Evaluation of Student Pharmacist and Pharmacist Impact on Disease State Management and Patient Satisfaction in Adult Patients with Asthma

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Introduction

Asthma is a chronic disease state involving inflammation of the airways in the lungs and affects over 18.9 million adults and 7.1 million children living in the United States today. This condition involves reversible obstruction of respiratory airways, restricting airflow to the lungs, which can result in episodes of coughing, wheezing, chest tightness and shortness of breath. These episodes are commonly referred to as “asthma attacks.” Episodes such as these can be brought on by various triggers, for instance, dust, cold air, pollen, and respiratory infections. While there is no cure for asthma, the ultimate goal of treatment is to gain and maintain control of symptoms in order to improve the patient’s quality of life.

Being that asthma is a chronic disease state that affects millions of people nationwide, finding medications that can adequately control the symptoms of the condition is very important. Among the many medication classes currently used to treat asthma in both children and adults are long and short-acting beta-2 adrenergic agonists, inhaled corticosteroids, and leukotriene inhibitors, in addition to a variety of combination products. In many asthma cases, patients must utilize a combination of multiple inhalers, nebulizer devices, and sometimes even the addition of oral medications to adequately control their disease state; however, the mainstay for treatment in all stages of asthma is inhaled medications. In further exploring the treatment and self-management of asthma, many studies have supported that the two most common reasons for inadequate control of the condition are non-compliance with medication regimens and poor technique with utilizing inhaled medications. There is a possibility that patients who do not use their inhalers correctly, and thus do not obtain complete control of their symptoms, may as a result have poor medication compliance. This study sought to investigate this potential correlation and the impact that student pharmacist and pharmacist intervention can have.

Inhalers used in the treatment of asthma can be both complicated and difficult to use, providing an opportunity for community student pharmacists and pharmacists to intervene and assist patients in utilizing the proper inhalation techniques to receive the most benefit from their inhaled medication. Through an exhaustive literature review on asthma control and adherence, it was found that the vast majority of studies conducted have focused on the effects of pharmacist intervention on the self-management of asthma. The studies ultimately showed that when comparing a group of patients that were counseled by pharmacists on their asthma medications and devices to a group of patients treated with usual care, the pharmacist-counseled group would have better control of their condition and better adherence to their medications. A review of twenty five published studies on pharmacist involvement in asthma treatment showed substantial benefits of including a pharmacist in the care of asthma, with half of the studies showing improvements in asthma severity upon pharmacist intervention and seventy five percent of the studies finding improvements in healthcare utilization.
While a positive correlation has been shown between pharmacist education and proper inhalation technique, there have been no longitudinal studies that evaluate the pharmacist’s impact on disease state control and patient satisfaction. While it is assumed that student pharmacists can play a similar role in improving patient outcomes in those with asthma through education about the disease and counseling on appropriate inhaler usage, no studies to date specifically measure the effect of student pharmacist-provided education on a patient’s asthma control. This study evaluated the utilization of student pharmacists in this area of practice and how they can contribute to research and community-based clinical services. The purpose of this study is to evaluate the impact that student pharmacists, under pharmacist supervision, can have on patient satisfaction and disease state control in adult patients diagnosed with asthma.

**Methods**

*Patient Recruitment*

The patient population for this study consisted of adults between the ages of 18-65 years who had been prescribed any type of prescription inhaler medication (rescue or maintenance) for asthma treatment. Patients were excluded from the study if they fell outside the required age range, had a diagnosis of exercise-induced asthma or other respiratory disorder such as chronic obstructive pulmonary disease, or were diagnosed with asthma but only prescribed an oral tablet medication. This study exclusively dealt with asthmatic patients since the validated instruments used were specifically designed to address asthma control and severity. It was a necessity for all patients enrolled in the study to have at least one inhaled medication for asthma since inhaler usage technique was measured throughout the study. The study was conducted using a six-month rolling enrollment of participants as they were identified, met the appropriate inclusion criteria, and were interested in participating. Multiple recruitment sites and strategies were employed to gain patient interest in the study as described in the next sections.

*Site Selection*

Participants of this study were recruited from five locations encompassing three separate entities: three locations of a regional chain grocery store pharmacy, one location of an independent chain pharmacy, and on the primary researcher’s university campus. The community pharmacy locations, both chain and independent, were selected for study inclusion for several reasons. First, the participating pharmacies had the availability of a clinical, non-dispensing pharmacist present to supervise the students in data collection. Second, these stores were chosen due to the consistency of student pharmacists available at these locations. The pharmacy sites were also selected due to their proximity in geographic location, their similarities in patient demographics of patients with private health insurance, and their general interest in participation. As a way to help increase enrollment, recruitment also occurred on the primary researcher’s college campus to allow for faculty, staff, and student participation.

*Study Recruitment*

At the pharmacy locations, a table was set up next to the pharmacy with a sign offering free spirometry screenings to any potential participant who met study inclusion criteria. Flyers were placed at both the drop-off and pick-up counter as a way to advertise the study. These same flyers were utilized as “bag stuffers” placed in prescription bags at the pharmacy locations. For recruitment at the university level, flyers were placed in lecture halls, student unions, parking garages, and campus athletic facilities in an attempt to gain additional interest from university
personnel and students. Interested patients from any location could call the clinical, non-dispensing pharmacist to schedule an appointment to determine their eligibility for study enrollment. As a way to incentivize patients to participate in the study, an Apple® iPad Mini was raffled off to those enrollees completing the study in its entirety.

**Instruments**
This study incorporated many different types of interventions so as to gauge each patient’s inhaler technique and disease state control. The following sections describe the instruments utilized in this study.

**Asthma Control Test**
The Asthma Control Test (ACT), a validated, five-question survey for patients 12 years of age and older, was used to determine control of each patient’s asthma. The ACT is recognized by the National Institutes of Health in its 2007 asthma guidelines, *Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma* (EPR-3 2007). The survey was completed by the patient with assistance from the student pharmacist if needed. Following completion, the student pharmacist discussed results of the survey with the patient. Scores less than or equal to 19 out of a possible 25 points indicated uncontrolled asthma.

**Asthma Control Satisfaction Surveys**
Pre and post-study asthma control satisfaction surveys were designed by the study investigators as a way to determine the patient’s satisfaction with their level of asthma control, a factor not captured in the ACT. The same survey, given at both the first and last intervention, used a seven point scale to assess the patient’s agreement with several statements regarding their inhaler use and asthma control. The pre-study asthma control satisfaction survey was completed by the patient during the first face-to-face encounter with the student pharmacist and pharmacist. Information for the post-study asthma control satisfaction survey was collected by a phone call from a student pharmacist at the completion of the study. A sample of this survey can be seen in Figure 1.

**Inhaler Technique Checklists**
Inhaler technique checklists made by the researchers specific to each prescription inhaler type were utilized during patient demonstration of inhaler usage in order to assess and “score” the patient’s inhaler utilization technique prior to education from the student pharmacist and pharmacist. Proper inhaler technique is crucial to ensure that medication reaches the lungs and is effective. With improper technique, fully prescribed doses may not be received, and thus, asthma not controlled. In order to understand the patient’s current inhaler technique, the student pharmacist observed and documented the patient’s demonstrated use of their inhaler. Once assigning the patient a score of their inhaler technique using the checklist, the student pharmacist then demonstrated the appropriate technique specific to the patient’s inhaler type. This same checklist was used at two face-to-face interventions to assess patient baseline inhaler technique (first intervention), and then to assess patient recollection of student pharmacist inhaler technique education one month later (second intervention). See Figure 2 for a sample inhaler technique checklist utilized in this study.

**Spirometry Screening**
Spirometry is a test employed in those with asthma to measure pulmonary function. It measures how much and how quickly air can be moved out of the lungs. This test measures FEV\textsubscript{1}, FVC, and FEV\textsubscript{1}/FVC, which are referred to as the pulmonary function tests (PFTs). FEV\textsubscript{1}, or forced expiratory volume at one second, is a measurement of the maximal amount of air that can be exhaled with force in one second. FVC, or forced vital capacity, is a measurement of the amount of air that can be exhaled with force after a full and deep inhalation. These measurements are based upon the patient’s age, height, ethnicity, and gender. They are expressed as a percentage of the patient’s expected value. Values less than 80% of that particular patient’s predicted value are considered abnormal. In asthmatics, FEV\textsubscript{1} and FEV\textsubscript{1}/FVC are typically lower than the predicted value and FVC is typically normal or lower than the predicted value. This study was designed to capture two spirometry readings for each enrolled patient in order for the student pharmacist and pharmacist to gauge lung function and disease state severity. Potential improvements seen in spirometry results may impact inhaler adherence and patient satisfaction with disease control as patients notice an objective improvement as a result of using their inhaler correctly. Student pharmacists, overseen by a pharmacist, were responsible for screening study patients. The spirometer used in this study was an OHD KoKo Spirometer\textregistered available through the university’s school of pharmacy.

**Interventions**

Study enrollment and initial intervention appointments took place at each pharmacy location for three hours in the afternoon one day per week for six months. Appointments were scheduled at the university location as needed. A total of three interventions occurred throughout this study: two face-to-face interventions and one telephonic follow-up. Figure 3 illustrates the steps that occurred at each intervention, which are described in detail below.

The initial intervention consisted of a face-to-face interaction between the patient and the student pharmacist and supervising pharmacist. At this appointment, asthma inhaler technique was assessed using the aforementioned inhaler technique checklist, followed by counseling on appropriate inhaler use and technique demonstration by the student pharmacist. The ACT and pre-study asthma control satisfaction survey was provided to the patient to complete during the visit. The student pharmacist then discussed the results of both surveys with the patient, addressing any questions or concerns they had. Spirometry testing was completed next, followed by documentation of specific lung function measurements obtained from spirometry such as FVC, FEV\textsubscript{1}, and FEV\textsubscript{1}/FVC. At the conclusion of the initial intervention appointment, the patient was scheduled for a face-to-face follow-up appointment in one month at either the university or one of the four participating pharmacy locations.

Follow-up appointments were conducted for each patient one month after their initial baseline appointment. At this face-to-face visit, asthma inhaler technique was re-evaluated using the inhaler technique checklist, spirometry testing was again completed, and patient counseling and education on asthma, inhaler technique, and proper inhaler usage was completed as needed.

Final follow-up interventions were conducted by the student pharmacists via telephone six months from the date of the first intervention. Through this phone call, the ACT was administered by the student pharmacist and results were discussed with the patient. The student
pharmacist also addressed any remaining questions that the patient may have had. Lastly, the post-study asthma control satisfaction survey was administered by the student pharmacist.

**Student Involvement**

Student pharmacists on advanced pharmacy practice experience (APPE) rotations were involved in performing the data collection and counseling aspects of this study which included: assisting the patients in completing all intake forms and surveys, performing the spirometry testing, scoring patients on inhaler technique using the provided checklist, conducting post-survey follow-up phone calls, and counseling patients on their survey, technique, and spirometry results under pharmacist supervision. Additionally, students aided in patient recruitment by identifying patients through their normal interactions at the pharmacy sites and hanging flyers at the study locations. These students were trained by a school of pharmacy faculty member through a half-day training session at the university prior to their APPE rotation at one of the study locations. The training session consisted of an asthma disease state review, inhaler technique review for all inhaler types, spirometry training with the OHD KoKo Spirometer®, and training on all forms and documentation utilized in the study (ACT, patient satisfaction survey, informed consent).

This study was conducted in compliance with the university’s Institutional Review Board committee requirements and an informed consent was obtained from each participant prior to any intervention.

**Results**

After six months of active recruitment, a total of 12 patients met study criteria and enrolled in the study. Seven of the 12 patients were recruited from the pharmacy chain locations, one from the independent pharmacy study location, and four from the university campus. Of these 12 patients, six completed the study in its entirety by participating in all three interventions (50%). All metrics, measurements, and survey questions were evaluated using a repeat-measures ANOVA test in SPSS v. 16.0. A baseline level was measured against clinical findings to assess a difference post-intervention. An alpha of 0.05 was used to determine statistical significance. It was determined that 20 patients were needed to treat to reach a power of 80%. This number was determined a priori using GPower v. 3.0.10. An intention to treat methodology was used since the study was a pilot; a true difference between baseline and post-intervention was desired.

As mentioned previously, an OHD KoKo Spirometer® was used to assess each patient’s FEV₁, FVC, and FEV₁/FVC. An average FEV₁/FVC of 0.85 was seen at baseline compared to 0.84 post-intervention. An average ACT score of 19.8 (out of 25; average 79.2% controlled) was noted at baseline, with 22.2 (average 88.8% controlled) post-intervention. In composite, all metrics seen in the ACT and satisfaction surveys saw an increase in terms of patient confidence and satisfaction with asthma control. Please refer to tables 1 and 2 which depict these results.

**Discussion**

This study showed important findings in terms of the efficacy of student pharmacists in patient disease state intervention in an ambulatory setting. While not enough patients completed the study to show true statistical significance, improvements in all measured areas were noted. These included improved patient satisfaction with disease state control, improved ACT scores, and improved pulmonary function tests. Students were able to adequately educate patients on the
disease state of asthma which led to these improvements. Previous study findings have shown that when patients better understand their asthma and how to use their inhaled medications, adherence and disease state management will improve.[5]

Another important finding was the improvement in patient asthma inhaler technique. While studies have previously shown improvement in patient inhaler technique following pharmacist education, the counseling in this study was provided by student pharmacists with pharmacist oversight. This is an important finding since student pharmacists that practice in the community setting can assist pharmacists in expanding the various types of clinical services offered to patients. If the study were to be conducted over a greater period of time, it can be assumed that patients would show statistically significant improvements in inhaler technique. Spirometry results would also reflect this change in proper inhaler technique. It is difficult to note dramatic changes in FEV$_1$, FVC, and FEV$_1$/FVC over a short period of time. Similar to proper inhaler technique, if the patient were to be re-assessed at six months and one year, improvement in lung function could be seen. Overall, the results did not show statistical significance in all parameters of the study, but positive trends in all aspects prove clinical significance.

**Limitations**
The most significant study barriers were patient enrollment and study completion. It was difficult to find patients who met the enrollment criteria and were willing to participate, and even more difficult to not lose enrolled patients to follow-up. Due to the funding source of this study, recruitment was stopped at six months which contributed to the inability to obtain more than 12 patients. The time commitment associated with multiple interventions caused some patients to drop out of the study prematurely. This patient fatigue led to a smaller sample size which could have impacted the analysis of results obtained from the study. As noted in the results section, this number was insufficient to show statistical significance; however, the study was still conducted as the researchers felt that this intervention was important in the treatment of adult patients with asthma. Furthermore, this served as a valuable learning experience for APPE students in recruiting and conducting pharmacy clinical services in the community setting.

**Conclusion and Next Steps**
Pharmacists are accessible healthcare professionals who are able to provide clinical preventive services. Whether it be measuring a patient’s blood pressure or checking cholesterol levels, pharmacists are attempting to play a larger role in assisting patients and other practitioners with patient preventive health. Spirometry testing for measuring pulmonary function is just one of the many screenings that can be offered by pharmacists in the community and ambulatory settings. Pharmacists also provide many other services to patients including immunization administration, blood pressure measurement, cholesterol screening, and medication therapy management services. Spirometry is an easy to use ambulatory test pharmacists can utilize to help patients understand how well their asthma is controlled. This service, coupled with medication counseling, would be highly beneficial in regards to patient adherence and disease state control.

This study showed the ease with which student pharmacists on APPE rotations can be utilized to help implement these types of preventive services. Future studies should further investigate the impact of student pharmacists on patient health outcomes. Larger studies that incorporate a
control and intervention group should be conducted to further validate the findings of this pilot project.

Acknowledgements: The authors wish to acknowledge the following students at the time that the study was conducted for their help in study design and data collection: Ashley Kearney, Amanda Liszewski, Courtney Lynch, Lanette Sipple, and Alexis Spina. The authors also wish to acknowledge the Pennsylvania Pharmacists Association Educational Foundation whose grant funded this study.

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