Complete Summary

GUIDELINE TITLE

Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline from the American College of Physicians.

BIBLIOGRAPHIC SOURCE(S)

Qaseem A, Snow V, Shekelle P, Sherif K, Wilt TJ, Weinberger S, Owens DK, Clinical Efficacy Assessment Subcommittee of the American College of Physicians. Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2007 Nov 6;147(9):633-8. [54 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Chronic obstructive pulmonary disease

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Pulmonary Medicine

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

The purpose of this guideline is to present the available evidence on the diagnosis and management of chronic obstructive pulmonary disease (COPD)

TARGET POPULATION

All adults with chronic obstructive pulmonary disease (COPD)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Diagnosis using spirometry
2. Treatment
    - Monotherapy (long acting inhaled beta-agonists, long-acting inhaled anticholinergics, inhaled corticosteroids)
    - Combination therapy (long-acting beta-agonists, corticosteroids)
    - Oxygen therapy
    - Pulmonary rehabilitation

MAJOR OUTCOMES CONSIDERED

- Frequency of exacerbations
- Respiratory health status measures
- Hospitalization
- Mortality rate
- Adverse effects of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The guideline is based on a systematic evidence review and the Agency for Healthcare Research and Quality-sponsored Minnesota Evidence-based Practice Center evidence report (see the "Availability of Companion Documents" field).

Data Sources and Selection

For the previous report, PubMed and the Cochrane Library were searched for articles published in English from 1966 through May 2005. The current review extends the search related to chronic obstructive pulmonary disease (COPD) therapies through March 2007 by using search terms used in a 2003 review to identify randomized, controlled trials (RCTs), controlled clinical trials, meta-analyses, and reviews published since the completion of the search in 2002. To supplement the search, the developers examined the Cochrane Database of Systematic Reviews of Effectiveness, examined bibliographies of published articles, and contacted experts. Interventions were categorized as 1) inhaled medications (beta$_2$-agonists, anticholinergics, combination beta$_2$-agonists and anticholinergics, inhaled corticosteroids, and combination inhaled corticosteroids and long-acting beta$_2$-agonists or anticholinergics), 2) pulmonary rehabilitation, 3) disease management programs, and 4) oxygen therapy.

Two reviewers used standardized data abstraction sheets to examine titles and abstracts of newly identified references. If both reviewers agreed on eligibility, the article was included. Disagreement among reviewers, although rare, was resolved by discussion, with final decision by the lead author. Trials were eligible if they were randomized; involved persons with COPD that was defined clinically or by spirometry; and measured clinical outcomes, including exacerbations, standardized respiratory health status measures, hospitalizations, and deaths. Studies reporting only spirometry outcomes were ineligible. Inhaled therapy trials had to include 50 or more participants per treatment group and at least 3 months of follow-up. Trials of pulmonary rehabilitation programs had to include at least 6 weeks of follow-up and a usual care comparison group. The guideline developers excluded studies that compared different types of pulmonary rehabilitation, and included systematic reviews and meta-analyses of COPD therapies.

NUMBER OF SOURCE DOCUMENTS

74

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

This guideline grades the evidence and recommendations by using the American College of Physicians' clinical practice guidelines grading system adopted from the classification developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) workgroup (see "Rating Scheme for the Strength of the Recommendations" field, below).

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction

Two individuals extracted data onto standardized forms. The lead author resolved any disagreements. Main outcomes for all interventions were the percentage of participants experiencing at least 1 exacerbation, mean change in respiratory health status, hospitalization, and death. Respiratory health status was assessed by the validated St. George Respiratory Questionnaire (SGRQ) or the Chronic Respiratory Disease Questionnaire (CRDQ). A 4-unit reduction (out of 100) on the SGRQ and a 0.5-unit increase per question on the 7-question CRDQ are defined as clinically noticeable improvements. For pulmonary rehabilitation, the guideline developers collected information on the 6-minute walk test and defined a minimally clinically significant effect size as 53 meters or more.

The guideline developers collected data on adverse effects of long-acting inhaled therapies (including specifically described adverse effects, "serious adverse effects," treatment adherence, study withdrawals, and withdrawals due to adverse effects) from trials that lasted at least 1 year and from systematic reviews that specifically addressed adverse effects. They assessed whether these studies used placebo or active control run-in periods, as well as the number and reasons for exclusion of potentially eligible patients from randomization during the run-in period.

Study Quality Assessment

The guideline developers used the methods of Schulz and colleagues to assess the quality of randomized trials on the basis of allocation concealment. They assessed blinding, intention-to treat analysis, length of follow-up, withdrawals or loss to follow-up, and funding source. They rated the quality of systematic reviews or meta-analysis according to the Strength of Recommendation Taxonomy. A randomized controlled trial (RCT) was considered high quality if it had allocation concealment, blinding (if possible), intention-to-treat analysis, adequate size, and adequate follow-up (>80%). Systematic reviews or meta-analysis with high-quality studies and consistent findings are indicated as good-quality, patient-oriented evidence.

Data Synthesis and Analysis

Intervention effectiveness was described according to baseline respiratory symptom status, spirometrically defined level of airflow obstruction, acute change in spirometry, or spirometric change over time (inhaled medications and use of spirometry to guide therapy). The magnitude of effect across interventions (inhaled therapies and oxygen) was based on relative risks and absolute risk differences, as well as comparison with previously determined, minimally important clinical differences in respiratory health status and exercise capacity. Study results were combined, if appropriate, to produce pooled estimates. The developers calculated relative risks and 95% confidence intervals (CIs) for categorical variables and weighted mean differences and 95% CIs for continuous variables. Analyses were conducted by using a Der Simonian–Laird random-effects model in Review Manager software, version 4.2 (The Cochrane Collaboration, Oxford, United Kingdom). Heterogeneity was assessed by using a

chi square test and the I^2 test. An I^2 *statistic* of 50 or greater indicates substantial heterogeneity. If heterogeneity existed, sensitivity analyses were conducted to explore potential causes of heterogeneity.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Guideline developers systematically reviewed the literature to address the following questions:

1. What is the value of clinical examination for prediction of airflow obstruction (AO)?
2. What is the incremental value of spirometry for case finding and diagnosis of adults who are COPD treatment candidates?
3. What management strategies are effective for the treatment for COPD (inhaled therapies, pulmonary rehabilitation programs, and supplemental long-term oxygen therapy)?

The guideline developers reviewed the evidence addressing the questions posed by this report and based the recommendations on the gathered evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

This guideline grades the evidence and recommendations by using the American College of Physicians' clinical practice guidelines grading system adopted from the classification developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) workgroup (see Table below).

American College of Physicians' Clinical Practice Guidelines Grading System*		
Quality of Evidence	Strength of Recommendation	
	Benefits Do or Do Not Clearly Outweigh Risks	Benefits, Risks, and Burdens Are Finely Balanced
High	Strong	Weak
Moderate	Strong	Weak
Low	Strong	Weak
Insufficient evidence to determine net benefits or harms	I recommendation	

* Adopted from the classification developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) workgroup.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This guideline was approved by the American College of Physicians Board of Regents on July 14, 2007.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of evidence (high, moderate low, insufficient evidence to determine benefits or risks) and strength of recommendations (strong, weak, I recommendation) are repeated at the end of the "Major Recommendations."

Recommendation 1: *In patients with respiratory symptoms, particularly dyspnea, spirometry should be performed to diagnose airflow obstruction. Spirometry should not be used to screen for airflow obstruction (AO) in asymptomatic individuals.* **(Grade: strong recommendation, moderate-quality evidence.)**

Targeted use of spirometry for diagnosis of AO is beneficial for individuals with respiratory symptoms, particularly dyspnea. Evidence does not support the use of spirometry to screen for AO in asymptomatic individuals, including those who have risk factors for chronic obstructive pulmonary disease (COPD). No high quality evidence supports obtaining and providing spirometry results to improve smoking cessation, or to identify and treat asymptomatic individuals to prevent future respiratory symptoms or reduce spirometric decline in lung function.

Recommendation 2: *Treatment for stable COPD should be reserved for patients who have respiratory symptoms and forced expiratory volume in 1 second (FEV_1) less than 60% predicted as documented by spirometry.* **(Grade: strong recommendation, moderate-quality evidence.)**

Evidence shows that individuals who will benefit the most from therapy are those who have respiratory symptoms and clinically significant AO (FEV_1 <60% predicted). No evidence supports treating asymptomatic patients, because treatment does not improve outcomes. The evidence does not support periodic spirometry after initiation of therapy to monitor ongoing disease status or to modify therapy. This recommendation does not address the occasional use of bronchodilators for acute symptomatic relief.

Recommendation 3: *Clinicians should prescribe 1 of the following maintenance monotherapies for symptomatic patients with COPD and FEV_1 less than 60% predicted: long acting inhaled* beta-*agonists, long-acting inhaled anticholinergics,*

or inhaled corticosteroids. **(Grade: strong recommendation, high-quality evidence.)**

Monotherapy with a long-acting inhaled beta-agonist, a long-acting inhaled anticholinergic, or an inhaled corticosteroid is beneficial in reducing exacerbations. Inhaled corticosteroids and long-acting inhaled bronchodilators have similar effectiveness but differ in adverse effects, reductions in deaths, and hospitalizations. The review did not systematically evaluate all other outcomes. Evidence is insufficient to recommend 1 monotherapy over another.

Recommendation 4: *Clinicians may consider combination inhaled therapies for symptomatic patients with COPD and FEV_1 less than 60% predicted.* **(Grade: weak recommendation, moderate-quality evidence.)**

When to use combination therapy instead of monotherapy has not been clearly established. In one trial, combination therapy with long-acting beta-agonists and corticosteroids reduced exacerbations more than did monotherapy. Although deaths with combination therapy decreased in the trial compared with monotherapy, the reduction did not reach the predetermined level of statistical significance. In a recent randomized trial, addition of salmeterol–fluticasone to tiotropium therapy did not statistically influence rates of COPD exacerbation but did improve lung function, quality of life, and hospitalization rates in patients with moderate to severe COPD. However, studies of combination therapies do not consistently demonstrate benefits of combination therapy over monotherapy.

Recommendation 5: *Clinicians should prescribe oxygen therapy in patients with COPD and resting hypoxemia ($PaO_2 \leq 55$ mm Hg).* **(Grade: strong recommendation, moderate quality evidence.)**

Use of supplemental oxygen for 15 or more hours daily can help improve survival in patients with severe AO (FEV_1 <30% predicted) and resting hypoxemia.

Recommendation 6: *Clinicians should consider prescribing pulmonary rehabilitation in symptomatic individuals with COPD who have an FEV_1 less than 50% predicted.* **(Grade: weak recommendation, moderate-quality evidence.)**

Evidence supports the use of pulmonary rehabilitation programs for patients with severe AO, because they reduce hospitalizations and improve health status and exercise capacity. However, the evidence is not clear for individuals with FEV_1 greater than 50% predicted.

Definitions:

This guideline grades the evidence and recommendations by using the American College of Physicians' clinical practice guidelines grading system adopted from the classification developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) workgroup (see Table below).

American College of Physicians' Clinical Practice Guidelines Grading System*

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Insufficient evidence to determine net benefits or harms	I recommendation	

* Adopted from the classification developed by the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) workgroup.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of patients with chronic obstructive pulmonary disease (COPD), leading to a reduction in hospitalizations, improved health status and exercise capacity

POTENTIAL HARMS

Adverse effects associated with treatment.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The authors of this article are responsible for its contents, including any clinical or treatment recommendations. No statement in this article should be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources
Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Qaseem A, Snow V, Shekelle P, Sherif K, Wilt TJ, Weinberger S, Owens DK, Clinical Efficacy Assessment Subcommittee of the American College of Physicians. Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2007 Nov 6;147(9):633-8. [54 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Nov

GUIDELINE DEVELOPER(S)

American College of Physicians - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

Clinical practice guidelines are guides only and may not apply to all patients and all clinical situations. Thus, they are not intended to override clinicians' judgment.

All ACP clinical practice guidelines are considered automatically withdrawn or invalid 5 years after publication or once an update has been issued.

The authors of this article are responsible for its contents, including any clinical or treatment recommendations. No statement in this article should be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

SOURCE(S) OF FUNDING

American College of Physicians

GUIDELINE COMMITTEE

Clinical Efficacy Assessment Subcommittee of the American College of Physicians

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Stock ownership or options (other than mutual funds): S. Weinberger (GlaxoSmithKline).

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GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American College of Physicians (ACP) Web site.

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Wilt TJ, Niewoehner D, MacDonald R, Kane RL. Management of stable chronic obstructive pulmonary disease: a systematic review for a clinical practice guideline. Ann Intern Med. 2007;147:639-53 Electronic copies: Available from the Annals of Internal Medicine Web site.
- Wilt TJ, Niewoehner D, Kim CB, Kane RL, Linabery A, Tacklind J, et al. Use of spirometry for case finding, diagnosis, and management of chronic obstructive pulmonary disease (COPD). (Prepared by the Minnesota Evidence-based Practice Center under contract 290-02-0009.) Rockville, MD: Agency for Healthcare Research and Quality; September 2005. AHRQ publication no. 05-E017-2.

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

The following are also available:

- Diagnosis and management of stable chronic obstructive pulmonary disease: a clinical practice guideline from the American College of Physicians. Audio summary. Electronic file: Available from the Annals of Internal Medicine Web site.
- Diagnosis and management of stable chronic obstructive pulmonary disease. Continuing medical education (CME) course. Available from the Annals of Internal Medicine Web site.

PATIENT RESOURCES

The following is available:

- Summaries for patients. Diagnosis and management of chronic obstructive pulmonary disease: a clinical practice guideline from the American College of Physicians. Ann Intern Med 2007 Nov 6; 147(9):I-41

Electronic copies: Available from the Annals of Internal Medicine Web site.

Print copies: Available from the American College of Physicians (ACP), 190 N. Independence Mall West, Philadelphia PA 19106-1572.

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NGC STATUS

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