. The simultaneous implication and limitation of this finding is that while face-to-face follow-up visits may yield higher retention, they require more resources, and, as noted in this study, the overall yield from the ED (102 [72%] of 142 enrollment rate) was greater than that from follow up (28% enrollment rate). An additional limitation of this finding is the uncertain fraction of eligible enrollees who were neither seen at the ED nor visited at home, which, if considerable, may indicate that alternate means of enrollment would be preferable (eg, through schools or asthma specialty clinics).

Participants enrolled in the second year of the study were more likely to be retained in the study. This finding was expected, given the revision in the protocol during the second year. Protocol revisions resulted in increased oversight and management of the CHWs, incentives for enrollees completing periodic activities, and focused screening of children and their families to determine their ability and commitment to be retained in the study long term. Personnel changes also affected the workload and management of the CHWs. All these actions played a role in decreasing study attrition in the second year. Although these factors were not individually assessed for impact, the finding of increased second-year retention stresses the importance of pilot testing and anticipatory study management to define the personnel and resources necessary for executing and ensuring a successful study.

These residential, staff, and logistical findings add to the knowledge about participant retention in asthma research. Previous studies have identified participant factors (ie, sex, intelligence testing, problem solving abilities, behavioral problems), caretaker stress, decreased social support, and inability to provide alternate contacts as associated with study attrition in asthma studies[1,2] One of these studies was undertaken in similar inner-city communities and reported a >80% completion rate (for 3 interviews) among all participants.[1] Significant resources were employed, such as face-to-face recruitment, reminder calls, monetary incentives, and a distributed data system, to enhance retention.[1] Our study was smaller and more intensive, therefore requiring substantially more time and effort from both the staff and the families. Study retention might have improved if we had provided incentives from the beginning of the study, used

the collected data to assist and direct staff management at the onset, and allowed participants who missed visits to remain in the study.

One key lesson learned from this study, which may be especially pertinent for studies in inner-city communities, is the need for methodological flexibility. Because most of the dropouts were involuntary and resulted from missed visits, a protocol designed to accommodate participants who were willing to continue making study visits outside the allowable time window would have had higher retention. Although the specific reasons for missed visits were not collected in a standardized fashion for this study, the CHWs anecdotally reported that in the majority of cases, missed visits occurred not because of lack of desire for continued participation, but because of other demands and responsibilities that the parents of the child had to chose over meeting the study activity deadline. Therefore, proactively developing a methodology to accommodate and analyze for less than perfect follow up in longitudinal studies is necessary for working with populations in complex and challenging environments and enables a better understanding of the reasons for not making study visits and the assistance necessary to address this.

The findings of this paper have implications not only for research studies, but also for asthma programs in inner-city communities. Granted, asthma programs would tend to be less invasive and provide greater direct benefits to the child and the family than would asthma intervention studies. However, our study's findings could be interpreted as identifying the characteristics of hard-to-reach populations and specifications on possible ways to engage them successfully. Creative program approaches that deliver proven services for quality asthma care are necessary for these populations. Therefore, when implementing an asthma program for hard-to-reach populations, we need to recognize that clients may not have resided at their address for very long, that the ED may not be the optimal site for enrollment, and that time and long-term community-based staff are needed in order for a program to successfully reach a high percentage of its intended target population. These findings are not new, but lend further credence to the formation of multiple community partnership programs, which have been encouraged and developed to address some of these issues pertaining to the complexity of asthma in inner-city communities.[17,18]

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In summary, this study identified important residential, staff and logistical characteristics associated with retention in an inner-city asthma intervention study. These factors must be anticipated and strategies employed, such as residency duration screening, methodological flexibility for <100% participation, pilot testing, and data driven staff management, especially for longitudinal studies and programs in urban communities to guard against low retention.

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