CEDARVILLE UNIVERSITY

Excerpts in Pharmacy Research Journal

Volume 2
Number 1 *Fall 2016*

Article 4

2016

# Implementation of an Outpatient, Pharmacist-Directed Clinic for Chronic Obstructive Pulmonary Disease

Heather N. Folz
*Notre Dame of Maryland University*, hnfolz0707@email.campbell.edu

Bethany L. Murphy
*Union University School of Pharmacy*, bmurphy@uu.edu

# Implementation of an Outpatient, Pharmacist-Directed Clinic for Chronic Obstructive Pulmonary Disease



**Abstract**

**Objective:** To describe development and challenges of implementing a pharmacist-led chronic obstructive pulmonary disease (COPD) clinic in the primary care setting.

**Methods**: Starting in October 2014, patients scoring 10-30 on the COPD Assessment Test (CAT) were assigned to the intervention or control group. Intervention patients met with a pharmacist, who provided medication and lifestyle counseling and therapy recommendations to the patients' primary provider per protocol. Control patients were encouraged to make an appointment with their primary provider for standard care. Two months following the initial CAT administration, the survey was administered again to both study groups by phone. The primary outcome was a comparison of change in CAT scores from baseline between the groups. Secondary outcomes included an analysis of medications, smoking status, vaccination status, hospital stays, visit attendance, and self-evaluation of disease progression.

**Results**: Of the 163 patients contacted, 29 were enrolled. Ninety-one percent of the patients screened with the CAT were eligible based on the CAT requirement with an average baseline CAT score of 18.75. The primary outcome, change in follow up CAT scores, were similar for intervention patients (n=18) versus control patients (n=11), +0.8 versus +0.7 respectively. Four of the intervention patients attended their clinic visit resulting in a 22% show rate.

**Conclusion**: Although our study was underpowered to detect between group differences, the elevated baseline CAT scores support the need for therapy optimization in patients with COPD. Pharmacists are well qualified to meet this need by providing medication counseling, smoking cessation, and therapy management. Additional randomized controlled studies are needed to support improved outcomes for patients with COPD when pharmacists are part of the clinical patient care team.

**Keywords**

Pharmacist intervention study, chronic obstructive pulmonary disease, COPD Assessment Test (CAT), primary care

# Implementation of an Outpatient, Pharmacist-Directed Clinic for Chronic Obstructive Pulmonary Disease

Heather N. Folz, PharmD
*Assistant Professor of Pharmacy Practice, School of Pharmacy, Notre Dame of Maryland*
Bethany L. Murphy, PharmD, BCACP, BC-ADM
*Assistant Professor of Pharmacy Practice, School of Pharmacy, Union University*

## Abstract

**Objective:** To describe development and challenges of implementing a pharmacist-led chronic obstructive pulmonary disease (COPD) clinic in the primary care setting.

**Methods**: Starting in October 2014, patients scoring 10-30 on the COPD Assessment Test (CAT) were assigned to the intervention or control group. Intervention patients met with a pharmacist, who provided medication and lifestyle counseling and therapy recommendations to the patients' primary provider per protocol. Control patients were encouraged to make an appointment with their primary provider for standard care. Two months following the initial CAT administration, the survey was administered again to both study groups by phone. The primary outcome was a comparison of change in CAT scores from baseline between the groups. Secondary outcomes included an analysis of medications, smoking status, vaccination status, hospital stays, visit attendance, and self-evaluation of disease progression.

**Results**: Of the 163 patients contacted, 29 were enrolled. Ninety-one percent of the patients screened with the CAT were eligible based on their CAT score with an average baseline score of 18.75. The primary outcome, change in follow up CAT scores, were similar for intervention patients (n=18) versus control patients (n=11), +0.8 versus +0.7 respectively. Four of the intervention patients attended their clinic visit resulting in a 22% show rate.

**Conclusion**: Although our study was underpowered to detect between group differences, the elevated baseline CAT scores support the need for therapy optimization in patients with COPD. Pharmacists are well qualified to meet this need by providing medication counseling, smoking cessation, and therapy management. Additional randomized controlled studies are needed to support improved outcomes for patients with COPD when pharmacists are part of the clinical patient care team.

## Introduction

As the third leading cause of death in the United States, the economic burden of chronic obstructive pulmonary disease (COPD) is approximately $50 billion in direct and indirect healthcare costs.[1] This cost is expected to increase as disease progression continues.[1] With hospital stays from COPD exacerbations accounting for the majority of this expense, optimal pharmacotherapy to limit exacerbations is vitally important. Despite the high cost of COPD exacerbations, Make and colleagues' retrospective analysis of over 50,000 patients with either commercial or Medicare insurance found that greater than 66% of privately insured patients and over 70% of the Medicare population with COPD were not prescribed standard maintenance COPD pharmacotherapy.[2] Their analysis found that the majority of patients were not receiving any COPD medications, and merely 5%-7% of patients were prescribed a short-acting β2-agonist, standard of care therapy for all individuals with COPD.[3] This study reveals that as many as 7 out of 10 patients with COPD may benefit from inhaler treatment optimization.

The impact of pharmacist involvement in the management of COPD has been evaluated in several recent studies in community and health-systems settings.[4,5,7-11] In a 2014 community-based study, significant reduction in the use of high-dose steroid therapy, an indicator of an acute exacerbation, was seen with pharmacist-led interventions in patients with asthma and COPD.[4] This study involving over 109,000 patients demonstrated improvements related to inhaler technique, adherence to maintenance therapy, and cessation of suboptimal medications.

Few studies have been conducted that evaluate pharmacist intervention in the primary care setting. With direct access to general practitioners, the ambulatory care setting is especially conducive to the integration of clinical pharmacy services with standard practice. One study in this setting did show improvement in COPD outcomes including hospitalization, adherence, and disease knowledge; however, the study was unable to detect a significant increase in health-related quality of life.[5] A drawback of the study was the utilization of the St. George Respiratory Questionnaire (SGRQ), a 76-item tool used to assess symptoms, activity, and impact.[6] Although this tool is validated and designed for patients with COPD, it is cumbersome and not practical for use by healthcare providers on a routine basis. A 2014 meta-analysis focusing on the impact of pharmacist care for outpatients with COPD yielded similar results. This review by Zhong and colleagues' included 8 randomized controlled trials and supported positive pharmacist impact on medication adherence, hospital admission, and health-related costs.[7]

The aim of our study was to provide much needed data on the impact of clinical pharmacists in the primary care setting using methods that can feasibly be replicated in general practice. The primary evaluation tool used in our study was the COPD Assessment Test (CAT). This 8-question, validated test allows for scores from 0-40 with higher numbers indicating poorer COPD control.[12] The questionnaire is designed to assess symptoms using a 1-5 scoring system that a patient could self-administer. Patients scoring 10-30 on the CAT indicate that they are at a medium to high risk of a COPD exacerbation and were the target population for this study. A 2-point change in CAT score is considered a significant difference.[13,14] The CAT user guide recommends for patients to be routinely screened with the test every 2 to 3 months based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines.[3] Positive trial results would support the expansion of clinical services offered by ambulatory care clinical pharmacists while strengthening collaboration with general practitioners to optimize patient care. Challenges faced in this study were also examined to aid in the implementation and enhancement of future pharmacist-directed, outpatient COPD management clinics.

## Methods

This prospective pilot study was conducted within a private family physician practice with 2 separate clinical sites in West Tennessee. Following institutional review board approval in September of 2014, the clinic's information technology department created a patient call list for study recruitment. The study inclusion criteria required patients to be at least 40 years of age, to have a current diagnosis of COPD based on active ICD-9 codes, and to score 10-30 on the COPD Assessment Test (CAT). Patients were excluded if they were unable to complete the CAT or provide informed consent, non-English speaking, or pregnant. Patients were also excluded if their CAT score was less than 10, indicating a low exacerbation risk, or greater than 30, indicating very high risk.[13] Patients scoring greater than 30 were encouraged to meet with their primary care physician (PCP) for referral to a pulmonary specialist. Nine of the PCPs within the practice signed the study protocol, allowing their patients to be enrolled in the study.

The patient call list contained the names and phone numbers of clinic patients who met the age and diagnosis requirements of the study and had visited their

participating PCP in the last 2 years. These patients were initially administered the CAT by phone from October through November of 2014. A standardized patient phone script was used to recruit patients. Study enrollees were originally assigned in a 1:1 ratio to either the intervention group or control group. The intervention group patients were scheduled to meet with the pharmacy resident for a face-to-face visit at their PCP's clinic location. The control group was encouraged to make an appointment with their PCP for standard care. Due to the low clinic visit show rate in the intervention group, patients were assigned to the intervention group at an increased ratio in the latter half of study recruitment. In both groups, a follow up CAT was to be administered 2 months from the initial CAT.

The intervention visit with the pharmacist followed a standardized protocol that included a COPD staging assessment based on the GOLD guidelines.[3] The visit included a review of relevant medical history, inhaler technique evaluation, smoking cessation counseling, exercise coaching, and immunization recommendations as needed. Pharmacist recommendations to optimize COPD inhaler therapy were discussed with the PCP prior to initiation and followed a standardized protocol. Patients were also provided with an individualized goal sheet and visit summary.

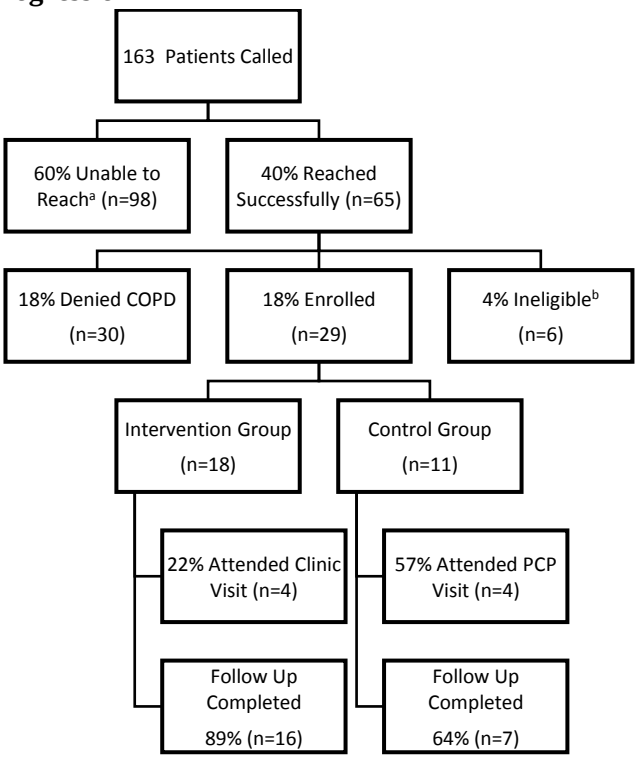
The primary outcome of our study was an intention-to-treat comparison of changes in CAT scores from baseline between the intervention and standard care groups. Secondary outcomes include an analysis of COPD medications, smoking status, vaccination status, hospital stays, clinic visit attendance, and self-evaluation of disease progression.

## Results

Twenty-nine patients were enrolled in the study with 18 and 11 patients assigned to the intervention group and control group respectively (Figure 1). Forty-six percent (n=30) of the patients who were successfully contacted by phone denied a diagnosis of COPD. These patients confirmed lack of current inhaler use or breathing-related health problems. Of the remaining 104 patients called, the majority either had wrong numbers recorded in the clinic's database or were unable to be reached by phone. Three patients were no longer patients of the participating providers. Three patients did not qualify based on their CAT scores of 5, 6, and 31 respectively. The patient with a score greater than 30 was referred to the PCP for evaluation and potential follow up with a pulmonary specialist per the study protocol.

Four of the eighteen patients in the intervention group attended their scheduled pharmacist clinic visit, resulting in a show rate of 22%. Fifty-seven percent of the control group attended an appointment with their PCP in between the initial and follow up CAT. The follow up CAT was completed in 89% (n=16) and 64% (n=7) of the intervention and control group subjects respectively.

**Figure 1. Study Population Recruitment and Progression**




[a]Patients were unable to be reached by phone due to either inaccurate phone numbers or not answering the phone.
[b]Of the 6 ineligible patients, 3 patients had changed primary care providers, and 3 patients were excluded due to CAT scores of 5, 6, and 31.

The average initial CAT score in the intervention group was 20.6 and 16.9 in the control group (Table 1). The 2-month follow up CAT score was 21.4 and 17.6 in the intervention and control groups respectively. The primary outcome, difference in CAT scores from baseline, was an increase of 0.8 in the intervention group versus an increase of 0.7 in the control group. Information collected on secondary outcomes is included in Table 2. Three of the intervention group patients reported that they felt their COPD symptoms had improved two months from the initial CAT versus zero

patients in the control group. The intervention group was comprised of 50% active tobacco users versus 9% in the control group.

| **Table 1.** Comparison of CAT[a] Scores | | |
|---|---|---|
| Average CAT Scores | Intervention Group (SD[b]) | Control Group (SD) |
| Initial | 20.6 (4.3) | 16.9 (4.3) |
| 2-Month Follow Up | 21.6 (6.0) | 17.6 (4.9) |
| Difference | +0.8 (5.5) | +0.7 (2.3) |

[b]SD = standard deviation
[a]CAT = Chronic Obstructive Pulmonary Disease Assessment Test

| **Table 2.** Comparison of Secondary Data Collection | | |
|---|---|---|
| Outcome | Intervention Group (%) N=18 | Control Group (%) N=11 |
| Perceived Change in COPD Control | | |
| Worsened | 4 (22) | 3 (27) |
| Improved | 3 (17) | 0 (0) |
| Same | 11 (61) | 8 (73) |
| Tobacco Cessation During Study | 1 (6) | 0 (0) |
| Medication Change | 4 (22)[a] | 2 (18)[b] |
| Vaccinations Received | 1 (6) | 0 (0) |
| Hospital Stays | 1 (6) | 1 (9) |

[a]Percentages based on intent-to-treat analysis out of the total number of patients enrolled. Patients lost to follow up assessment were included in percent calculations with no change in secondary items.
[b]Medication changes include initiation of 2 albuterol inhalers and 1 tiotropium inhaler
[c]Medication change included initiation of an ipratropium/albuterol combination inhaler and one steroid dose pack

## Discussion

There were several challenges and limitations identified during this study. The primary limitation was our inability to run statistics due to the small sample size. A decrease in the 2-month CAT score of at least 2 points from baseline would have supported the benefit of pharmacist intervention from standard care. In our study, the 2-month CAT scores for both groups increased slightly. Although the significance of this less than 1-point increase cannot be determined, we have identified several potential contributing factors. Firstly, baseline characteristics were dramatically different between groups. For example, 50% of the intervention group reported to be active smokers compared to 9% in the control group. Also, the average initial CAT score in the intervention group was 3.7 points higher than in the control group. Secondly, the subjective nature of the CAT may have led to non-COPD related changes in CAT scores. While these outliers may not impact the integrity of overall CAT scores for a large study population, our small cohort was especially vulnerable to potential confounders. For example, 2 of the intervention patients reported factors such as a heart failure exacerbation and family stress as the causes for the worsening of their COPD symptoms. Lastly, the CAT score did not consistently reflect our patients' perceived change in COPD control. Although 2-month follow up CAT scores did not improve, 3 of the intervention group patients reported improvement in the COPD control while no patients reported improvement in the control group. Perceived COPD control and quality of life are areas for future research.

The main contributor to our limited study size was slow patient enrollment. Patient screening was based on ICD-9 codes to eliminate the initial time lag associated with reliance on provider referral. Although this approach allowed the pharmacist to recruit patients immediately upon study approval, it resulted in a time-consuming recruitment process. Only 40% of the patients called were successfully reached by phone. Of those patients successfully reached, about half denied a diagnosis of COPD. Patients who denied having COPD confirmed that they currently had no difficulty breathing and were not using any type of inhaler therapy. This discrepancy in confirmed diagnosis of COPD and ICD-9 codes was consistent with that seen in a study by Cooke and colleagues.[15] As a solution to reduce this administration error, Cooke's analysis supports using a combination approach such as ICD-9 codes and chart documentation of COPD medication prescriptions. A limitation of this method is that it excludes patients with COPD who are not currently prescribed COPD medications but who may benefit from therapy initiation. A similar limitation would be faced with requiring pulmonary function tests. While greater reliance would be placed on provider support, physician referral to a pharmacist-led COPD clinic would bypass these challenges.

In addition to slow recruitment, clinic visit attendance was low in both study arms. As seen in figure 1, 4 patients in each study group attended a clinic visit during the study. Although reasons for clinic no-shows varied, lack of transportation was reported to be a common barrier to visit attendance. Clinic room space and availability limited flexibility for scheduling appointments as well. Neither of the clinic sites were the pharmacists' main practice sites, limiting flexibility for rescheduling or impromptu appointments. The low show

rate could also indicate low health literacy or inaccurate beliefs regarding disease state severity and the possibility of improved symptoms control. In a cohort by Kale and colleagues, low health literacy was associated with illness beliefs that were determinants for decreased adherence to self-management and COPD medications.[16] These issues again may potentially be mitigated by physician referral to the COPD management service along with scheduling these pharmacist visits in conjunction with provider visits to reduce travel burden.

The high cost of inhaler therapy was an additional barrier identified in our patient population. Patients were reluctant to initiate and adhere to expensive medication therapy. Providers were sometimes hesitant to prescribe these high cost COPD treatments, especially in patients with concomitant health issues and many additional medications. The pharmacist's role in navigating patients through the medication assistance process and consequent impact on patient adherence and provider outlook is a potential avenue for future research.

Lastly, primary care provider support was a key factor in our study. As with all new services, the benefit of the service needs to be effectively communicated to both the patients and their providers. In our experience, the vast majority of providers welcomed pharmacist involvement in spending focused time with their patients to optimize COPD therapy. For future study, utilization of provider support of this service could potentially improve the patient recruitment processes as well as visit attendance.

## Conclusion

The study's sample size was underpowered to apply a statistical analysis for primary and secondary endpoints. However, the study did strongly support the need for optimization of COPD therapy in our patient population with CAT scores in 9 out of 10 patients indicating a medium to high risk of a COPD exacerbation. Our study identified that despite an initial lag time, recruitment by provider referral could provide several benefits. Provider referral could potentially reduce recruitment time, labor, and administrative screening error while increasing patients' perceived value of the service. In addition, coupling pharmacist-led, COPD clinic visits with provider appointments could be an effective method to improve patient show rate. Areas for future COPD study include maximizing provider support, evaluating the pharmacist's role in the medication assistance process, and assessing patient beliefs regarding disease state severity and the possibility of improved symptoms control.

## References


1. Guarascio AJ, Ray SM, Finch CK, et al. The clinical and economic burden of chronic obstructive pulmonary disease in the USA. Clinicoecon Outcomes Res. 2013;5:235-45.
2. Make B, Dutro MP, Paulose-Ram R, et al. Undertreatment of COPD: a retrospective analysis of US managed care and Medicare patients. Int J Chron Obstruct Pulmon Dis. 2012;7:1-9.
3. Global Initiative for Chronic Obstructive Lung Disease: Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (Updated 2015). www.goldcopd.org (Accessed 15 June 2015).
4. Ottenbros S, Teichert M, de Groot R, et al. Pharmacist-led intervention study to improve drug therapy in asthma and COPD patients. Int J Clin Pharm. 2014;36(2):336-44.
5. Jarab AS, Alqudah SG, Khdour M, et al. Impact of pharmaceutical care on health outcomes in patients with COPD. Int J Clin Pharm. 2012;34(1):53-62.
6. Jones PW, Quirk FH, Baveystock CM, Littlejohns P. A self- complete measure of health status for chronic airflow limitation. The St. George's Respiratory Questionnaire. Am Rev Respir Dis. 1992;145:1321–7.
7. Zhong H1, Ni XJ, Cui M, et al. Evaluation of pharmacist care for patients with chronic obstructive pulmonary disease: a systematic review and meta-analysis. Int J Clin Pharm. 2014;36(6):1230-40
8. Van Boven JF, Tommelein E, Boussery K, et al. Improving inhaler adherence in patients with Chronic Obstructive Pulmonary Disease: a cost-effectiveness analysis. Respir Res. 2014;15:66.
9. Khdour MR, Agus AM, Kidney JC, et al. Cost-utility analysis of a pharmacy-led self-management programme for patients with COPD. Int J Clin Pharm. 2011;33(4):665-73.
10. Hämmerlein A, Müller U, Schulz M. Pharmacist-led intervention study to improve inhalation technique in asthma and COPD patients. J Eval Clin Pract. 2011;17(1):61-70.
11. Takemura M, Mitsui K, Ido M, et al. Effect of a network system for providing proper inhalation technique by community pharmacists on clinical

outcomes in COPD patients. Int J Chron Obstruct Pulmon Dis. 2013;8:239-44. Qual Life Res. 2014;23(4):1193-7.

12. Jones PW, Tabberer M, Chen W. Creating scenarios of the impact of COPD and their relationship to COPD assessment test (CATTM) scores. BMC Pulmonary Medicine 2011; 11: 42.
13. Kon SS, Canavan JL, Jones SE, et al. Minimum clinically important difference for the COPD Assessment Test: a prospective analysis. Lancet Respir Med. 2014;2(3):195-203.
14. Jones PW, Bruselle G, Dal Negro RW, et al. Properties of the COPD assessment test in a cross-sectional European study. Eur Respir J 2011; 38: 29-35
15. Cooke CR, Joo MJ, Anderson SM, et al. The validity of using ICD-9 codes and pharmacy records to identify patients with chronic obstructive pulmonary disease. BMC Health Serv Res. 2011;11:37.
16. Kale MS, Federman AD, Krauskopf K, et al. The association of health literacy with illness and medication beliefs among patients with chronic obstructive pulmonary disease.
PLoS One. 2015; 10(4).