ICSI

INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Health Care Guideline:

Diagnosis and Management of Chronic Obstructive Pulmonary Disease (COPD)

Seventh Edition
January 2009

The information contained in this ICSI Health Care Guideline is intended primarily for health professionals and the following expert audiences:

- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- health care teaching institutions;
- health care information technology departments;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

This ICSI Health Care Guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. If you are not one of the expert audiences listed above you are urged to consult a health care professional regarding your own situation and any specific medical questions you may have. In addition, you should seek assistance from a health care professional in interpreting this ICSI Health Care Guideline and applying it in your individual case.

This ICSI Health Care Guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. An ICSI Health Care Guideline rarely will establish the only approach to a problem.

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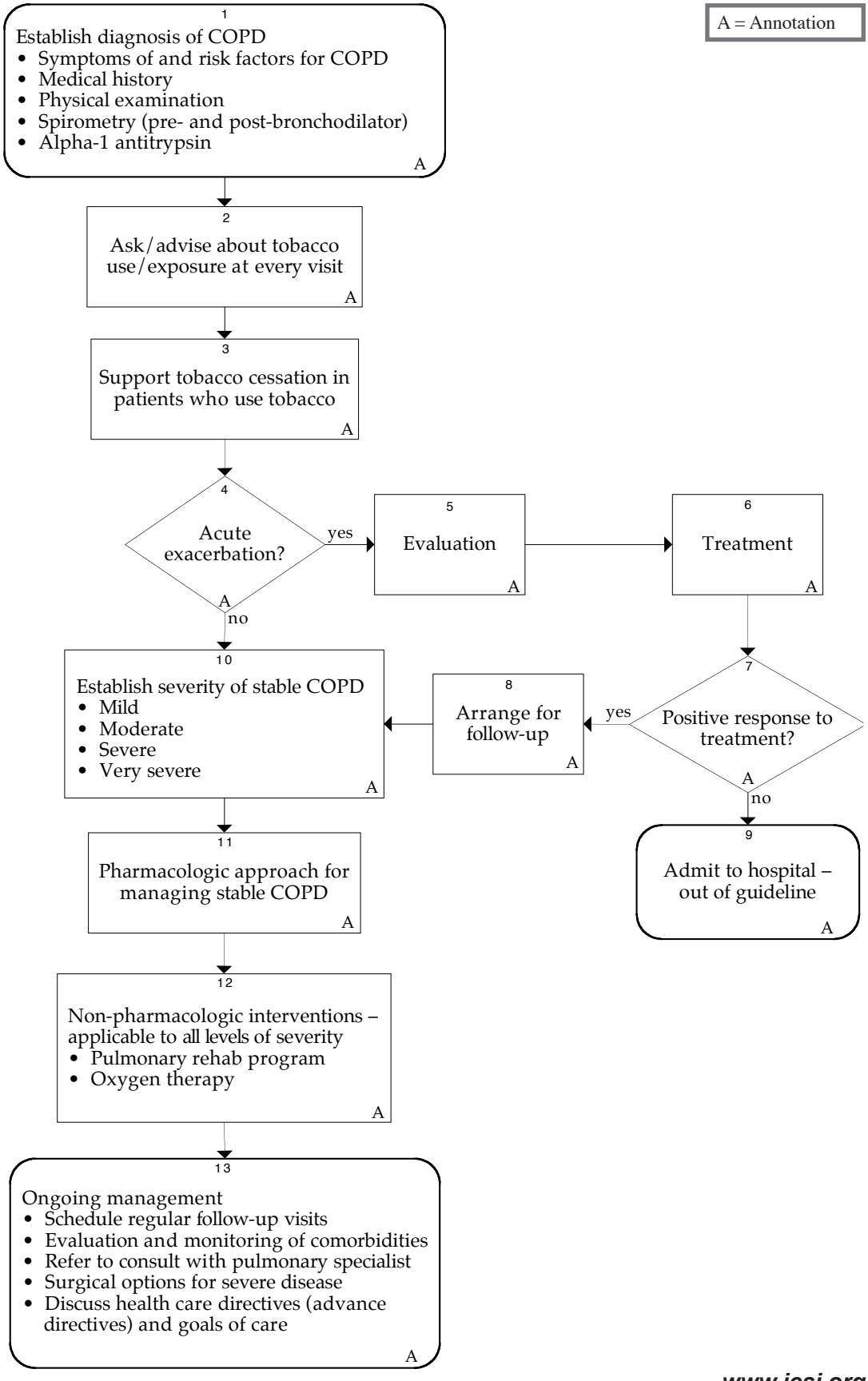

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Work Group Leader
Charlene McEvoy, MD, MPH
HealthPartners Regions Hospital

Work Group Members
Family Medicine
Allen Horn, MD
CentraCare Clinic
G. Paul Kerestes, MD
Allina Medical Clinic
Barbara Yawn, MD
Olmsted Medical Center

Nursing and Health Education
Rhonda Schneider, RN, MSN
Marshfield Clinic
Catherine Youngman, RN
HealthPartners Medical Group

Pharmacy
Anne Schullo-Feulner, PharmD
Park Nicollet Health Services

Pulmonary & Critical Care Medicine
Blair Anderson, MD
HealthPartners Medical Group

Respiratory Therapy
Scott Copeman, RRT, RCP
Mayo Clinic
Jeff Norton, CRT, RCP
Fairview Health Services

Facilitators
Teresa Hunteman, MA, CPHQ
ICSI
Linda Setterlund, MA, CPHQ
ICSI

Foreword

Scope and Target Population

Although chronic obstructive pulmonary disease (COPD) can occur in adults of any age, especially smokers, it most commonly occurs in people 45 years and older. The target population for this guideline is people with symptoms of stable COPD, as well as acute exacerbations of COPD in the outpatient setting.

Clinical Highlights and Recommendations

- Assess patients for symptoms and risk factors for COPD, including asking about tobacco use/exposure at every visit. (*Annotations #1, 2; Aim #2)*
- Tobacco cessation is the only known intervention that can slow progression of lung function loss. *(Annotations # 2, 3; Aim #2)*
- Establish diagnosis and severity of COPD through spirometry, pre- and post-bronchodilator, in addition to history and physical examination. *(Annotation #1; Aim #1)*
- After establishing severity, assess patient needs for pharmacologic and non-pharmacologic treatment and provide appropriate therapy as indicated. *(Annotations #11, 12, 13; Aims #3, 4)*
- Inhaled steroids are warranted in patients with COPD who have recurrent exacerbations. *(Annotation #11; Aims #3, 4)*
- Pulmonary rehabilitation is beneficial for all COPD patients in all stages. *(Annotation #12; Aim # 5)*
- For patients with severe symptoms, despite maximal medical therapy, lung volume reduction surgery and transplantation may be an option. *(Annotation #13)*
- Physicians should discuss advance directives/health care directives and goals of care as early as possible. *(Annotation #13; Aim #5)*

Priority Aims

1. Increase the quality and use of spirometry testing in the diagnosis of patients with COPD.
2. Increase the number of patients with COPD who receive information on the options for tobacco cessation and information on the risks of continued smoking.
3. Reduce COPD exacerbation requiring emergency department (ED) evaluation or hospital admission.
4. Increase the appropriate use of therapy prescribed for patients with COPD.
5. Increase patients' education and management skills with COPD.

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. A model of patient education should be established in the clinics based upon individual learning needs assessments and including coordinated plans jointly developed by educators, patients and their families. Patient education should include core learning and needs objectives based upon individual needs.
2. Establish tobacco status at each visit. Advise to quit and provide supportive interventions including pharmacotherapy if appropriate.

Related ICSI Scientific Documents

Guidelines

- Diagnosis and Management of Asthma
- Palliative Care
- Respiratory Illness in Adults and Children

Technology Assessment Reports

- Lung Volume Reduction Surgery for Emphysema (#23, 2003)

Disclosure of Potential Conflict of Interest

ICSI has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (guidelines, order sets and protocols). This applies to all work groups (guidelines, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee and Respiratory Steering Committee).

Participants must disclose any potential conflict and competing interests they or their dependents (spouse, dependent children, or others claimed as dependents) may have with any organization with commercial, proprietary, or political interests relevant to the topics covered by ICSI documents. Such disclosures will be shared with all individuals who prepare, review and approve ICSI documents.

Charlene McEvoy, MD, has been a part of a Speaker's Bureau and participated in Research/Grant Funding for Pzifer and Spiration, Inc. All funds go to HealthPartners Research Foundation.

Barbara Yawn, MD, has received honorariums and participated in Research/Grant Funding for BJ/Pzifer, GSK and AZ. All funds paid to Olmsted Medical Center. No funds received personally.

No other work group members have potential conflicts of interest to disclose.

Introduction to ICSI Document Development

This document was developed and/or revised by a multidisciplinary work group utilizing a defined process for literature search and review, document development and revision, as well as obtaining input from and responding to ICSI members.

For a description of ICSI's development and revision process, please see the Development and Revision Process for Guidelines, Order Sets and Protocols at http://www.icsi.org.

Evidence Grading System

A. Primary Reports of New Data Collection:

Class A: Randomized, controlled trial

Class B: Cohort study

Class C: Non-randomized trial with concurrent or historical controls
Case-control study
Study of sensitivity and specificity of a diagnostic test
Population-based descriptive study

Class D: Cross-sectional study
Case series
Case report

B. Reports that Synthesize or Reflect Upon Collections of Primary Reports:

Class M: Meta-analysis
Systematic review
Decision analysis
Cost-effectiveness analysis

Class R: Consensus statement
Consensus report
Narrative review

Class X: Medical opinion

Citations are listed in the guideline utilizing the format of *(Author, YYYY [report class])*. A full explanation of ICSI's Evidence Grading System can be found at http://www.icsi.org.

Algorithm Annotations

Introduction

COPD (chronic obstructive pulmonary disease) includes both emphysema and chronic obstructive bronchitis. COPD is the fourth leading cause of death in the United States and is the only common chronic illness for which mortality rates continue to increase *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*.

Historically viewed as a man's disease, more women have died of COPD than men each year since 2000 *(National Center for Health Statistics, 2004)*. Cigarette smoking is the cause of 80%-90% of COPD cases, with occupational exposure accounting for 10%-20% and Alpha 1-antitrypsin deficiency accounting for 3%-4% *(American Thoracic Society, 1995a [R]; American Thoracic Society/European Respiratory Society, 2003 [R])*.

Early diagnosis and treatment, including pulmonary rehabilitation and pharmacologic intervention, can improve the quality of life in COPD sufferers *(Lacasse, 1996 [M])*. Smoking cessation and oxygen for severe hypoxemia can prolong life *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*. Therefore, COPD should be considered a preventable and treatable illness.

What is COPD?

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable disease with some significant extrapulmonary effects that may contribute to the severity in individual patients. Its pulmonary component is characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*.

Chronic inflammation of the small airways and gradual destruction of the alveoli characterize COPD *(Barnes 2000 [R])*. Chronic inflammation results in fibrosis, which in turn leads to narrowing of the airways. Neutrophils drive the inflammation observed in COPD, which is different from the eosinophil-based inflammation of asthma *(Barnes, 2000 [R])*. Various protease enzymes released by neutrophils damage the elasticity and destroy the supporting tissues of the alveoli. These problems are aggravated by excessive mucus, which clogs the airways, resulting in spasm of the muscles that surround them. Terminal bronchioles collapse or are blocked by mucus plugs, and their alveoli die. Air becomes trapped in the distal airways, causing hyperinflation. Alveolar dead space (alveoli that are ventilated but not perfused) is increased. Hyperinflation, in combination with narrowed airways and reduced gas exchange from loss of alveoli, lead to breathlessness, exercise intolerance, and hypoxia. Hypoxia increases pulmonary vascular resistance, causing pulmonary hypertension and, in severe cases, right-heart failure. Treatment is aimed at slowing this progression *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*.

Causes of COPD

Cigarette smoking causes 80%-90% of all cases of COPD, and a smoker is 10 times more likely to die of COPD than a non-smoker *(American Thoracic Society, 1995a [R]; American Thoracic Society/European Respiratory Society, 2003 [R])*. Other risk factors for COPD include:

- middle/old age
- genetic factors (including deficiency of the anti-protease enzyme alpha-1 antitrypsin)
- indoor air pollution especially from burning biomass fuels in confined spaces – especially in women *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*

- passive exposure to cigarette smoke or environmental tobacco smoke *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*
- occupational dusts and chemicals (vapors, irritants and fumes)

Symptoms of COPD

Chronic cough (may or may not be productive) is often the first symptom of COPD, and patients often brush this off as the "typical smoker's cough." By 40 to 50 years of age, the person with COPD may begin to experience progressive shortness of breath that limits activities. Many patients simply adjust activities to their exercise tolerance and incorrectly assume that their inability to climb two or three flights of stairs or to keep up with children or grandchildren is a normal part of aging *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*. Therefore simply waiting for patients to report symptoms is unlikely to identify the millions of Americans who have undiagnosed COPD. Asking specific questions about shortness of breath on mild exertion, changes in the ability to exercise (at work and at play), and a productive chronic cough may be helpful.

1. Establish Diagnosis of COPD

Key Points:

- The diagnosis of COPD should be suspected based on the patient's medical history and physical examination.
- Spirometry is necessary for COPD diagnosis.

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) defines COPD as follows:

- A preventable and treatable disease characterized by chronic airflow limitation that is not fully reversible. Airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lungs.
- Chronic obstructive bronchitis is defined as partially reversible airflow limitation as well as the presence of chronic productive cough for three months in each of two successive years in a patient in whom other causes of chronic cough have been excluded.
- Emphysema is defined as an abnormal permanent enlargement of the air spaces distal to the terminal bronchioles, accompanied by destruction of their walls and without obvious fibrosis.

(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])

Definition of COPD from Other Guidelines:

The American Thoracic Society (ATS) defines COPD as follows:

- COPD is a disease characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema; the airflow obstruction is generally progressive, may be accompanied by airway hyperreactivity and may be partially reversible *(American Thoracic Society, 1995a [R])*.

The British Thoracic Society (BTS) defines COPD as follows:

- A chronic, slowly progressive disorder characterized by airflow obstruction that does not change markedly over several months. Most of the lung function impairment is fixed, although some reversibility can be produced by bronchodilator.

- The diagnosis requires a history of chronic progressive symptoms (cough and/or wheeze and/or breathlessness) and objective evidence of airway obstruction – ideally by spirometric testing – that does not return to normal with treatment.
- The presence of chronic cough and sputum production for at least three months of two consecutive years in the absence of other diseases is used as a definition of chronic bronchitis, but does not necessarily signify the presence of airway obstruction or a diagnosis of COPD.

(British Thoracic Society, 1997 [R])

The European Respiratory Society (ERS) defines COPD as follows:

- A disorder characterized by reduced maximum expiratory flows and slow, forced emptying of the lungs; features do not change markedly over several months
- Airflow limitation due to varying combinations of airway disease and emphysema
- Patients exhibit minimal reversibility of airflow limitation with bronchodilators

(European Respiratory Society, 1995 [R])

Recommended Etiological Evaluations for the Diagnosis of COPD from Other Guidelines

- Spirometry recommended by ATS, BTS, ERS and GOLD
- Pre- and post-bronchodilator recommended by ATS, BTS, ERS and GOLD
- Screening for Alpha 1-antitrypsin concentration recommended by ERS, GOLD and ATS in patients who develop COPD at a young age
- Resting oxygen saturation measurement suggested by ERS in moderate or severe disease, and BTS in severe disease
- Arterial blood gas (ABG) measurement recommended by ERS in moderate or severe disease or if oxygen saturation is less than 92%, by ATS in moderate or severe disease, and by BTS and GOLD in severe disease

Symptoms of and Risk Factors for COPD

COPD may be indicated by the presence of one of the following symptoms:

- Chronic cough (duration greater than three months) with or without sputum production
- Dyspnea with or without wheezing

COPD should also be considered if the patient has one or more of the following risk factors:

- History of tobacco use or prolonged exposure to secondhand or environmental smoke
- Asthma
- Occupations with exposure to dust and chemicals (e.g., firefighters, welders)
- Alpha 1-antitrypsin deficiency
- Chronic respiratory infections

The diagnosis of COPD should be suspected based on the patient's medical history and physical examination, but requires spirometry to determine the degree of airflow limitation. Spirometry is necessary for the diagnosis of COPD *(U.S. Preventive Services Task Force, 2008 [R])*.

Signs/symptoms for which COPD may be suspected:

- Wheezing, prolonged expiratory phase of respiration, rhonchi and cough
- Dyspnea (exertional or at rest)
- Chronic sputum production
- Hyperinflation of the chest with increased anterior-posterior (A-P) diameter
- Use of accessory muscles of respiration
- Pursed-lip breathing
- Signs of cor pulmonale:
  - Increased pulmonic component of the second heart sound
  - Neck vein distention
  - Lower extremity edema
  - Hepatomegaly

    NOTE: finger clubbing is not characteristic of COPD and should alert the clinician to another condition such as idiopathic pulmonary fibrosis (IPF), cystic fibrosis, lung cancer or asbestosis.

Spirometry

Spirometry is an established and important method of measuring lung function for the diagnosis and management of patients with COPD. It is recommended for symptomatic patients at risk of COPD, particularly smokers greater than 45 years of age, and for regular follow-up of patients with documented COPD *(Wilt, 2005 [M])*. Large population screening is not recommended.

Airflow obstruction is measured by spirometry and shows a reduced forced expiratory volume in one second (FEV_1) and FEV_1/FVC (forced vital capacity) ratio. Measuring pre- and post-bronchodilator spirometry is important to identify those patients with partial reversibility of airflow obstruction. Partial reversibility is defined as improvement in airflow by 12% of baseline and 200 mL after administration of a bronchodilator.

Pre- and Post-bronchodilator FEV_1

It is important to distinguish COPD from asthma, because treatment and prognosis differ. Measurement of pre- and post-bronchodilator FEV_1 can assist with this differentation. In asthma, the spirometric abnormality tends to return to normal with bronchodilators, although this distinction between COPD and asthma is not strictly rigid. Factors commonly used to distinguish COPD from asthma include age of onset, smoking history, triggering factors and occupational history.

If the results of available spirometry are unclear, formal spirometry in a pulmonary function test lab should be considered. Full pulmonary function tests with lung volumes and diffusion capacity (DLCO) are not recommended nor necessary to establish diagnosis or severity of COPD.

Spirometry, interpretation strategies, selection of reference values and quality control should be performed in compliance with the American Thoracic Society Statement on Standardization of Spirometry *(American Thoracic Society, 1995b [R])*.

- The spirometer must meet or exceed requirements proposed by the American Thoracic Society.

- Automated maneuver acceptability and reproducibility messages must be displayed and reported. Spirometers should produce a paper record.
- The use of a nose clip for all spirometric maneuvers is strongly recommended.
- Subjects may be studied in either the sitting or standing position.
- Universal precautions should be applied in all instances in which there is potential for blood and body fluid exposure. Appropriate use of gloves and hand washing are highly recommended.
- Patients suspected of having M. tuberculosis or other airborne organisms should be tested in areas complying with the U.S. Public Health Service recommendations for air exchange and ventilation.
- Daily calibration prior to testing using a calibrated known volume syringe with a volume of at least three liters performed to manufacturer's recommendations is recommended. A log documenting instrument calibrations should be maintained.
- Discussion of spirometry results with current smokers should be accompanied by strong advice to quit smoking and referral to smoking cessation resources.

(American Association for Respiratory Care Clinical Practice Guideline, 1996 [R]; American Thoracic Society, 1995a [R]; Ferguson, 2000 [R])

Although peak flow meters should not be used to diagnose or monitor COPD, monitoring of peak expiratory flow at home and at work can be used in certain situations to determine reversibility of and variability in airway obstruction.

Reversibility Testing (measurement of pre- and post-bronchiodilator)

- Global Initiative for Chronic Obstructive Lung Disease (GOLD):
  - Generally performed only once at time of diagnosis, this test is useful to help rule out asthma, to establish a patient's best attainable lung function, to gauge a patient's prognosis, and to guide treatment decisions.
  - Even patients who do not show a significant FEV_1 response to a short-acting bronchodilator test can benefit symptomatically from long-term bronchodilator treatment.
- British Thoracic Society, COPD Guidelines Group of the Standards of Care Committee:
  - A positive bronchodilator response (FEV_1 greater than 200 mL and 15% over baseline value) suggests asthma.
  - More than 20% variability in absolute measurement of serial peak expiratory flow may suggest asthma.
- European Respiratory Society (ERS):
  - Atopy and marked improvement of spirometry with administration of bronchodilators or glucocorticosteroids favor the diagnosis of asthma.
  - Testing of bronchoconstrictor response is of doubtful clinical value in patients with established airflow limitation.
- American Thoracic Society (ATS):
  - Significant reversibility is indicated by an increase of over 12% and 200 mL after inhaling a short-acting bronchodilator.

- Alpha 1-antitrypsin

  Alpha 1-antitrypsin deficiency (A1AD or Alpha-1) is a genetic disorder caused by defective production of alpha 1-antitrypsin (A1AT), leading to decreased A1AT activity in the blood and lungs, and deposition of excessive abnormal A1AT protein in liver cells *(Stoller, 2005 [R])*. There are several forms and degrees of deficiency. Severe A1AD causes emphysema and/or COPD in adult life in nearly all people with the condition. Cigarette smoke is especially harmful to individuals with A1AD. In addition to increasing the inflammatory reaction in the airways, cigarette smoke directly inactivates alpha 1-antitrypsin by oxidizing essential methionine residues to sulfoxide forms, decreasing the enzyme activity by a factor of 2000. A1AD screening is appropriate in patients of Caucasian descent who develop COPD at a young age (less than 45 years) or who have a strong family history of the disease *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*.

Differential diagnosis

The chest radiograph in COPD is often normal but may show signs of hyperinflation, a flattened diaphragm, or bullae.

In addition to asthma, possible differential diagnoses for COPD include bronchiectasis, cystic fibrosis, obliterative bronchiolitis, congestive heart failure and upper airway lesions.

For more information on diagnosis and treatment of asthma, please refer to the ICSI Diagnosis and Treatment of Asthma guideline.

2. Ask/Advise About Tobacco Use/Exposure at Every Visit

Key Points:

- Tobacco cessation and oxygen therapy for those with resting hypoxemia are the only interventions proven to prolong survival of patients with COPD.

Ten to fifteen percent of long-term smokers develop COPD with accelerated rates of decline in FEV_1. Advice and support from physicians and other health professionals are potentially powerful influences on tobacco cessation. According to the U.S. Surgeon General, tobacco use is one of the most important public health issues of our time. The National Cancer Institute, which is the primary federal agency for tobacco control, states that the keys to patient awareness and education about tobacco cessation in a clinical setting are:

ASK	about tobacco use at every visit
ADVISE	all users to stop
ASSESS	users' willingness to make a quit attempt
ASSIST	users' efforts to quit
ARRANGE	follow-up

3. Support Tobacco Cessation in Patients Who Use Tobacco

Reinforcement of tobacco cessation and follow-up for patients with COPD are extremely important. Pharmacotherapy, social support and skills training/problem solving are the key treatments for tobacco cessation. Nicotine patches, nasal sprays, inhalers and oral medication are all available to help patients achieve cessation *(Dale, 2001 [A]; Fiore MC, 2008 [R])*.

Generic	Brand	Dosage Form	Initial Dose	Maintenance Dose
Varenicline	Chantix®	0.5 mg tablet 1 mg tablet	Days 1-3: 0.5 mg daily; Days 4-7: 0.5 mg twice daily	1 mg twice daily
Bupropion SR	Zyban®	150 mg tablet	Days 1-3: 150 mg daily	150 mg twice daily
Nicotine patch	NicoDerm CQ®	7 mg/ 24 hour 14 mg/ 24 hour 21 mg/ 24 hour	14-21 mg/24 hours x 4-6 weeks; 14-7 mg/24 hours x 2 weeks; 7-0 mg/24 hours x 2 weeks	160-320 mcg
Nicotine gum	Nicorette®	2 mg chew 4 mg chew	Weeks 1-6: 2-4 mg every 1-2 hours; weeks 7-9: 2-4 mg every 2-4 hours; weeks 10-12: 2-4 mg every 4-8 hours	MAX: 96 mg/day
Nicotine lozenge	Commit®	2 mg chew 4 mg chew	Weeks 1-6: 2-4 mg every 1-2 hours; weeks 7-9: 2-4 mg every 2-4 hours; weeks 10-12: 2-4 mg every 4-8 hours	MAX: 96 mg/day
Nicotine inhaler	Nicotrol®	10 mg cartridge (4 mg/actuation)	6-16 cartridges/day	
Nicotine intranasal spray	Nicotrol NS®	10 mg bottle (0.5 mg/spray)	1-2 sprays/hour	MAX: 10 sprays/hour

References: Clinical Pharmacology, Drug Information Handbook, Micromedex (Accessed November 2008)

4. Acute Exacerbation?

Signs and symptoms of an acute exacerbation of COPD may include any of the following:

- Increased dyspnea
- Increased heart rate
- Increased cough
- Increased sputum production
- Change in sputum color or character
- Use of accessory muscles of respiration
- Peripheral edema
- Development or increase in wheezing

- Change in mental status
- Fatigue
- Fever
- Increased respiratory rate
- Decrease in FEV_1 or peak expiratory flow
- Hypoxemia
- Chest tightness

Change in mental status or a combination of two or more of the following new symptoms indicates a severe acute exacerbation:

- Dyspnea at rest
- Cyanosis
- Respiratory rate of greater than 25 breaths per minute
- Heart rate of greater than 110 beats per minute
- Use of accessory muscles of respiration

5. Evaluation

When a patient with known COPD presents with a moderate to severe exacerbation, the following key elements of the history, physical examination and laboratory/radiology evaluation should be considered:

History

- Baseline respiratory status
- Present treatment regimen and recent medication use
- Signs of airway infection, e.g., fever and/or change in volume and/or color of sputum
- Duration of worsening symptoms
- Limitation of activities
- History of previous exacerbations
- Increased cough
- Decrease in exercise tolerance
- Chest tightness
- Change in alertness
- Other non-specific symptoms including malaise, difficulty sleeping and fatigue
- Symptoms associated with comorbid acute and chronic conditions
- Although rarely used, non-selective beta-blockers may contribute to bronchospasms

Physical Examination

- Measurement of heart rate and blood pressure
- Measurement of respiratory rate
- Measurement of oxygen saturations using pulse oximetry
- Measurement of temperature
- Respiratory distress
- Accessory respiratory muscle use
- Increased pulmonary findings (e.g., wheezing, decreased air entry, prolonged expiratory phase)
- Peripheral edema
- Somnolence and/or hyperactivity
- Acute comorbid conditions

Laboratory/Radiology

- Chest radiograph (in patients with suspected pneumonia)
- Arterial blood gas (if oxygen saturation less than 88%, positive history of hypercapnia, questionable accuracy of oximetry, somnolence or other evidence of impending respiratory failure [e.g., respiratory rate greater than 40 breaths per minute])
- Theophylline level (if theophylline is being utilized)
- White blood count (in patients with suspected severe respiratory infection)
- A sputum culture with susceptibilities, if available, should be performed when an infectious exacerbation does not respond to initial antibiotic treatment *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*. It is important that the sputum specimen is of good quality.
- Brain natriuretic peptide (BNP), a simple blood lab test, can be of some use in evaluating a patient presenting with dyspnea, although its interpretation needs to be carefully applied along with clinical and other lab data such as chest radiograph and echocardiogram. Its sensitivity and specificity in this setting increase at levels above 400 but do not differentiate between acute left ventricular (LV) failure, cor pulmonale or pulmonary embolism *(McCullough, 2002 [B])*. It is of particular value if the level is very low. The probability of left ventricular failure as a cause of dyspnea is less than 10% if the brain natriuretic peptide is less than 100 *(Maisel, 2002 [B])*.

In patients with an acute COPD exacerbation, spirometry is of little value. For that reason, oximetry and/or arterial blood gases should be monitored.

There is little evidence regarding the contribution of additional laboratory testing or the usefulness of electrocardiography or echocardiography in an acute exacerbation of COPD. They may be a useful consideration if the diagnosis is unclear, in order to evaluate other comorbid conditions.

(McCrory, 2001 [M])

6. Treatment

Key Points:

- Albuterol is the preferred bronchodilator in the setting of an acute exacerbation of COPD because of its rapid onset of action.
- Ipratropium may be added to produce additive bronchodilation and allow the use of lower doses of albuterol.
- Steroids should be used in acute exacerbations.
- It is mandatory to check oxygen saturation or arterial blood gas measurement.

Bronchodilators

Albuterol is the preferred bronchodilator in the setting of an acute exacerbation of COPD because of its rapid onset of action. If clinical improvement does not occur promptly, ipratropium may be added to produce additive bronchodilation and allow the use of lower doses of albuterol, thus diminishing dose-dependent toxicity. Administration of either agent by metered-dose inhaler and spacer or by nebulization is acceptable *(Moayyedi, 1995 [A]; Patrick, 1990 [A]; Turner, 1997 [M])*.

Role of Levalbuterol in COPD

There are many theoretical advantages of levalbuterol over albuterol in the treatment of bronchospasm. Albuterol is a racemic combination of two isomers: the "R" isomer (levalbuterol) that is a potent bronchodilator, and the "S" isomer that has been shown in animal studies to counteract bronchodilation and can promote inflammation. Unfortunately, clinical studies in human subjects with bronchospasm have not consistently shown greater bronchodilation, or fewer side effects of levalbuterol over equivalent doses of a racemic agent such as albuterol. In individual patients with COPD and acute bronchospasm who demonstrate excessive tachycardia and/or tremor, ipratropium is the next bronchodilator of choice. Levalbuterol may be an acceptable alternative as a trial agent, especially in patients whose bronchospasm worsens or shows no improvement on ipratropium *(Costello, 1999 [R]; Nelson, 1999 [R]; Scott, 2003 [C])*.

Systemic Steroids

Studies have demonstrated the benefits of systemic glucocorticosteroids in the management of COPD exacerbations. Doses of oral prednisone at 30 to 40 mg a day for 7 to 14 days have been shown to reduce symptoms and reduce the likelihood of hospitalization. Treatment beyond two weeks does not provide any additional benefit, but does increase the likelihood of significant side effects such as hyperglycemia. There is no need to discontinue inhaled steroids while the patient is taking oral prednisone (*Aaron, 2003 [A]; Davies, 1999 [A]; McEvoy, 2000 [R]; Niewoehner, 1999 [A]; Thompson, 1996 [A])*.

Antibiotics

In the presence of an exacerbation with purulent sputum, an antibiotic is warranted. Trimethoprim/sulfamethoxazole (TMP/SMX) and doxycycline are considered adequate "first-line" agents. This is based on a lack of evidence to support the use of newer or broader spectrum antibiotics. The use of "second-line" agents can be considered when there is concern about antibiotic resistance, either from previous cultures of the patient being treated or known local antibiogram, the patient is considered to have a more severe exacerbation, or other factors including side effect profiles. The "second-line" agents include second-generation cephalosporins, azithromycin, clarithromycin and amoxicillin-clavulanate. Duration of antibiotic therapy need not be longer than 10 days, and in most clinical settings, seven days would be adequate *(Amsden, 2003 [A]; Anthonisen, 1987 [A]; Chodosh, 1998 [A])*.

Oxygen Saturation/Arterial Blood Gas Measurement

Oxymetric evaluation of patients with COPD exacerbations is mandatory. Patients with oxygen saturations of 80%-90% on room air can be titrated with supplemental oxygen to a saturation level of 90% with little concern of significant hypercarbia, unless such intervention results in somnolence. In such cases, or if the oxygen saturation is less than 80% upon presentation, an arterial blood gas should be obtained. If the pH is less than 7.32, admission to the hospital should be arranged because of the risk of acute respiratory failure. If outpatient management has been decided upon, the patient should be ambulated to determine what oxygen flow is needed to maintain oxygen saturations at 90% while walking. Home oxygen then needs to be arranged *(Bone, 1978 [D])*.

7. Positive Response to Treatment?

The following criteria may be used as evidence of improvement in COPD exacerbation:

- Decreased work of breathing and improved oxygen exchange
- Decrease in cough, sputum production, fever or dyspnea
- Decrease in respiratory rate
- Decrease in heart rate
- Decrease in accessory muscle use
- Increase in function and endurance

8. Arrange for Follow-Up

A follow-up appointment between the primary care clinician and the patient should occur within one to four weeks to reassess management strategies and supplemental oxygen needs.

9. Admit to Hospital – Out of Guideline

The following may be indications to consider hospital admission for an acute exacerbation of COPD:

- Marked increase in intensity of symptoms, such as sudden development of resting dyspnea
- History of severe COPD, especially if mechanical ventilation was required
- Onset of new physical signs (e.g., cyanosis, peripheral edema)
- Failure of exacerbation to respond to initial outpatient medical management
- High-risk comorbidities, pulmonary (e.g., pneumonia requiring hospitalization) or cardiac symptoms
- Increasing hypoxemia despite supplemental oxygen
- New or worsening carbon dioxide (CO_2) retention or pH less than 7.32
- Marked decrease in ability to ambulate, eat or sleep due to dyspnea
- History of prolonged, progressive symptoms
- Newly occurring arrhythmias
- Diagnostic uncertainty

- Older age
- Insufficient home support
- Decrease in alertness

(McCrory, 2001 [M])

10. Establish Severity of Stable COPD

Key Points:

- Both spirometry and/or signs and symptoms are used to establish severity.

The signs, symptoms and airflow limitation in COPD vary with the severity of the disease. The stages of severity of COPD may be categorized according to Table #I.

Table I

Stage of COPD	FEV_1 (% predicted)	Typical Symptoms and Signs
Mild	80 or greater	No abnormal signs Cough (± sputum) Little or no dyspnea
Moderate	Between 50 and 79	Breathlessness (± wheeze on moderate exertion) Cough (± sputum) Variable abnormal signs (general reduction in breath sounds, presence of wheezes) Hypoxemia may be present
Severe	Between 30 and 49	Dyspnea with any exertion or at rest Wheeze and cough often prominent
Very severe	Less than 30	Lung hyperinflation usual; cyanosis, peripheral edema and polycythemia in advanced disease Hypoxemia and hypercapnia are common

The best correlation with morbidity and mortality is decrease in FEV_1. With FEV_1 greater than 1.0 L, there is a slight increase in mortality at 10 years. With FEV_1 less than 0.75 L, the approximate mortality rate at one year is 30%, and at 10 years is 95%. Because of the relationship of prognosis and FEV_1, the severity of COPD is staged on the basis of this spirometry measurement. Patients are categorized as mild, moderate, severe or very severe. The COPD work group selected the COPD severity categories recommended by Global Initiative for Chronic Obstructive Lung Disease because they are straightforward and correlate with clinical experience. However, it is clear that there are widespread differences relative to disease severity classification among published guidelines *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R]; Hodgkin, 1990 [R])*.

11. Pharmacologic Approach for Managing Stable COPD

Key Points:

- Drug therapy is determined by severity of symptoms.

Each level of severity in Table II represents an intervention that should be considered only if the previous course of action fails to improve symptoms of COPD.

A table of estimated comparative daily dosages for inhaled corticosteroids is attached in Appendix A, "Estimated Comparative Daily Dosage for Inhaled Corticosteroids."

A table of hydrofluoro-alkane (HFAs) is attached in Appendix B, "Hydrofluoro-alkane (HFA) Directory."

Table II

	Lung Function Parameters		Therapy
			All severities— • Pulmonary rehabilitation • Annual influenza immunization • Pneumococcal vaccine • Smoking cessation support • Trigger avoidance • Inhaler technique training • COPD education • Caretaker support
COPD Severity	**FEV_1 % Predicted**	**FEV_1/FVC**	Add:
Mild	≥ 80%	< 0.7	• Short-acting bronchodilators as needed for symptoms
Moderate	50%-79%	< 0.7	• Daily long-acting bronchodilators (single or combination of beta-agonists and anticholinergics)
Severe	30%-49%	< 0.7	• Daily long-acting bronchodilators as above plus inhaled corticosteroids to reduce exacerbations • Oral steroid bursts for exacerbations
Very severe	< 30% or < 50% plus chronic renal failure	< 0.7	• Combination therapy as above • Oral steroids as needed • Oxygen supplementation

Information contained in Global Initiative for Chronic Obstructive Lung Disease, 2008

Bronchodilator Medications

Albuterol, Ipratropium or Tiotropium

Albuterol and ipratropium are equipotent as bronchodilators, improving dyspnea and exercise tolerance equally well. No dramatic evidence showing an advantage of either albuterol or ipratropium as a scheduled first-step therapy for COPD symptoms or improved quality of life has been shown in the medical literature.

Albuterol is recommended as the first-line treatment for patients with symptoms of mild COPD because the onset of bronchodilator effect (15 minutes) is more rapid than ipratropium (30-90 minutes). The dose-response curve of albuterol for improvement in FEV_1 continues to increase to at least eight puffs. Ipratropium is to be used on a regularly scheduled basis rather than as needed because its dose-response time is too long to titrate its use to control symptoms.

Ipratropium bronchodilator duration (two puffs for four hours) is greater than albuterol (two puffs for two or three hours). The dose-response curve for ipratroprium levels off above six puffs, whereas therapeutic efficacy for albuterol continues to increase at higher doses, although side effects such as tremor can develop. Studies were small and may not have been of a statistical power to detect differences between bronchodilators.

(Blosser, 1995 [A]; Easton, 1986 [A]; Rennard, 1996 [M])

Clinicians should consider replacing ipratropuim with tiotropium as a scheduled bronchodilator because it provides improved benefits and only requires once-a-day dosing *(Oostenbrink, 2004 [M])*.

Tiotropium

Tiotropium, a new dry powder, once-daily long-acting anticholinergic, was compared to salmeterol in a six-month study. Significant improvements in bronchodilation, symptoms and quality of life were demonstrated by tiotropium over salmeterol. Improved morning pre-dose bronchodilation was also seen at six months *(Donahue, 2004 [A])*. Due to these benefits and the once-daily dosing, tiotropium offers significant advantages as a scheduled bronchodilator to patients whose symptoms are not controlled by albuterol. Tiotropium replaces the use of ipratropium in the setting of stable COPD. Tiotropium has additive effects to long-acting beta-agonists *(Cazzola, 2004 [A]; van Noord, 2006 [A])*. In patients with moderate to severe COPD, tiotropium has also been demonstrated to significantly reduce both exacerbations and hospitalizations when added to the COPD treatment regimen *(Hvizdos, 2002 [R]; Niewoehner, 2005 [A])*.

If a patient with COPD has unacceptable symptoms while on tiotropium, a long-acting beta-agonist can be added *(Brusasco, 2003 [A]; van Noord, 2006 [A])*.

No studies have compared the additive effects of tiotropium with steroids as a single agent in effectiveness of COPD management.

Combination Albuterol and Ipratropium

Many studies show that the combination of ipratropium 0.5 mg and albuterol 2.5 mg provides greater bronchodilator effect compared to each alone; however, the same effect could probably be achieved by doubling the dose of either agent. This is reflective of the additive bronchodilator effect of both, as expected. No study compares the combination of ipratropium and albuterol to an equivalent dose of albuterol or ipratropium (e.g., four puffs of combination to four puffs of albuterol or ipratropium).

One study also showed that patients randomized to albuterol two puffs four times/day had 18% more COPD exacerbations than those randomized to ipratropium two puffs four times/day (therefore "more expensive" $p<0.05$). Baseline FEV_1 and FVC with ipratropium was greater than with albuterol after 90 days ($p<0.05$ and <0.01). No significant difference in quality of life was demonstrated, however. After 90 days, the albuterol group was less responsive to albuterol than the ipratropium group was responsive to albuterol ($p>0.0001$).

(Dorinsky, 1999 [A]; Moayyedi, 1995 [A])

Long-Acting Beta-Agonists (LABAs)

Currently available LABAs are analogues of albuterol, giving them a half-life of approximately 12 hours (as opposed to albuterol's 4-6 hours) enabling twice-daily dosing. LABAs should be viewed as maintenance therapy and should not be used as rescue therapy.

Formoterol

Twice-daily dosing of formoterol offers advantages similar to those of salmeterol. Data also show that formoterol has quicker onset of action than salmeterol *(Dahl, 2001 [A]; Kottakis, 2002 [A])*.

Salmeterol

Glaxo-Wellcome, Inc., maker of salmeterol, funded a study that showed salmeterol gave greater increase in FEV_1 and FVC than albuterol or ipratropium, much longer duration of bronchodilation and, therefore, greater "area under the curve." Improvements in dyspnea and exercise tolerance were similar to those using ipratropium. Sixteen weeks of salmeterol therapy provided an increased baseline FEV_1 of 7%. Salmeterol at doses of eight puffs produced no significant cardiovascular effects in patients with COPD (heart rate or PVCs). However, tremor developed after four puffs. Quality of life indicators increased with salmeterol compared to as-needed use of albuterol. Significant evidence exists for salmeterol to be used as a scheduled treatment for COPD. When compared to other beta-agonists, its benefits include a higher and more prolonged bronchodilation effect. In addition, salmeterol's twice-daily dosing compared to four times/day dosing required by albuterol and ipratropium may improve compliance *(Matera, 1995 [A]; Matera, 1996 [A]; Patakas, 1998 [A])*.

Summary

Albuterol is the preferred agent for as-needed control of symptoms in patients with mild COPD and as an additive as-needed agent to a scheduled bronchodilator in patients with more severe COPD because the onset of bronchodilator effect (15 minutes) is more rapid than ipratropium (30-90 minutes).

Tiotropium has been shown to be a superior scheduled bronchodilator to salmeterol and ipratropium.

As a scheduled bronchodilator, salmeterol has the main advantage of requiring only twice-daily dosing, and therefore may improve compliance.

Albuterol and ipratropium are equipotent as bronchodilators, improving dyspnea and exercise tolerance equally well. Salmeterol is a long-acting bronchodilator that is a suitable agent for scheduled administration.

(Brusasco, 2003 [A]; Donohue, 2002 [A]; Hvizdos, 2002 [R])

Glucocorticosteroids

The effects of both inhaled and oral corticosteroids are much less robust in patients with COPD when compared to asthma. Therefore, the role of glucocorticosteroids in the mangagement of stable COPD is limited to specific situations *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*. The dose-response relationships and long-term safety of inhaled glucocorticosteroids are not known.

Inhaled glucocorticosteroids. Regular use of inhaled corticosteroids does not modify the decline in FEV_1 observed in patients with COPD *(Burge, 2000 [A]; Pauwels, 1999 [A]; Vestbo, 1999 [A])*. However, with regular treatment, inhaled steroids have been shown to reduce the frequency of exacerbations and improve health status in patients with FEV_1 less than 50% predicted and history of frequent exacerbations. An inhaled corticosteroid combined with a long-acting beta-2-agonist is more effective than the individual components in reducing exacerbations and improving lung function as well as health status. However, treatment with inhaled glucocorticosteroids or a combination inhaler increases the likelihood of pneumonia and does not reduce overall mortality *(Calverley, 2007 [A])*.

Oral glucocorticosteroids. There is insufficient evidence to recommend a therapeutic trial of oral glucocorticosteroids in patients with COPD to determine whether a patient will benefit from long-term treatment of either oral or inhaled glucocorticosteroids. There is also insufficient evidence to demonstrate that long-

term use of an oral glucocorticosteroid provides benefits for patients with COPD. Given the toxicity of long-term treatment and the lack of prospective studies on the long-term effects, long-term treatment with oral glucocorticosteroids is not recommended in the management of stable COPD *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*.

Oral corticosteroids in modest doses (30 to 40 mg a day of prednisone or its equivalent) and for no longer than two weeks are indicated in the treatment of acute exacerbations of COPD (*Aaron, 2003 [A]; Davies, 1999 [A]; Niewoehner, 1999 [A]; Thompson, 1996 [A])*.

Methods of Drug Delivery

Metered-dose inhaler (MDI) with spacer

Some studies support the use of spacers to obtain effective metered-dose inhaler drug delivery. The increased distance slows the velocity of the fine particles, increasing their chances of reaching the bronchial tree. It is of utmost importance to train and retrain patients, nurses, physicians and pharmacists in proper inhaler technique for optimal drug delivery. Evidence of the effectiveness of one type of spacer over another is variable and controversial.

Chlorofluorocarbons (CFCs) are freon compounds commonly used as propellants in commercial aerosols including metered-dose inhalers. Concerns have been raised about the toxicity of freon and its role in depleting the ozone layer. The production of ozone-depleting substances is being phased out worldwide under terms of an international agreement. As of December 31, 2008, the production and sale of CFC-containing inhalers is banned.

Hydrofluoro-alkane (HFA) is now used as the propellant in many metered-dose inhalers. Clinicians should be aware of some important points regarding these inhalers and instruct patients accordingly:

1) Particle size is smaller with HFA propellants than CFC. This produces a mist that may feel different to the patient.

2) Priming the inhaler requires two to four pumps. The inhaler should be re-primed if not used for two weeks.

3) Manufacturers recommend cleaning the casing every two weeks to prevent clogging of the nozzle.

Dry powder inhaler (DPI)

Dry powder inhalers are an alternative to metered-dose inhalers and are strongly supported by study data. Dry powder inhalers deliver drugs in dry powder form without the use of propellants. In addition, dry powder inhalers are breath-activated, eliminating the need to synchronize inhalation with actuation.

Dry powder inhalers have been developed as a response to concerns about freon toxicity. Newer dry powder inhaler products deliver pure drug from self-enclosed, multiple-dose devices that help avoid the potential adverse effects of additives used in metered-dose inhalers.

Table III contrasts features of conventional pressurized metered-dose inhalers and dry powder inhalers.

Table III: Contrasting Features of Conventional Pressurized Metered-Dose Inhaler and Dry Powder Inhaler

Metered-Dose Inhaler	Dry Powder Inhaler
1. Aerosol generation dependent on propellants.	1. Aerosol generation does not require any propellants.
2. Requires coordination of actuation with inhalation.	2. Relatively easy to administer, since it is breath activated.
3. With correct technique, the lung deposition of an HFA inhaler is higher than that with a CFC inhaler. From different studies the deposition has ranged from 24% to 60%.	3. Lung deposition of drug from a DPI inhaler may be similar to a MDI using HFA propellant. It is not clear if there are any relevant differences in drug deposition between these.
4. A spacer device might increase lung deposition with a HFA inhaler. However, whether any clinically meaningful differences exist is not clear.	4. No add-on spacer device needed.
5. Because of propellants and other additives, patients "feel" the drug delivered.	5. Patient may not "feel" the drug delivered and may be uncertain of the drug dosing.
6. No dose indicators. Risk of continued use of empty inhaler.	6. Newer multidose DPIs have a window with dose indicator.

Adapted from *Cheng, 1998 [C]; Haussermann, 2007 [C]; Leach, 2005 [C]; Vaswani, 1998 [R].*

See Appendix B for a hydrofluoro-alkane directory.

Nebulizers

Aerosol particle diameters range from 1-5 mcg in a small-volume nebulizer, which are comparable to those from a metered-dose inhaler or dry powder inhaler. Studies have shown no difference in the efficacy of the delivery methods. Reports suggest that between 47% and 89% of adults may have unacceptable inhaler technique. Clinical situations in which nebulized therapy is preferable to either metered-dose inhaler or dry powder inhaler include:

- Patients incapable of performing metered-dose inhaler or dry powder inhaler maneuver
- Adults who have a vital capacity less than 1.5 times their predicted tidal volume (7mL/kg)

Aerosol therapy via nebulizer is generally considered expensive, inconvenient and inefficient. Nebulizer therapy should be considered a second choice when compared with other modes of aerosol delivery, e.g., metered-dose inhalers and dry powder inhalers.

The following is a comparison of the advantages and disadvantages of aerosol delivery via nebulizer.

Table IV: Comparison of Nebulizers and Metered-dose Inhalers

Nebulizers	
Advantages	**Disadvantages**
Pneumatic small-volume nebulizers (SVN)	
Limited patient coordination	Expensive compressed gas source required
High dose levels possible	Greater time required (expense)
Continuous therapy available	Some medications not readily available
No chlorofluorocarbon (CFC) release	
Covered by Medicare	
Ultrasonic small-volume nebulizers (USN)	
Less patient coordination	Expensive initial purchase
Fast delivery	Contamination possible
No CFC release or compressed gas source required	Electrical or mechanical malfunction
	Not portable
	Some medications not available

Adapted from *Ward, 1997 [NA]*.

Theophylline

Theophylline has a narrow therapeutic index with potentially significant adverse effects and drug interactions that must be carefully considered and closely monitored during therapy.

Lower doses have been shown to reduce exacerbations, and higher doses to provide effective bronchodilator activity; however, due to theophylline's potential toxicity (particularly at or near effective dosing), inhaled bronchodilators are preferred when available. In patients on regular long-acting bronchodilator therapy who need additional symptom control, adding theophylline may produce additional benefits.

Toxicities positively associated with higher serum concentration include seizure and tachyarrhythmia. Other, more common adverse events occurring throughout the dosing range include headache, insomnia, nausea and heartburn. Theophylline is extensively hepatically metabolized; as a result, several drugs, cigarette smoking and hepatic insufficiency in addition to cardiac decompensation and age may alter clearance. A table of drug interactions with theophylline has been published *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R]; Michalets, 1998 [R])*.

Other Pharmacologic Interventions

Antibiotics

The routine use of antibiotics is not recommended except for treatment of bacterial exacerbations of COPD.

Antitussives

Regular use of antitussives is not recommended in COPD since cough can have a significant protective effect.

Antiviral Agents

Antiviral medications are available to treat and prevent influenza, but should not be used as a substitute for vaccination unless it is contraindicated. When treatment with antivirals is initiated within 48 hours of symptom onset, severity and duration of symptoms may be reduced *(Centers for Disease Control and Prevention, 2008 [R])*. (http://www.cdc.gov/flu/professionals/antivirals/agents.htm accessed 11/6/08).

There are two types of antiviral medications for influenza: adamantanes and neuraminidase inhibitors. The adamantanes (amantadine and rimantadine) are no longer recommended for the treatment or chemoprophylaxis of influenza viruses due to increased resistance. Oseltamavir* (Tamiflu®) and Zanamivir (Relenza®) are neuraminidase inhibitors that are licensed for the treatment and chemoprophylaxis of influenza A and B viruses in adults for the 2008-2009 influenza season. Zanamivir (Relenza®) is not recommended for use in patients with chronic lung disease such as asthma or chronic obstructive lung disease *(Centers for Disease Control and Prevention, 2008 [R])*. http://www.cdc.gov/flu/professionals/antivirals/agents.htm accessed 11/6/08).

* Note: CDC has issued an alert that in some cases, influenza A (H1N1) strains are resistant to Oseltamavir. See this Web address for more information: http://www.cdc.gov/flu/professionals/antivirals/index.htm.

Antiviral Medication Dosing for Patients with COPD

Drug	Treatment	Chemoprophylaxis
Oseltamavir	75 milligrams by mouth twice daily for 5 days	75 milligrams by mouth once daily for 10 days

Note: In cases of community or institutional outbreaks, longer periods of prophylaxis may be needed.

Leukotriene Modifiers

This drug class has not been adequately tested in COPD patients, and its use cannot be recommended until additional evidence relative to its efficacy is available.

Mucolytics

In theory, reducing mucus viscosity and enhancing cough clearance or mucociliary clearance of mucus could improve pulmonary function and reduce the incidence of respiratory infections in individuals with COPD. Ideally, treatment would result in both objective (increase in FEV_1) and subjective (better sense of well-being) improvement for those individuals.

To date, there has been no conclusive evidence for significant improvement in pulmonary function with any of the agents studied so far. Guaifenesin is widely used as an over-the-counter expectorant, but documented objective or even subjective improvement has not been consistently demonstrated. Iodinated glycerol was once thought to promote a decrease in symptoms and overall improvement in subjects with COPD, but this result could not be confirmed in subsequent investigations *(Petty, 1990 [A])*.

Some evidence for improvement in subjects with chronic bronchitis is present using other agents, including inhaled surfactant, amiloride, hypertonic saline, N-acetylcysteine and acetylcysteine, but for now is not substantial enough to be conclusive. Albuterol may have some effect in improving mucociliary clearance, which may add to its utility as a bronchodilator.

(Houtmeyers, 1999 [R]; Rubin, 1999 [C]; Rubin, 1996 [A])

Oral Beta-Agonists

Inhaled bronchodilator therapy is preferred.

Vaccines

Influenza and pneumococcal pneumonia together are the sixth leading cause of death in the U.S. among persons 65 years of age or older. Immunization with pneumococcal and influenza vaccines is recommended by the U.S. Public Health Service's Advisory Committee on Immunization Practices to reduce infectious complications involving the respiratory tract. A recent study suggests that despite strong recommendations, immunization rates for influenza and pneumococcal are low. The main reason for not being vaccinated was the lack of information regarding the vaccines *(Schoefer, 2007 [NA])*.

Pneumococcal

The American Thoracic Society and the U.S. Public Health Service's Advisory Committee on Immunization Practices (ACIP) recommend pneumococcal vaccine for all COPD patients *(Centers for Disease Control, 1997 [R])*.

Pneumoccal vaccine is recommended in all COPD patients over 65 and those younger with an FEV_1 of less than 40% of predicted *(Alfageme, 2006 [A]; Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*.

Influenza

Influenza vaccine should be provided on an annual basis because of new antigens and waning immunity from the previous year. The optimal time for influenza vaccination is usually from early October through mid-November. To avoid a missed opportunity, vaccination can be done as soon as vaccine is available, but not prior to September. Vaccine may be given even after flu activity is known to be occurring in the community *(Couch, 2000 [R]; Fiore, 2008 [R])*.

12. Non-Pharmacologic Interventions – Applicable to All Levels of Severity

Key Points:

- Pulmonary rehabilitation programs are effective in improving exercise capacity, quality of life and perception of symptoms, regardless of age *(Di Meo, 2008 [C])*.
- Long-term oxygen therapy (more than 15 hours per day) improves survival and quality of life in hypoxemic patients.

Pulmonary Rehabilitation Program

The primary goal of pulmonary rehabilitation is to decrease symptoms, improve quality of life and increase participation in everyday activities. To achieve these goals, pulmonary rehabilitation uses a multidisciplinary approach, including education and exercise training, and should be considered for COPD patients at all stages of disease *(Berry, 1999 [D])*. Benefits have been demonstrated from rehabilitation programs conducted in inpatient, outpatient and home settings *(Lacasse, 1996 [M]; McGavin, 1977 [A]; Ries, 2007 [R])*. Pulmonary rehabilitation has been evaluated in several large clinical trials. The various benefits are listed below.

Benefits of pulmonary rehabilitation in COPD

- Improves exercise capacity
- Reduces perceived intensity of breathlessness
- Improves health-related quality of life
- Reduces the number of hospitalizations and days in hospital
- Reduces anxiety and depression associated with COPD
- Strength and endurance training of the upper limbs improves arm function
- Benefits extend well beyond the immediate period of training
- Improves survival
- Respiratory muscle training is beneficial, especially when combined with general exercise training
- Psychosocial intervention is helpful

More information is needed regarding patient selection for pulmonary rehabilitation programs. Again, COPD patients at all levels of severity have been demonstrated to benefit from exercise training programs with an improvement in exercise tolerance and a reduction in dyspnea and fatigue. These benefits do appear to wane after the program ends, but if exercise is maintained at home, the patient's health status continues to remain above pre-rehab levels. There currently is not sufficient evidence to determine whether repeated courses increase the likelihood a patient will maintain the benefits gained during the initial course.

Refer to Appendix D, "Summary of Structure and Services – Pulmonary Rehabilitation Program."

Oxygen Therapy

Important Points:

- Long-term oxygen therapy (more than 15 hours per day) improves survival and quality of life in hypoxemic patients.
- Arterial blood gas measurement is recommended for initiation of oxygen therapy, as well as to determine PCO_2 and acid-base status.
- Pulse oximetry is a good method for monitoring oxygen saturation and can be used in adjusting the oxygen flow setting.
- Indications for long-term oxygen therapy have been adopted by Medicare as reimbursement criteria.*
- Patients considered for long-term therapy may benefit from assessment by a pulmonologist.
- Supplemental long-term oxygen therapy should be provided at a flow rate sufficient to produce a resting P_aO_2 of greater than 55 mm Hg, or S_aO_2 greater than 89%.
- Titrate liter flow to goal at rest: add 1 L/min during exercise or sleep or titrate during exercise to goal of S_aO_2 greater than 89%. Titrate sleep liter flow to eight-hour sleep of S_aO_2 greater than 89%.
- Consider referral for sleep evaluation if patient experiences cyclic desaturation during sleep but is normoxemic at rest.

- Recheck S_aO_2 or P_aO_2 in one to three months if hypoxia developed during an acute exacerbation. Rechecks should be performed annually if hypoxia is discovered in an outpatient with stable COPD.

* Appendix C contains a summary of Medicare Oxygen Coverage guidelines.

Oxygen Delivery Methods

The dual-prong nasal cannula is the standard means of continuous flow oxygen delivery for the stable COPD patient with hypoxemia. It is not only well tolerated, but is also simple and reliable. Care must be taken when assigning an estimated FiO_2 to patients as this low-flow system can have great fluctuations *(American Association for Respiratory Care, 1996 [R])*.

Reservoir cannulas, demand pulse delivery devices, and transtracheal oxygen delivery are oxygen-conserving devices that can improve the portability of oxygen therapy, reduce the overall costs of home oxygen therapy, especially in patients requiring higher flow rates, and can more effectively treat refractory hypoxemia. These devices function by delivering all of the oxygen during early inhalation. They reduce oxygen requirements by 25%-75% compared to continuous flow oxygen. Disadvantages of these devices are that they are bulky on the face, mechanically more complicated, and require additional care as well as additional training of the user *(Bower, 1988 [D]; Gibson, 1976 [D]; Kory, 1962 [D]; Soffer, 1985 [C])*.

COPD and Air Travel

Airline travel is safe for most patients with COPD. Hypoxemic patients should be evaluated clinically and a decision should be made regarding oxygen requirements. Patients with COPD receiving continuous oxygen at home will require supplementation during flight.

Many airlines will allow the use of battery-operated Portable Oxygen Concentrators (POCs) on board during flight. POCs were first approved for use by the FAA in the summer of 2005. As of September 12, 2006, the following POCs have been approved for use during flight by FAA:

- Inogen One – pulse dose
- Sequal Eclipse – continuous flow
- Airsep Lifestyle – pulse dose
- Airsep Freestyle – pulse dose
- Respironics Evergo – pulse dose

Most major airlines favor the Inogen One, which includes batteries, car/mobile adaptors, AC power supply and cart with handles and wheels.

Each airline has its own policy regarding on-board oxygen transport and in-flight oxygen usage. Patients need to contact the airline for their current policies regarding oxygen.

- Patients should notify oxygen supply company two weeks in advance.
- Many airlines have their own airline specific medical form for the physician to fill out.
- POC rentals can be per day/week/month.
- Patients should always carry a copy of their oxygen prescription.
- Insurance typically will not pay for in-flight oxygen; it is considered a luxury. Patient may want to contact their insurance carrier to determine coverage.

www.homeoxygen.org/airtran accessed on November 27, 2008

www.aeromedical.com accessed on November 27, 2008

13. Ongoing Management

Key Points:

- Obtaining the opinion of a pulmonary specialist may be beneficial at any stage of the disease.
- For patients with severe symptoms, despite maximal medical therapy, lung volume reduction surgery and transplantation may be an option. Referral to a pulmonologist should be made to evaluate candidacy.
- Physicians are encouraged to initiate and facilitate conversations about living wills and durable power of attorney for health care.

Schedule Regular Follow-Up Visits

Follow-up visits should be jointly established between primary care physicians and pulmonary specialists, and should be tailored to the learning stage and comorbidities of individual patients.

The exact frequency of clinician visits is a matter of clinical judgment; however, the following may serve as a general guide for patients with stable COPD.

Severity	Regular Follow-Up Visit
Mild	Yearly
Moderate	Three to six months
Severe	Two to four months or more frequently as needed

Evaluation and Monitoring of Comorbidities

In treating patients with COPD, it is important to consider the presence of concomitant conditions such as bronchial carcinoma, tuberculosis, sleep apnea, depression, pulmonary embolism, osteoporosis and heart failure. The appropriate diagnostic tools (chest radiograph, electrocardiogram, etc.) and referral to clinical specialists should be used whenever symptoms (e.g., hemoptysis) suggest one of these conditions *(Global Initiative for Chronic Obstructive Lung Disease, 2008 [R])*.

Refer to Consult with Pulmonary Specialist

Obtaining the opinion of a pulmonary specialist may be beneficial at any stage of the disease. Referral may be indicated to confirm the diagnosis, facilitate tobacco cessation and optimize appropriate treatment.

Consider referral/consultation (if available):

- When lung function deficits are not consistent with symptoms
- To confirm the diagnosis and rule out other diagnoses
- When pulmonary function tests show mixed restrictive and obstructive lung disease
- When patient with COPD has less than 10 year pack history of smoking
- When considering alpha-1 antitrypsin deficiency (age 45 or younger or strong family history)

- When patient has been hospitalized for COPD
- When patient has frequent respiratory infections or exacerbations
- When patient has a rapid decline in FEV_1
- For consideration/monitoring of oxygen therapy
- When patient may be a candidate for lung transplantation or volume reduction surgery
- When uncomfortable with managing patient alone

Surgical Options for Severe Disease

Lung volume reduction surgery for emphysema

The goal of lung volume reduction surgery (LVRS) is to relieve disabling dyspnea in patients in whom emphysema has limited activities of daily living and has proved refractory to optimal medical management. Following surgery, improvement has been noted in lung elastic recoil, respiratory function, ventilation/perfusion matching, and cardiovascular function. A variety of surgical approaches and reduction techniques have been used. Results of the National Emphysema Treatment Trial (NETT) have been published.

1. Overall, lung volume reduction surgery did not demonstrate a survival advantage over medical therapy. Lung volume reduction surgery yielded a survival advantage only for patients with upper lobe emphysema and low baseline exercise capacity. Lung volume reduction surgery demonstrated increased mortality and no functional improvement for patients with non-upper-lobe emphysema.
2. Lung volume reduction surgery showed improvement in exercise capacity only among a small subgroup of patients: those with upper lobe emphysema. Most patients' improvements returned to baseline after two years.
3. Significantly more patients with upper lobe emphysema randomized to lung volume reduction surgery had improved quality of life after two years as compared to non-surgical patients.
4. Due to the strictness of the exclusion criteria, conclusions from the NETT trial cannot be extended to the general population of patients with emphysema.
5. Preoperative evaluation includes ability to complete a six-minute walk of over 140 meters, completion of a pulmonary rehabilitation program, full pulmonary function tests, chest computerized tomography, echocardiogram, and possibly a right heart catheterization and a radionuclide stress test.
6. Lung volume reduction surgery should be performed only in medical centers with appropriately trained surgeons and availability of necessary equipment.

(American Thoracic Society, 1995a [R]; Institute for Clinical Systems Improvement, 2003 [R]; National Emphysema Treatment Trial Research Group, 2003 [A])

Bullectomy

Giant bullous emphysema is a rare subset of patients in whom single or multiple large bullae encompass 30% or more of a hemithorax, often displacing potentially functional lung tissue as these large airspaces increase in volume. In appropriate cases, surgical resection of these bullae can restore significant pulmonary funcion and improve symptoms. Computerized tomography scan is essential in evaluating these patients and referral to a pulmonary specialist is indicated *(Boushy, 1968 [D]; Laros, 1986 [A])*.

Lung transplantation

Unilateral or bilateral lung transplantation is a treatment option in highly selected patients with severe COPD *(Arcosoy, 1999 [A])*. A few studies show improvement in quality of life parameters but no increase of survivability *(Hosenpud, 1998 [C])*.

General selection guidelines for candidate selection for lung transplantation in COPD patients

Relative contraindications	Age limits Heart-lung transplants ~55 yrs Double lung transplant ~60 yrs Single lung transplant ~65 yrs Symptomatic osteoporosis Oral corticosteroids greater than 20 mg day-1 prednisone Psychosocial problems Requirement for invasive mechanical ventilation
Absolute contraindications	Severe musculoskeletal disease affecting the thorax Substance addiction within previous six months Dysfunction of extrathoracic organ, particularly renal dysfunction HIV infection Active malignancy within two years except basal or squamous cell carcinoma of skin Hepatitis B antigen positively Hepatitus C with biopsy-proven evidence of liver disease

Source: Arcasoy, 1999 [A]

Following the position of the American Thoracic Society and the European Respiratory Society (*American Thoracic Society/European Respiratory Society COPD Standards, 2004 [R]*), appropriate candidate selection is as follows:

- FEV_1 less than or equal to 25% predicted (without reversibility)
- Resting room air $PaCO_2$ greater than 55 mm Hg
- Elevated $PaCO_2$ with progressive deterioration requiring long-term oxygen therapy
- Elevated pulmonary arterial pressure with progressive deterioration

A number of studies show that single lung transplant is safer and gives equal or improved spirometric parameters as compared to bilateral lung transplant *(Arcosoy, 1999 [R])*. Survival after transplant is 81.7%, 61.9% and 43.4% at one, three and five years. Perioperative mortality, rejection, bronchiolitis obliterans, cytomegalovirus, fungal and bacterial infections, and lymphoproliferative disease are associated with transplant surgery. Donor lung availability, high initial and ongoing immunosuppressive regimen costs are also factors that must be considered.

Discuss Health Care Directives (Advance Directives) or Living Will and Durable Power of Attorney for Health Care

Many patients have an interest in discussing living wills, but their wishes tend to be passive and unspoken.

Physicians are encouraged to initiate and facilitate conversations about living wills and durable power of attorney designate with all COPD patients at routine outpatient visits.

In patients with severe disease, it is also helpful to discuss specific treatment preferences. Treatment preferences may include home care only, hospitalization for comfort care, initiation of full life support if there is

a reasonable chance for recovery to functional independence, or continuation of indefinite life support in a chronic nursing facility.

Objectives of discussion

- To encourage physicians to discuss health care directives with COPD patients
- To give patients control over their end-of-life care decisions
- To reassure that patients' wishes will be carried out at the end of their life
- To increase the number of COPD patients who have written health care directives
- To increase the number of patients with severe COPD who have discussed specific treatment preferences and goals of care
- To name a durable power of attorney for health care or an appropriate surrogate decision-maker

Plan for discussion

- For the patient with moderate to severe COPD, at a routine office visit ask the question, "***Do you have a living will?***"

  Action: If ***yes***, ask what it consists of (especially whether there is a designation of durable power of attorney and who that person is) and request that a copy be placed in the patient's medical record.

  Action: If ***no***, offer the patient written information on health care directives, encourage him/her to fill out a health care directive including designation of power of attorney for health care and offer to discuss any questions at the next office visit.

- For the patient with severe COPD, at a routine office visit ask the question, "***What are your treatment preferences in regards to hospitalization, life support (including cardiopulmonary resusitation, endotracheal intubation and non-invasive ventilation), and end-of-life care?***"

  Action: Encourage the patient to discuss these treatment preferences with family or health care surrogate and record them in a health care directive.

  Action: Document the patient's treatment preferences in the patient's medical record and request that a copy of the health care directive be placed in the patient's medical record.

For more information on living wills, please consult your state's statutes outlining requirements for health care directives.

See the ICSI Palliative Care guideline for more information regarding end-of-life care.

Appendix A – Estimated Comparative Daily Dosage for Inhaled Corticosteroids

Inhaled Steriods				
Generic	**Dosage Form**	**Low Dose**	**Medium Dose**	**High Dose**
beclomethasone*	7.3 gram inhaler (40 mcg/actuation)	40-160 mcg	160-320 mcg	320-640 mcg
	7.3 gram inhaler (80 mcg/actuation)			
budesonide*	90 mcg/actuation	180-360 mcg	360-540 mcg	540-1440 mcg
	180 mcg/actuation			
	0.25 mg/2 ml neb	0.25 mg#	0.5 mg#	1 mg#
	0.5 mg/2 ml neb			
	1 mg/2 ml neb			
ciclesonide*	12.5 gram inhaler (50 mcg/actuation)	160 mcg	160-320 mcg	320-640 mcg
flunisolide*	7 gram inhaler (250 mcg/actuation)	500-1,000 mcg	1,000-2,000 mcg	2,000 mcg
	8.9 gram inhaler (80 mcg/actuation)	160-320 mcg	320-480 mcg	480-640 mcg
fluticasone	10.6 gm inhaler (44 mcg/actuation)	88-264 mcg	264-660 mcg	660-1,760 mcg
	12 gm inhalers (110 mcg/actuation)			
	12 gm inhalers (220 mcg/actuation)			
	50mcg/actuation	100-300 mcg	300-600 mcg	600-2,000 mcg
mometasone*	220 mcg oral powder inhaler (200 mcg/actuation)	220 mcg	440-660 mcg^	880 mcg^
triamcinolone*	20 gm inhaler (75 mcg/actuation)	400-1,000 mcg	1,000-2,000 mcg	2,000 mcg
Inhaled Steroid/Beta-2 Agonist Combination				
budesonide/formoterol*	10.2 gram inhaler (80 mcg budesonide /4.5 mcg formoterol)	160 mcg budesonide/9 mcg formoterol every 12 hours^^	320 mcg/budesonide/9 mcg formoterol every 12 hours^^	
	10.2 gram inhaler (160 mcg/4.5 mcg)			
fluticasone/salmeterol**	12 g inhaler (45 mcg fluticasone/ 21 mcg salmeterol)	90 mcg fluticasone/42 mcg salmeterol every 12 hrs	230 mcg fluticasone/42 mcg salmeterol every 12 hrs	460 mcg fluticasone/42 mcg salmeterol every 12 hrs
	12 g inhaler (115 mcg fluticasone/ 21 mcg salmeterol)			
	12 g inhaler (230 mcg fluticasone/ 21 mcg salmeterol)			
	100/50 diskus inhaler (100 mcg fluticasone/50 mcg salmeterol)	100 mcg fluticasone/50 mcg salmeterol every 12hrs	250 mcg fluticasone/50 mcg salmeterol every 12 hrs	500 mcg fluticasone/50 mcg salmeterol every 12 hrs
	250/50 diskus inhaler (250 mcg fluticasone/50 mcg salmeterol)			
	500/50 diskus inhaler (500 mcg fluticasone & 50 mcg salmeterol/actuation)			

* No FDA approved indication for COPD

**Fluticasone 250 mcg/salmeterol 50 mcg Diskus twice daily is the only approved dosage for the treatment of COPD associated with chronic bronchitis. Higher doses, including fluticasone 500 mcg/salmeterol 50 mcg Diskus, are not recommended.

#Budesonide inhalation suspension is only FDA approved for use in asthmatic patients 12 months to 8 years of age.

^May be given in the evening or in divided doses twice daily

^^Patients should be advised NOT to take more than 2 inhalations twice daily of either strengths.

Bold indicates the CFC inhalers the FDA proposes eliminate. FDA believes there are non-CFC containing alternatives for each and recommends that removal take effect December 31st, 2009.

Notes: The most important determinant of appropriate dosing in the clinican's judgement of the patient's response to therapy. The clinican must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of COPD is acheieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effect.

References: Clinical Pharmacology, Drug Information Handbook, Facts & Comparisons, Micromedex (Accessed November 2008)

Appendix B – Hydrofluoro-alkane (HFA) Directory

HFA MDIs	Active Ingredient	Maximum Number of Sprays	Dose Counter	Priming Instructions	Frequency of Washing
ProAir HFA	Racemic albuterol 90 mcg per dose	200	No	Before first use: 3 sprays	Wash plastic actuator weekly with warm water; air dry
Proventil HFA	Racemic albuterol 90 mcg per dose	200	No	Before first use: 4 sprays	Wash plastic actuator weekly with warm water; air dry
Ventolin HFA	Racemic albuterol 90 mcg per dose	200 (or replace 6 months after opening)	Yes	Before first use: 4 sprays After 2 weeks non-use: 4 sprays After MDI is dropped: 1 spray After washing: 1 spray	Wash plastic actuator with warm water weekly; air dry
Xopenex HFA	Levalbuterol 45 mcg per dose	200	No	Before first use: 4 sprays After 3 days non-use: 3 sprays	Wash plastic actuator with warm water weekly; air dry
Atrovent HFA	Ipratropium bromide 21 mcg per spray	200	No	Before first use: 2 sprays After 3 days non-use: 3 sprays	Wash plastic actuator with warm water weekly; air dry
Advair HFA	fluticasone 45,115,230 mcg salmeterol 21 mcg	120	Yes	Before first use: 4 sprays After 4 weeks non-use or if dropped: 2 sprays	Wash plastic actuator with warm water weekly: air dry

Adapted from Allergy and Asthma Network Mothers of Asthmatics (www.aanma.org, 2008)

- Each HFA inhaler has unique characteristics, cleaning requirements, expiration dates, number of doses and ingredients.
- The change in propellants required a massive overhaul of inhalers' delicate valves and gaskets – virtually the entire canister and contents for each brand.
- Since the ingredients are different for every brand, each has its own care instructions covering expiration dates, priming, shaking and cleaning.
- HFA inhalers spray a finer mist, with smaller particles that are easier to inhale deep into the airways. The patient may feel and taste less of the medicine in his or her mouth.
- Most brand name HFAs are about the same price as the CFCs they are replacing. Generic albuterol HFAs will not be on the market until at least 2010.
- Individual medications can be referenced at www.fda.gov/cder (click on Drugs @ FDA) or in the Physicians Desk Reference.

Appendix C – Medicare Standard for Oxygen Coverage

Oxygen Therapy

Medicare Standards for Oxygen Coverage include the following parameters:

Laboratory Evidence

- Testing must be performed either with the patient in a chronic stable state as an outpatient, or within two days prior to discharge from an inpatient facility to home.
- If the test is not taken under these conditions, additional documentation must be obtained from the physician.

P_aO_2	S_aO_2	Additional Documentation
55 mm Hg or less	88% or less	None
56-59 mm Hg	89%	Congestive Heart Failure/Edema EKG evidence of "P" pulmonale with P wave greater than 3 mm in lead I, II, III or AVF. Hematocrit greater than 56%.
60 mm Hg	90% or greater	Coverage rare or unlikely; requires extensive physician documentation for approval.

- Requires recertification and retesting 61-90 days after the initial start of therapy.

Portable Oxygen

- May qualify as a system by itself or as a complement to stationary oxygen system.
- If the patient qualifies for reimbursement under the oxygen coverage guidelines noted previously, **and** the patient is **mobile** within the home.

Oxygen Prescription

Oxygen for patients with COPD is covered under Medicare. The prescription for home oxygen therapy must include:

- flow rate: liters/minute – flow rate must be increased during exercise and sleep,
- duration of need: specific number of months or indefinitely,
- laboratory evidence,
- blood gas or oximetry required while at rest on room air, and
- acceptable P_aO_2 or S_aO_2.

Diagnosis

- Severe primary lung disease (includes COPD, emphysema, chronic bronchitis)
- Secondary conditions related to lung disease
- Significant hypoxemia in the chronic stable state

Additional medical documentation: other forms of treatment have been tried and have not been successful and oxygen therapy is still required.

Start of therapy: within one month of last visit.

Appendix D – Summary of Structure and Services – Pulmonary Rehabilitation Program

Check for consistency with GOLD

Disciplines involved in pulmonary rehabilitation can include, but are not limited to the following:

Physicians	Nurses
Respiratory Therapists	Physical Therapists
Occupational Therapists	Cardiorespiratory Technicians
Recreational Therapists	Clerics
Dieticians	Pharmacists
Exercise Physiologists	Psychologists
Social Workers	Psychiatrists

Interventions can generally be divided into education, exercise/conditioning, psychosocial/psychological aspects and medical intervention.

Education

- Basic lung anatomy and physiology/COPD pathophysiology
- Breath retraining
    1. Diaphragmatic breathing
    2. Pursed-lip breathing
- Diet and nutrition
- Energy conservation
- Safe travel
- Airway management
- Benefits of exercise
- Safe use of oxygen
- Role of medications
    1. How medications work
    2. Long-term control: medications that prevent symptoms
    3. Stress importance of using medications
- Skills of using medications
    1. Metered-dose inhaler use (patient should demonstrate correct inhaler technique)
    2. Small-volume nebulizer
    3. Spacer/holding chamber use

- Symptom assessment and knowledge of when to seek medical help
- Smoking cessation
- Environmental irritant avoidance
- Respiratory and chest therapy techniques

Exercise/conditioning

- Lower extremity training/exercise
- Upper extremity training/exercise
- Inspiratory muscle training/exercise
- Emphasis on in-home exercise as lifestyle change

Psychosocial/psychological aspects

- Counseling
    1. Stress management
    2. Coping skills, anxiety, panic control

Medication

Patients may benefit from antidepressants.

Indications for referral

- Symptomatic COPD (characterized by airway obstruction and reduced expiratory airflow)
- Functional limitations that affect quality of life
- Has a medical regimen that has been maximized, e.g., bronchodilator, oxygen therapy
- Able to learn about the disease; patients who are mentally capable of learning about their disease have improved outcome including decreased anxiety and fear
- Motivated to participate in a pulmonary rehabilitation program

Relative contraindications for participation in pulmonary rehabilitation

- Patients with conditions that might interfere with the patient undergoing a rehabilitation program, e.g., coronary artery disease, cognitive impairment interfering with learning, severe psychiatric disturbances.
- Patients with conditions that might place the patient at risk during exercise training; many patients with COPD are older with a history of cigarette smoking and are at risk for heart disease. Cardiac and pulmonary stress testing should be routinely performed to exclude silent cardiac disease and assure safety during exercise training.

Types of Rehabilitation Programs

Type of Program	Advantages	Disadvantages
Hospital or Community-based Outpatient Pulmonary Rehabilitation	Widely available	Potential transportation issues
	Less costly	Long-term benefits have not been demonstrated
	Less intrusive to family	Inability to observe home plan
Home Program	Transportation not an issue	Potential inability for multidisciplinary team to participate
	Familiar surroundings may facilitate better adherence to goals	Patient may not have access to exercise equipment
	Long-term benefits have been demonstrated	Lack of supervision by trained personnel

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Diagnosis and Management of Chronic Obstructive Pulmonary Disease (COPD)

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Original Work Group Members

Scott Copeman, RRT
Respiratory Therapy
Mayo Clinic

Tom Dashiell, MD
Internal Medicine
HealthEast Clinics

Beth Duffy, RRT
Respiratory Therapy, Health Education
HealthPartners Medical Group

Jane Gendron
Measurement Advisor
ICSI

Janine Graham, RN, CCM
Case Management, Health Education
Aspen Medical Group

Allen Horn, MD
Family Practice
CentraCare

James Mickman, MD
Pulmonary & Critical Care Medicine
HealthPartners Medical Group

Ashok M. Patel, MD
Pulmonary & Critical Care Medicine, Work Group Leader
Mayo Clinic

Jeff Rabatin, MD
Pulmonary & Critical Care Medicine
Mayo Clinic

Mary Stadick, MA
Facilitator
ICSI

Suzanne Tschida, PharmD
Pharmacy, Health Education
HealthPartners Medical Group

Catherine Youngman, RN
Nursing, Health Education
HealthPartners Medical Group

Contact ICSI at:
8009 34th Avenue South, Suite 1200; Bloomington, MN 55425; (952) 814-7060; (952) 858-9675 (fax)
Online at http://www.ICSI.org

Brief Description of Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the guideline.

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This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the guideline.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
  - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Resources
- Resources Available

Priority Aims and Suggested Measures

1. Increase the quality and use of spirometry testing in the diagnosis of patients with COPD.

   Possible measure for accomplishing this aim:

   a. Percentage of spirometry tests performed that meet the ATS Statement of Standardization of Spirometry.

   b. Percentage of patients with a diagnosis of COPD who received routine spirometry testing at the time of diagnosis.

2. Increase the number of patients with COPD who receive information on the options for tobacco cessation and information on the risks of continued smoking.

   Possible measures for accomplishing this aim:

   a. Percentage of patients with COPD who are asked about smoking cessation (if patient a smoker) at every visit.

   b. Percentage of patients with COPD who have documented assessment of readiness to attempt tobacco cessation.

   c. Percentage of patients who receive a smoking cessation intervention.

   d. Percentage of patients with COPD who quit smoking (100% quit-rate goal).

3. Reduce COPD exacerbation requiring emergency department (ED) evaluation or hospital admission.

   Possible measures for accomplishing this aim:

   a. Number of emergency room encounters for patients with COPD in a one-month period.

   b. Number of hospital admissions for patients with COPD in a one-month period.

   c. Number of patients with two or more hospitalizations within a 12-month period.

4. Increase the appropriate use of therapy prescribed for patients with COPD.

   Possible measures for accomplishing this aim:

   a. Percentage of patients with COPD who are prescribed appropriate therapy, including:

      - an influenza vaccine in the previous 12 months
      - a pneumococcal vaccine
      - long-term oxygen assessment and prescription for long-term home oxygen for those who are hypoxic and meet criteria
      - short-acting bronchodilator (when needed)
      - long-acting bronchodilator (when needed)
      - corticosteroids (when needed)

5. Increase patients' education and management skills with COPD.

   Possible measures for accomplishing this aim:

   a. Percentage of patients with moderate or severe COPD who have been referred to a pulmonary rehabilitation or exercise program.

   b. Percentage of patients with COPD instructed on the use of inhaler with spacer technique and with documentation that inhaler technique was observed by a health care professional.

   c. Percentage of patients with COPD who express satisfaction with the supporting information about COPD and the level of their own participation in care.

   d. Percentage of patients with COPD who have discussed health care directives (or advanced directives) and goals of care with their health care professional.

Measurement Specifications

Possible Success Measure #2a

Percentage of patients with COPD who are asked about smoking cessation (if patient a smoker) at every visit.

Population Definition

Patients with COPD who have any indication on their charts that they are users of tobacco who presented to the clinic within a designated time period.

Data of Interest

$$\frac{\text{\# of patients with documentation who are asked about tobacco status and/or readiness to quit}}{\text{Total \# of patients with COPD who are smokers}}$$

Numerator/Denominator Definitions

Numerator: Documentation in the chart that the patient was asked about a change in smoking status and/or readiness to quit.

Denominator: Patients with a diagnosis of COPD who have an indication in their charts that they are users of tobacco who present for a clinic visit within the reporting month.

Method/Source of Data Collection

Identify patients with a clinic visit in the reporting month who meet the inclusion criteria. Data may be collected by medical record review.

Time Frame Pertaining to Data Collection

Randomly selected cases may be reviewed monthly.

Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. A model of patient education should be established in the clinics based upon individual learning needs assessments and including coordinated plans jointly developed by educators, patients and their families. Patient education should include core learning and needs objectives based upon individual needs.
2. Establish tobacco status at each visit. Advise to quit and provide supportive interventions including pharmacotherapy if appropriate.

Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Diagnosis and Management of Chronic Obstructive Pulmonary Disease (COPD) guideline work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the guideline.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are ***only*** available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to http://www.icsi.org/improvement_resources. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

Resources Available

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	American Association for Respiratory Care	Comprehensive Web sites for respiratory care professionals with links to a site tailored to COPD patients and their families.	Health Care Providers; Patients and Families	Health Care Providers: http://www.aarc.org Patient and Families: http://www.aarc.org/klein
	American Association of Colleges of Nursing	Provides information on conferences, products and resources for nurses on all aspects of end-of-life care. Most resources available for a fee.	Health Care Providers	http://www.aacn.nche.edu/elnec/index.htm
	American College of Chest Physicians	Evidence-based clinical practice guidelines	Health Care Providers	http://www.chestnet.org
	American Lung Association (Minnesota Chapter)	Primarily provides support for patients with COPD and other lung diseases. Also contains health care providers education tools developed by the Minnesota COPD Coalition: • Quick Glance Guide to COPD Guidelines • Quick Glance Guide to Spirometry • Quick Glance Guide to Oxygen Therapy • COPD Action Plan • COPD Billing Codes and Service	Health Care Providers; Patients and Families	http://www.alamn.org
	American Thoracic Society	Comprehensive Web site for COPD. Includes definition, diagnosis, risk factors, pathology.	Health Care Providers; Patients and Families	http://www.thoracic.org/sections/COPD
	Global Initiative for Chronic Obstructive Lung Disease (GOLD)	Guidelines for professionals in the diagnosis and treatment of COPD. Resources include pocket guides, patient guides, teaching and educational materials.	Health Care Providers; Patients and Families	http://www.goldcopd.com
	Mayo Clinic	Health information on various diseases and conditions.	Patients	http://www.mayohealth.org

* Available to ICSI members only.