

# Evaluating Adherence With the GOLD Guidelines for Treating Stage II (Moderate) COPD at a Single Tribal Facility

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This retrospective, observational study evaluated 1 tribal facility's adherence to the GOLD guidelines when prescribing treatment for patients who have stage II (moderate) COPD. The cost impact of adding tiotropium to the facility's formulary was also examined.

**T**he National Heart, Lung, and Blood Institute (NHLBI) states that more than 12 million people have a diagnosis of chronic obstructive pulmonary disease (COPD) and estimates that another 12 million have the disease but are unaware of their condition. COPD is the fourth leading cause of death in the United States.<sup>1</sup> Decreasing the prevalence of this disease is linked directly to reducing the risk factors for COPD developing in the first place. The greatest risk factor is tobacco use.<sup>1</sup> It is estimated that 75% of deaths in patients with COPD are directly caused by tobacco use.<sup>2</sup> Preventing, accurately diagnosing, and properly managing the disease are

the ultimate goals for any health care facility.

In a health care setting that serves the Native American population, COPD is expected. Reports approximate that 41% of Native Americans use tobacco, the highest rate of tobacco use among every age, gender, and ethnic group.<sup>2,3</sup> Tobacco is considered sacred among some Native Americans and is used during religious ceremonies and as traditional medicine. Such uses are often not distinguished from routine tobacco use in this population. Additionally, tobacco companies have targeted Native Americans by sponsoring or funding cultural events. Tobacco products sold on Native American lands are often untaxed by state and local authorities, resulting in lower prices. According to the American Lung Association, this lower price has been associated with increased smoking rates.<sup>4</sup> Despite these speculations, little documentation exists to explain why smoking rates are so much higher in the Native American population.

Many facilities offer care to Native

Americans. Our research focused on 1 tribal facility and the conventional therapy provided for patients with COPD, specifically the treatment of stage II (moderate) COPD, the stage at which maintenance therapy is first indicated. The Chickasaw Nation provides health care services to more than 40,000 Native Americans. The facility's disease management practices were contrasted with the guidelines issued by the Global Initiative for Chronic Obstructive Lung Disease (GOLD). The GOLD guidelines are a culmination of evidence with contributions from the NHLBI, the World Health Organization, the American Thoracic Society, and the European Respiratory Society. Guidelines use pulmonary function tests (PFTs), including forced expiratory volume in 1 second ( $FEV_1$ ), forced vital capacity (FVC), and the ratio of  $FEV_1$  to FVC, to confirm the presence of—and to assess the severity of—the disease. COPD should be considered when any shortness of breath, chronic cough, or sputum production, and/or exposure to risk factors are present. It should be de-

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finitively diagnosed when  $FEV_1/FVC$  is  $< 70\%$ . Stage II COPD is classified when  $FEV_1$  is  $< 80\%$  and  $> 50\%$ .<sup>3</sup> We used the GOLD guidelines to assess proper diagnosis, adequate therapy, and proper management of COPD when we evaluated which therapies the facility was providing to stage II COPD patients.

For patients in stage II COPD, the GOLD guidelines indicate adding a long-acting inhaled bronchodilator to the medication regimen.<sup>5</sup> The currently available inhalers in this class are formoterol, salmeterol, and tiotropium. Formoterol and salmeterol are both  $\beta_2$ -agonists. These medications work by stimulating  $\beta_2$ -adrenergic receptors, which relax airway smooth muscle. Long-acting, inhaled  $\beta_2$ -agonists have a duration of at least 12 hours, and regular use has been shown to improve health status.<sup>5</sup> Tiotropium is a once-daily, inhaled, dry powder medication. It is an anticholinergic drug that provides bronchodilation specifically at the site, antagonizing the muscarinic receptor,  $M_3$ . Tiotropium has proven itself to provide improvement in dyspnea and lung function, a decrease in exacerbations, and an increase in patients' health-related quality of life when compared with other inhaled medications.<sup>6,7</sup>

The purpose of our study was to evaluate this facility's adherence to the GOLD guidelines when prescribing treatment for patients with stage II COPD. Because several local Native American health facilities have recently added tiotropium to their formularies, a secondary goal was to determine the cost impact of adding this medication to the formulary.

### METHODS

We submitted the research design for our retrospective, observational study to the institutional review board



after an approved list of all patients with an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code for COPD (496) was acquired. Although COPD is not usually seen in patients  $< 40$  years of age, patients were excluded only if they were  $< 18$  years of age. We kept our criteria broad to help increase the potential study population. Patients must have retained an electronic health record (EHR) within the Chickasaw Nation Health System. The EHR provided simple access to patients' pertinent medical information, thereby reducing any time spent requesting paper records and sifting through unnecessary information. All patients with a documented diagnosis of COPD with a recent PFT,

defined as completed between 2005 through 2008, were included.

With the study population established, we examined each stage II COPD patient's EHR for age, gender, date of most recent PFT and corresponding values, current inhaled medications, medication adherence, and tobacco history. The facility's computer software was capable of listing both active and inactive medications, as well as dates the medications were filled. We reviewed all medical records for relevant medication therapy, including tiotropium use. Current inhaled medications were defined as either appropriate or inappropriate. Appropriate agents at this facility were albuterol, ipratropium, and/or albuterol/ipratropium.

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Inappropriate therapy was defined as any combination of medications that include a steroid inhaler, such as flunisolide. The average number of refills was reviewed to assess compliance.

Due to inadequate documentation, the most accurate means to identify all complete PFTs was to review the hard copies maintained within the respiratory therapy department, thus increasing the study population.

We also reviewed patients' EHRs for the number of visits made to a primary care physician for both chronic and acute care. EHR was implemented at this facility in 2005. Implementation was conducted in phases, with inpatient records being one of the last areas to use EHR for documentation. For this reason, the years 2006 to 2008 were used to evaluate any hospitalizations.

Tiotropium use was limited to those patients who had an indication for a long-acting bronchodilator. To completely establish the cost impact of adding tiotropium to the facility's formulary, we reviewed the EHRs of all patients in stage II COPD or beyond with a  $FEV_1 < 80\%$ . We determined the acquisition cost for tiotropium and multiplied it by the number of patients who had proper documentation to support the use of an inhaled maintenance bronchodilator. We then calculated the cost to determine an annual cost to the facility.

## RESULTS

Our analysis revealed that 611 patients had COPD documented in their EHRs as the purpose of their visit; of these patients, only 101 had PFTs that met our criteria. Thirty-eight patients were determined to be in stage II COPD (Figure 1). This population had an average age of 66.4 years, and 65.8% were men (Table).

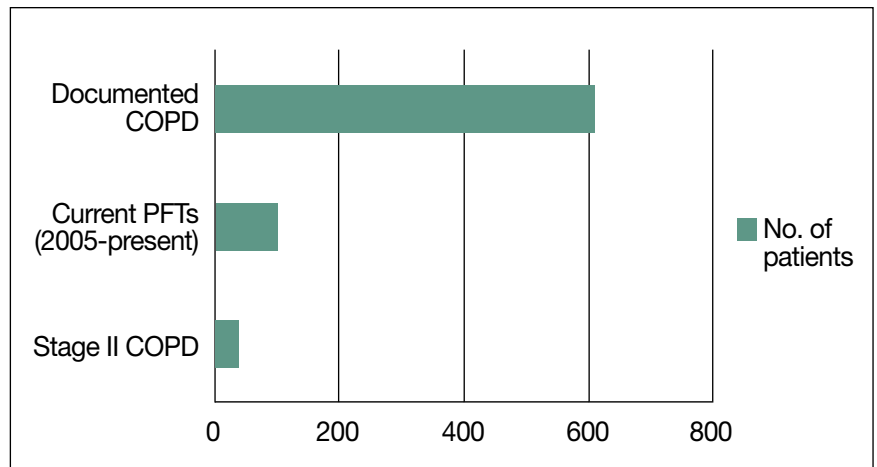


Figure 1. Patient COPD and PFT data. COPD = chronic obstructive pulmonary disease; PFTs = pulmonary function tests.

## Tobacco history

During the patient visit, smoking was discussed between the provider and the patient. Of the 38 patients in the study, 42% were current smokers, whereas 16% never smoked. History was unknown for 2 patients (5%), while 37% of patients smoked in the past (Figure 2).

## Pharmacotherapy

For any patient with COPD, the GOLD guidelines recommend a rescue inhaler, such as albuterol. Eleven patients (29%) were not prescribed any rescue inhaler or any other medications for use in COPD. Stage II COPD therapy consists of maintenance treatment with a long-acting agent or more frequent use of the short-acting inhaler. Two patients were being maintained with albuterol only, and 6 were controlled with appropriate agents (Figure 3). Thirty-seven percent of the patient population was sustained with inappropriate therapy. The facility does have a medication assistance program that allows Chickasaw citizens an expanded formulary. In using this program, 2 patients were able to be

on ideal therapy, defined as albuterol and tiotropium. After reviewing each patient's EHR, we found medication adherence to be at 47.4%.

## Physician visits and hospitalizations

We reviewed any physician visit or hospitalization related to the patient's COPD. From 2006 to 2008, the average number of physician visits per year was 3.5. These visits monitored the patient's disease and any change in symptoms. Thirteen percent of the patients in stage II COPD were hospitalized with an exacerbation from 2006 to 2008.

## Cost – Impact analysis

In evaluating the cost of adding the long-acting anticholinergic, tiotropium, we determined that 6 patients were in stage III (severe) or stage IV (very severe) COPD, bringing the total patient population indicated for such an agent to 44. Projected cost to the facility was \$44,352 for 1 year's therapy.

## DISCUSSION

Our primary objective—to evaluate this facility's adherence to the

**Table. Patient demographics<sup>a</sup>**

| Characteristic                        |              |
|---------------------------------------|--------------|
| Age—y                                 | 66.4 ± 9.9   |
| Weight—kg                             | 83.2 ± 21.8  |
| Blood pressure—mm Hg                  |              |
| Systolic                              | 138.4 ± 22.9 |
| Diastolic                             | 78.4 ± 12.2  |
| Male gender—no/total no (%)           | 25/38 (65.8) |
| Pulmonary function tests              |              |
| FEV <sub>1</sub>                      | 52.7 ± 9.6   |
| FEV <sub>1</sub> /FVC                 | 60.2 ± 7.3   |
| Medication compliance—no/total no (%) | 18/38 (47.4) |
| Comorbidities—no/total no (%)         |              |
| Diabetes mellitus                     | 8/38 (21.1)  |
| Hypertension                          | 32/38 (84.2) |
| Gastrointestinal disorders            | 12/38 (31.6) |
| Dyslipidemia                          | 9/38 (23.7)  |
| Coronary artery disease               | 11/38 (28.9) |

FEV<sub>1</sub> = forced expiratory volume in 1 second; FVC = forced vital capacity; FEV<sub>1</sub>/FVC = the ratio of FEV<sub>1</sub> to FVC; .  
<sup>a</sup> Plus-minus values are means ±SD.

GOLD guidelines when prescribing treatment for patients with stage II COPD—was difficult to achieve. Evaluation of therapy may have been limited due to the small study population. The dramatic lack of current PFTs for the documented cases of COPD was an area of weakness, and only 10% of the possible patient population was eligible for inclusion.

The facility provides care for more than 40,000 patients. The service area is more than 7,500 square miles, covering 13 counties.<sup>8</sup> The Chickasaw Nation Health System includes 4 outlying clinics and 1 main hospital campus. The PFTs are performed at the main campus. One potential problem may have been that patients lacked means of transportation to the main campus. This setback may be reduced with a portable spirometer that could be used at the outlying clinics monthly, thereby enhancing accessibility to patients. Improvements may also include working within the EHR to extend its use to better document results after the test is performed.

The number of current smokers was alarming. Smoking cessation education was discussed at each physician visit. However, the magnitude of existing smokers was greater than any facility would want for patients who have stage II COPD. Smoking cessation assistance is offered through a statewide program. The behavioral health department within the tribal facility is also available to assist with cessation efforts. In 2009, the facility instituted a tobacco-free policy. It would be interesting to investigate the impact this strategy may have on smoking rates. The deficit in preventing disease progression will continue to be a focus for all health care providers.

Within the study population, we noted that several patients had another provider outside of the tribal

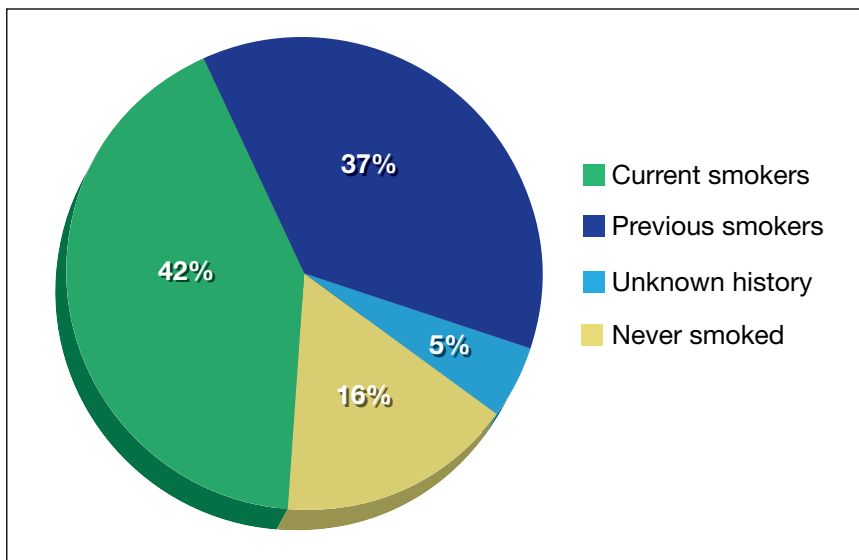


Figure 2. Tobacco history.

facility. This may explain the low number of completed PFTs. Patients may receive health care beyond the tribal facility and use the facility only to receive medications at no cost.

As noted in our results, rescue inhalers were prescribed to only 71% of patients. This finding is problematic, because rescue inhalers are recommended for all patients with COPD.<sup>5</sup> One way to improve this practice would be to institute a template for providers to follow during a visit with a COPD patient. This template could include the medications available on the formulary that are recommended for each stage of COPD. The physician could then select which medications are needed or document if the patient receives medications outside this facility.

Guidelines exist to direct therapy, but often they cannot account for the considerable influence symptoms have on pharmacotherapy. Treating a patient's symptoms improves the patient's quality of life. A patient's PFT results may indicate stage II COPD, but their symptoms may point toward a more severe disease stage. This consideration may identify the basis for the percentage of the study population using inappropriate therapy, such as inhaled corticosteroids, and the 8% of patients using oxygen. Inhaled corticosteroids have been shown to decrease the frequency of exacerbations but not to reduce the progression of the disease state. Therefore, the use of inhaled corticosteroids is only recommended to prevent exacerbations in stage III or stage IV COPD.<sup>5</sup> Without further examination and potential discussion with patients and/or providers, the extent of inappropriate therapy will remain unknown.

Compliance with the patient's COPD medications was determined based on refill history and found to

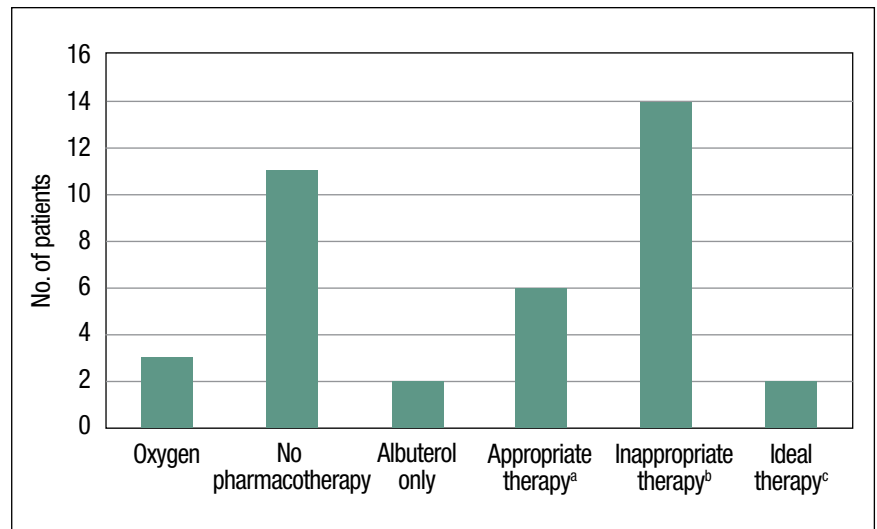


Figure 3. Pharmacotherapy provided. <sup>a</sup>Appropriate therapy included albuterol, ipratropium, and/or albuterol/ipratropium; <sup>b</sup>Inappropriate therapy included any combination of medications that include a steroid inhaler, such as flunisolide; <sup>c</sup>Ideal therapy included albuterol and tiotropium.

be 47.4%. Medication adherence observed within this study population was slightly higher than that found in other studies.<sup>9,10</sup>

Progression of COPD can be slow, but often intensified, by an exacerbation; therefore, we investigated physician appointments and any hospitalizations. The number of physician visits and hospitalizations was comparable to those reported in previous literature.<sup>7</sup> Research did not find any tangible explanation for pharmacotherapy changes resulting from any hospitalization.

Making tiotropium available for use within this tribal facility would not greatly impact the pharmacy budget. The documented and verified patient population that would be eligible for this medication is small. The calculated pharmacy impact may be somewhat underestimated, because some patients may currently be receiving tiotropium from an outside pharmacy. However, we believe this would not significantly change the

cost as less than half of the patient population has outside prescription insurance. It may be beneficial to require that patients needing tiotropium for stage II COPD or greater have a current PFT before receiving a prescription. Ensuring that the patient has a current PFT before filling any prescription for tiotropium would increase the quantity of patients with documented COPD and a recent PFT study.

The goal of our study was to determine how well the facility followed the GOLD guidelines for stage II COPD and the impact of adding tiotropium to the formulary. We found that the guidelines were not well followed and have mentioned areas for potential improvement. These areas could include improving the ordering, completion, and documentation of PFTs to confirm diagnosis and/or developing a template for the implementation of pharmacotherapy. Making these improvements could increase pharmacy costs. If the

changes were implemented, the cost would need to be reassessed. However, some of the initial costs could be offset with long-term cost savings associated with decreased physician visits and/or hospitalizations.

### CONCLUSION

Our study retrospectively analyzed the management of stage II COPD within a tribal facility. The results revealed areas of weakness that can be used to enhance the care offered to the Native American population within the facility. Improving these limitations will further the facility's goal to provide evidence-based medicine and follow the standards of care established in the GOLD guidelines. ●

### Author disclosures

*The authors report no actual or potential conflicts of interest with regard to this article.*

### Disclaimer

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