



## Special Article

# Health-Care Quality Standards in Chronic Obstructive Pulmonary Disease

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## ABSTRACT

Although clinical practice guidelines have contributed to improving the quality of health care offered to patients with chronic obstructive pulmonary disease (COPD), the level of adherence to recommendations continues to be inadequate and variable. Standards of care in COPD are written after applying an evidence-based approach, with the aim of unifying health-care criteria, establishing levels of acceptable adherence, and providing a way to assess quality; the ultimate goal is to improve patient care. In this statement we propose a series of health-care quality criteria and related indicators that will facilitate the quantitative evaluation of adherence to recommendations. The level of adherence that should be required is stipulated. This statement is not intended to provide a detailed description of how COPD should be managed. The aim is rather to set out quality assurance criteria that will contribute to the improvement of health-care access and equity, guaranteeing application of the highest levels of scientific and technical quality possible within the constraints of available resources, with the final purpose of satisfying the patient with COPD. The quality criteria have been grouped in 3 categories: *a*) so-called key criteria, to which adherence is essential; *b*) a set of conventional quality standards; and *c*) health-care administrative standards. Finally, we propose a framework on which to base the eventual accreditation of health-care quality for COPD patients.

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## Estándares de calidad asistencial en la EPOC

### RESUMEN

Aunque las guías de práctica clínica han contribuido a mejorar la asistencia que se ofrece al paciente con enfermedad pulmonar obstructiva crónica (EPOC), el grado de cumplimiento sigue siendo insuficiente y variable. Los estándares de calidad asistencial de la EPOC son un documento que, empleando una metodología basada en la evidencia, pretende unificar criterios de asistencia, establecer unos márgenes de cumplimiento y un sistema de evaluación con el objetivo final de mejorar la atención del paciente con EPOC. Con esta finalidad se propone una serie de criterios de calidad asistencial, a los que se asigna un indicador que permite cuantificar su aplicación, y se establece cuál debe ser el grado de cumplimiento exigible. El documento no pretende ser una descripción detallada del manejo de la EPOC, sino que busca implantar unos criterios de calidad encaminados a garantizar la accesibilidad y equidad en la atención con la mejor calidad científico-técnica posible, teniendo en cuenta los recursos disponibles, a fin de lograr la satisfacción del paciente con EPOC. Los estándares de calidad se estructuran en 3 categorías: *a*) los denominados estándares de calidad clave, de obligado cumplimiento; *b*) un grupo de estándares de calidad convencionales, y *c*) un tercer bloque dirigido a la Administración sanitaria. Finalmente, el documento también propone las bases para una futura acreditación de calidad asistencial en la EPOC.

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### Palabras clave:

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## Introduction

Chronic obstructive pulmonary disease (COPD) is indisputably among the most significant chronic diseases in Western countries. The estimated prevalence in the population aged 40 to 69 years is 9.1%,<sup>1</sup> meaning that in Spain the number of sufferers would be over a million and a half. Predictions are equally discouraging given the recent adoption of smoking by women and the still elevated rate of consumption in this country, among other factors. Beyond the raw prevalence rates, the actual situation of individuals with COPD is one of gradual deterioration that leads to exercise intolerance, recurrent exacerbations, and premature death. The chronic, progressive nature of COPD, its high prevalence, and inadequate control associated with frequent episodes of respiratory decompensation are the main causes of pressure on the health-care system. Nearly 10% to 12% of primary care medical visits and 10% of hospital admissions are attributable to COPD,<sup>2</sup> which is now the fifth leading cause of death in Spain and the fourth leading cause worldwide, surpassed only by heart and cerebrovascular diseases and cancers. COPD is the only one of these that is still on the rise.<sup>3</sup> By 2020, this chronic disease is expected to reach third place as a cause of death and fifth as a cause of disability.<sup>4</sup>

In order to improve this outlook, the main Spanish<sup>5</sup> and international<sup>6-8</sup> scientific associations have issued clinical practice guidelines that unify criteria with the aim of improving each and every aspect of health care for COPD patients. Among the specific goals of such guidelines are the following: to analyze available scientific evidence, improve quality of care, achieve uniformity of clinical care, improve the cost-effectiveness ratio, guide regulatory agencies, and identify the main areas of uncertainty where research efforts should be concentrated. However, the reality of clinical practice remains far removed from this ideal situation. For example, nearly 80% of patients found to have COPD in the IBERPOC study had not been previously diagnosed, and somewhat more than 50% of patients with severe disease were not receiving specific treatment.<sup>1</sup> In the EFRAM study, slightly more than 85% of patients admitted to hospital with a COPD exacerbation had not participated in pulmonary rehabilitation programs during the previous year,<sup>9</sup> even though the main clinical practice guidelines recommend such treatment even at initial stages of disease.<sup>5-8</sup> These figures indicate that current adherence to clinical practice guidelines in Spain is still inadequate, with great variability, and that health-care quality can be improved. These obstacles are not specific to Spain but are reported for other developed countries as well. One study designed to assess quality of care of COPD patients in the United States found that the disease was being managed in accordance with guidelines in only 58% of the cases.<sup>10</sup> Adherence was better during exacerbations (60.4%) than for periods of stability (46.1%). That study also detected wide geographic variation and lower quality of care reaching patients in low income brackets, underscoring the need to take measures to promote equity of care. A recent audit addressing the issue of hospital admissions for COPD in the United Kingdom revealed that better-organized departments had lower mortality rates, a finding that encourages the search for approaches to improving quality of care.<sup>11</sup>

Aware of these disparities in the delivery of health care, the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) asked its Standards of Care Committee to propose a set of standard criteria for managing this disease, with the aim of improving equity in access to first-rate care for COPD patients.

## Objective of This Statement

The first purpose of this statement is to gather together the criteria that will facilitate improvements in quality of care for patients with COPD in Spain. A second aim is to suggest a means for evaluating the health care that is being provided. These quality standards focus on the process of delivering health care to patients with COPD and by no means are intended to offer a detailed description of diagnostic or therapeutic management, as such guidance can be found in other recently published papers or clinical guidelines.<sup>5-8</sup> The target readership for this statement includes a) health-care professionals involved in the diagnosis and treatment of COPD patients at any level of the health-care system, and b) administrative personnel, given that quality assurance requires measures to provide structures, staff, and training opportunities.

## Definitions

*Health-care quality standards:* a set of standards whose purpose is to assure that access to services is equitable and that care is delivered with optimal professionalism within the constraints of available resources, with a view to achieving patient adherence and satisfaction.

*Dimensions of quality:* attributes or components of quality. The dimensions most often mentioned in the medical literature are efficiency, effectiveness, scientific and technical quality (professional competence and practice), accessibility, and user satisfaction or approval.

*Quality criteria:* conditions a health-care activity, intervention, or process must meet in order to be judged acceptable.

*Quality indicators:* a quantitative measure that can be used to monitor and evaluate the quality of activities; the particular way in which each quality criterion is numerically assessed (normally on a scale).

*Quality standards:* the degrees of due compliance with quality criteria. In other words, quality standards define a range of acceptable care for a specific process, setting minimum and maximum levels for an indicator of quality. A standard therefore sets the minimum level below which the quality of a health-care process would be compromised. If that standard is not met, a practice (a product or service) would not be said to be of sufficient quality.

## Methods

These standards of health-care quality in COPD have been developed with guidance from and under the auspices of SEPAR's Standards of Care Committee and the association's Assembly on COPD. A working group of respiratory medicine specialists with expertise in COPD evaluated current guidelines available in the literature, applying an evidence-based medicine approach. Table 1

**Table 1**  
Levels of Evidence

Evidence Category	Source of Evidence
A	Randomized controlled clinical trials with large datasets
B	Randomized clinical trials with small datasets
C	Nonrandomized clinical trials or observational studies
D	Expert consensus statements

shows the levels of scientific evidence that provide support for the recommendations made in this statement. Many quality criteria finally included have been derived from expert opinion and have therefore been assigned an evidence level of D. We have nevertheless included these criteria because it is also our opinion that they will contribute to improving the care of COPD patients. These criteria should be reassessed in the future from a scientific standpoint and we therefore believe that research to validate them should be undertaken.

In the first phase of writing this statement, 2 authors drafted each section independently. A second draft was created by all authors in collaboration, using the first drafts as the starting point. The second draft was then sent to a group of 18 experts in COPD in different parts of Spain. Final approval of the manuscript was based

on the responses of these external reviewers. The authors synthesized the main components of current clinical practice guidelines,<sup>5-8</sup> with particular attention to the COPD guidelines issued by SEPAR and the Latin American Thoracic Society (ALAT).<sup>5</sup> However, as the aim of the committee was not to produce a detailed description of COPD management, but rather to establish the most important quality criteria, general criteria were given priority over specific ones.

Five groups of quality standards have been established in order to facilitate their distribution. The first are based on the key criteria (Table 2). This group provides a set of principles of greatest importance for achieving a minimum standard of health care. We therefore consider that compliance with these criteria is mandatory. If any key criterion is not fulfilled, overall quality of care will be

**Table 2**  
Key Health-Care Quality Standards for the Management of COPD

	Quality Criterion	Evidence Level	Key Indicator
Diagnosis of COPD			
S1	Patients over 40 years of age with risk factors for COPD, such as smoking history of >10 pack-years and relatively irreversible airflow limitation demonstrated by spirometry (defined as a postbronchodilator ratio of FEV <sub>1</sub> to FVC <0.70)	D	No. of patients correctly diagnosed with COPD/No. of patients classified in the chart as having COPD
Treatment of stable-phase COPD			
S2	Patients with COPD who continue to smoke, regardless of age, should be encouraged to quit and offered specific cessation therapy <sup>a</sup> that is available at any time	A	No. of active smokers with COPD for whom a specific smoking cessation intervention has been prescribed/No. of active smokers with COPD
S3	SEPAR has published guidelines for the treatment of smoking dependence <sup>12</sup> SABDs are effective for rapid control of symptoms. They should be used on demand when symptoms worsen	A	No. of patients prescribed an SABD for on-demand treatment/No. of patients with COPD
S4	LABDs provide greater control for patients who are often symptomatic. They improve both quality of life and lung function, reducing the number of exacerbations, and should be prescribed for all COPD patients who regularly experience symptoms. Patients who have persistent symptoms, in spite of LABD use, should be prescribed a second LABD	A	No. of patients prescribed an LABD/No. of symptomatic COPD patients
S5	Combination of an LABA and inhaled corticosteroids: Patients with moderate or severe COPD experience additional improvement in lung function, symptoms, and quality of life with this combination of drugs. They experience fewer exacerbations, although no statistically significant effect on survival has been observed. This treatment is prescribed for patients with severe COPD and for those with more than 1 exacerbation per year	A	No. of patients prescribed combined treatment with LABAs and inhaled corticosteroids/No. of patients for whom such treatment is indicated
S6	CHOT for at least 15 hours daily should be prescribed in the following cases: 1. PaO <sub>2</sub> = 55 mm Hg 2. PaO <sub>2</sub> = 56-60 mm Hg, when the patient has pulmonary arterial hypertension, polycythemia (hematocrit >55%), cardiac arrhythmia, or signs of right heart failure	A C	No. of patients on CHOT/No. of patients for whom CHOT is indicated
	SEPAR has published guidelines for oxygen therapy in general and for therapy in specific circumstances such as on airline flights <sup>13,14</sup>		
Treatment of exacerbations			
S7	SABD (a β <sub>2</sub> -antagonist or ipratropium bromide) therapy should be intensified during an exacerbation	A	No. of patients with exacerbated COPD for whom the bronchodilator dosage is increased/total No. of patients with exacerbated COPD
S8	Systemic corticosteroid therapy is the treatment of choice for severe COPD exacerbation and should also be applied in cases of exacerbated mild or moderate COPD if the clinical course is not favorable	A	No. of patients with exacerbated COPD on systemic corticosteroids/No. of patients with exacerbated COPD in whom this treatment is indicated
S9	Antibiotic therapy is required in exacerbations that present with an increase in sputum volume or purulence with respect to the patient's usual baseline, in addition to dyspnea	A	No. of patients prescribed antibiotics/No. of patients for whom this treatment is indicated
S10	A recent consensus statement by several scientific associations offers guidelines for antimicrobial therapy in COPD <sup>15</sup> Supplemental oxygen should be administered during exacerbations that progress to respiratory failure in order to bring PaO <sub>2</sub> >60 mm Hg and avoid acidosis	C	No. of patients on oxygen/No. of patients for whom this treatment is indicated

Abbreviations: CHOT, continuous home oxygen therapy; FEV<sub>1</sub>, forced expiratory volume in 1 second; FVC, forced vital capacity; LABA, long-acting β<sub>2</sub>-agonists; LABD, long-acting bronchodilator; SABD, short-acting bronchodilator; SEPAR, Spanish Society of Pulmonology and Thoracic Surgery.

<sup>a</sup> Any intervention aiming to encourage a smoker to quit, including medical advice, psychological counseling, or pharmacologic treatment

**Table 3**  
Additional Health-Care Quality Standards for the Evaluation of COPD

	Quality Criterion	Evidence Level	Key Indicator
Initial clinical assessment			
S11	The medical history of a patient suspected of having COPD should include a record of the following information: smoking history <sup>a</sup> and/or risk factors for COPD, comorbidity, presence of relevant symptoms (dyspnea, cough, and/or sputum production), and exacerbations	D	No. of charts with complete patient records/No. of charts for patients with COPD
Classification			
S12	Patients with COPD are grouped according to postbronchodilator FEV <sub>1</sub> expressed as a percentage of theoretical. The stages are as follows: Mild COPD (stage I): FEV <sub>1</sub> =80% Moderate COPD (stage II): FEV <sub>1</sub> = 50 and <80% Severe COPD (stage III): FEV <sub>1</sub> = 30 and <50% Very severe COPD (stage IV): FEV <sub>1</sub> <30% or FEV <sub>1</sub> <50% and chronic respiratory failure (PaO <sub>2</sub> <60 mm Hg)	D	No. of correctly classified COPD patients/No. of patients with COPD
Criteria for referral to a specialist			
S13 (NASC)	Symptomatic patients should be evaluated by a specialist in respiratory medicine at least once	D	No. of symptomatic COPD patients who have been evaluated by a pulmonologist at least once/No. of patients with COPD
Additional tests			
S14	The following tests should be performed during the first visit: Complete blood count Electrocardiogram Chest x-ray (posteroanterior and lateral projections)	D	No. of patients for whom test results are complete/No. of patients with COPD
S15 (NAPC)	Plasma α <sub>1</sub> -antitrypsin concentrations should be determined for all COPD patients at least once SEPAR has published recommendations for α <sub>1</sub> -antitrypsin plasma concentration testing <sup>16</sup>	D	No. of COPD patients with at least 1 laboratory report of α <sub>1</sub> -antitrypsin plasma concentration/No. of patients with COPD
S16 (NAPC)	Patients with severe or very severe COPD should undergo the following tests at least once: Measurement of static lung volumes Carbon monoxide diffusing capacity Arterial blood gas analysis at rest Stress test <sup>b</sup> Nutritional assessment	D	No. of patients with severe or very severe COPD who have undergone all these tests at least once/No. of patients with severe or very severe COPD

Abbreviations: FEV<sub>1</sub>: forced expiratory volume in 1 second; NAPC, not applicable in primary care; NASC, not applicable in specialist care.

<sup>a</sup>Record current smoking habit, daily smoking and duration in years. Exposure should be expressed in pack-years.

<sup>b</sup>This item encompasses both maximal stress tests performed on a cycle ergometer or treadmill or a submaximal stress test such as a 6-minute walk test or shuttle walk test.

considered deficient. The remaining standards in the tables address various issues. Table 3 concerns the diagnosis, classification, and follow-up of COPD; Table 4, treatment while the patient is in a stable phase of disease; and Table 5, the management of exacerbations. Finally, Table 6 shows a set of quality standards that should be met by health-care administrators.

#### Evaluation of Health-Care Quality

Most quality standards are matched to a specific indicator of health-care quality that serves as an evaluative measure. Just as there are 2 categories for quality-of-care standards, there are 2 groupings for indicators: the so-called key indicators and all the remaining indicators. Key indicators are particularly relevant to the final objective of achieving better health care and they are therefore weighted differently.

In a set of 42 indicators, 10 of which are considered key, 25 address conventional aspects of health care and 7 refer to administrative issues. Each result is expressed as a percentage, with a range of 60% to 120% considered to indicate acceptable care. Percentages outside this range are considered an indication of deficient care. The selected cutpoints are arbitrary and, therefore, require validation. However, the working group charged with setting these quality standards for COPD care believe that they provide a necessary starting point. The upper limit of 120% was set to reflect

the group's attempt to detect overactivity as a type of poor health-care practice.

Scoring will vary depending on whether an indicator is considered key or not, as follows:

- For key indicators:
  - A percentage considered to identify deficiency on a key indicator (<60% or >120%) = 0 points
  - A percentage considered acceptable on a key indicator (≥60% and ≤120%) = 5 points.
- For other indicators:
  - A percentage indicating deficiency (<60% or ≥120%) = 0 points
  - A percentage indicating acceptability (=60% and ≥120% ≤2 points)

Some quality standards are not applicable in all settings. For example, certain indicators, such as those pertaining to referral to hospital, can only be quantified at the primary care level. Others will only be relevant to specialized care settings. Likewise, if a hospital emergency service is being audited, only indicators that are meaningful in that context can be taken into consideration. The overall score, therefore, should be adjusted in accordance with the number of potentially applicable indicators in the setting being audited. Administrative quality indicators should be assessed separately so that the results do not affect the evaluation of a department, hospital, or other service being audited.

**Table 4**  
Health-Care Quality Standards for the Management of Stable COPD

	Quality Criterion	Evidence Level	Key Indicator
<b>General recommendations</b>			
S17	Regular exercise should be recommended to all COPD patients	C	No. of COPD patients who are advised to exercise regularly/No. of patients with COPD
S18	Influenza vaccination should be recommended to all COPD patients	A	No. of COPD patients vaccinated against influenza/No. of patients with COPD
S19	Pneumococcal vaccination should be offered to patients with severe COPD and to all COPD patients over 65 years of age	B	No. of COPD patients vaccinated against the pneumococcus/No. of patients for whom such vaccination is indicated
<b>Pharmacotherapy</b>			
S20	"Triple" drug combination (long-acting anticholinergic agents, LABA, and inhaled corticosteroids) is justified in severe or very severe COPD if the patient experiences symptomatic deterioration in spite of LABD treatment	B	No. of patients prescribed "triple" drug therapy (LABA, inhaled corticosteroids, and tiotropium)/No. of patients for whom such therapy is indicated
S21	Theophyllines should be used whenever a patient remains symptomatic in spite of treatment appropriate for stage of disease, or in the few cases in which an oral route is required SEPAR has published guidelines for COPD treatment according to stage of disease <sup>5</sup>	D	No. of prescribed theophyllines/No. of COPD patients who remain symptomatic in spite of disease-stage-appropriate treatment
S22	Oral corticosteroids are not recommended for maintenance therapy in stable COPD	A	No. of COPD patients who are not on oral corticosteroids/No. of patients with stable COPD
<b>Pulmonary rehabilitation</b>			
S23 (NAPC)	Pulmonary rehabilitation should be prescribed for all COPD patients who continue to experience limitations in activities of daily living due to dyspnea after stage-appropriate pharmacologic treatment SEPAR has published guidelines for pulmonary rehabilitation programs <sup>17</sup>	A	No. of patients enrolled in a rehabilitation program/No. of patients for whom rehabilitation is indicated
<b>Other therapeutic strategies</b>			
S24	Lung reduction surgery should be considered for patients with heterogeneous emphysema predominantly in the upper lobes if they have low tolerance for exercise	A	No. of patients who undergo lung reduction surgery/No. of patients for whom the procedure is indicated
S25	Lung transplantation should be considered for patients under 65 years of age with very advanced disease who meet the general conditions for that procedure SEPAR has published guidelines on evaluating lung transplant candidates <sup>18</sup>	C	No. of patients evaluated for a lung transplant/No. of patients for whom a transplant is indicated
<b>Follow-up</b>			
S26	All patients with COPD should be followed, with regular visits scheduled at least once a year	D	No. of COPD patients who are seen by a physician at least once a year/No. of patients with COPD

Abbreviations: LABA, long-acting  $\beta_2$ -agonists; NAPC, not applicable in primary care; NASC, not applicable in specialized care; SEPAR, Spanish Society of Pulmonology and Thoracic Surgery.

As mentioned, all 10 key standards must be met. If any of the key indicators proves unsatisfactory, the evaluation process is detained. If percentages for all 10 key indicators are acceptable (50 points), points are then added based on other indicators (2 points for each non-key quality criterion on which a satisfactory percentage is achieved). The total score will be expressed according to the maximum possible score, depending on the number of quality standards considered applicable, according to the following formula:

Overall quality score:

$$= \frac{\text{Total score on applicable indicators}}{\text{Maximum theoretical score on applicable indicators}} \times 100$$

Overall quality of health care will be classified as follows:

- Deficient quality of health care: This category is assigned whenever passing percentages are not achieved on all 10 key indicators.
- Adequate quality of health care: This category is assigned whenever passing percentages are achieved on all 10 key indicators and the total number of points earned falls between

50% and 84% of the maximum possible score on applicable indicators.

- Excellent quality of health care: This assessment is assigned whenever passing percentages are achieved on all 10 key indicators and the total number of points earned is at least 85% of the maximum possible score on applicable indicators.

As mentioned, scores on administrative quality standards (Table 6) shall not be taken into consideration when evaluating quality of health care and, therefore, will not affect the accreditation process. However, results on administrative quality standards should appear in the final accreditation report, as they are considered relevant to the ultimate purpose of the report: to improve quality of health care for the patient. The report should distinguish results for a department, hospital, or service requesting accreditation (standards 1-35) from the results attributable to the corresponding administration (standards 36-42).

#### Accreditation Process

Accreditation is understood to involve an external audit to confirm the level of compliance with a series of quality standards for

**Table 5**  
Health-Care Quality Standards for the Management of COPD Exacerbations

	Quality Criterion	Evidence Level	Key Indicator
Diagnosis S27	The patient's chart should record the following basic information: symptoms (dyspnea, sputum color, and volume), prior exacerbations, comorbidity, previous treatment	D	No. of exacerbations in which all necessary information is recorded/No. of COPD exacerbations
Criteria for referral to a specialist S28 (NASC)	<p>Patients with exacerbations should be referred to a specialist under the following conditions:</p> <ol style="list-style-type: none"> <li>If the course of COPD includes any of the following signs: <ul style="list-style-type: none"> <li>Respiratory failure</li> <li>Persistent tachypnea</li> <li>Recruitment of accessory muscles</li> <li>Evidence of right heart failure</li> <li>Hypercapnia</li> <li>Impossibility of disease management at home</li> <li>Severe associated comorbidity</li> <li>Diminished level of consciousness</li> <li>Lack of improvement evident in a follow-up appointment after exacerbation</li> </ul> </li> <li>Need to rule out other diseases: <ul style="list-style-type: none"> <li>Pneumonia</li> <li>Pneumothorax</li> <li>Left heart failure</li> <li>Pulmonary embolism</li> <li>Bronchopulmonary cancer</li> <li>Upper airway obstruction</li> </ul> </li> </ol>	D	No. of patients referred to hospital/No. of patients who meet the criteria for referral
Additional tests S29 (NAPC)	<p>The following tests should be performed in all patients who come to the hospital with an exacerbation:</p> <ul style="list-style-type: none"> <li>Chest x-ray</li> <li>Arterial blood gas analysis, noting the inspired oxygen fraction administered during the test</li> <li>Electrocardiogram</li> <li>Complete blood workup, including complete blood count and biochemistry, with electrolyte balance and kidney function</li> <li>Sputum sample for Gram staining and culture in patients with frequent exacerbations, those in need of assisted ventilation, and or in cases of antibiotic failure</li> </ul>	D	No. of patients who have undergone all tests/No. of patients with a COPD exacerbation attended in the hospital
S30 (NAPC)	In patients who are initially hypercapnic and require high-flow oxygen, arterial blood gases should be checked approximately 30 min after start of therapy	D	No. of patients who undergo a second arterial blood gas analysis/No. of patients in whom a second analysis is indicated
Invasive mechanical ventilation S31 (NAPC)	NIV should be prescribed for patients who develop respiratory acidosis (pH <7.35) in spite of optimal treatment	A	No. of patients on NIV/No. of patients for whom NIV is indicated
S32 (NAPC)	Invasive mechanical ventilation should be used in patients with severe respiratory acidosis (pH <7.25), diminished level of consciousness, and/or hemodynamic instability	C	No. of patients on invasive ventilation/No. of patients for whom this form is indicated
Hospital discharge S33 (NAPC)	The discharge report should include a written, specific treatment plan	D	No. of patients prescribed a specific treatment plan on discharge/No. of patients discharged after hospitalization for COPD exacerbation
Follow-up S34 (NASC)	All patients with exacerbations who are not admitted should have a follow-up visit within 72 hours	D	No. of outpatients with exacerbated COPD who are checked within 72 h of initial treatment/No. of outpatients with exacerbated COPD who are treated
S35 (NAPC)	Patients discharged after hospitalization should be given an appointment for a follow-up visit in 2 weeks	D	No. of patients seen within 2 wk of discharged after hospitalization for exacerbated COPD/No. of patients admitted for COPD exacerbation who are discharged

Abbreviations: NAPC, not applicable in primary care; NASC, not applicable in specialized care; NIV, noninvasive ventilation.

**Table 6**  
Health-Care Quality Standards for Administrators of Programs for COPD Patients

	Quality Criterion	Evidence Level	Key Indicator
S36	All physicians who provide care for patients with COPD should have access to spirometry	D	No. of health-care facilities with a spirometer/No. of facilities
S37	Spirometry should be carried out by trained staff using validated spirometry systems. All health-care facilities where spirometry is performed should have trained staff with sufficient time to implement these specific tests SEPAR has published guidelines on the performance of spirometry <sup>19</sup>	D	No. of high-quality spirometries/No. of spirometries evaluated
S38	Specialists in respiratory medicine should have equipment for performing arterial blood gas analysis and to determine lung volumes and carbon monoxide diffusing capacity	D	No. of specialist respiratory care facilities with the appropriate equipment for these tests/No. of specialist care facilities
S39	Primary care facilities offer the ideal setting in which to initiate smoking cessation programs. Antismoking campaigns should be put into effect to facilitate specialized treatment in every health-care area	D	No. of dedicated smoking cessation teams/No. of health-care areas studied
S40	All hospitals should offer pulmonary rehabilitation as an integral component of care. SEPAR has published guidelines for pulmonary rehabilitation programs <sup>17</sup>	D	No. of hospitals with a pulmonary rehabilitation program/No. of hospitals studied
S41	All hospitals treating patients with COPD should have NIV devices, the means to record data, and staff trained in how to provide this therapy	A	No. of hospitals with the capability to administer NIV/No. of hospitals attending patients with exacerbated COPD
S42	Surveys should be undertaken in a representative sample of COPD patients to assess their perception of level of satisfaction with quality of care	D	Performance of COPD patient satisfaction surveys

Abbreviations: NIV, noninvasive ventilation; SEPAR, Spanish Society of Pulmonology and Thoracic Surgery.

whatever facility, department, or service wishes to be accredited. The accrediting body will designate a team of qualified external auditors who will review compliance with quality standards over a specified period of time. If the facility receives a favorable evaluation, the accrediting body will issue a statement to that effect. If the evaluation is unfavorable, the audit team may ask the facility, department, or service for an action plan to be implemented within a fixed time frame. The audit team will prepare a report evaluating the action plan, if the accrediting body so requires, in order to move forward toward accreditation, re-accreditation, or partial or full revocation of accreditation.

### Duration and Validation of the Standards

The working group believes these standards should be considered applicable for a maximum of 3 years, after which time they should be revised. Before that time, arrangements should be made to validate them. We have intentionally not included "outcomes indicators" in the present statement. Such indicators, in our opinion, should be introduced during the validation process, given that they are conditioned by compliance with the quality standards. However, once the standards are validated, outcomes indicators could be incorporated into future health-care quality standards. Examples of such indicators might be the in-hospital mortality rate, mortality after discharge (30, 90, and 360 days), the rate of treatment failure or the readmission rate, hospital stay, the rate of orotracheal intubation, results of patient satisfaction surveys, health-related quality of life, consumption of health resources, lost work due to illness, cost-effectiveness analysis, etc.

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### References

- Sobradillo Pena V, Miravittles M, Gabriel R, Jiménez-Ruiz CA, Villasante C, Masa JF, et al. Geographical variations in prevalence and underdiagnosis of COPD. Results of the IBERPOC multicentre epidemiological study. *Chest*. 2000;118:981-9.
- Soler JJ, Sánchez L, Latorre M, Alamar J, Román P, Perpiña M. Impacto asistencial hospitalario de la EPOC. Peso específico del paciente con EPOC de alto consumo sanitario. *Arch Bronconeumol*. 2001;37:375-81.
- Jemal A, Ward E, Hao Y, Thun M. Trends in the leading causes of death in the United States, 1970-2002. *JAMA*. 2005;294:1255-9.
- Murray CJL, López AD. Mortality by cause for eight regions of the world: Global Burden of Disease Study. *Lancet*. 1997;349:1269-76.
- Peces-Barba G, Barberà JA, Agustí A, Casanova C, Casas A, Izquierdo JL, et al. Guía clínica SEPAR-ALAT de diagnóstico y tratamiento de la EPOC. *Arch Bronconeumol*. 2008;44:271-81.
- Rabe KF, Hurd S, Anzueto A, Barnes PJ, Buist SA, Calverley P, et al. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. GOLD executive summary. *Am J Respir Crit Care Med*. 2007;176:532-55.
- National Institute for Clinical Excellence (NICE). Chronic obstructive pulmonary disease. National clinical guideline on management of chronic obstructive pulmonary disease in adults in primary and secondary care. *Thorax*. 2004;59 Suppl 1:1-232.
- Celli BR, MacNee W. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. *Eur Respir J*. 2004;23:932-46.
- García-Aymerich J, Barreiro E, Farrero E, Marrades RM, Morera J, Antó JM, and the EFRAM investigators. Patients hospitalized for COPD have a high prevalence of modifiable risk factors for exacerbation (EFRAM study). *Eur Respir J*. 2000;16:1037-42.
- Mularski RA, Asch SM, Shrank WH, Kerr EA, Setodji CM, Adams JL, et al. The quality of obstructive lung disease care for adults in the United States as measured by adherence to recommended processes. *Chest*. 2006;130:1844-50.
- Price LC, Lowe D, Hosker HSR, Anstey K, Pearson MG, Roberts CM, et al. UK national COPD audit 2003: impact of hospital resources and organization of care on patient outcome following admission for acute COPD exacerbation. *Thorax*. 2006;61:837-42.
- Jiménez-Ruiz CA, Solano S, González de Vega JM, Ruiz M, Flórez S, Ramos A, et al. Normativa para el tratamiento del tabaquismo. *Arch Bronconeumol*. 1999;35:499-506.

13. Sánchez Agudo L, Cornudella R, Estopá R, Molinos L, Servera E. Indicación y empleo de la oxigenoterapia continuada domiciliaria (OCD). Arch Bronconeumol. 1998;34:87-94.
14. García-Río F, Borderías L, Casanova C, Celli BR, Escarrabill S, González Mangado N, et al. Patología respiratoria y vuelos en avión. Arch Bronconeumol. 2007;43:101-25.
15. Miravittles M, Monsó E, Mensa J, Aguarón Pérez J, Barberán J, Bárcena M, et al. Tratamiento antimicrobiano de la agudización de la EPOC: documento de consenso 2007. Arch Bronconeumol. 2008;44:100-8.
16. Vidal R, Blanco I, Casas F, Jardí R, Miravittles M. Diagnóstico y tratamiento del déficit de alfa-1-antitripsina. Arch Bronconeumol. 2006;42:645-9.
17. De Lucas P, Guell R, Sobradillo V, Jiménez CA, Sangenis M, Montemayor T, et al. Rehabilitación respiratoria. Normativa SEPAR. Arch Bronconeumol. 2000;36:257-74.
18. Varela A, Álvarez KA, Roman A, Ussetti P, Zurbano F. Normativa sobre el estudio y seguimiento del receptor de un trasplante pulmonar. Arch Bronconeumol. 2001;37:307-15.
19. Grupo de trabajo de la SEPAR para la práctica de la espirometría en clínica. Normativa para la espirometría forzada. Barcelona: Doyma; 1985.