

A Randomized, Controlled Trial of a Simple Emergency Department Intervention to Improve the Rate of Primary Care Follow-up for Patients With Acute Asthma Exacerbations

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Study objective: We determined whether a simple emergency department intervention improves the likelihood of primary care provider (PCP) follow-up after ED discharge for an acute asthma exacerbation.

Methods: This randomized, controlled clinical trial was conducted in an urban university-based ED. Participants were patients with asthma between the ages of 16 and 45 years who were treated and discharged from the ED. The study intervention was usual care or an intervention that consisted of a free 5-day course of prednisone, vouchers for transportation to and from their PCP, and a 48-hour telephone reminder to make an appointment with their PCP. The main outcome was whether the patient received follow-up care as determined by PCP contact at 4 weeks.

Results: One hundred ninety-two patients with asthma were enrolled over 8 months; 178 (93%) had complete follow-up. The intervention and control groups were similar with regard to age, sex, ethnicity, or years of education. The 2 groups were also comparable with respect to multiple measures of baseline access/barriers to care and severity of ED exacerbation. Patients receiving the intervention were significantly more likely to follow up with their PCP than control patients (relative risk 1.6; 95% confidence interval [CI] 1.1, 2.4). When adjusted for other factors influencing PCP follow-up care (ethnicity, prior PCP relationship, insurance status, regular car access), intervention patients were more likely to follow up with their PCP (odds ratio 3.1; 95% CI 1.5, 6.3).

Conclusion: Providing medication, transportation vouchers, and a telephone reminder to make an appointment increased the likelihood that discharged patients with asthma obtained PCP follow-up.

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INTRODUCTION

Asthma continues to be one of the most prevalent chronic diseases, affecting at least 5% of the US population with annual health care costs exceeding \$6 billion.¹ Emergency departments play a large role in the care of patients with asthma, with approximately 2 million visits annually in the United States.^{1,2} Dependence on the ED as a site for episodic, crisis-oriented asthma care has been viewed as a marker for increased morbidity and is associated with poor self-management practices.³⁻⁵ Increased utilization of the ED by some patients with asthma also has been linked to inadequate health insurance. However, underutilization of preventive primary care services and reliance on ED services cannot be fully explained by financial barriers.⁶ Many asthmatic patients who are reliant on ED care actually have primary care providers (PCPs).⁶⁻¹⁰

Effective and timely outpatient care of asthma prevents adverse asthma outcomes and reduces hospitalization and ED visits.¹¹⁻¹⁵ Follow-up after an acute asthma exacerbation requiring hospitalization has been associated with a reduction in subsequent hospital admissions and improvement in asthma symptoms.¹⁶ As a result, the 1997 National Asthma Education and Prevention Program (NAEPP) Guidelines Expert Panel Report-2 recommends close PCP follow-up by instructing patients to make an appointment within 3 to 5 days after an ED visit.¹⁷

Several studies have proposed methods to enhance ED-PCP linkage for patients with asthma. Strategies including ED-based asthma education, scheduling of appointments for patients before ED discharge, distribution of medications, and improved communication between primary care physicians and the ED have been proposed.¹⁸⁻²⁰ Few studies have tested specific interventions in a systematic fashion. We performed a randomized, controlled trial to determine whether a simple, inexpensive, 3-part ED intervention would increase the likelihood of PCP follow-up for patients treated and discharged from the ED for an acute asthma exacerbation. We hypothesized that patients receiving this intervention would be more likely to have PCP follow-up than the control patients who received usual discharge care.

MATERIALS AND METHODS

This study was a prospective randomized, controlled trial of a simple ED intervention to improve the rate of PCP follow-up for patients with acute asthma exacerbations. The study was conducted in the ED of the Hospital of the University of Pennsylvania, an urban tertiary care center with an annual patient census of approximately 47,000 visits. There is no observation or short-stay unit available at the study institution for the extended ED care of asthmatic patients. The study was approved by the University of Pennsylvania Committee on Research Involving Human Subjects.

Consecutive patients older than 16 years and younger than 46 years who presented to the ED between March 5 and November 15, 1998, with a chief complaint consistent with an acute asthma exacerbation were eligible for inclusion. During the study period, dedicated research assistants were present in the ED, from 8 AM until midnight, 7 days per week to identify potential study patients. These time periods were selected because review of ED logs before study commencement demonstrated that more than 80% of all eligible patients present during this 16-hour period.

All patients with complaints of shortness of breath, wheezing, difficulty breathing, respiratory distress, cough, chest tightness, or asthma were screened for study eligibility. Patients were excluded if they were unable/unwilling to provide informed consent, or were non-English-speaking, previously enrolled in this study, or admitted for inpatient care. Enrollment did not take place until the patient met all criteria.

Patients who met study inclusion criteria were administered a 46-item structured closed-question survey to ascertain demographic information, as well as details of baseline asthma severity (medications, intubation history, and comorbid illnesses), current asthma severity (vital signs, initial peak flow, oxygen saturation), and barriers to primary and ED care.

Patients were randomly assigned to 1 of 2 groups. The intervention group received a self-contained "fanny pack" of materials designed to enhance the likelihood of scheduling timely follow-up on release from the ED. This intervention consisted of a 5-day course of oral prednisone (50 mg/d), 2 taxicab vouchers specifically designated for transportation to and from their PCP, an asthma information card, and written instructions for the use of the medications and the vouchers. In addition, patients in the intervention group were contacted by telephone

within 48 hours of ED release and reminded to make an appointment with their PCP if they had not already done so. In our ED, it is standard practice that all discharged asthmatic patients receive a short course of steroid therapy. Control patients received ED discharge instructions and medication prescriptions at the discretion of the treating physician. Both the control and intervention patients without a PCP were referred to a hospital-based asthma clinic that had agreed to accept referrals.

Randomization was performed using a computer-generated block randomization scheme by 1 of the nonclinical investigators. Randomization was performed in blocks of 100 patients. Study packages were prepared and sealed by 2 investigators not involved in patient enrollment. The research assistants who performed patient enrollment were blinded to the randomization scheme. Because of the nature of the intervention, it was neither desirable nor possible to blind the patients to the study intervention.

Attempts were made to contact all intervention patients 48 hours after the ED visit to remind them to make an appointment with their PCP if they had not already done so. Two nonmedical personnel used a script to make these calls. Three attempts were made to reach the patient. If patients were unavailable after 2 contact attempts, a message was left when possible.

ED logs were checked on a daily basis for the duration of the study and for 1 month after the termination of the study to ascertain if any study patient had a relapse. Relapse was defined as any ED revisit for asthma prompted by a failure of symptoms to improve or resolve within 21 days after the index visit. No attempt was made to monitor ED visits of study patients to hospitals in the surrounding geographic area.

The main outcome for this study is whether patients kept an appointment with their PCP for asthma follow-up within 4 weeks of the index ED visit. A single investigator who contacted each patient's PCP at the end of this 4-week period assessed this outcome. Attendance was confirmed for all scheduled appointments. This investigator was blinded to study group assignment. During the initial consent procedure, each study patient signed a release granting permission to review medical records and to speak to the PCP.

Sample size determination was based on an expected overall PCP follow-up rate of 17%, as determined by pilot data in patients without health insurance at our institution. For an absolute improvement in the follow-up rate of 20%, we calculated a required sample size of 87 patients

per group ($\alpha=.05$, $\beta=.85$; PASS, version 6.0 [1997], NCSS Statistical Software, Kaysville, UT). We anticipated a refusal/withdrawal rate of less than 10% and therefore targeted a total study sample of 200 patients.

Data were analyzed on an intention-to-treat basis. Differences between control and intervention group patients and differences between PCP follow-up and no follow-up were assessed by χ^2 or Fisher exact tests for categorical data, and Student's *t* test for continuous data. Categorical data are presented as the percent frequency of occurrence. Continuous data are presented as means \pm SD. The association between questionnaire items and PCP follow-up are presented as relative risks with 95% confidence intervals (CIs).

Because certain factors are known to affect asthma follow-up rates with a PCP (ie, health insurance status, ethnicity, prior relationship with a PCP) both stratified analyses using Cochran-Mantel-Haenszel statistics and multiple logistic regression were used to adjust for possible confounding of these factors. Data are presented as summary risk ratios and adjusted odds ratios with 95% CIs, respectively.

All data were analyzed using SAS statistical software (SAS/STAT version 6.12, SAS Institute, Cary, NC). Statistical significance was defined as $P<.05$.

RESULTS

During the study period, 218 patients were evaluated in the ED. Review of ED logs identified 21 of the 218 eligible patients were not enrolled, leaving 197 patients who met the inclusion criteria. Three patients refused enrollment, and 2 patients were mistakenly enrolled in an incorrect group. Therefore, 192 patients entered the study protocol (98 in the intervention group and 94 in the control group). These data are consistent with the anticipated 80% enrollment rate. Patients who met study eligibility but were not included in the trial were similar to patients included in the trial with respect to demographic characteristics, baseline asthma severity, and current asthma severity.

We were able to verify whether the patients presented to the PCP after the index ED visit in 178 of 192 enrolled patients. Patients visited their PCP a median of 13 days after the index ED visit (interquartile range, 6 to 25 days). The 14 patients lost to follow-up were similar to the 178 patients with verifiable follow-up data with respect to demographic characteristics, baseline asthma severity, and current asthma severity. The Figure is a flow diagram showing patient progress through the study protocol.

Of the 178 patients who completed the study protocol, 95 patients were in the intervention group and 83 patients were in the control group. Baseline demographic characteristics, baseline asthma severity, and current asthma severity for study patients are shown in Tables 1 and 2. The 2 groups were similar with respect to age, sex, ethnicity, symptom duration, current and maintenance use of asthma medications, historical markers of asthma severity, vital signs on presentation, initial peak expiratory flow rate, initial oxygen saturation, and multiple measures of access to care including type of health insurance.

We successfully contacted 89% of intervention patients by telephone at 48 hours. Utilization of the transportation vouchers by intervention patients was also tracked by study personnel for up to 8 weeks after the termination of the study; 27% of the vouchers were used by patients for travel to and from PCP appointments.

Twenty-two patients returned to the ED during the study period (mean 72 days). Only 6 of these patients returned within 21 days of their initial ED visit; these patients were considered to have a relapse. They were divided evenly among the intervention and control groups (3 patients in each group).

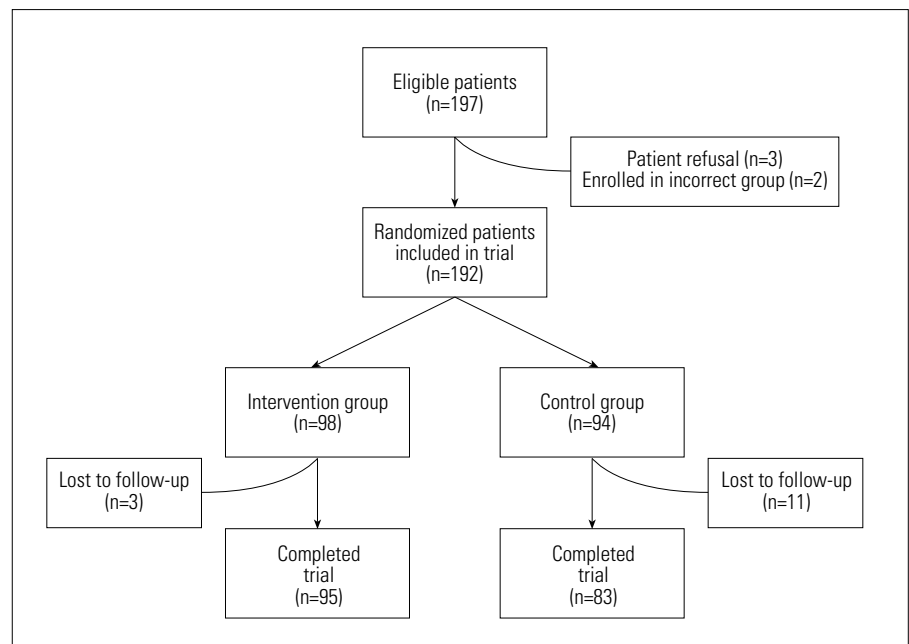
Our main outcome, successful follow-up with a PCP, was more common in patients who received the intervention. Forty-four (46.3%) patients in the intervention group and 24 (28.9%) patients in the control group fol-

lowed up with their PCP (relative risk [RR] 1.6; 95% CI 1.1, 2.4). Other variables also associated with an increased likelihood of PCP follow-up are shown in Tables 3 and 4. Characteristics associated with PCP follow-up were older patient age, a prior relationship with a PCP (RR 4.4; 95% CI 1.9, 10.2), black race (RR 0.54; 95% CI 0.37, 0.79), lack of health insurance coverage (RR 0.33; 95% CI 0.11, 0.96), and regular access to transportation for scheduled medical care (RR 1.4; 95% CI 0.94, 1.9). Historical and current markers of asthma severity were not associated with increased PCP follow-up rates.

Key factors known to affect follow-up rates (prior PCP relationship, ethnicity, and insurance status) were stratified to assess efficacy of the intervention on follow-up rates (Table 5). In all cases, the intervention improved follow-up rates (ethnicity RR 1.6, 95% CI 1.1, 2.3; prior PCP relationship RR 1.7, 95% CI 1.2, 2.6; insurance status RR 2.1, 95% CI 1.1, 4.0). For patients with no prior PCP relationship, 5 (17.2%) who received the intervention went for follow-up visits, whereas no control patients did.

To adjust for key and other variables (age, transportation availability) associated with PCP follow-up, we used logistic regression, and the intervention was still associated with increased likelihood of follow-up with an adjusted odds ratio of 3.0 (95% CI 1.5 to 6.3). Variables that were no longer statistically significant in the multivariate analysis were transportation and insurance status.

Figure.
Patient flow diagram.



DISCUSSION

Our study demonstrated that a simple 3-part ED intervention given to discharged asthmatic patients resulted in an increased rate of follow-up with PCPs compared with discharged asthmatic patients who did not receive the intervention. This difference in PCP follow-up between intervention and control patients remained statistically significant even after adjustment for other factors associated with enhanced follow-up, including prior relationship with a PCP.

Because our study design used a combination 3-part intervention to enhance the rate of PCP follow-up, it is not possible to ascertain exactly which component of the intervention was successful. The increased time that study personnel spent with study patients may have increased compliance with follow-up in both groups (Hawthorne effect), despite the fact that follow-up rates in both groups were suboptimal.

Only 27% of patients in the intervention group used the transportation vouchers; however, this accounts for more than half of the 46% of intervention patients who did follow up with their PCP. In addition, the 17% absolute difference between control and intervention group follow-up might be fully explained by the use of transportation vouchers. On the other hand, it is possible that some other component of the intervention might have been responsible for increasing the follow-up rate and the patients simply used the available vouchers.

Table 1.

Comparison of intervention and control groups: patient characteristics.

| Variable | Control (n=83) ±SD No. (%) | Intervention (n=95) ±SD No. (%) |
|--|----------------------------------|---------------------------------------|
| Age (y) | 30.5±8.1 | 31.1±8.7 |
| Temperature (°F) | 98.1±1.1 | 98.1±0.9 |
| Pulse (beats/min) | 94.8±14.8 | 95.4±17.3 |
| Respiratory rate (breaths/min) | 21.2±9.7 | 21.3±7.5 |
| Pulse oximetry (O ₂ saturation %) | 97.1±2.1 | 96.6±2.9 |
| PEFR (L/min) | 242±90 | 249±100 |
| No. of times inhaler used past 24 h | 4.7±4.8 | 4.9±6.1 |
| Days work/school missed | 1.5±3.9 | 0.8±1.1 |
| Grade level | 12.5±2.2 | 12.3±1.8 |

PEFR, Peak expiratory flow rate.

We believe that the 48-hour telephone reminders and the complimentary study medications may have also enhanced the likelihood of PCP follow-up. Strategies to improve ED-PCP linkage have been studied for several other health conditions, and it is known that ED patients

Table 2.

Comparison of intervention and control groups: patient characteristics.

| Variable | Control Frequency (%) | Intervention Frequency (%) |
|--|--------------------------|-------------------------------|
| Have physician | 66 (79.5) | 66 (69.5) |
| Car access | 44 (53.0) | 51 (53.7) |
| Transportation to physician | | |
| Taxicab | 0 (0) | 7 (7.4) |
| Own car | 28 (33.7) | 20 (21.1) |
| Public transportation | 27 (32.5) | 40 (42.1) |
| Walked | 14 (16.9) | 16 (16.8) |
| Friend/family car | 12 (14.5) | 8 (8.4) |
| Asthma checkups | | |
| Don't go | 36 (46.8) | 48 (51.6) |
| Once/y | 7 (9.1) | 12 (12.9) |
| Twice/y | 10 (13.0) | 8 (8.6) |
| 3-4 times/y | 9 (11.7) | 13 (14.0) |
| >4 times/y | 15 (19.5) | 12 (12.9) |
| Called physician before coming to ED | 21 (28.0) | 29 (35.8) |
| Can get appointment with physician if emergency | 50 (75.8) | 58 (79.5) |
| Intubations | 8 (10.1) | 4 (4.4) |
| Inhaled steroids | 31 (37.8) | 44 (46.8) |
| Oral steroids | 10 (12.4) | 13 (13.8) |
| Sex: female | 62 (74.7) | 66 (69.5) |
| Ethnicity | | |
| Asian | 4 (4.9) | 3 (3.2) |
| Black | 67 (82.7) | 79 (85.0) |
| Hispanic | 2 (2.5) | 1 (1.1) |
| White | 8 (9.9) | 10 (10.8) |
| Transportation to ED | | |
| Taxicab | 10 (12.1) | 5 (5.3) |
| Own car | 12 (14.5) | 17 (17.9) |
| Public transportation | 11 (13.3) | 20 (21.1) |
| Walked | 10 (12.1) | 5 (5.3) |
| Friend/family car | 28 (33.7) | 30 (31.6) |
| Ambulance | 11 (13.3) | 18 (19) |
| Symptom duration (h) | | |
| <6 | 15 (18.1) | 24 (25.5) |
| 6-12 | 10 (12.1) | 8 (8.5) |
| 12-24 | 9 (10.8) | 18 (19.2) |
| >24 | 49 (59.0) | 44 (46.8) |
| Type of insurance | | |
| Government-HMO | 28 (34.2) | 43 (45.7) |
| Government/military | 4 (4.9) | 3 (3.2) |
| HMO | 18 (22.0) | 20 (21.3) |
| None | 11 (13.4) | 11 (11.7) |
| Private | 21 (25.6) | 17 (18.1) |

HMO, Health maintenance organization.

are often noncompliant with prescription filling and appointment making.²¹⁻²³ Thomas et al²¹ determined that only 12% of ED patients who had been advised to take a medication had even filled their prescriptions. Similarly, 33% of patients who had been instructed to make a follow-up appointment did not do so.²¹ Although we did not attempt to monitor compliance with medication, we had very few ED relapses among intervention patients. In addition, we were able to reach 89% of intervention patients by telephone at 48 hours, encouraging compliance with appointment making. It is worth noting that complementary study medication may result in a bias toward reduced PCP linkage. Better asthma management might decrease patients' perceived need for routine medical follow-up.

Although we did not perform a detailed cost-benefit analysis, our study intervention is relatively inexpensive. A 5-day course of prednisone is less than \$5 at local outpatient pharmacies. Each study patient received a maximum of \$30 worth of transportation vouchers; 27% were used. Averaging the cost of the transportation vouchers over the whole intervention group provides a reasonable cost estimate of \$8 per patient. Assuming clerical personnel at a salary of \$8 per hour called patients for the 48-hour telephone reminders, we estimate an overall cost of \$2 per patient per telephone call. Therefore, the total cost of this 3-part intervention is estimated to be approximately \$15 per patient.

Although this trial demonstrated success in increasing PCP linkage after an ED visit, it did not assess the impact of this linkage on other important parameters such as

quality of life. The NAEPP guidelines recommend close PCP follow-up after an asthma exacerbation requiring ED care. Patients may derive positive benefits from close follow-up for several reasons. Recidivism among asthmatic patients seen in the ED is common, especially before linkage with a PCP.²² This occurs despite routine prescriptions of short courses of oral corticosteroids on discharge.²²⁻²⁴ Timely PCP intervention might allow for a more prolonged course of steroids after the initial ED visit, when needed.

PCP follow-up after an ED visit also allows the provider to be a more active participant in overall disease

Table 3.

Comparison of patients who followed up with PCP visit versus those who did not.

| Variable | PCP Follow-up (n=68) ±SD No. (%) | No PCP Follow-up (n=110) ±SD No. (%) |
|----------------------------------|---|---|
| Age (y) | 34.5±8.1 | 28.5±7.8 |
| Temperature (°F) | 97.9±1.0 | 98.2±0.9 |
| Pulse (beats/min) | 96.6±16.7 | 94.2±15.8 |
| Respiratory rate (breaths/min) | 21.4±8.4 | 21.2±8.7 |
| Pulse oximetry (%) | 97.0±2.8 | 96.7±2.4 |
| PEFR (L/min) | 241±100 | 248±92 |
| No. times inhaler used past 24 h | 5.3±5.9 | 4.5±5.3 |
| Days work/school missed | 0.8±1.1 | 1.2±3.4 |
| Grade level | 12.6±2.0 | 12.3±2.0 |

PEFR, Peak expiratory flow rate.

Table 4.

Comparison of patients who followed up with PCP visit versus those who did not.

| Variable | PCP Follow-up No. (%) | No PCP Follow-up No. (%) | RR | 95% CI |
|--|-----------------------------|--------------------------------|------|-------------|
| Asthma checkups | | | 0.6 | 0.40, 0.83* |
| Don't go | 24 (35.3) | 60 (58.8) | | |
| Once/y | 11 (16.2) | 8 (7.8) | | |
| Twice/y | 6 (8.8) | 12 (11.8) | | |
| 3-4 times/y | 11 (16.2) | 11 (10.8) | | |
| >4 times/y | 16 (23.5) | 11 (10.8) | | |
| Called physician before coming to ED | 26 (39.4) | 24 (26.7) | 1.4 | 0.96, 2.0 |
| Can get appointment with physician if emergency | 49 (83.1) | 59 (73.7) | 1.4 | 0.81, 2.4 |
| Intervention | 44 (64.7) | 51 (46.4) | 1.6 | 1.1, 2.4 |
| Intubations | 4 (6.2) | 8 (7.6) | 0.87 | 0.38, 2.0 |
| Inhaled steroids | 37 (55.0) | 38 (34.9) | 1.7 | 1.1, 2.4 |
| Oral steroids | 9 (13.6) | 14 (12.8) | 1.04 | 0.60, 1.8 |
| Sex: female | 52 (76.5) | 76 (59.4) | 1.3 | 0.81, 2.0 |
| Ethnicity | | | 0.54 | 0.37, 0.79 |
| Asian | 3 (4.6) | 4 (3.7) | | |
| Black | 48 (73.9) | 98 (89.9) | | |
| Hispanic | 1 (1.5) | 2 (1.8) | | |
| White | 13 (20.0) | 5 (4.6) | | |
| Type of insurance | | | 0.33 | 0.11, 0.96 |
| Government-HMO | 25 (37.3) | 46 (42.2) | | |
| Government/military | 4 (6.0) | 3 (2.7) | | |
| HMO | 20 (29.8) | 18 (16.5) | | |
| None | 3 (4.5) | 19 (17.4) | | |
| Private | 15 (22.4) | 23 (21.1) | | |
| Car access | 37 (54.4) | 58 (52.7) | 1.04 | 0.72, 1.5 |
| Have physician transportation to physician | 63 (92.7) | 69 (62.7) | 4.4 | 1.9, 10.2 |
| Taxicab | 5 (7.4) | 2 (1.8) | 1.4 | 0.94, 1.9 |
| Own car | 23 (33.8) | 25 (22.7) | | |
| Public transportation | 22 (32.4) | 45 (40.9) | | |
| Walked | 9 (13.2) | 21 (19.1) | | |
| Friend/family car | 9 (13.2) | 11 (10.0) | | |

*P<.05.

management. Adjustments in long-term control or maintenance medications can reduce exacerbation symptoms and morbidity from asthma,¹²⁻¹⁴ reducing the need for episodic ED care and improving overall quality of life.¹⁶ These important end points (recidivism and quality of life) should be incorporated into the design of any future studies testing ED interventions.

There are some potential limitations to our study. Enrollment of patients was nonconsecutive. Although the percentage of missed patients was small, and missed patients were found to be similar to included patients, it is not known if this group would have been more or less likely to follow up with PCPs. It was not possible to blind patients to the intervention being tested. However, investigators who verified follow-up, the main outcome, were blinded to group assignment. This intervention was successful in an academic, urban ED but its generalizability to other settings should be tested. We were not able to determine how the taxicab vouchers were used nor could we ensure that the vouchers were used solely for the purpose of transportation to the PCP. We did not use a methodologically rigorous protocol to determine whether relapse had occurred at any institution outside our health care system. Finally, our control and intervention groups had small but unequal numbers of patients in whom we could not verify the presence or absence of PCP follow-up. Reanalysis of our data, assuming that all patients in whom PCP follow-up was uncertain had actually followed up, would not have significantly altered our main results.

Table 5.

Stratified analyses on selected variables affecting follow-up rates.

| Variable | Intervention PCP Follow-up No. (%) | Control PCP Follow-up No. (%) | RR | Summary RR | 95% CI |
|--------------------------|--|-------------------------------------|-----|---------------|-----------|
| Sex | | | | 1.5 | 1.1, 2.2 |
| Female | 32 (48.5) | 20 (32.3) | 1.5 | | |
| Male | 12 (41.4) | 4 (19.1) | 2.2 | | |
| Ethnicity | | | | 1.6 | 1.1, 2.3 |
| Black | 32 (40.5) | 16 (23.9) | 1.7 | | |
| Other | 12 (75.0) | 8 (50.0) | 1.5 | | |
| Type of insurance | | | | 1.5 | 1.1, 2.2 |
| None | 2 (18.2) | 1 (9.1) | 2.0 | | |
| Some | 42 (50.0) | 23 (31.9) | 1.6 | | |
| Have PCP | | | | 1.6 | 1.1, 2.3 |
| Yes | 39 (59.1) | 24 (36.4) | 1.6 | | |
| No | 5 (17.2) | 0 (0) | ND | | |

ND, Not defined.

In summary, we found that a simple 3-part ED intervention, including medication, transportation vouchers, and 48-hour telephone reminders, increased the likelihood that discharged asthmatic patients obtained PCP follow-up. The impact of this enhanced PCP linkage on quality of life, disease management, and ED utilization deserves further study.

Author contributions: JMB, SAS, and RP conceived the study, designed the trial, and obtained research funding. JMB, BI, SR, JD, and JEH supervised the conduct of the trial, subject recruitment, and data collection. JMB, BI, SR, JD, and FSS managed the data including quality control. JMB, FSS, RP, and JEH provided statistical advice, study design, and data analysis. JMB, FSS, BI, and JEH wrote the draft of manuscript. JMB, FSS, SAS, RP, and JEH revised the manuscript. JMB takes responsibility for the paper as a whole.

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