Hospital-Based Clinical Pharmacy Services to Improve Ambulatory Management of Chronic Obstructive Pulmonary Disease

Journal of Pharmacy Technology
2017, Vol. 33(1) 8–14
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DOI: 10.1177/8755122516675635
journals.sagepub.com/home/pmt

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Abstract

Background: No systematic evaluations of a comprehensive clinical pharmacy process measures currently exist to determine an optimal ambulatory care collaboration model for chronic obstructive pulmonary disease (COPD) patients. **Objective:** Describe the impact of a pharmacist-provided clinical COPD bundle on the management of COPD in a hospital-based ambulatory care clinic. **Methods:** This retrospective cohort analysis evaluated patients with COPD managed in an outpatient pulmonary clinic. The primary objective of this study was to assess the completion of 4 metrics known to improve the management of COPD: (1) medication therapy management, (2) quality measures including smoking cessation and vaccines, (3) patient adherence, and (4) patient education. The secondary objective was to evaluate the impact of the clinical COPD bundle on clinical and economic outcomes at 30 and 90 days post-initial visit. **Results:** A total of 138 patients were included in the study; 70 patients served as controls and 68 patients received the COPD bundle from the clinical pharmacist. No patients from the control group had all 4 metrics completed as documented, compared to 66 of the COPD bundle group ($P < .0001$). Additionally, a statistically significant difference was found in all 4 metrics when evaluated individually. Clinical pharmacy services reduced the number of phone call consults at 90 days ($P = .04$) but did not have a statistically significant impact on any additional pre-identified clinical outcomes. **Conclusion:** A pharmacist-driven clinical COPD bundle was associated with significant increases in the completion and documentation of 4 metrics known to improve the outpatient management of COPD.

Keywords

ambulatory care, chronic obstructive pulmonary disease, documentation interventions/outcomes, clinical pharmacy, cost benefit

Introduction

Chronic obstructive pulmonary disease (COPD) is the third leading cause of death in the United States, accounting for 2.7 million deaths and health care resource costs exceeding \$50 billion annually.^{1–3} Optimal management of COPD includes appropriate prescribed medication therapies, patient adherence to complex medication regimens, and proper inhaler technique.^{4,5} Despite the development of several practice guidelines, physicians face many challenges managing COPD, and disease control remains suboptimal.^{6,7} Studies demonstrate that more than 50% of COPD patients have poor adherence and 31% of nonadherence is due to high out-of-pocket costs for inhalers.^{8–10} Published evidence also shows that improper inhaler technique results in poor disease state control and increased costs.¹¹ Research suggests that a multidisciplinary approach is required to

improve the management of COPD and achieve optimal disease control.¹²

The Global Initiative for Chronic Obstructive Lung Disease identifies pharmacists as key professional collaborators to improve the management of COPD and implement the guideline recommendations.⁶ Pharmacists are uniquely suited to positively influence medication management by optimizing medication therapy, recognizing nonadherence, and implementing strategies to improve compliance

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to prescribed medication regimens. Due to their training, pharmacists are also well positioned to educate patients on how to properly use inhalers and to reassess inhaler technique.¹² Previous studies demonstrate that pharmacist's care of COPD patients enhance outcomes, improve inhaler technique, and increase patient satisfaction.¹³⁻¹⁸ Additionally, management programs in community pharmacies have improved patient adherence, quality of life, and smoking cessation rates.^{7,19,20} These studies emphasize the impact of patient education interventions provided by a community pharmacist, in addition to provider care; however, limited literature exists evaluating clinical pharmacists' collaboration for patients with COPD in hospital-based ambulatory care clinics. Process measures relevant to these clinical pharmacy services are also not fully described in the literature, although they are best suited to evaluate clinical pharmacy services.^{21,22} Given that quality outcomes are supported by process measures, it is important to establish the impact pharmacists can have on process indicators to improve patient outcomes. No systematic evaluations of a comprehensive clinical pharmacy service, including process measures, currently exist to determine an optimal ambulatory care collaboration model for COPD patients. The purpose of this study was to evaluate the impact of a clinical pharmacist COPD bundle on the ambulatory management of COPD within a new collaborative practice model in a hospital-based ambulatory care setting.

Methods

Study Setting

The study was conducted at the Henry Ford Hospital (HFH) Pulmonary Clinic, an outpatient center associated with Henry Ford Health System, in Detroit, Michigan. The clinic provides medical services to patients with a variety of lung diseases and serves as a training location for medical residency and fellowship programs. In April 2014, a hospital-based ambulatory care pharmacist was incorporated into the clinic workflow. The clinical pharmacist and pulmonary physicians partnered to develop a new COPD patient care model with the purpose of improving care, reducing exacerbations, and achieving optimal outcomes through medication adherence assessment, COPD medication therapy optimization, and patient education. The pharmacist-provided care model was designed around 4 metrics known to positively influence the management of COPD: (1) medication therapy management, (2) quality measures including smoking cessation and vaccines, (3) medication access, and (4) patient education.^{7,12,19,20}

Description of Clinical Pharmacy Services

The hospital-based ambulatory care clinical pharmacy services began in May 2014 with a shared-faculty pharmacist

providing services 3 half-days per week (approximately 16 hours per week). Pharmacy students and residents rotated through the clinic, and all clinical activities were directly supervised. The clinical pharmacist provided a standardized clinical bundle service for all COPD patients seen during pharmacy clinic hours (see Figure 1). Providers and inpatient pharmacists could also refer patients for the bundle service on discharge from the hospital if the patient had been admitted for a COPD exacerbation. Initial patient visits with the pharmacist ranged from 45 to 60 minutes, and in-person follow-up appointments were scheduled between 2 and 12 weeks based on the severity of the patient's drug-related problem list and disease state control. Patients who had changes to their COPD medication regimen during their pulmonary clinic visit also received a follow-up phone call 1 week after the clinic visit to reinforce the importance of adherence and the COPD action plan. Barriers to medications, including financial, were evaluated on a case-by-case basis by the clinical pharmacist. In order to overcome financial barriers, patients were provided with manufacture coupons, enrolled in patient assistance programs, or provided with formulary alternatives to reduce monthly out-of-pocket expenses. The pharmacist placed a reminder in the electronic medical record (EMR) to proactively identify when patient assistance would expire, preventing lapses in therapy due to cost. The pharmacist contacted the patient via phone, inquired about the need for financial assistance, and worked with the patient to continue assistance if necessary. Face-to-face collaboration occurred between the clinical pharmacist and providers prior to the patient's initial visit with the clinical pharmacist and longitudinally throughout patient management. All patient care activities and recommendations were documented in the EMR using a standard note template for the hospital-based ambulatory care pharmacist in the pulmonary clinic.

Study Design and Objectives

This retrospective cohort analysis included patients with COPD managed in the HFH outpatient pulmonary clinic from August 2014 to March 2015. Patients were identified from appointment records, and data were obtained from the EMR. The study population was divided into 2 groups: patients who saw only a provider were assigned to the control arm, and patients who saw both a provider and the clinical pharmacist were assigned to the case arm. Patients were included in the study if they were 18 years of age or older, treated in the HFH pulmonary outpatient clinic with a diagnosis of COPD (defined by an International Classification of Disease Code 9-496.0 and confirmed by a spirometric test interpreted by a pulmonologist). Exclusion criteria included pregnant women, patients enrolled in hospice or palliative care, patients with lung cancer, and patients who were previously included in either study arm.

Figure 1. Standardized COPD bundle delivered by hospital-based clinical pharmacist.

Abbreviations: COPD, chronic obstructive pulmonary disease; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity.

Figure 2. Standardized clinical chronic obstructive pulmonary disease (COPD) bundle metric definitions.

The primary objective was to evaluate the impact of a pharmacist-provided clinical COPD bundle on the management of COPD in a hospital-based ambulatory care clinic. The primary outcome was defined as satisfactory completion of all 4 metrics of the clinical COPD bundle known to improve management of COPD (Figure 1). In order to achieve satisfactory completion, all components of each metric had to be performed and documented in the EMR on

the initial visit date. The definitions for each metric can be found in Figure 2. The secondary objective was to evaluate the impact of the clinical COPD bundle on clinical and economic outcomes at 30 and 90 days post-initial visit. The predetermined clinical outcomes included clinical worsening of COPD and health care utilization including emergency department visits, hospitalizations, follow-up appointments, or patient phone calls related to COPD.

Clinical worsening of COPD was defined as an increase in symptoms, need for increased maintenance COPD medication therapy, or the addition of steroids or antibiotics to the patient's medication regimen. Economic outcomes were defined as patient savings, calculated from patients' out-of-pocket costs for COPD medications pre- and postclinical pharmacy intervention. Out-of-pocket costs were collected from the dispensing pharmacies and verified with the patient's insurance company claim data. This study was reviewed and approved by the institutional review board of Henry Ford Hospital.

Statistical Analysis

Based on a published systematic analysis, it was determined that a total of 58 patients in each group would detect a 50% improvement in completion and documentation of the 4 bundle metrics (α of .05, 80% power).²³ Based on internal quality data, it was estimated that approximately 20% of patients would be referred for the clinical pharmacy COPD bundle following discharge. In order to ensure that these patients did not differ significantly from the patients not referred, an additional 12 patients were added to each group to account for a planned sensitivity analysis. Descriptive statistics were reported using mean, median, and range. Categorical data were analyzed using the χ^2 test or Fisher's exact test. The Student's *t* test or Mann-Whitney *U* test was used to analyze continuous data. Logistic regression analysis was also used to account for confounding variables. A post hoc analysis of the components of the medication therapy management metric was also completed. JMP, Version 11 (SAS Institute Inc, Cary, NC), was used for all statistical analyses.

Results

During the study period, there were 406 patients with a diagnosis of COPD scheduled for a pulmonary clinic appointment. A total of 146 patients did not show to their clinic appointment, 63 patients did not meet the criteria for the diagnosis of COPD, 37 patients were previously included in the study, and 22 patients had lung cancer. In total, 138 patients were included in the study; 70 patients served as controls and 68 patients received the COPD bundle from the clinical pharmacist. The majority of the study patients were African American, female, former smokers, and had moderate to severe COPD (Table 1). All other baseline clinical characteristics were similar with the exception of race and incidence of osteoporosis. Seventeen patients were referred for the clinical COPD bundle following discharge for a COPD exacerbation; there were no statistical differences in baseline demographics when these patients were excluded for the sensitivity analysis.

Completion and documentation of the 4 metrics of the clinical COPD bundle significantly improved with pharmacist services (0% vs 97.1%, $P < .0001$). Additionally, a statistically significant difference was found in all 4 individual metrics (Table 2). A post hoc analysis of the medication therapy management metric components showed that clinical pharmacist services significantly improved documented medication reconciliation, COPD medication therapy optimization, and medication adherence. No statistical differences were detected in the primary outcome following the planned sensitivity analysis (0% vs 96%, $P < .0001$).

The clinical pharmacy services did not have a statistically significant impact on any pre-identified secondary outcomes at 30 and 90 days post-initial visit except for reducing the number of phone call consults at 90 days (Table 3). The planned sensitivity analysis did not show any statistical differences in these outcomes; however, by removing the referred patients, the data showed trends toward improvement in health care utilization and clinical worsening at 30 and 90 days except for hospitalization and increased use of maintenance medications at 30 days. The clinical pharmacist identified and solved barriers to medication access for 15 patients (22%) in the COPD bundle group; 6 of these interventions resulted in significant out-of-pocket savings for the patient. Table 4 depicts each patient's out-of-pocket costs before and after the pharmacist intervention. The extrapolated patient savings per year for these 6 patients was found to be greater than \$22 500, or \$1500 per patient per year.

Discussion

A pharmacist-driven clinical COPD bundle was associated with significant increases in the completion and documentation of 4 metrics known to improve the outpatient management of COPD. Compliance with these processes can translate to an overall improvement in hospital compliance with quality measures and benefit a health system. Given that process measures are needed to evaluate where clinical pharmacy services can benefit patients and health systems, this study provides new data supporting the role of a hospital-based ambulatory care pharmacist in a pulmonary clinic.^{21,22} In this study, no control patients had all metrics documented, and the rate of completion for each individual metric was less than 13%. In comparison, 97% of the COPD bundle group had all metrics completed and documented. The rate of completion for each individual metric was 85% or more. These results suggest a clinical pharmacist in a hospital-based ambulatory care clinic can improve the process measures known to benefit patients with COPD and may improve clinical outcomes.

Given that pharmacists are uniquely suited to provide medication therapy management, the clinical COPD bundle's impact on medication therapy management processes

Table 1. Patient Demographics.

Variable	Control (n = 70)	COPD Bundle Group (n = 68)	P
Age, years	64	66	.12
Sex, n (%)			.13
Male	26 (37)	34 (50)	
Female	44 (63)	34 (50)	
Race, n (%)			.005*
African American	40 (57)	48 (71)	
Caucasian	29 (42)	14 (20)	
Other	1 (1)	6 (9)	
Smoking status, n (%)			.53
Current	17 (24.3)	15 (22)	
Former	47 (67.1)	43 (63.2)	
Never	6 (8.6)	10 (14.8)	
COPD severity, n (%)			.3
Mild	1 (1.4)	5 (7.4)	
Moderate	29 (41.4)	30 (44.1)	
Severe	28 (40)	25 (36.8)	
Very severe	12 (17.2)	8 (11.7)	
Comorbidities, n (%)			
Anxiety/depression	22 (31.4)	12 (17.6)	.06
Asthma	15 (21.4)	11 (16.2)	.43
Cardiovascular disease	60 (85.7)	61 (89.7)	.48
Diabetes	19 (27.1)	16 (23.5)	.63
Interstitial lung disease	7 (10)	6 (8.8)	.81
Osteoporosis	7 (10)	1 (1.5)	.03*
Pulmonary hypertension	7 (10)	5 (7.4)	.58

Abbreviation: COPD = chronic obstructive pulmonary disease.

*Significance at $P < 0.05$

Table 2. Documentation of COPD Metrics.

Metric	Control (n = 70)	COPD Bundle Group (n = 68)	P
Overall completion and documentation of COPD clinical bundle, n (%)	0 (0)	66 (97.1)	<.0001
Medication therapy management, n (%)	9 (12.9)	58 (85.3)	<.0001
Quality measures, n (%)	10 (14.3)	63 (92.6)	<.0001
Access analysis, n (%)	3 (4.3)	66 (97.1)	<.0001
Patient education, n (%)	8 (11.4)	68 (100)	<.0001

Abbreviation: COPD = chronic obstructive pulmonary disease.

further supports pharmacy practice models in the management of COPD. This study demonstrated that pharmacists can significantly improve the documentation of medication reconciliation, COPD medication therapy optimization, and medication adherence. Although not powered to show statistical significance, the trend toward improvements in health care utilization and COPD clinical worsening provide an opportunity for further investigation.

Another important component of COPD management is patient adherence. Previous studies have demonstrated that rates of medication adherence are correlated with patient out-of-pocket expenses and access to medications, so another

important finding of this study was the impact of the pharmacist's clinical services on patient out-of-pocket expenses.^{9,24} Reducing out-of-pocket costs can enhance patient empowerment and engagement, thus increasing adherence. In this study, the clinical pharmacist identified 6 patients with financial barriers to medication access and these patients saved approximately \$356 per month. While it is unknown how these savings improved patient adherence, this is a significant impact on these patients' out-of-pocket monthly expenses. Prior to implementation of the clinical COPD bundle, there was no process in the clinic to address potential financial barriers to medication adherence. These data could suggest a

Table 3. Secondary Outcomes at 30 and 90 Days Post-Initial Visit.

Metric	30 Days Control (n = 70), n (%)	30 Days COPD Bundle Group (n = 68), n (%)	P	90 Days Control (n = 70), n (%)	90 Days COPD Bundle Group (n = 68), n (%)	P
Increase of symptoms	12 (17.14)	6 (10)	.24	22 (31.43)	20 (29.41)	.8
Increased maintenance therapy	4 (5.71)	1 (1.47)	.18	10 (14.29)	6 (8.82)	.32
Addition of antibiotics or steroids	9 (12.86)	7 (10.29)	.64	18 (25.71)	16 (23.53)	.77
Emergency department visits	7 (10)	3 (4.4)	.2	12 (17.1)	10 (14.7)	.70
Hospitalizations	5 (7.14)	2 (2.94)	.26	4 (5.71)	10 (14.71)	.08
Follow-up visits	18 (25.71)	11 (16.18)	.17	26 (37.14)	29 (42.65)	.51
COPD phone consults	16 (22.86)	10 (14.71)	.22	28 (40)	16 (23.53)	.04*

Abbreviation: COPD = chronic obstructive pulmonary disease.

*Significance at $P < 0.05$ **Table 4.** Savings for Patients With Barriers to Medication Access^a.

Cost per Month Prior to Pharmacist Intervention	Cost per Month Post- Pharmacist Intervention	Monthly Savings	Yearly Savings
600	53.30	546.67	6560.04
30	0	30	360
140	0	140	1680
680	71.12	608.88	7306.56
272	59.88	212.12	2545.44
720	120	600	7200
Total savings		2137.67	25652.04

^aAll data presented as US dollars.

pharmacist may be able to play a role in identifying and resolving financial barriers to adherence in a pulmonary clinic.

This study is not without limitations. First, this retrospective study may not fully represent the overall population of COPD patients as they were evaluated in an inner-city, specialty clinic. As such, the selected sample may not reflect populations at other hospital-based clinics. Additionally, the selected sample included patients who were referred for pharmacy services on discharge and as such may include patients who utilize more health care resources after discharge. The sensitivity analysis helped control for this group as a potential confounder. The pharmacy services were also designed to target metrics known to improve COPD management. Thus, patients who met with the pharmacist are likely to have higher completion and documentation of these metrics due to the COPD clinical bundle. However, there was no clear data defining compliance with these metrics for our providers, and the results of this study provide internal insight into compliance with these metrics. Additionally, the study builds on previous studies that demonstrate the need for comprehensive care management.⁷ Last, health care utilization was tracked in the health system; however, health care utilization outside

of the system is unknown and serves as a limitation to the study.

This study demonstrates a newly defined role for a hospital-based ambulatory care clinical pharmacist in a COPD clinic and the direct impacts on process measures. Additionally, these clinical pharmacy services can promote patient empowerment by reducing out-of-pocket costs and facilitating medication adherence. As clinical pharmacists are uniquely suited to assist with these complex and time-consuming tasks, future studies should evaluate the clinical impact of these process measures and the reduction in health care costs for both the hospital system and the patient.

Conclusion

A pharmacist-driven clinical COPD bundle improved the outpatient management of patients with COPD by increasing medication therapy management, quality metrics, and patient savings.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References

- Centers for Disease Control and Prevention. Chronic obstructive pulmonary disease (COPD). <http://www.cdc.gov/copd/data2.html>. Accessed July 10, 2015.
- Mannino DM, Homa DM, Akinbami LJ, Ford ES, Redd SC. Chronic obstructive pulmonary disease surveillance—United States, 1971-2000. *MMWR Surveill Summ*. 2002;51(SS06):1-16.
- Centers for Disease Control and Prevention. Public health strategic framework for COPD prevention. http://www.cdc.gov/copd/pdfs/Framework_for_COPD_Prevention.pdf. Accessed July 10, 2015.
- Fink JB, Rubin BK. Problems with inhaler use: a call for improved clinician and patient education. *Respir Care*. 2005;50:1360-1374.
- Davis KJ, Landis SH, Oh YM, et al. Continuing to Confront COPD International Physician Survey: physician knowledge and application of COPD management guidelines in 12 countries. *Int J Chron Obstruct Pulmon Dis*. 2015;10:39-55.
- Global Initiative for Chronic Obstructive Lung Disease: Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. https://www.goldcopd.it/materiale/2015/GOLD_Report_2015.pdf. Accessed July 10, 2015.
- Mehuys E, Boussery K, Adriaens E, et al. Management of COPD in community pharmacy [in French]. *J Pharm Belg*. 2010;(1):10-15.
- Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med*. 2005;353:487-497. doi:10.1056/NEJMr050100.
- Castaldi PJ, Rogers WH, Safran DG, Wilson IB. Inhaler costs and medication nonadherence among seniors with chronic pulmonary disease. *Chest*. 2010;138:614-620. doi:10.1378/chest.09-3031.
- Lareau SC, Yawn BP. Improving adherence with inhaler therapy in COPD. *Int J Chron Obstruct Pulmon Dis*. 2010;5:401-406. doi:10.2147/COPD.S14715.
- Melani AS, Bonavia M, Cilenti V, et al. Inhaler mishandling remains common in real life and is associated with reduced disease control. *Respir Med*. 2011;105:930-938. doi:10.1016/j.rmed.2011.01.005.
- American Pharmacists Association Foundation. White paper on expanding the role of pharmacists in chronic obstructive pulmonary disease: American Pharmacists Association Foundation. *J Am Pharm Assoc* (2003). 2014;51:203-211. doi:10.1331/JAPhA.2011.11513.
- Khdour MR, Agus AM, Kidney JC, Smyth BM, Elnay JC, Crealey GE. Cost-utility analysis of a pharmacy-led self-management programme for patients with COPD. *Int J Clin Pharm*. 2011;33:665-673. doi:10.1007/s11096-011-9524-z.
- Mapel DW, Petersen H, Roberts MH, Hurley JS, Frost FJ, Marton JP. Can outpatient pharmacy data identify persons with undiagnosed COPD? *Am J Manag Care*. 2010;16:505-512.
- Fuller L, Conrad WF, Heaton PC, Panos R, Eschenbacher W, Frede SM. Pharmacist-managed chronic obstructive pulmonary disease screening in a community setting. *J Am Pharm Assoc* (2003). 2012;52(5):e59-e66.
- Fathima M, Naik-Panvelkar P, Saini B, Armour CL. The role of community pharmacists in screening and subsequent management of chronic respiratory diseases: a systematic review. *Pharm Pract (Granada)*. 2013;11:228-245.
- Bosnic-Anticevich SZ, Sinha H, So S, Reddel HK. Metered-dose inhaler technique: the effect of two educational interventions delivered in community pharmacy over time. *J Asthma*. 2010;47:251-256.
- Solomon DK, Portner TS, Bass GE, et al. Clinical and economic outcomes in the hypertension and COPD arms of a multicenter outcomes study. *J Am Pharm Assoc (Wash)*. 1998;38:574-585.
- Khdour MR, Kidney JC, Smyth BM, McElnay JC. Clinical pharmacy-led disease and medicine management programme for patients with COPD. *Br J Clin Pharmacol*. 2009;68:588-598. doi:10.1111/j.1365-2125.2009.03493.x.
- Hoogendoorn M, van Wetering CR, Schols AM, Rutten-van Mölken MPMH. Is INTERdisciplinary COMMunity-based COPD management (INTERCOM) cost-effective? *Eur Respir J*. 2010;35:79-87.
- Kirwin J, Canales AE, Bentley ML, et al. Process indicators of quality clinical pharmacy services during transitions of care. *Pharmacotherapy*. 2012;32:e338-e347. doi:10.1002/phar.1214.
- Bruchet N, Loewen P, de Lemos J. Improving the quality of clinical pharmacy services: a process to identify and capture high-value "quality actions". *Can J Hosp Pharm*. 2011;64(1):42-47.
- Lemmens KMM, Nieboer AP, Huijsman R. A systematic review of integrated use of disease-management interventions in asthma and COPD. *Respir Med*. 2009;103:670-691. doi:10.1016/j.rmed.2008.11.017.
- Campbell JD, Allen-Ramey F, Sajjan SG, Maiese EM, Sullivan SD. Increasing pharmaceutical copayments: impact on asthma medication utilization and outcomes. *Am J Manag Care*. 2011;17:703-710.