

The value of community pharmacist interventions in improving the healthcare of asthma patients - Asthma Care Improvement Initiative Study (ACII STUDY)*

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Background: Asthma is a significant medical condition in the State of Delaware and throughout the United States resulting in significant morbidity, mortality and healthcare expenditures. Community pharmacists are highly accessible healthcare professionals who may through interactions with their patients significantly improve the quality of care of patients with asthma.

Objective: The purpose of the study is to demonstrate the value community pharmacists can provide to improving healthcare of Asthma patients through the use of a relatively simple, minimally time invasive questionnaire technique to identify patients who are potentially “higher risk” for treatment failure, poor therapeutic outcomes, reduced quality of life and increased healthcare expenditures.

Methods: Patients were attempted to be recruited for participation when receiving new or refill prescriptions for Asthma medications in 3 pharmacy locations. Participating pharmacists in study locations attempted to recruit patients, assess patients using a questionnaire screening device, and follow a process of care corresponding to specific screening result criteria. Patients requiring more advanced training were intended to be referred to a specially trained Certified Asthma Educator Pharmacist.

Results: N/A

Conclusion: N/A

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Background

An estimated 14 to 15 million persons in the United States have asthma (about 5% of the population or one in twenty Americans) and is the most common chronic disease among children, affecting 4.8 million (6.9%). Minorities, particularly those in the inner city, share a disproportionate burden of the disease. African Americans have a 19% higher incidence of asthma than whites and are twice as likely to be hospitalized. Approximately 9.3 million visits annually to office-based physicians result in a principal diagnosis of asthma.

Asthma continues to be a significant cause of absenteeism from school in children, with over 10 million school days missed in 1990. This resulted in an estimated cost of \$900 million lost to parents from staying home to care for their children. Healthcare costs for asthma care have been estimated at more than \$6 billion a year. For all physician visits, asthma was the sixth most frequently reported principal diagnosis and the 11th most frequent diagnosis in emergency departments, with 1.9 million emergency room (ER) visits.

Asthma morbidity and mortality has been steadily increasing despite the availability of effective medications and with these increases the cost of asthma has been steadily increasing as well, from an estimated at \$6.2 billion dollars in 1990 to more recently, in 1998, estimated at 11.3 billion dollars.^{1,2} These figures represent a 182% increase over a time period of 8 years. Based on the NIH Asthma Fact Sheet published in 1999¹, by the NIH, Asthma has been attributed with the following asthma morbidity and mortality statistics throughout the United States:

- 500,000 hospitalizations
- 1.8 million emergency room visits

- 6500 deaths
- 9 million lost workdays
- 10 million lost school days
- 3.6 billion dollar expended due to hospitalizations

Asthma is also a disease with physical symptoms that can impair a person's functioning to the point of interfering with work and social activities.³ According to the Asthma in America survey, almost half of persons with asthma (48%) say their asthma limits their ability to take part in sports or recreation; more than a third (36%) say it limits their normal physical exertion; many say it limits them in their lifestyle (31 %) or social activities (25%).

The value of pharmacist interventions in the treatment of Asthma has been studied previously by several investigators. In 1993, 75 patients were followed for a period of 24 months and compared to the 12 months prior to the study. The impact of pharmacist interventions with the asthmatic patients demonstrated a 66% reduction in ER visits, 83% reduction in 24 hour ER holding, 48% reduction in hospitalizations, and 54% reductions in hospital length of stay.²

In 1995, pharmacist interventions demonstrated a dramatic impact in improved care of asthmatic patients.⁴ Fifty-five patients who frequented the ER over the previous two-year period were enrolled in a pharmacist intervention program that involved a one-hour education prior to discharge with follow-ups at a clinic. Before the interventions the mean number of ED visits per patient for the previous two years was 4.4 ± 2.7 and after the intervention, 2.6 ± 2.6 ($p < 0.01$) while the control group showed no difference in the number of ED visits. After the pharmacist intervention, the mean number of hospitalizations decreased significantly in the treatment group.

A pharmacist-managed, physician directed program examined the effect of pharmacist interventions resulting in a reduction in the number of ED visits during a six-month study period in 25 asthmatic patients was reduced from 47 to 6 compared to the same 6 month period from the previous year.⁵ As illustrated in this study, a collaborative relationship between the physician and the pharmacists is essential for the long-term asthma control involving proper and adequate assessment and monitoring, pharmacologic therapy, control of factors contributing to asthma, and patient education.

Study Rationale

In the State of Delaware, while there are no individual statistics for the incidence, morbidity, and costs of Asthma, it has been assumed by some investigators that Delaware would have a proportional representation of the national figures above based on the population of the state. Through the use of this assumption, Delaware would have approximately 60,000 patients with Asthma. These patients based on calculations of NIH national statistics above would therefore represent a total expense of \$4.9 million dollars within the state. This total expense would include expenditures for estimated 2,200 hospital admissions and 7,900 emergency room visits attributed to the improper management and treatment of the disease.

The State of Delaware specifically has identified Asthma and its spiraling costs, as a target for the development of new and innovative programs for state employees and state Medicaid recipients, designed to improve treatment, improve outcomes and reduce overall expenditures attributed to morbidity and mortality of the disease. Through initial discussions with the state and the concurrent initiation of a broad based clinical based pharmacy services within Happy Harry's, with the specific goal of improving patient therapeutic outcomes and reducing overall healthcare expenditures, the Asthma Care Improvement Initiative (ACII) was developed.

Study Overview

Happy Harry's designed a demonstration project to investigate the treatment patterns, healthcare resource utilization, and costs in patients with asthma before and after a pharmacist initiated

educational intervention at four sites throughout Delaware. The analysis was a 2-year study in a northeast managed care group.

ACII design was to identify patients receiving Asthma medications from four Happy Harry's Pharmacy locations, who were determined to be in need of counseling, education, training, monitoring or referral to a physician in order to improve the management of their condition, improve therapeutic outcomes, improve their quality of life and reduce the overall expense to the healthcare system for the treatment of that individual patient's disease state. ACII attempted to demonstrate the value pharmacists can provide to improving; healthcare of Asthma patients through the use of a relatively simple, minimally time invasive questionnaire technique to identify patients who are at potentially "higher risk" for treatment failure, poor therapeutic outcomes, reduced quality of life, and increased healthcare expenditures required for management of their disease state. As well, the study attempted to document the potential value of disease state management and education services provided by specially trained pharmacists in Asthma care, as demonstrated by a reduction in patient emergency room visits, hospitalizations, and overall expenditures on healthcare.

Objectives

- 1) To demonstrate effective 'high risk' patient identification through pharmacist questionnaire screening.
- 2) To demonstrate that community pharmacists and advanced practice pharmacists can provide effective counseling, training, education, and monitoring for patients identified with a need for such programs in conjunction with regular daily practice responsibilities in a community pharmacy.
- 3) To demonstrate improved outcomes and patient care through pharmacist collaborative practice with physicians and specialists.
- 4) To describe the asthmatic patient population of Delaware covered on state employee benefit plan.
- 5) To determine treatment patterns of project participants enrolled with a state employee benefit plan before and after pharmacist intervention.
- 6) To determine the healthcare resource utilization and cost for asthma patients in Delaware enrolled in a state employee benefit plan before and after pharmacist intervention.
- 7) To reduce the overall number of ER visits, hospitalizations, and overall healthcare expenditure for patients for patients in the program.
- 8) To improve the quality of life of patients identified in the program.

METHODS

Study population

Patients were identified at a participating site when obtaining a prescription for an asthma medication meeting the following criteria:

- Patients were required be insured through state employee benefits program
- Patients were required to be at least 18 years of age or have parental consent if less than 12 years of age

Procedures

Patients meeting all inclusion criteria had a screening questionnaire attached to their prescription bag. Upon receipt of the prescription, the pharmacist approached the patient or caregiver to inform them of the study and their possible participation.

- If the patient did not want to participate, a notation was made in their record so they were not approached again for participation.

- A log of the date, patient code, and pharmacist's initials was kept for all patients choosing not to participate
- If the patient desired to participate, informed consents and HIPAA documents were signed

If patients were enrolled they were presented with a questionnaire for completion. Based on pre-determined study criteria, the pharmacist will assess the questionnaire and classify the patient into one of the following two groups:

- **Non-intervention Group** - patient was classified as doing well utilizing present therapy - no indication for further action by the pharmacist
 - upon refill, the patient or caregiver was provided with an assessment questionnaire at intervals no more frequently than monthly
 - The questionnaires were intended to be assessed at least quarterly by the community pharmacist to determine if the patient needs to be reclassified

- **Intervention Group** - patient has been identified through pharmacist assessment as requiring a specific intervention:
 - Requiring additional training, counseling, education or reinforcement of basic concepts on their medication or treatment regimens provided by a pharmacist
 - Pharmacist provided additional training, education, or counseling and address specific issues identified through the questionnaire
 - Requiring significant education and/or training and disease state management by an advanced practice pharmacist who has completed a certificate training program in Asthma education
 - Patient was to be contacted by a clinical care pharmacist to arrange for follow-up education and training sessions.
 - Training, education, and monitoring will be through predetermined protocols
 - Requiring immediate referral to a participating ACII Asthma care program physician specialist or immediate care with patient's own specialist.
 - Pharmacist would recommend a patient visit with a specialist coordinated through the clinical care pharmacists.
 - Requiring immediate urgent or emergency medical attention.
 - Pharmacist would refer patient to a facility that provides emergency medical attention.
 - The clinical care pharmacists would follow-up within seven days to document the outcome of the intervention

All information for each subject was to be faxed to one location and entered into software for compilation and analysis. All documentation was reviewed for completeness and accuracy by a clinical care pharmacist and all discrepancies were resolved. All information was also to be forwarded to the patient's primary care physician and specialist and well as to the primary medical director of the study. Patient adherence data from the patient's prescription profile record was also to be forwarded to the primary care physician, specialist, and primary medical director. All recommendation follow-up to the specialist or primary care physician was to be conducted by a clinical care pharmacist to determine if recommendations were accepted and implemented. If recommendations were not accepted, attempts were to be made to as to why the recommendations were not accepted and forwarded to the medical director for analysis into one of the following:

- Medical director agrees with recommendation made by pharmacist and deems the recommendation to have been clinically significant

- Medical director agrees with patient's specialist that recommendation made by pharmacist was not relative or clinically important to the patient's care
- Medical director does not agree with either pharmacist or physician recommendations regarding this individual patient.

Study Database

1. Patients were to be identified on a site level through the fill or refill of an asthma medication prescription
2. The date of the first prescription fill or refill within the Intake period will be defined at the Index Date
3. Eligibility must be continuous for 1 year preceding the Index Date
4. Patients were to be excluded if they have less than 12 months eligibility pre-Index Date and 12 months post-Index Date
5. Patients were intended to be followed longitudinally to the end of eligibility or to the end of data availability. This data stream will be used to determine treatment patterns for asthma, healthcare resource utilization, and cost.
6. Treatment and treatment frequency patterns were to include:
 - a. Medication
 - b. Medical procedure
 - c. Laboratory tests
7. The frequency distribution of doses

8. Attributable healthcare resource utilization for asthma was to be presented as percentage of patients with:
 - a. Office visit
 - b. ER visit
 - c. Hospitalizations
 - d. Other facility (clinic) or specialist

9. Attributable healthcare resource cost for asthma was to be presented as percentage of patients with:
 - a. Office visit
 - b. ER visit
 - c. Hospitalizations
 - d. Other facility (clinic) or specialist

10. Healthcare resource utilization over follow-up in patients was to be determined for:
 - a. Office visits
 - b. Pharmacy scripts
 - c. Medical procedures
 - d. Laboratory tests
 - e. Outpatient/ER facility uses
 - f. Hospitalizations

11. Costs of healthcare resource utilization over follow-up in patients with asthma was to be determined for:
 - a. Office visits
 - b. Pharmacy scripts
 - c. Medical procedures
 - d. Laboratory tests

- e. Outpatient/ER facility uses
- f. Hospitalizations

Data Analysis

Descriptive statistics was to include means (\pm standard deviation [SD]) and relative frequencies for continuous and categorical data, respectively. Statistical comparisons within the pre- and post- data cohort were to incorporate the use of a multivariate regression model(s) to determine statistically significant differences in outcomes. If found appropriate by both HealthCore and Happy Harry's, the second stage was to incorporate the use of a multivariable regression model(s) to determine statistical significant differences in outcomes.

Resource Utilization Counts and Unequal Observation Time

The duration of observation post-index will not be uniform for all patients secondary to plan uptake and attrition. For service utilization counts, normalization will be achieved by appropriately dividing the sum of each individual's time of observation. These crude incident densities will be compared as crude rate ratios (e.g office visits per 10 patients per month); and 95% confidence intervals will be constructed by using the Exact method. If rate ratios based on multiple explanatory variables is desired, negative binomial regression" will be employed. For all analyses, an a priori two-tailed level of significance will be set at the 0.05 level.

RESULTS

No results were able to be attained for this study.

CONCLUSION

No conclusion could be drawn for this study.

DISCUSSION

During the course of the study only twelve patients were successfully enrolled in the study. Initial screening assessments were conducted and one additional follow-up was achieved. For this extremely limited population all patients were classified into the first intervention group and provided with education, counseling and a peak flow meter. All of the study subjects enrolled failed to complete the study and were lost to follow-up, thus leaving no results to report.

The ACII study, while based on a viable premise, had many limitations which included the investigator resources, study design, study conduction and retention of subjects. The first major difficulty encountered in this study was pulling the various resources together in order to conduct the study. Because of the difficulty we experienced in preparing materials for IRB submission and in the recruiting of a physician to serve as a medical director we found it necessary to contract with Healthcore, a health outcomes research organization. The level of expertise provided by our contracted partners enabled the investigators to be building the final study design in scientifically correct terms and successfully navigate the IRB submission process.

The next major limitation was obtaining the permission from the State of Delaware Employee Benefits Committee for the use of individuals covered under their health plan as potential study participants. This challenge was unforeseen when the study design was conceived. It was originally intended that correspondence about the study would be made available to the employees in the designated study geographic areas, however, in the end we were only permitted to advertise the study within the study pharmacies on a patient by patient basis.

An additional limitation experienced which significantly impacted the study was unpredictable and unforeseen changes in pharmacist staffing in our IRB approved study locations. The personnel changes were so significant that one of the IRB approved locations was unable to participate, since the new personnel at the site were unwilling and incapable of serving as study pharmacists. This reduction in study sites provided a significant limiting factor in recruitment of potential participants.

Another limitation was the impact of mail order pharmacy on enrolling potential study participants. The basis of our study design was centered on targeting employees and dependents covered under the State of Delaware Employee Benefits Plan, when they filled their asthma medications at one of our retail study locations. Administrator incentives which occurred during the study period which encouraged patients to utilize the mail order prescription service led to the community pharmacy dispensing of maintenance medications including asthma medication to decrease. This reduction in prescription volume provided additional limitations on potential study participant enrollment.

The three study sites which did initiate the study and attempted to enroll patients found it extremely difficult to effectively target the correct patients for potential study participation. When patients were potentially identified by coverage in the specified PBM, more often than not the patients did not meet the inclusion criteria. In addition, because the enrollment required an intervention at the point of dispensing and that all pharmacists at the study locations were not participating in the program, due to unforeseen personnel changes, opportunities were missed for recruitment of patients. If given the opportunity to outreach to individual patients through a mailing or other mechanism, post-retrospective data analysis of pharmacy data, study participation most likely would have increased.

The follow-up of patients was also extremely difficult due to the many limitations of the study. When study investigators were able enroll a patient we found it next to impossible to retain participants for the study term. The lack of incentives for participation significantly contributed to the unwillingness to continue with the study.

The ACII study provided us with insight on providing this type of community research. First, that the capabilities and resources of most community pharmacies are not sufficient to support this type of research project. The contracting with parties who could provide study support and assistance, the procurement of a medical director at a higher expense than anticipated, the expense of supplies, and the significant time expenditure by investigators brought the realization to us that partnering with those who can provide support while conserving monetary resources is highly advisable. As we discovered, it is highly advisable to partner with academic institution or investigators with significant research experience who have a desire to perform practice based research in community pharmacies. In this design, researchers can effectively design and implement the study, obtain IRB approval and contribute material resources to the project that may be presently available. In addition while intentionally limiting our study population to a very specific population may have resulted in the inability to successfully recruit patients for completion in the study. Lastly, while personnel changes can not be foreseen, contingency plans should be developed in the event that changes occur.

The screening tools and process of care are based on sound clinical practice and may be of use to the pharmacist in the community setting. While the ACII study failed to prove that the pharmacist interventions may have impact, pharmacists desiring to elevate their practice may find the methods and materials designed for the study to be useful. Further research should be conducted to establish the value of community pharmacist based interventions on patients with this chronic condition which results in high rates of morbidity and mortality and excessive healthcare resources in the U.S.

References:

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