# Implementation of a clinical pathway: Management of acute exacerbations of chronic obstructive pulmonary disease (AECOPD)

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#### Abstract

Rationale aims, and objectives: Clinical pathways (CP) have the ability to educate providers on guideline-driven recommendations and reduce readmission rates. The aim of this study was to evaluate adherence to the 2020 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guideline recommendations for the management of an AECOPD after the implementation of an educational CP. Methods: This study was an observational quality improvement study targeting COPD exacerbation hospitalizations with a three-month pre-intervention period from January to March 2020 and a five-month post-intervention period from January to May 2021, following the implementation of a CP. Patients were included if they were hospitalized with a primary diagnosis of an AECOPD. The primary endpoint was to assess adherence to guideline recommendations. Secondary endpoints included an evaluation of oxygen support requirement, hospital length of stay (LOS), 30-day readmission rates, admission to the intensive care unit (ICU), and requirement of mechanical ventilation (MV). Results: There were a total of 78 patients included in this study. There was a significant improvement in guideline appropriate inhalers prescribed at discharge [85%, n=24 vs. 44%, n=22, p=0.01], antibiotic therapy for an AECOPD [90%, n=25 vs. 61%, n =30, p =0.02], smoking cessation pharmacotherapy [80%, n=22 vs. 29%, n=14, p=0.004] and counseling [89%, n=25 vs.15%, n=8, p=0.002] prior to discharge within the post-intervention group compared to the pre-intervention group. A significant reduction in the requirement of oxygen support was demonstrated within the post-intervention group after the implementation of a CP (p=0.03). Conclusion: The implementation of a CP can improve adherence to guideline recommendations and reduce the need of oxygen support for the management of AECOPD.

# Original Paper

Implementation of a clinical pathway: Management of acute exacerbations of chronic obstructive pulmonary disease (AECOPD)

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#### Abstract

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**Methods** : This study was an observational quality improvement study targeting COPD exacerbation hospitalizations with a three-month pre-intervention period from January to March 2020 and a five-month post-intervention period from January to May 2021, following the implementation of a CP. Patients were included if they were hospitalized with a primary diagnosis of an AECOPD. The primary endpoint was to assess adherence to guideline recommendations. Secondary endpoints included an evaluation of oxygen support requirement, hospital length of stay (LOS), 30-day readmission rates, admission to the intensive care unit (ICU), and requirement of mechanical ventilation (MV).

**Results:** There were a total of 78 patients included in this study. There was a significant improvement in guideline appropriate inhalers prescribed at discharge [85%, n=24 vs. 44%, n=22, p=0.01], antibiotic therapy for an AECOPD [90%, n=25 vs. 61%, n =30, p =0.02], smoking cessation pharmacotherapy [80%, n=22 vs. 29%, n=14, p=0.004] and counseling [89%, n=25 vs.15%, n=8, p=0.002] prior to discharge within the post-intervention group compared to the pre-intervention group. A significant reduction in the requirement of oxygen support was demonstrated within the post-intervention group after the implementation of a CP (p=0.03).

**Conclusion:** The implementation of a CP can improve adherence to guideline recommendations and reduce the need of oxygen support for the management of AECOPD.

## Keywords

chronic obstructive pulmonary disease, clinical practice guideline, clinical pathway, pharmacy

# Introduction

Chronic obstructive pulmonary disease (COPD) is a common respiratory condition characterized by progressive airflow obstruction and respiratory symptoms.<sup>1</sup> It is currently the fourth leading cause of mortality in the United States, with a 30-day readmission rate of 22.6%.<sup>2,3</sup> While the mortality associated with COPD is significant, morbidity and costs associated with the disease also have an impact on patients, their families, and the healthcare system.<sup>4</sup> In the United States, AECOPD result in a significant economic burden on healthcare systems, accounting for \$13.2 billion of the nearly \$50 billion annual direct costs for COPD.<sup>5</sup> Despite the availability of a widely recognized clinical guideline for the management of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD), current in-hospital management of AECOPD remains suboptimal. Previous literature reports an adherence rate of less than 60% to the use of COPD guidelines.<sup>6-10</sup> Clinical pathways (CP), are tools used to guide evidence-based practice for a specific group of patients, that have the ability to educate providers on guideline driven recommendations, and reduce readmissions rates.<sup>7,8</sup>

Patients may experience an acute worsening of their COPD, characterized by changes in their baseline respiratory symptoms that may require hospitalization and a change in therapy.<sup>1</sup>The American College of Physicians use increased cough, sputum volume, and purulence as a diagnostic criteria to define the severity

of AECOPD. Hospital admission is usually required if there are significant risk factors for poor outcomes, anticipated need for ventilator support, and/or insufficient home support.<sup>11</sup> Short-acting beta-2 agonists (SABAs) with or without short-acting muscarinic antagonists (SAMAs) are preferred bronchodilators for an AECOPD. Systemic glucocorticoids, when added to the bronchodilator therapies improve lung function, and shorten recovery time. Hospitalized patients may also be candidates for antibiotic treatment for 5-7 days if they have purulent sputum with one or more of the following symptoms: increased dyspnea or sputum production. Antibiotics are selected based upon local antibiogram resistance patterns with commonly used agents being azithromycin and doxycycline. Inhaled long-acting bronchodilators should be optimized prior to discharge based upon respiratory symptoms and forced expiratory volume in 1 second (FEV<sub>1</sub>) to reduce readmission rates. AECOPD may also be prevented by counseling patients at discharge on smoking cessation, pneumococcal and influenza immunization, and proper inhaler technique and adherence to medications.<sup>12-13</sup>The aim of this study was to assess adherence to guideline recommendations for AECOPD after the implementation of an educational CP.

## Methods

This was a single-center, observational, chart review study targeting COPD hospitalizations with a threemonth retrospective pre-intervention period from January to March 2020 and a five-month post-intervention period from January to May 2021 following the implementation of an educational clinical treatment pathway (Appendix A). Prior to the post implementation phase, medicine teaching services were educated on the COPD CP and provided with educational materials. Patients were included if they were hospitalized during the study period for a primary diagnosis of an AECOPD for at least 48 hours. Patients were excluded if they were less than 40 years of age, had a diagnosis of asthma, severe heart failure classified as New York Heart Association class IV or used long-term oxygen therapy at home.

#### 2.1 Endpoints

The primary endpoint was to assess adherence to guideline recommendations including inhaler combinations prescribed, antibiotic usage, smoking cessation pharmacotherapy and counseling, bedside inhaler counseling at discharge, and appropriate discharge follow-up appointments. Secondary endpoints included an evaluation of oxygen support requirement, hospital length of stay (LOS), 30-day readmission rates, admission to the intensive care unit (ICU), and requirement of mechanical ventilation (MV). Oxygen support was defined as the requirement of nasal cannula (NC), high flow nasal cannula (HFNC), non-re-breather mask (NRB) or bi-level positive airway pressure (BiPAP) during hospital stay.

## 2.2 Statistical Analysis

Demographic and clinical variables were expressed as means and standard deviations for continuous variables, and

## frequencies for categorical variables

Demographic and clinical variables are expressed as medians and interquartile ranges for continuous variables, and frequencies for categorical variables. Comparison of continuous parametric variables was analyzed with the Mann-Whitney test, and comparison of categorical variables was analyzed by the  $\chi^2$  analysis or Fisher's exact test, when appropriate. All statistical tests were performed at a two-sided 0.05 level of significance.

#### Results

There was a total of 50 patients included in the pre-intervention group, and after a CP was created and education was provided to the medical teams, there were 28 patients included in the post-intervention group. Baseline characteristics are depicted in **Table 1**. The median age of the pre-intervention cohort was similar to the post-intervention cohort [71.5 (IQR: 61-80) vs. 65.5 (IQR: 60.8-75.8), p=0.40]. Notable differences among the two cohorts included an increase in Hispanic ethnicity within the pre-intervention group compared to the post-intervention group [22%, n =11 vs. 4%, n=1, p=0.031] and lower history of malignancy in the pre-intervention group compared to the post intervention group [6%, n=3 vs. 25%, n=7, p=0.03].

After provider education and the implementation of CP, there was a significant improvement in guideline appropriate inhalers prescribed at discharge [85%, n=24 vs. 44%, n=22, p=0.01], antibiotic therapy for an AECOPD [90%, n=25 vs. 61%, n =30, p =0.02], and smoking cessation pharmacotherapy [80%, n=22 vs. 29%, n=14, p=0.004], within the post-intervention group compared to the pre-intervention group, respectively (Figure 1). Additionally, there was significant improvement in smoking cessation counseling prior to discharge within the post-intervention cohort when compared to the pre-intervention cohort [89%, n=25 vs.15%, n=8, p=0.002]. There was no difference seen in inhaler counseling prior to discharge within the post-intervention group [98%, n=27 vs. 95%, n=47, p =0.135]; however, this was already implemented within the institution prior to the CP (Figure 2). The addition of pharmacy involvement in helping to schedule post-discharge follow-ups led to a significant increase in the number of patients with a pulmonary clinic follow-up appointment within one week of discharge in the post intervention group compared to the pre-intervention group [64%, n=18 vs. 22%, n=11, p=0.0002].

There was a significant reduction in the need of oxygen support in patients within the post-intervention group compared to the pre-intervention group [39%, n=11 vs. 64%, n= 32, p=0.03]. There was no difference detected within the post-intervention group compared to the pre-intervention group for length of hospital days [4.5 (IQR: 3 -8) vs. 5 (IQR: 4-5), p=0.69], 30-day readmission rates [14 %, n=4 vs. 4 %, n=2, p=0.10], admission to the ICU [11%, n=3 vs. 4%, n=2, p=0.25], and requirement of mechanical ventilation [21 %, n=6 vs. 4%, n=2, p=0.06], respectively. (Table 2).

#### Discussion

Evidence-based clinical guidelines improve the quality of care and standardization of practice to improve patient outcomes. The implementation of a COPD CP, after providing provider education, demonstrated a significant improvement in guideline appropriate inhalers prescribed at discharge, antibiotic therapy, and smoking cessation pharmacotherapy. While the data is lacking regarding adherence to COPD guidelines, similar results have been demonstrated in provider adherence to infectious disease, cardiology, asthma, and diabetes guidelines after the implementation of a CP.<sup>14, 15-18</sup> Portillo et al. evaluated the impact of pharmacist inclusion as part of the COPD Coordinated Access to Reduce Exacerbations (CARE) service. The COPD CARE service group demonstrated improved patient transitions of care in prescribed inhaler therapy and delivery of bedside inhaler counseling at discharge, by collectively adhering to the COPD guidelines.<sup>19</sup>

Although some patients with AECOPD benefit from antibiotics, it is important to note that up to 60% of AECOPD are due to viral infections.<sup>20</sup> Therefore, antibiotics are only recommended in patients that meet the following criteria: purulent sputum with one or more of the following symptoms: increased dyspnea or sputum production without sputum purulence. Antibiotics are only recommended in this population due to the reported treatment failure with incomplete resolution, persistence, or worsening of symptoms at rate of <10% of patients when use is not indicated.<sup>21</sup> Excessive and unwarranted use of antibiotics has been associated with an increase in bacterial resistance.<sup>21, 22</sup> A retrospective data analysis of 354 patients living with COPD suggested that 27% of these patients, developed resistance to an antimicrobial agent within 21.5 months of follow up (p = 0.026) due to inappropriate use of antibiotics<sup>23</sup> In recent years, there has been an increase in antibiotic resistance among common respiratory pathogens.<sup>24</sup> Overall rate of resistance in the United States to macrolide antibiotics, including azithromycin, was 14.3% and 18.1% for amoxicillin.<sup>25</sup> This highlights the importance of appropriate and targeted antibiotic therapy for COPD exacerbations.

COPD is a growing cause of morbidity and mortality with smoking being recognized as an important contributing factor. Smoking cessation is an important component of effective COPD management and can result in a reduction of mortality in up to 22% of patients. <sup>26, 27</sup> Therefore, the implementation of smoking cessation counseling and pharmacotherapy can achieve long-term success rates of smoking cessation up to 25% of the time.<sup>13</sup> Face-to-face individual counselling from a healthcare provider has shown to be effective at aiding smokers to quit (RR 1.57, 95% confidence interval (CI) 1.40 to 1.77).<sup>28</sup> Data suggests that smoking cessation services provided by pharmacists are effective in assisting patients to successfully quit. <sup>29, 30-36</sup> Our pharmacy transitions of care (TOC) program also helped to arrange follow-ups within one week of hospital discharges to ensure optimal management has been established. Services like this has shown to improve medication reconciliations and patient education to result in a reduction in 30-day readmission rates by a relative risk reduction of 64% in a variety of disease states.<sup>37</sup>

A significant reduction in the requirement of oxygen support was demonstrated within the post-intervention group after the implementation of a CP. It is unknown the rationale of this key finding, but it can be hypothesized that the significant adjustment in guideline appropriate inhalers, patient education, and smoking cessation contributed to a reduction in the need for oxygen. A retrospective analysis evaluated the benefit of smoking cessation efficacy on COPD patients' nocturnal and daytime respiratory function and demonstrated that patients who quit smoking displayed a reduction in their oxygen desaturation index by 3 points (p = 0.01) and an increase in their FEV1 by 7 % (p = 0.01).<sup>38</sup>

The implementation of a CP for the management of AECOPD did not result in a significant difference in hospital LOS. There is currently conflicting literature related to differences in LOS after the implementation of utilizing practice guidelines in patients hospitalized with AECOPD.<sup>7,39-41</sup> However, previous literature had a higher number of active smokers in their patient population compared to our study which may have contributed to the lack of a significant reduction in the LOS. 30-day readmission rates were also similar among both cohorts in our study which is similar to other published literature.<sup>7, 42</sup> These patients may require evaluation of longer follow-up periods of 60 or 90-day readmission rates, since the average readmission rate for a COPD patient is 60 days.<sup>36</sup> Additionally, it may take longer than 30 days to determine the full benefit of implementation of a CP within an institution.

Our study had several limitations including its small sample size. The COVID-19 pandemic within New York City impacted the time frame and sample size for the post-intervention group. As a result, the time frame was extended to five months due to reduced cases, as patients admitted for COVID-19 were not included in this study. Additionally, repeated education did not occur to all medical providers during this short time period. It has been recommended to provide daily education rounds during the first month of implementing a CP, and three times a week for an additional month thereafter to increase adherence. Additionally, provider feedback was not received in this study which could have allowed for adjustments to be made in the CP. Establishing a CP education committee throughout the institution and among all disciplines has been shown to be beneficial and was not conducted in this short study. <sup>43</sup> Lastly, provider's own personal preference may have resulted in deviation from the clinical pathway regarding pharmacotherapy recommendations.

## Conclusion

CPs are widely used for optimizing adherence to guidelines and improving patient outcomes. We have developed and implemented a clinical pathway for the management of AECOPD at our institution. Our study results suggest that the implementation of an in-hospital CP for the management of AECOPD can result in a significant improvement in adherence to guideline recommendations and reduce the need of oxygen support. We recommend its usage in other institutions to improve care provided to patients with AECOPD. Additional studies are needed to understand how CPs will affect long term outcomes and healthcare costs.

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## **Conflict of Interest**

Dr. Elizabeth Gavioli is a full time employee of Dompé U.S. Inc. No other authors declare any conflict of interest.

## **Ethics Statement**

No ethical approval is required for this study.

Table 1: Patient Demographics & Comorbidities

	Pre-intervention (n=50)	Post-intervention $(n=28)$	P-value
Age, years, median (IQR)	71.5 (61-80)	65.5(60.8-75.8)	0.40

	Pre-intervention (n=50)	Post-intervention (n=28)	P-value
Gender, male, no (%)	25 (50)	14 (50)	0.99
<b>BMI</b> , $kg/m^2$ , median (IQR)	25.6 (21.1-31.6)	26.7(21.7-34.4)	0.69
<b>Race</b> , no (%)	<b>Race</b> , no (%)	<b>Race</b> , no (%)	Race, no $(\%)$
White	15 (30)	6 (21)	0.41
African American	17(24)	10(35)	0.88
Other	18(36)	10(35)	0.98
Ethnicity, no (%)	<b>Ethnicity</b> , no $(\%)$	<b>Ethnicity</b> , no $(\%)$	Ethnicity, no (%)
Hispanic	11(22)	1 (4)	0.03
Non-Hispanic	39(78)	28 (100)	0.33
<b>Smoking Status</b> , no (%)	<b>Smoking Status</b> , no $(\%)$	Smoking Status, no $(\%)$	Smoking Status,
Current	13 (26)	12 (43)	0.13
Former	8 (16)	12 (43)	0.23
Never	29(58)	4 (14)	0.01
Past medical history, no (%)	Past medical history, no (%)	Past medical history, no (%)	Past medical hist
Hypertension	19 (38)	24 (86)	0.38
Diabetes Mellitus	14(28)	13 (46)	0.11
Heart Failure	9 (18)	10 (36)	0.13
Coronary Artery Disease	7(14)	14(50)	0.09
Cerebrovascular Accident	6(12)	8 (29)	0.79
Atrial Fibrillation	7(14)	5(18)	0.92
Chronic Kidney Disease	19(38)	6 (21)	0.29
End-Stage-Renal Disease	4 (8)	1(3)	0.77
Malignancy	3(6)	7 (25)	0.03
Home inhalers, no $(\%)$	Home inhalers, no $(\%)$	Home inhalers, no $(\%)$	Home inhalers, no
SABA or SAMA	50(100)	23 (82)	0.01
ICS	3(6)	1 (4)	0.64
LABA/ICS	11(22)	18 (64)	0.12
LAMA	29 (58)	10 (36)	0.06
LAMA/LABA	1(2)	1(4)	0.67

Table 2: Secondary Endpoints

	Pre-intervention $(n=50)$	Post-intervention $(n=28)$	P-value
Length of hospital stay.	5 (4-5)	4.5 (3-8)	0.69
days, median (IQR)	- ( -)	- ()	
30-day readmission rates, no (%)	2(4)	4 (14)	0.18
Admission to the	2(4)	3 (11)	0.25
(%)			
Requirement of mechanical ventilation	2(4)	6 (21)	0.06
no (%)			
Requirement of oxygen support, no (%)	32 (64)	11(39)	0.03

Figure 1: Pharmacotherapy GOLD Guideline Adherence before and after the implementation

## of an education CP

Figure 2: Provider GOLD guideline adherence of patient bedside counseling before and after the implementation of an education CP

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## Pharmacotherapy Guideline Adherence

Figure 1: Pharmacotherapy GOLD Guideline Adherence before and after the implementation of an education CP

Counseling Guideline Adherence

Figure 2: Provider GOLD guideline adherence of patient bedside counseling before and after the implementation of an education CP