

COPD Strategy for the National Health System

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COPD Strategy for the National Health System

Approved by the Inter-regional
Council of the National Health
System on June, 3rd, 2009



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GOBIERNO DE ESPAÑA MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD



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Preface

The 2nd Presidents' Conference held in September, 2005, entrusted the Ministry of Health and Consumer Affairs with implementing a group of measures in order to improve the efficacy and quality of healthcare by the National Health System. Said command resulted in a Quality Plan, and one of its lines of action is to undertake a review of the assistance procedures for patients who suffer diseases with a high prevalence, such as Chronic Obstructive Pulmonary Disease (COPD).

This initiative intends to identify any potential deficiencies and flaws in the healthcare system in terms of this specific condition, and to establish objectives and recommendations for improvement by consensus for the whole National Health System.

According to recent estimates by the WHO (2007), there are currently 210 million persons who suffer COPD. Out of these, 80 million have a moderate or severe form of the disease. In 2005, 3 million people died for this cause, which represents 5% of all deaths during that year. It is estimated that by 2020, COPD will have become the fourth cause of global death. This disease has a high impact on health, as well as social and economic consequences. Its morbidity and the disability associated are frequently underestimated by patients and their caretakers.

Studies conducted in Spain estimate the prevalence of COPD in our country between 6.4 and 11.4% depending on geographical regions. The IBERPOC study reported 9.1% in 1998, and the recent EPI-SCAN study estimates the current prevalence of COPD in 10.2% among the overall population between 40 and 79 years of age. According to the Hospital Morbidity Survey of 2005, discharges by COPD represented 6.5% of the total. The total cost associated with this disease is equal to 0.2% of the Gross Domestic Product. Besides, it is estimated that over 70% of cases are left undiagnosed, which indicates that the problem could be even greater, due to an "iceberg" effect.

This Strategy is justified by the high prevalence of this condition and its under-diagnosis, associated with the disease burden it generates and its high cost for public health services.

A rigorous approach to any complex condition requires a comprehensive plan of action which establishes tested criteria, agreed to by consensus,

about guidelines to follow in terms of prevention, early diagnosis, assistance during the acute stage, rehabilitation, professional training, and research. The COPD Strategy for the National Health System (NHS) identifies unmet needs and proposes improvement measures for these and other issues, suggesting a series of objectives and recommendations intended to improve each one of these aspects.

Expert associations in all disciplines associated with COPD have been involved in the preparation of this Strategy, as well as patient associations, coordinated by Dr. Julio Ancochea Bermúdez. Representatives of the Regional Health Ministries have also participated, as well as experts from the Ministry of Health and Social Policy. The most recent scientific evidence has been taken into account, as well as actions and plans implemented not only in Spain, but also at an international level.

The COPD Strategy for the NHS represents a collaborative effort among Autonomous Regions, the Ministry of Health and Social Policy, Scientific Societies and Patient Associations, in order to reach the highest efficacy and quality in addressing and treating this condition throughout all health services which form the public health system. Thus, this Strategy will make a contribution towards social cohesion, which will undoubtedly benefit citizens, regardless of their place of residence.

Finally, I would like to express my gratitude to all those who have participated in the preparation of this document, because without their commitment and effort, it would have been impossible to have this instrument which will undoubtedly help to improve the quality of healthcare within the National Health System.

Trinidad Jiménez García-Herrera
Minister of Health and Social Policy

Introduction

COPD is a disease characterized by the presence of chronic and progressive airflow limitation with poor reversibility, associated with an anomalous inflammatory reaction, mostly due to tobacco smoke. Even though it is a severe and very incapacitating disease, which presents frequent extra-pulmonary symptoms and co-morbidities associated with the disease itself and with smoking and ageing, COPD can be prevented and treated. The main risk factor for COPD is smoking.

The National Health Survey of 2006 estimates the prevalence of smoking in our country in 26.4% of the population over 16 years of age, and during recent years there has been a slow and progressive decrease of the number of smokers within the overall population.

Due to its high prevalence, associated morbi-mortality and economic and social cost, currently COPD represents a full-scale socio-sanitary problem. Nevertheless, we are aware that epidemiologic studies projected upon the overall population usually underestimate the prevalence of COPD. This is so because this disease is typically diagnosed in advanced stages.

Therefore, one of this condition's characteristics is its under-diagnosis. This can be gathered from the IBERPOC study, which analyzed the prevalence of COPD in 1997 within the Spanish overall population ranging from 40 to 69 years of age, which resulted in 9.1%. A very significant conclusion from this study is that only 22% of those patients identified as suffering COPD had been diagnosed.

Furthermore, the preliminary results of the EPI-SCAN study (Epidemiologic Study of COPD in Spain) confirm the high rate of COPD under-diagnosis in Spain. The primary objective of this epidemiologic, transversal and multicentre study is to estimate COPD prevalence in the population from 40 to 80 years of age.

In order to reverse this situation, it is necessary to consider diagnosis in individuals over 40 years of age with a current or past history of smoking over 10 packets-year, which is equivalent to smoking 20 cigarettes per day during 10 years, and with respiratory symptoms.

Diagnosis must be confirmed by conducting a forced spirometry to prove the existence of airflow limitation, defined by a FEV1 /FVC ratio < 0.70, after a bronchodilator test.

In terms of COPD treatment, the greatest efforts must focus on preventing the disease progression, achieving symptom relief, improvement of tolerability to exercise and overall health status, as well as preventing and treating complications and exacerbations, and reducing mortality.

In order to achieve these objectives, a good treatment plan should address the following aspects: risk factor reduction, multidimensional assessment of the disease, stable COPD treatment, treatment of exacerbations, and comprehensive management of COPD during advanced stages of the disease.

Given that so far no medication has proven a true reduction of long-term pulmonary function, and that this is a chronic disease, it becomes essential to conduct an adequate and early diagnosis, as well as a comprehensive management of the disease, including the encouragement to make lifestyle changes, such as suppressing the smoking habit and increasing physical exercise, as well as boosting those abilities required to endure the disease, optimizing both pharmacological and non-pharmacological treatment, and facilitating an appropriate personal and family support.

Based on what has been said so far, it is not difficult to identify and list a complete set of reasons to justify the implementation of a COPD Strategy for the National Health System: this initiative has been based upon the high prevalence of a “disease that can be prevented”, its degree of under-diagnosis and under-treatment, and the morbidity, co-morbidity, disability and mortality associated with this condition, as well as the high use of resources that it generates, both in direct and indirect or intangible costs, and the need to improve the coordination between professionals and healthcare levels in the comprehensive management of a disease. To all this we must add the need to guarantee the principles of availability, efficacy and equity attached to our National Health System, and that will turn this Strategy into one of the best instruments for social cohesion.

In short, this Strategy puts forward a new approach to an old disease, which we currently define as preventable and treatable, and that will undoubtedly allow us to be more ambitious in terms of wishing to live longer and to live better.

Julio Ancochea Bermúdez
Scientific Coordinator for the Strategy

Technical Note

This document consists of five parts:

1. Overall aspects, including the Strategy justification, COPD definition, risk factors, status and healthcare for the disease, the regulatory framework for the Strategy, and the methodology used.
2. Development of strategic lines and objectives, and recommendation for actions proposed for each one of them, agreed upon by consensus and prioritized by the Technical Drafting Committee and the Institutional Committee for the Autonomous Regions, and approved by the Inter-regional Council of the National System on June, 3rd. 2009.
3. Assessment and information system for the Strategy, which must allow following up those actions proposed.
4. Examples of good practice developed in Spain, which have proven their efficacy and efficiency.
5. Appendixes which deal in depth with specific aspects in the Strategy.

1. Overall Aspects

1.1. Justification

According to the WHO, 210 million people throughout the world suffer COPD¹. In 2005, over 3 million persons died due to this disease, which represented 5% of all deaths registered in that year. In 2004, it is estimated that 30.2 million Disability Adjusted Life Years (DALYs) were lost globally. This figure represents 2.0% of total DALY. In developed countries, relative figures are slightly higher, with a loss of 3% of total DALY¹.

The WHO predicts that by 2030, COPD will be the cause of 7.8% of all deaths, and of 27% of deaths associated with smoking, only outnumbered by cancer (33%) and cardiovascular diseases (29%)². In this context, it is worth highlighting that the risk of lung cancer, which is the most frequent neoplasia, as well as the risk of cardiovascular disease, increases significantly in COPD sufferers.

Besides these mortality figures, it is foreseen that its prevalence will also increase until well into the 21st century, because nowadays there are more persons who smoke than in any other point in the history of humanity, and demographic changes associated with population ageing favor an increase in COPD prevalence³.

Traditionally, there has been an age-old lack of epidemiological data about overall respiratory conditions, and specifically about COPD, which explains to a great extent the lack of proportion between the problem's magnitude and its low impact upon public opinion, as well as the reduced perception of the need and urgency to sort out this problem.

Besides, due to under-diagnosis, COPD is a clear example that the problem could be even higher, due to an "iceberg" effect. If the estimated number of persons diagnosed with COPD during the year 2000 in USA was 10 million adults, the outcomes of the NHANES III study seem to indicate that up to 24 million of USA people could be affected by the disease⁴.

In Spain, it is estimated that between 9% and 10% of the adult population over 40 years of age suffers COPD, and that over 70% of them remain undiagnosed⁵.

In the IBERPOC study^{5,6}, the prevalence of COPD according to genders was 14.3% in males and 3.9% in females. In terms of smoking habit, the prevalence was 15% in smokers, 12.8% in past smokers, and 4.1% in non-smokers. The IBERPOC study also found major differences in terms of geographical areas, from 4.9% in Cáceres to 18% in Manlleu (Barcelona); these differences are possibly associated with environmental or work fac-

tors which have not been studied. It was estimated that over 1,200,000 Spanish people had non-reversible airflow obstruction compatible with COPD.

Within this context, it is required to initiate categorical activities which allow improving disease prevention, primary as well as secondary, establishing an effective and good quality comprehensive care, and encouraging first-class coordinated research, which will ultimately lead to a reduction in the disease morbi-mortality, and to overcome the traditional nihilistic attitude typical of healthcare staff responsible for COPD.

Therefore, one of the first challenges met by this Strategy is to break with this reality, and to encourage a proactive attitude in healthcare professionals, which allows reaching the objectives put forward by this document. In this sense, some of the following actions are considered a priority in this Strategy:

1. Primary Disease Prevention. Smoking is the main cause of the disease in our setting. Therefore, the fight against smoking at all levels must be one of the axes upon which this Strategy will swing.

2. Secondary Disease Prevention. The fight against under-diagnosis and under-treatment must orientate the master lines of action in the Strategy. The IBERPOC study detected a pocket of under-diagnosis close to 80%. This figure is unacceptable. However, due to the initiatives generated after that study, currently this figure might have possibly been reduced. In any case, under-diagnosis continues being a very relevant problem. The general use of spirometry tests, or the implementation of screening programs, for example, must be initiatives to be considered. However, results are affected by the low level of quality in spirometry tests conducted out of hospital. Continuing training or new technologies might help in this task.

3. Healthcare Quality, understood as a set of activities aimed at guaranteeing optimal assistance. This term includes different aspects which should be driving forces for this Strategy, including: 1) guarantee for accessibility and equity for all persons suffering COPD, regardless of their geographical zone of residence and their socio-economic condition; 1) the need to offer optimal professional assistance with high scientific-technical quality; 3) consideration of available resources, by using cost-efficacy criteria, and 4) compliance and satisfaction by users with healthcare received. This Strategy is imbued with this concept of healthcare quality.

4. Coordinated and First Class Research. Current challenges in terms of COPD morbid-mortality demand the exploration of different initiatives which will allow a better knowledge of the inner etiopathogenic mecha-

nisms of the disease, and all those aspects which affect its natural history. To achieve this, it is absolutely necessary to establish multidisciplinary research teams that, working in a coordinate manner and with adequate resources, may collaborate in the development of innovative and more efficacious therapeutic strategies. This Strategy must motivate global leadership for Spanish research in COPD.

5. Information. Even though COPD is a very frequent and incapacitating disease, with high mortality, there is no awareness within the general population, and there is no adequate acknowledgement by Health Authorities. The initiative represented by this document must reverse this situation, and try to attract enough resources so that all generated expectations can be fulfilled.

In order to achieve all objectives put forward by this document, and develop those strategic lines established, it is necessary that the different social agents, the Health authorities, healthcare staff, the country's research network and even society itself, join forces in a coordinated way. A comprehensive and coordinated action by all these agents is an essential element, which must be guided by the following principles and values:

– **Patient Orientation:** The axle upon which the system gyrates must be the patient, so that the whole assistance chain must be directed to satisfying patients' needs. Relationships between assistance levels must be energized, insisting upon the need to establish comprehensive care programs which ensure healthcare continuity.

Adequate information, humanized treatment, and respect for the opinion and decision of the person who suffers COPD, are some of the essential elements in this orientation. In this sense, the consecutive implementation of palliative care programs seems necessary in order to provide adequate care for the last stage of the disease.

– **Equity and Accessibility.** The strategy must promote that COPD patient care meets some minimum quality requirements throughout the country. The possibility to have access to an adequate diagnosis, to a program for smoking cessation, to comprehensive respiratory rehabilitation or, for example, to an adequate support ventilation, must always be present in all planning projects for implementing this Strategy.

– **High Quality Scientific-Technical Care.** All different agents in the COPD healthcare network must be guided by principles of scientific-technical quality based on the best scientific evidence. The development of clinical practice guidelines, common and by consensus must help to reduce variability, ultimately increasing quality. However, we understand it is not

enough to promote these initiatives. It is also necessary to make them work, and for that aim, this Strategy must encourage their implementation and monitor their execution. It is essential to boost transnational research in COPD with the highest possible level of quality.

1.2. Definition

COPD is characterized by the presence of chronic airflow limitation with poor reversibility, it is typically progressive, and associated with an anomalous inflammatory reaction, mostly due to tobacco smoke. This disease also presents a series of pathologic changes in the lung, and has associated extrapulmonary symptoms and major comorbidities which contribute to the severity of the patient⁷.

Alterations in airways (chronic bronchitis, bronchiolitis) and in lung parenchyma (emphysema) can co-exist in different proportions in persons who suffer COPD. Chronic bronchitis is defined clinically by the presence of coughing and expectorating during more than 3 months per year and during more than 2 consecutive years, without any other known causes. Pulmonary emphysema is a disease defined according to an anatomopathologic criterion of permanent enlargement of airspaces distal to the terminal bronchiole, with destruction of alveolar walls, without apparent fibrosis⁸.

These two conditions, chronic bronchitis and emphysema, usually appear simultaneously in the same patient, and are very difficult to differentiate *in vivo*. That is the reason why both terms have been eliminated in most recent definitions⁹. Besides, some patients with chronic bronchitis and/or emphysema have no associated bronchial obstruction, and therefore cannot be classified as COPD.

The difference between COPD and other diseases which also involve a chronic airflow reduction is that these have a specific cause, such as happens with upper airway limitation, cystic fibrosis, bronchiectasis or obliterating bronchiolitis. Bronchial asthma usually involves a reversible airflow limitation, which can be completely corrected, and which differentiates it conceptually from COPD. The use of computerized tomography scans has shown that many persons with COPD have associated bronchiectasis. These are usually basal and have a small size and a cylindrical morphology¹⁰. The presence of this type of bronchiectasis does not include a COPD diagnosis.

Currently, COPD cannot be cured, but it can be prevented and treated efficaciously, with symptom control, reduction of its progression rate and number of exacerbations, with the objective to improve prognosis and quality of life of people who suffer it. This multidimensional approach is starting to produce benefits in terms of survival.

Diagnosis, Symptomatology, and Prognostic Factors for COPD

Persons who smoke, are 40 years old or over, and have respiratory symptoms, must be suspected to be a potential COPD sufferer. It is necessary to conduct a forced spirometry test in order to confirm or rule out this diagnosis.

These persons are considered to suffer COPD if the FEV₁/FVC ratio (maximum volume exhaled during the first second / forced vital capacity) after bronchodilator is under 0.7. Once the diagnosis has been established, COPD severity is assessed based on FEV₁ value after bronchodilator, expressed as a percentage of that expected. However, the current multidimensional approach for COPD includes other important clinical variables in severity assessment^{9,11}.

In our country, the person with COPD typically smokes or has smoked during a prolonged time, and usually reports coughing, expectorating, and/or dyspnea during exercise. However, patients often reduce their habitual level of physical activity in order to avoid dyspnea (for example, they use the lift instead of climbing up stairs, or avoid going out), so the degree of dyspnea must always be associated with the level of exercise which originates it.

Symptoms usually appear at 40-50 years of age. The most frequent symptomatology is the following:

Dyspnea: Dyspnea or shortness of breath is the main symptom of COPD, even though this can be perceived differently by patients with the same level of airflow limitation. There are various tools for dyspnea measurement and assessment. The most widely used and recommended one is the scale by the British Medical Research Council¹² even though it is relatively insensible to slight changes along time.

Table 1. Medical Research Council Dyspnea Scale

Grade 0: Not troubled by breathlessness except on strenuous exercise.
Grade 1: Dyspnea when hurrying or walking up a slight hill.
Grade 2: Walks slower than contemporaries on level ground.
Grade 3: Stops for breath after walking about 30m or after a few minutes on level ground.
Grade 4: Too breathless to leave the house, or when dressing or undressing.

Source: Bestall JC, Paul EA, Garrod R, Garnham R, Jones PW, Wedzicha JA. Usefulness of the Medical Research Council (MRC) dyspnoea scale as a measure of disability in patients with chronic obstructive pulmonary disease. *Thorax* 1999; 54: 581-586.

Coughing and Expectorating: Over 50% of people who smoke present productive cough approximately 10 years after having started smoking. In 75% of cases, coughing leads to initial dyspnea. However, the latter is not associated with a performance deficit. Expectorations change colour and consistency to purulent and mucopurulent in infectious COPD exacerbations.

Intolerance to Exercise: This is the most incapacitating consequence for people who suffer COPD. Traditionally, it has been accepted to be directly proportional to lung function alterations and ventilatory involvement. However, lower limb weakness, rather than dyspnea, is the most typical symptom after exercise.

Other Symptoms: Anorexia and weight loss may appear in advanced disease stages, and these are markers for bad prognosis. Psychiatric symptoms are also frequent, and a reflection of the social isolation brought about by the disease, its chronicity, and the neurological effects of hypoxemia. Daytime hypersomnia may be an expression of hypercapnia, or be associated with the presence of respiratory disorders during sleep.

Prognostic factors typically assessed in COPD are: age, severity of airflow limitation (assessed through FEV₁, expressed as a percentage of the reference value according to age, gender and height), amount of PO₂ in arterial blood, and pulmonary arterial hypertension. More recently, other prognostic markers, such as patient's symptoms (dyspnea after exercise), level of pulmonary insufflation (air entrapment), exercise capacity, frequency of severe exacerbations and/or unintentional weight loss (mostly due to skeletal muscle atrophy) have also been identified as major prognostic factors, regardless of FEV₁.

The fact of their being independent factors, regardless of the degree of airflow limitation, is relevant because they identify therapeutic objectives beyond the standard bronchodilator treatment.

Celli and his colleagues¹³ picked up this idea and developed a multidimensional index capable of incorporating the main determining prognostic factors: the BODE Index. This Index collects data about: B (body mass index), O (obstruction), D (dyspnea) and E (exercise capacity) assessed by the 6-minute walk test. Each of these variables is divided into intervals which are assigned a value (Table 2).

Table 2. Classification of Multidimensional Severity (BODE Index) Proposed by Celli et al.

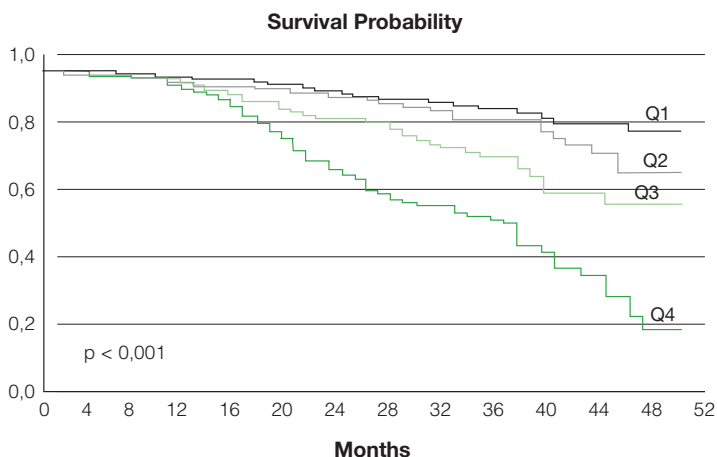
	0	1	2	3
B BMI (kg/m ²)	>21	≤ 21		
O FEV ₁ (%)	≥ 65	50 - 64	36 - 49	≤ 35
D Dyspnea (MRC)	0 - 1	2	3	4
E 6MW (m)	≥ 350	250 - 349	150 - 249	≤ 149

BMI: Body Mass Index. MRC: MRC Modified Scale; 6MW: distance walked in the 6-minute walk test.

Source: Celli BR, Cote CG, Marín JM, Casanova C, Montes de Oca M, Mendez RA, et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. *N Engl J Med* 2004; 350:1005-12

The final score has an interval between 0 and 10, and is grouped in four quartiles. An increase in a quartile of the BODE Index was associated to a 34% increase in mortality due to any cause (HR: 1.34; 95% CI: 1.26 - 1.42; $p < 0.001$) and 62% in mortality due to respiratory causes (HR: 1.62; 95% CI: 1.48 - 1.77; $p < 0.001$). (Figure 1) As a whole, the BODE Index is more valid than FEV₁ as a prognostic variable, therefore providing a better capacity to classify the disease severity. Currently, this index has proven to be useful as a prognostic marker in connection with various therapeutic interventions^{11,14,15}, and its capacity to predict exacerbations^{16,17} or to differentiate health conditions has also been assessed. However, its implementation is becoming slower than expected, maybe due to the need to conduct the 6-minute walk test.

Figure 1. Survival Probability in Quartiles according to the BODE Assessment



Source: Celli BR, Cote CG, Marín JM, Casanova C, Montes de Oca M, Mendez RA, et al. The body-mass index, airflow obstruction, dyspnea, and exercise capacity index in chronic obstructive pulmonary disease. *N Engl J Med* 2004; 350:1005-12.

Different modifications to the BODE Index have been recently proposed, either trying to maximize its capacity to predict death, or to simplify its implementation. Thus, for example, the BOD¹⁸ has been put forward, an index where the need for an exercise test is eliminated, or the BODEx¹⁹, where the exercise test is replaced by a registry of severe exacerbations, but that still requires to be validated (Table 3).

Table 3. Classification of Multidimensional Severity (BODEx Index)

	0	1	2	3
B BMI (kg/m ²)	>21	≤ 21		
O FEV ₁ (%)	≥ 65	50 - 64	36 - 49	≤ 35
D Dyspnea (MRC)	0 - 1	2	3	4
Ex Frequency of severe exacerbations*	0	1 - 2	≥ 3	

BMI: Body Mass Index, MRC: MRC Modified Scale; Severe exacerbations: meaning those exacerbations requiring hospital admission (emergency and/or hospitalization).

Source: Soler-Cataluña JJ, Martínez-García MA, Sánchez L, Perpiña T, Román S. Severe exacerbations and BODE index: two independent risk factors for death in COPD patients. *Respir Med.* 2009 May; 103(5):692-9.

Beyond the individual components of the BODE Index and its problems to become generalized, its development underlines a conceptual change in COPD, which highlights the need for a more comprehensive approach to the disease.

Etiopathogenesis

COPD is characterized by an inflammatory response by the airways, the pulmonary parenchyma and the pulmonary arteries to the inhalation of particles and gases. In our environment, these particles and gases are mostly associated with those contained in tobacco smoke. However, other potential sources (such as firewood or coal cookers and heating systems, exposure at the working place, atmospheric pollution) must not be ruled out, particularly in rural patients or those coming from developing countries.

COPD's characteristic inflammatory response involves macrophages, neutrophils and cytotoxic T lymphocytes (CD8+), and it entails structural changes which cause narrowing in the lumen of airways and arteries, and emphysema in the pulmonary parenchyma^{7, 20, 21, 22}. Inflammatory changes continue after smoking cessation, therefore other factors, possibly of genetic or immunologic susceptibility, might contribute to its pathogenesis⁷.

1.3. Smoking and other Risk Factors

The main risk factor for COPD is exposure to and/or inhalation of tobacco smoke, including environmental or passive exposure. Other risk factors have also been described, such as exposure to environmental contamination by combustion products of combustible biomass used for cooking or heating (frequently seen in rural patients or in developing countries), occupational exposure to dust (irritant vapours and gases), and respiratory infections frequent during childhood²³. Statistically significant associations with bronchial hyperreactivity, socioeconomic status, and certain genes, have also been described²⁴.

However, smoking represents the main causal and risk factor for COPD. The relationship between smoking and COPD is indisputable. In around 80% of cases with chronic airflow limitation, there is a past history of smoking⁵. Nevertheless, this percentage might even be higher, as many cases of ventilatory obstruction without any history of smoking might be secondary to other etiologies. In a British cohort²⁵ of 441 consecutive patients with post-bronchodilator FEV₁/FVC under 70%, 101 (22.9%) patients were non-smokers. However, after a thorough study (sputum eosinophilia, bronchodilator test, computerized axial tomography, self-antibodies, etc.), airflow obstruction of unknown cause was only documented in 25 cases (5.7%). On the other hand, it has been proven that a definitive smoking cessation is the main therapeutic measure, though not the only one, for COPD. Many studies have highlighted that when patients quit smoking there is a noticeable improvement in respiratory symptoms, and FEV₁ deterioration will slow down in people with COPD²⁶. However, in spite of these tests, the IBERPOC study confirmed that almost 70% of people with mild COPD continued smoking, and that many of them not even considered smoking cessation²⁷.

An important aspect to be highlighted is that the proportion of relapses in smoking for the general smoking population is 70-80 % during the first year, while in the group of smoking COPD patients these figures are significantly increased²⁸.

The following are some of the reasons put forward to explain the difficulties to achieve success in smoking cessation with COPD patients²⁹:

- Higher physical nicotine dependence among smoking COPD patients. 30% of smokers with COPD scored 7 points or more in the Fagerström Test for Nicotine Dependence, according to IBERPOC study data⁶. Those people with a higher dependence have more probabilities of relapse³⁰.
- Presence of psychiatric co-morbidity in COPD patients who smoke. In these patients, there is a higher proportion with depressive symp-

tomatology, which might help to explain a lower efficacy in the treatment for smoking cessation.

- Different degrees of motivation among different types of smokers with COPD. The clinical situation in terms of severity degree may have an impact on motivation for cessation. Therefore, patients with mild COPD, who often report little or no symptomatology, have a low motivation, particularly if compared with cases with higher severity and respiratory symptomatology, who will be the most motivated patients for smoking cessation.

Another important aspect is exposure to smoke and dust in the working place. Occupational exposure to inhaled toxic substances is an independent risk factor for developing COPD, and has an additional effect with tobacco smoke³¹.

1.4. Integrated COPD Care

General Measures

- Smoking cessation is the most important intervention in order to prevent the functional decline of the person who suffers COPD, and it must be indicated for all patients (Evidence A).
- Pharmacological treatment with bupropion, vareniclin, or replacement therapy with nicotine, together with supporting measures, allows increasing the smoking cessation rate (Evidence A).
- Influenza vaccination (Evidence A) and pneumococcal vaccination (Evidence B) must be recommended to all persons with COPD. Joint use of both vaccines may have a synergic effect and reduce the most severe forms of pneumonia (Evidence C).
- Regular physical exercise is recommended in all disease stages (Evidence C).

Clinical Management of COPD. International Recommendations

The Global Initiative for Obstructive Lung Disease (GOLD) works with healthcare professionals and public health agents throughout the world in order to increase the awareness of COPD and improve its prevention and treatment.

Table 4. Clarification about Evidence Categorization.

- A Randomized clinical trials (RCTs) with a great amount of data. Evidence comes from outcomes of well-designed clinical trials, which provide a solid pattern of findings in the population for whom the recommendation is prepared. Category A requires a considerable number of studies, including a considerable number of participants.
- B RCT with limited data. Evidence comes from outcomes of intervention studies which include only a limited number of patients, post-hoc analysis, or analysis of RCT sub-groups or meta-analysis. Generally, Category B is applied when there are few RCTs, these have a small-sized sample, they have been conducted in a population different to the one the recommendation is targeted at, or results are inconsistent to some degree.
- C Non-randomized clinical trials or observational studies. Evidence comes from outcomes of non-controlled or non-randomized clinical trials, or observational studies.
- D Consensus by the group of experts. This category has only be used in those cases where it has been considered relevant to prepare a recommendation, but clinical literature addressing the subject has been considered insufficient in order to justify the assignation of the other evidence categories. In these cases, the authors' consensus is based upon clinical experience or knowledge, which does not meet the criteria for the higher categories.

Source: Peces-Barba G, Barbera JA, Agusti AGN, Casanova C, Casas A, Izquierdo JL, Jardim J, López-Varela V, Montemayor T, Monsó E y Viejo JL. SEPAR-ALAT clinical guidelines for COPD diagnosis and treatment, Arch Bronconeumol. 2008; 44(5): 271-81

By drawing up guidelines based on evidence for clinical management of COPD, and events such as the annual celebration of the World COPD Day, GOLD is working to improve COPD patients' lives in every corner of the world.

GOLD was established in 1997 in collaboration with the National Heart, Lung and Blood Institute, the National Health Institute, USA health authorities and the WHO.

The GOLD program for COPD care is formed by committees of prominent experts from all over the world, some of them Spanish. Some of its objectives are:

- To recommend an effective management of COPD, and to prepare prevention strategies to be used in all countries.
- To increase awareness by the medical community, public health agents and the general population, about the fact that COPD represents a relevant public health issue.
- To reduce morbidity and mortality by COPD through the implementation and assessment of effective programs for its diagnosis and management.
- To promote the study of the reasons for the increase in COPD's prevalence.

- To put into practice effective programs for COPD prevention.

The Gold Initiative suggests the following treatment scheme:

Table 5. Treatment Scheme according to GOLD

	I Mild	II Moderate	III Severe	IV Very Severe
Reduction of risk factors.	[Green shaded area]			
Influenza vaccination.				
Add short-acting bronchodilators (when needed)	[Green shaded area]			
Add regular treatment with one or more long-acting bronchodilators (when needed)				
Add rehabilitation	[Green shaded area]			
Add inhaled glucocorticosteroids if repeated exacerbations				
Add long-term oxygen if chronic respiratory failure	[Green shaded area]			[Green shaded area]
Consider surgical treatments.	[Green shaded area]			

Source: 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: 532-555.

1.5. COPD Situation in Spain

The distribution and main causes of COPD in Spain have been recently reviewed³². As well as in the rest of the world, and compared with the enormous amount of epidemiological information available about cardiovascular diseases or cancer, for example, there is little information available about COPD epidemiology in Spain. The conclusion for this study is that risk factor monitoring and generation of new epidemiological data for COPD must be considered as a research priority in Spain.

1.5.1. Epidemiology of COPD

Epidemiology of Smoking

In Spain, smoking causes 60,000 deaths per year, and is the main cause of COPD and lung cancer^{33,34}. During recent years, different surveys have appeared (SEPAR, CIS, OCU, CNPT), which have analyzed the prevalence of smoking in our country with very similar methodologies, designs and outcomes. In order to be highly specific and combine the most relevant results, we will refer to the outcomes of the last National Health Survey (2006) conducted by the Ministry of Health and Consumer Affairs³⁵.

Table 6. Prevalence of Smoking in Spain 2006 (age ≥ 16 years)

Prevalence	Overall	Male	Female
Daily smokers	26.4 %	31.6 %	21.5 %
Occasional smokers	3.1 %	3.8 %	2.4 %
Ex-smokers	20.5 %	28.1 %	13.2 %
Never have smoked	50%	36.6 %	62.9 %

Source: National Health Survey 2006. Available in: www.msc.es/estadEstudios/estadisticas/encuestaNacional/home.htm. Last access: April, 2008

Table 7. Use of Tobacco in Spain 2006 (age ≥ 16 years)

Smokers of:	≥ 20 c/d*	10-19 c/d	1-9 c/d
Overall:	42.3 %	32.9 %	24.8 %
Male:	50.2 %	29 %	20.8 %
Female:	31.6 %	38.2 %	30.1 %

* cigarettes/day

Source: National Health Survey, 2006. Available in: www.msc.es/estadEstudios/estadisticas/encuestaNacional/home.htm. Last access: April, 2008

Table 8. Relevant data in terms of stratification by age and sex

Daily Smokers:

- The highest overall prevalence is observed in the 35-44-year old group: 35.33 %.
- Within males, the 25-34-year old group has the highest prevalence: 40.16 %.
- Within females, the highest prevalence is observed in the 35-44-year old group: 30.73 %.
- In the youngest group (16-24-year old), females smoke more (28.93%) than males (24.96%).

Occasional Smokers:

Prevalence is higher among younger subjects (16-24-year old): 4.98 % and in males (6.12%) vs. females (3.78%), though it's females who smoke over 3 times per week.

Ex-Smokers

Prevalence is higher in the 45-64-year-old group (27%), without any data to highlight between genders.

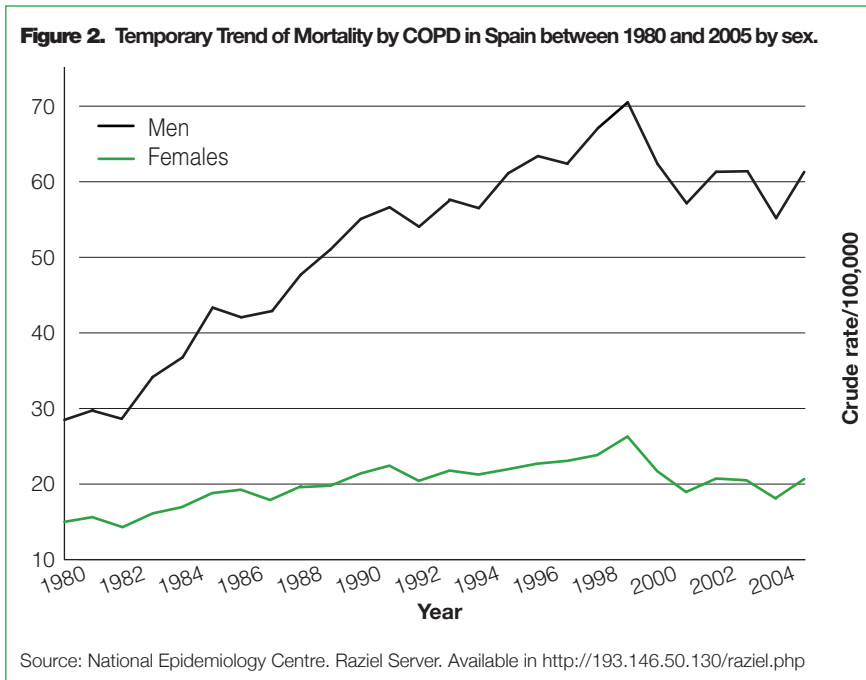
Source: National Health Survey, 2006. Available in: www.msc.es/estadEstudios/estadisticas/encuestaNacional/home.htm. Last access: April, 2008

Epidemiology of COPD

COPD is the cause of high morbidity, mortality and disability in Spain. According to data from the National Epidemiology Center³⁶, 17,517 people died in Spain during 2005 because of COPD (74.3% male and 25.7 % females). This figure has been increasing since 1980, with a tendency towards stabilization during recent years³⁶.

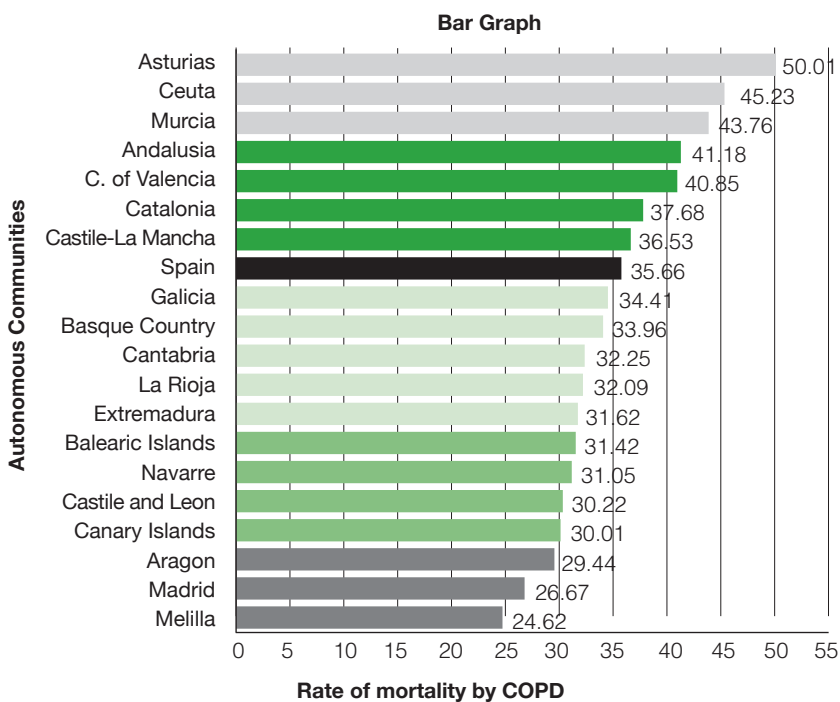
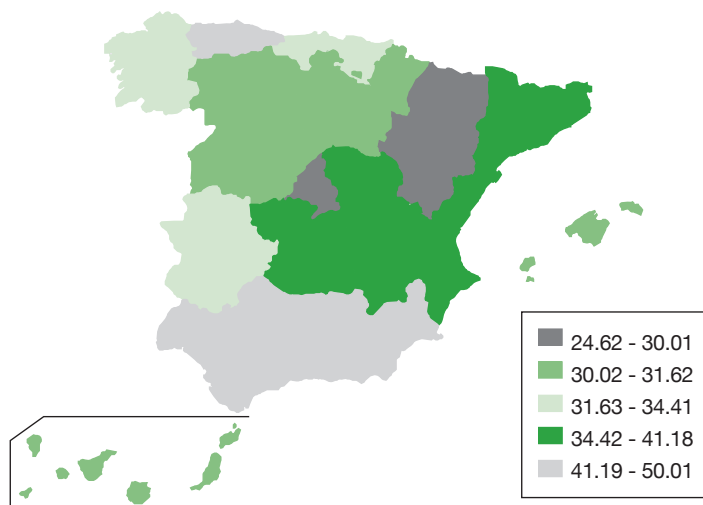
In Spain, COPD is the fifth cause of death among males, with an annual rate of 61 deaths per 100,000 inhabitants, and the seventh for females, with an annual rate of 20 deaths per 100,000 inhabitants during 2005. Annual mortality rate increases significantly by age group. In 2005, it varied from 7.8 in male and 1.1 in females in the 50 to 54-year old group, and it was more than 390 in males and 55 in females in the group over 75 years of age.

Median age for mortality due to COPD has shifted towards older ages since 1980. In 1990, it was 76.3 for males and 79.7 for females, while in 2005 it was 79.7 for males and 83.7 for females. Likewise, the years of life lost rate has moved from 105.5 in males and 33.9 in females (per 100,000) in 1990, to 62.3 in males and 17.7 in females during 2005.



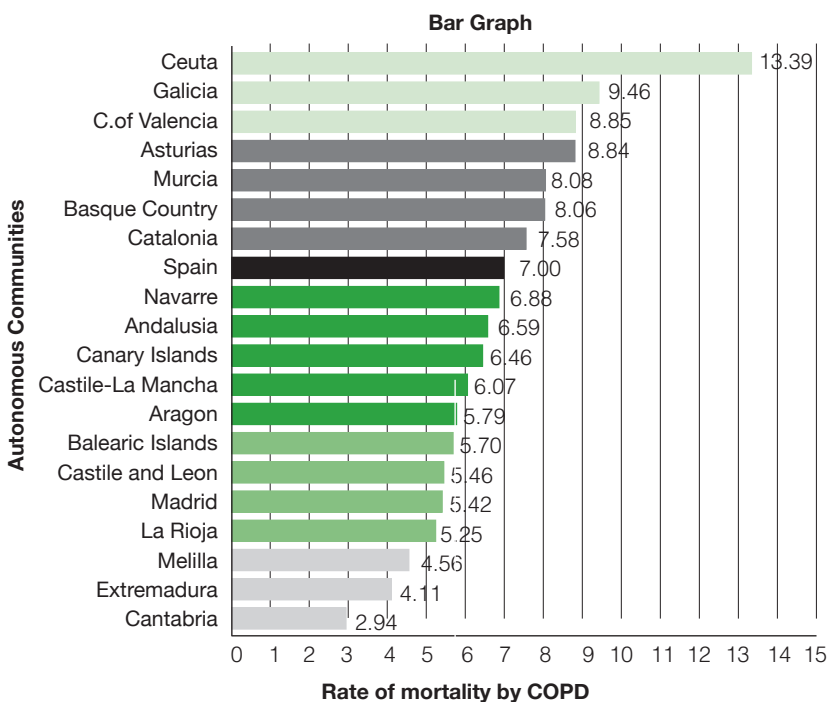
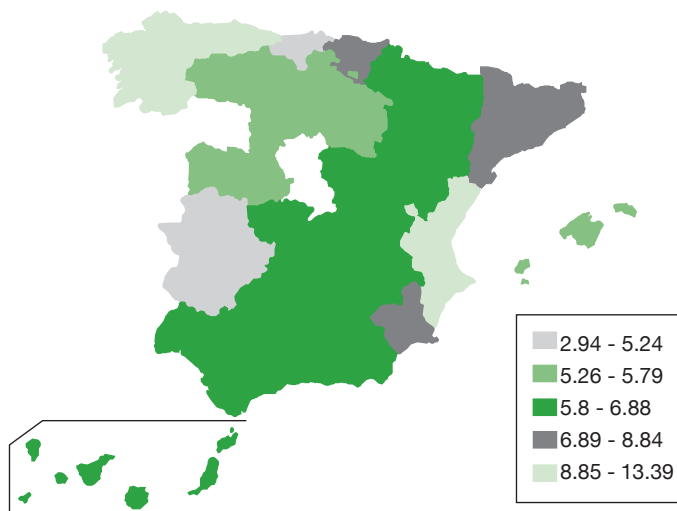
COPD mortality is not homogeneous across Spain. The following figures show the Comparative Mortality Index by provinces for Spain³⁶.

Figure 3. Map of Mortality by Autonomous Communities. 2006 (COPD). Rate adjusted to European population/100,000. Males.



Source: National Epidemiology Centre. Raziel Server. Available at <http://193.146.50.130/raziel.php>

Figure 4. Map of Mortality by Autonomous Communities. 2006 (COPD). Rate adjusted to European population/100,000. Females



Source: National Epidemiology Centre. Raziel Server. Available at <http://193.146.50.130/raziel.php>

In terms of COPD prevalence in Spain, various studies have been conducted. The following descriptions correspond to the main ones:

a) IBERPOC: The IBERPOC study was designed to measure the prevalence and variation in COPD distribution in Spain. It was conducted in seven different geographic areas (Burgos, Caceres, Madrid, Manlleu, Oviedo, Seville and Biscay), with a sample of 40-69-year old subjects, randomly recruited from the electoral register. COPD prevalence (defined according to old criteria by the European Respiratory Society as the $FEV_1/FVC < 88\%$ ratio vs. its theoretical value in males, and $< 89\%$ in females) was 9.1% (14.3% in males and 3.9% in females)^{5,6}.

In terms of smoking habits, prevalence was of 15% in smokers, 12.8% in ex-smokers, and 4.1% in non-smokers. The IBERPOC study also found very important differences according to geographical areas, from only 4.9% in Caceres to 18% in Manlleu, possibly associated with non-studied environmental or working factors. In this sense, the excess of cases detected in some geographical areas typically corresponded to females over 55 years of age, non-smokers, with a history of respiratory diseases during childhood, and who did not suffer any expectoration or wheezing symptoms³⁷.

A very important aspect in the results of the IBERPOC study was the high level of underdiagnosis, as 78-2% of cases confirmed through spirometry test had no previous COPD diagnosis, as well as the independent association between a higher likelihood of having a COPD diagnosis and living in urban areas, being male, with older age, high socio-economic status, a history of smoking, and a history of chronic bronchitis symptoms. IBERPOC estimated that 1,228,000 persons between 40 and 69 years of age suffered COPD in Spain.

Other studies in Spain have obtained similar figures for COPD prevalence. In the Catalan region of Vallès, with a sample based on the electoral register for adults between 20 and 70 years of age, the prevalence of airflow limitation (according to British Thoracic Society criteria: $FEV_1 < 80\%$ and $FEV_1/FVC < 70\%$) was 7.2% (10.4% in males and 4.1% in females), higher in older people, and in smokers and ex-smokers. In Valencia, Guipuzcoa, and Castellon, all population studies also found very similar prevalence figures. Another study in the province of Toledo, conducted in persons over 40 years of age, smokers or ex-smokers, found a 16.4% prevalence (95% confidence interval: 12.9% - 19.9%). These results show that detection of cases will be higher among smokers or ex-smokers.

Summing up, the IBERPOC study identified a COPD prevalence in Spain of around 9% of the adult population. Coinciding with this finding, a recent meta-analysis and systematic review of all 62 prevalence studies in population that have been published globally until 2004, has confirmed that COPD prevalence among the general population is estimated at around

1%, and increases up to 8-10% or more in adult subjects over 40 years of age³⁸. Complementary, the “Confronting COPD” study, conducted in North America and Europe, is the most recent international survey conducted in order to quantify the burden currently imposed by this disease upon society and its treatment. This study has confirmed that, in Spain and the other seven studied countries, COPD is a condition which affects females as well as males, and the age of its first clinical manifestation keeps getting lower³⁹.

b) EPI-SCAN: Preliminary results of the EPI-SCAN study, which has ended recently, provide highly enlightening data. EPI-SCAN was designed as an epidemiologic, observational, transversal, multicentre study, based on a reference population from 12 Spanish hospitals. Specifically, 3,824 subjects were studied (47.1% male) with an average age of 56.6 (DS 10.7), from a randomized list of telephone numbers from the general population.

Barcelona, Burgos, Cordoba, Huesca, Madrid, Oviedo, Seville, Requena (Valencia), Vic (Barcelona) and Vigo (Pontevedra) were the areas involved. Besides completing an extensive socio-demographic and clinical questionnaire, participants underwent the following tests: pre- and post-bronchodilator slow and forced spirometry tests, pulse oximetry, 6-minute walk test, quality of life measurement by specific questionnaire (Saint George’s Respiratory Questionnaire, SGRQ) and general questionnaire (EQ-5D), and daily life activities, Exhaled Breath Condensate, and collection of a blood sample to measure biochemical levels, biomarkers, and different inflammatory parameters. The primary objective of the EPI-SCAN study was to estimate COPD prevalence in the population from 40 to 80 years of age living in Spain in 2007⁴⁰.

COPD prevalence in the 40 to 80 year population was 10.2% (15.1% in males and 5.7 % in females). Compared with the IBERPOC study, conducted in 1997, COPD underdiagnosis in Spain was only slightly reduced from 78% to 73% (p: not significant), though a high reduction of COPD undertreatment in Spain was observed within that 10 year frame, from 81% to 54% (p<0.05)⁴¹.

1.5.2. Costs and Overall Burden of the Disease

In Spain, COPD causes a great impact upon the National Health System. Data from the 2005 Hospital Morbidity Survey show that, overall, COPD represents 9.3% of all hospitalizations by respiratory conditions in females, and 28.2% in males. COPD is the main cause of hospitalization by respiratory conditions in males between 55 and 89 years of age, and it represents 6.5% of all hospitalizations, and 42.5% of all hospitalizations associated with respiratory conditions⁴².

Overall expenses associated with COPD are equal to 0.2% of the Spanish Gross Domestic Product⁷.

Table 9. Hospital Morbidity by COPD and Bronchitis in Spain. Year 2005

Hospitalizations	All	460-519	490-492,	All	Respiratory
	Causes	VIII*. Respiratory Conditions	494,496. COPD and Bronchitis	Causes	System
Females					
Total	2,502,132	196,611	18,389	0.73	9.35
35-44-year old	329,331	9,702	322	0.10	3.32
45-54-year old	211,319	9,769	859	0.41	8.79
55-64-year old	235,689	13,603	1,646	0.70	12.10
65-74-year old	317,409	26,009	3,808	1.20	14.64
75-84-year old	365,400	46,600	6,907	1.89	14.82
85-89-year old	114,064	20,287	2,635	2.31	12.99
90-94-year old	55,321	11,587	1,311	2.37	11.31
Over 95-year old	13,977	3,343	314	2.25	9.39
Males					
Total	2,175,998	300,750	84,813	3.90	28.20
35-44-year old	202,895	14,819	687	0.34	4.64
45-54-year old	240,734	17,289	2,924	1.21	16.91
55-64-year old	321,672	29,118	9,826	3.05	33.75
65-74-year old	416,405	59,882	27,277	6.55	45.55
75-84-year old	376,678	75,693	33,943	9.01	44.84
85-89-year old	735,42	18,815	6,957	9.46	36.98
90-94-year old	26,928	7,308	1,907	7.08	26.09
Over 95-year old	5,685	1,669	317	5.58	18.99

* Code ICD-9

Source: INE, National Statistics Institute. Hospital Morbidity Survey, 2005 Available at: <http://www.ine.es/jaxi/menu.do?type=pcaxis&path=%2Ft15/p414&file=inebase&L=0>. Last access: April, 2008

The objective of Burden of Disease studies is to measure and compare the population's health loss by different causes, considering fatal and non-fatal consequences of the diseases⁴³ through the DALY synthetic index. DALY is a combination of Years of Life Lost (YLL) or early death, and Years Lived with Disability (YLD) or poor health.

In Spain, respiratory conditions represent the fourth cause of burden of disease (7.5% of the total DALY) (See Table 10), with an important disability component. Out of 365,114 DALYs lost during 2000, 62.7% were due to disability or poor health (YLD), and 37.3% were due to early death (YLL). Within this group of diseases, COPD stands out with 138,491

DALYs lost (2.9% of the total DALYs). Out of 100 DALYs lost due to COPD, 49.9% are due to early mortality (69,064 YLLs) and 50.1% are due to disability or poor health (69,427 YLDs). In males, COPD is one of the conditions with a higher number of DALYs (4.1% of total DALYs), behind alcohol abuse (6.1%), ischemic cardiopathy (6.1%), unipolar depression (5.5%), traffic accidents (5.5%) and malignant tracheal, bronchial and lung tumours (5.2%), while in females the burden of disease is slightly lower (1.3% of total DALYs)⁴⁴.

Table 10. Top Ten Categories* of Burden of Disease in Spain

Disease Categories	DALYs No.	
Mental and Neurological Diseases	1,339,096	27.62
Malignant Tumours	767,993	15.84
Cardiovascular Diseases	686,867	14.17
Respiratory Diseases	365,114	7.53
Unintentional Accidents and Injuries	346,631	7.15
Musculoskeletal Diseases	236,660	4.88
Digestive Diseases	227,244	4.69
Sense Organ Diseases	214,783	4.43
Infectious and Parasitic Diseases	130,607	2.69
Total Diseases	4,848,946	100.00

* Note: According to the burden of disease classification in the Global Burden of Disease study by the World Health Organization (Murray and López, 1996). The top ten disease categories represent 90% of total DALYs.

Source: Own preparation based on Génova-Maleras R, Ivarez-Martín E, Morant-Ginestar C. Disease of burden and morbidity trends in the Spanish population. In: Abellán-García A, Puyol-Antolín R. Ageing and Dependence: A look at the future scenario for Spanish population. Madrid: Mondial Assistance 2006; 107-124. The authors provided complementary information.

Besides representing a major burden of disease in terms of early death and disability, COPD causes an important impact in terms of economic costs and deterioration in quality of life⁴⁵ for the persons who suffer COPD and their relatives.

There are various estimative macro-economic studies (“top down”) about costs generated by COPD, based on statistical and epidemiological data. These studies have reported cost figures which range between 675 and 775 million euros per year in 1994 for all Spain^{46,47} and these figures include both direct and indirect costs. We must consider that by that time, the Spanish population reached 37 million inhabitants, and therefore COPD represented a burden between 18 and 21 € per inhabitant and per year. If we look only at healthcare resources (direct healthcare costs) targeted to these patients, a figure of 234 million euros per year was obtained for the whole of Spain, through a prevalence approach⁴⁷.

There are also various studies which intend to assess the real cost of a patient cohort, and extrapolate these results to the general COPD patient population (ascending or “bottom-up” studies) during a follow-up period of one year^{48, 49, 50, 51}.

There are discrepancies between some of the published estimations, either due to the type of patients included (e.g. previously diagnosed or not), the study design, or the variability in disease management among studied periods. Even though there are absolute differences between studies, cost distribution in relative terms was very similar in all of them. Thus, all studies showed that the highest costs were those direct healthcare costs incurred during hospitalization, as well as those associated to standard pharmacological treatment. The increase observed in average cost by patient and year, as the severity or progression of the disease increases, should also be highlighted.

A study conducted by Masa *et al*⁴⁸ with 363 patients showed that annual cost for COPD in Spain in 1997 was 238.82 million euros, assuming a 9% prevalence among population, and considering only direct healthcare costs. Hospital healthcare represented the highest cost (41.0% of the total), followed by the cost of pharmacological treatment (36.6%, taking into account treatment of exacerbations) and the cost of outpatient consultations (18.8%). Likewise, the average cost per patient and year was 198.17 euros, and due to the fact that 22% of patients were previously diagnosed and were using healthcare resources, the cost per patient with a previous COPD diagnosis was 910.57 euros per year. In terms of disease severity, the average cost per patient with severe COPD was three times higher than the cost per patient with moderate COPD, and over seven times higher than the cost of mild COPD.

Another study conducted in 192 COPD patients by García-Ruiz *et al*⁵⁰, estimated that, taking into account that only 22% of patients between 40 and 70 years of age are diagnosed with COPD in Spain, the direct healthcare costs for COPD after a follow-up year in Primary Care would be 463 million euros (in 1999 €); these results are in line with estimations obtained by other studies. Those healthcare resources used which originated a higher expense were pharmacological treatment (including oxygen therapy) for COPD (52.3% of the total), disease exacerbations (15.5%), treatment of comorbidities (14%) and healthcare consultations (12.8%).

On the other hand, the study by Izquierdo-Alonso JL and by Miguel-Díez J⁴⁹ shows that the pharmacological treatment represents a high impact in terms of direct healthcare costs for COPD, amounting to 38% of total costs. Considering a 9.1% prevalence, the annual cost due to pharmacological treatment was 293 million € in the year 2000.

In a transversal survey conducted across eight countries, one of which was Spain⁵¹, which included 403 COPD patients and which considered, be-

sides direct healthcare costs as all the other studies, those indirect costs associated with potential loss of work productivity from the society's point of view (annual indirect cost: 300.25 €/patient), it was observed that hospitalizations represented the highest item in terms of resources (84% of the total sum of direct costs), to a great extent due to exacerbation treatment which represent a major part of the use of resources by these patients.

In other study by Miravittles *et al*⁵² with 1,510 patients (766 of which were diagnosed with COPD), it was established that the cost for COPD in Spain for year 2002 was 506.52 million dollars (in year 2000 dollars). Drug purchase represented 42.5% of total COPD costs, followed by hospitalizations (41.6%) and out-of-hospital consultations (15.9%).

Having these data, we may estimate the approximate annual direct cost generated by COPD in a country such as Spain, from a prevalence point of view. If we take into account the data obtained in the epidemiologic IBERPOC study, we obtain a 9% COPD prevalence in the 40-69-year group⁶.

According to data from the 1997 Spanish census, there is a population of 13,645,000 persons between 40 and 70 years of age. If we accept a 9% prevalence for this group, we obtain the total number of 1,228,000 affected persons. Besides, if we adopt the conservative assumption that this prevalence continues in the age group with over 70 years of age, the result is that there are 1.7 million persons with COPD in Spain. However, we must take into account that COPD is an underdiagnosed disease, and therefore the same study showed that only 22% of those identified affected people had been previously diagnosed and was responsible for direct healthcare expenses³⁷. According to this, 270,000 COPD patients would be the total number of diagnosed and treated patients. Multiplied by the annual average, we obtain a total number of 473 million euros per year in direct healthcare expenses generated by COPD. This figure is superior to the one obtained by the initial approach; this could be due to methodological differences, and also partly due to differences in disease management appeared in 1994 and 1998.

It is interesting to verify how the expenses generated by persons with COPD is distributed; thus, in the majority of studies, it is observed that hospital expenses usually represent the most important part, with approximately 40-45% of costs, followed by expenses assigned to drugs, with 35-40%, and patient visits and diagnostic tests with 15-25%⁵¹.

Table 11. Cost Estimates for COPD in Spain

Authors, year (name of study)	Type of study, time horizon and population	Study perspective and included costs (year of reference)	Outcomes
Masa JF et al, 2004⁴⁸ (IBERPOC Study)	Cost Analysis (Bottom-up)* 1 year Cohort of 363 COPD patients Healthcare system (not explicit)	Healthcare system (not explicit) Direct healthcare costs in euros (€ 1997): drugs, home oxygen therapy, outpatient consultations, hospital E.R. admissions, hospitalizations, diagnostic tests, lab tests, etc.	Average cost per COPD patient: 198.17€ (previously diagnosed: 910.57 €) Cost** for mild COPD: 55.67 €/patient, Cost** for moderate COPD: 114.98 €/patient, Cost** for severe COPD: 413.52 €/patient
García-Ruiz AJ et al, 2003⁵⁰ (EPOC-AP Study)	Cost Analysis (Bottom-up)* 1 year Cohort of 192 COPD patients	Healthcare system (Primary Care) Direct healthcare costs in euros (€ 1999): Drugs; outpatient consultation, hospitalizations, referral to the Pulmonology Department and/or the Hospital E.R., complementary tests, preventive measures (influenza vaccination), etc.	Average cost per COPD patient: 1,712 € (95% CI: 1,554-1,870) Cost for regular COPD: 2,003 €/patient; Cost for mild COPD: 1,751 € / patient; Cost for moderate COPD: 1,576 €/patient; Cost for severe COPD: 1,680 €/patient.
Izquierdo-Alonso JL and de Miguel-Diez J, 2004⁴⁹ (IDENTEPOC Project)	Cost Analysis (Bottom-up)* 1 year Cohort of 560 COPD patients	Healthcare system Direct healthcare costs in euros (€ 2000): drugs, outpatient consultation, hospitalizations, visits to hospital E.R., exacerbation episodes, long-term oxygen therapy, etc.	Average cost per COPD patient: 2.061 € Cost for mild COPD (Stage I): 1.657 €/patient; Cost for moderate COPD (Stage II): 2.425 €/patient; Cost for severe COPD (Stage III): 3.303 €/patient.

Table 11. Cost Estimates for COPD in Spain

Authors, year (name of study)	Type of study, time horizon and population	Study perspective and included costs (year of reference)	Outcomes
Miravittles M et al, 2003⁵¹ (DAFNE Group)	Cost Analysis (<i>Bottom-up</i>) [*] 1 year Cohort of 1,510 patients with chronic bronchitis (n=744) and COPD (n=766)	Healthcare system (Primary Care) Direct healthcare costs in dollars (\$ 2000): drugs, oxygen therapy, outpatient consultation, E.R. admis- sion, hospitalizations, diagnostic tests, lab tests, etc.	Average cost per COPD patient: 1,760\$ Cost for mild COPD: 1,484 \$/pa- tient, Cost for moderate COPD: 2,047 \$/patient, Cost for severe COPD: 2,911 \$/patient
Izquierdo JL, 2003⁵²	Cost Analysis (<i>Bottom-up</i>) [*] 1 year Cohort of 402 COPD patients	Healthcare system Society Direct healthcare costs in euros (€, year not explicit in publication): drugs, oxygen therapy, outpatient consultation, E.R. admission, hospi- talizations, diagnostic tests, lab tests. Indirect costs in euros (€, year not explicit in publication): cost of loss of work productivity.	Average cost per COPD patient: 3,238 € (healthcare system) – 3,538 € (society) From the society's point of view: Cost for mild COPD: 1,316€/patient, Cost for moderate COPD: 2,569 €/patient, Cost for severe COPD: 9,850 €/patient

* Bottom-up ("ascending or " from bottom to top analysis): Cost is estimated taking into account a group of patients with the disease under study, and examining the use of resources during a given period. The total cost is estimated based on disease prevalence or incidence.

** Diagnosed and not previously diagnosed subjects

Source: Own preparation.

1.5.3. COPD Care in Spain

According to an *ad hoc* survey conducted by the Ministry of Health and Social Policy for the preparation of this Strategy, all Autonomous Communities regard COPD as a priority area in health intervention.

However, except in five Autonomous Communities, there is no active action plan for this condition or an organism responsible for planning or advisor committee. There are no rules either to regulate the COPD area. Only four Autonomous Communities use specific documentation or tools for COPD care, such as clinical practice guidelines, clinical pathways, procedures, protocols, or quality standards. However, 14 Autonomous Communities do have established plans to fight against smoking, and smoking cessation units.

According to said survey, 16 Autonomous Communities have spirometers in their Primary Care centers, though these tests are routinely conducted only in six of them. Only five Autonomous Communities have trained staff in over 75% of their Primary Care centers, and only three Autonomous Communities declare having screening plans for the early detection of patients with COPD risk.

It is also worth highlighting that only in seven Autonomous Communities there are specific actions by consensus among the Primary Care and Specialized Care levels, targeted to the integrated management of COPD.

In terms of hospitals, generally, almost all have an intensive-care unit (ICU) and the infrastructure for non-invasive mechanical ventilation, but there are few more specific intervention programs, such as respiratory rehabilitation, home care, multidisciplinary teams, palliative care, or coordination programs. Only three Autonomous Communities declare having COPD multidisciplinary teams in their hospitals.

In 13 Autonomous Communities there are well-defined support activities for patients and their families. However, other specific measures are seldom seen, such as healthcare-sociohealthcare coordination programs, palliative care plans specific for COPD patients, systematic satisfaction surveys or educational campaigns. Seven Autonomous Communities declare having healthcare quality indicators specific for COPD.

On the other hand, according to other *ad hoc* survey conducted by the Ministry of Health and Social Policy to the Scientific Societies involved in this Strategy, seven societies out of thirteen have work teams for COPD.

Summing up, affirmative answers to those survey questions about any type of activity specifically for COPD don't amount to 30%, and are mostly about the existence of consensus documents on COPD prepared jointly with other national and international Scientific Societies, about the preparation of COPD web contents, specific training programs, preparation of informative documents about COPD targeted to affected persons and their

families, and educational or communication campaigns for the general population.

The highest activity is reached in the research area, where 38% of Autonomous Communities claim to be involved, either directly or through some work group, in research lines or projects associated with COPD.

1.5.4. Clinical Guidelines for COPD

The *Guía de práctica clínica de diagnóstico y tratamiento de la EPOC* (Clinical Practice Guidelines on COPD Diagnosis and Treatment) are worth highlighting; these were prepared by “Guiasalud” in 2007, and are available at: <http://www.guiasalud.es/newCatalogo.asp>

“Guiasalud” is a National Health System organization in which all 17 Autonomous Communities are involved. Its objective is to promote the preparation and use of Clinical Practice Guidelines, as well as other tools and products based on scientific evidence. To this end, it has an organ formed by an Executive Council, an Advisory Council, and a Scientific Council; a collaboration network formed by professionals, institutions, scientific societies and patient associations. It has a central core or Secretariat for logistic support, which is formed by 20 professionals who carry out management and technical tasks.

“Guiasalud” is established around five programs, namely: program for preparation of Clinical Practice Guidelines, program for preparation of other Evidence-based Medicine products, training and information program, program for the implementation of Clinical Practice Guidelines, and research program.

According to the results of the survey already mentioned, only four Autonomous Communities use specific documentation or tools for COPD care, such as clinical practice guidelines, clinical pathways, procedures, protocols, or quality standards.

Meanwhile, seven out of thirteen scientific societies who answered the survey claim they have prepared some type of guide or protocol of action specifically for COPD. However, only three societies have developed other more specific aspects, such as quality standards or end of life recommendations.

A bibliographical search for this type of tools was conducted for the preparation of this Strategy, with the following results:

- Clinical Practice Guidelines for Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease. SEPAR-ALAT, 2007⁷ (Available at: <http://www.separ.es/doc/publicaciones/normativa/guia-epoc-2007-separ.pdf>)

- Grupo de trabajo de la SEPAR (SEPAR Working Team) .Guidelines for respiratory rehabilitation. Arch Bronconeumol 2000; 36: 257-274
- Vidal R, Blanco I, Casas F, Jardí R, Miravittles M; Committee on the National Registry of Individuals with Alpha-1 Antitrypsin Deficiency. [Guidelines for the diagnosis and management of alpha-1 antitrypsin deficiency] Arch Bronconeumol. 2006 Dec;42(12):645-59.
- Miravittles M, Monsó E, Mensa J, Aguarón Pérez J, Barberán J, Bárcena Caamaño M, Cañada Merino JL, *et al.* Tratamiento antimicrobiano de la agudización de la EPOC: Documento de consenso 2007. (Antimicrobial Treatment for COPD Worsening: Consensus Document, 2007). Arch Bronconeumol 2008; 44: 100-108
- Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Global Initiative for Chronic Obstructive Lung Disease⁹. (Available at: <http://www.goldcopd.org/Guidelines/guidelines-resources.html>)
- Celli BR, MacNee W; ATS/ERS Task Force. Standards for the diagnosis and treatment of patients with COPD: a summary of the ATS/ERS position paper. Eur Respir J. 2004 Jun; 23(6):932-46.
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- O'Donnell DE, Aaron S, Bourbeau J, Hernandez P, Marciniuk DD, Balter M, *et al.* Canadian Thoracic Society recommendations for management of chronic obstructive pulmonary disease – 2007 update. Can Respir J 2007; 14 (Suppl B): 5B- 32B.

Guidelines for Patient and Caregivers Support

- J. Giner, R. Cabarcos, F. Burgos, M. Calpena, F. Morante, V. Macián, I. Andres, I. Martínez, M. Benito, G. Peces Barba. Área de Enferme-

ría y Fisioterapia (Nursing and Physiotherapy Area). Controlling COPD. Spanish Pulmonology and Thoracic Surgery Society (SEPAR) and Spanish Lung Foundation – Respira Foundation. Available at: http://www.separ.es/doc/pacientes/libro_epoc.pdf

- Carme Hernández, Josep Roca. Chronic Obstructive Pulmonary Disease – COPD. Interactive Guide for Patients with Long-term Conditions. Forumclínic. Fundación BBVA · Hospital Clínic de Barcelona. Available at: <http://www.forumclinic.org/download/epoc/documentos/guaprctica/epocpdf?attachment=1> COPD Patient Association. Available at: <http://www.respiramos.com/respiramos/index.html>

1.5.5. Regulatory Framework

The General Health Law (Act 14/1986) (Ley General de Sanidad) is the legal tool which allowed the transit from the old Social Security healthcare model to our current National Health System model. This law formulates the right to health protection stated by section 43 of the Constitution, and establishes its fundamental principles, namely: universality, public funding, equity, and comprehensiveness and continuity of services. The law builds the new model based on Autonomous Communities, towards which health policy has been gradually decentralizing. The National Health System is defined as the coordinated set of Central Government Health Systems and Regional Health Systems, and it integrates all healthcare functions and assistance.

Royal Decree 63/1995, subsequently replaced by Royal Decree 1030/2006, established in a general manner the contents of healthcare assistance by the National Health System. However, recent scientific and technical advances have required a new definition of healthcare assistance and services by the National Health System, in order to ensure equity in terms of access.

Law 16/2003, dated May, 28th, on Health National System Coherence and Quality, establishes in its section 7.1 that the catalogue of services by the National Health System aims at ensuring basic and common conditions for comprehensive and on-going healthcare, with an adequate level. It considers as healthcare provisions by the National Healthcare System those services or set of services for prevention, diagnosis, treatment, rehabilitation and health promotion and preservation, targeted to citizens; and finally, it points out the services said catalogue will include.

Section 8 states that healthcare provisions in the catalogue will become effective through a portfolio of common services which, as established in article 20, will be agreed upon by the National Health System Interterritorial Council, and will be approved by Royal Decree.

At the same time, section 4.c) establishes that citizens will be entitled to receive, from the health service in the Autonomous Community where they might be temporarily, the assistance of the catalogue of services by the National Health System which they might require, in the same conditions and with identical guarantees as citizens living in said Autonomous Community.

Royal Decree 1030/2006, dated September, 15th, determines the portfolio of common services by the National Health System, and its updating procedure, including a specific section describing services to be offered to the population, both in the Primary Care and in the Specialized Care portfolio of services. This Royal Decree defines the characteristics of the portfolio of services in the following terms:

“Services included in this portfolio are considered basic and common, understood as those needed to provide an adequate, comprehensive and on-going healthcare to all NHS users.

The portfolio of common services by the NHS must ensure comprehensive care and continuity of assistance provided to users, regardless of the level of care required at each point.

Autonomous Communities, within their scope of competence, will be able to approve their respective portfolios of services, which will include, at least, the portfolio of common services by the NHS, which must be guaranteed to all its users.”

In the Royal Decree, Appendix II defines the portfolio of common services by Primary Care, and we can find the following services related to COPD:

- Section 2.1. mentions basic diagnostic procedures, including spirometry, measurement of maximum expiratory flow, and pulse oximetry.
- Section 5. addresses basic rehabilitation, including respiratory physiotherapy.
- Section 6.4.1. includes Chronic Obstructive Pulmonary Disease among those diseases where healthcare by protocol might be possible, as it is considered a chronic and prevalent disease.
- Section 6.4.4. discusses care for persons with risk behaviours, and points out that care for smokers and support for smoking cessation are included within the Primary Care portfolio of services. It includes an assessment of persons who smoke, information about the risk implied by smoking, advice for smoking cessation and healthcare support; as well as, if required, intervention with individualized behavioural support.

In terms of services at the specialized level, Section 5 in Appendix III lists respiratory diseases, and includes Chronic Obstructive Pulmonary Disease. In Section 5.2, under the title “Other Diagnostic and Therapeutic Procedures”, respiratory therapy techniques are listed, including techniques of respiratory therapy at home, which are regulated by the Order dated March, 3rd, 1999.

Section 8, which discusses rehabilitation for patients with recoverable functional deficit, includes rehabilitation for conditions involving the musculoskeletal system, the nervous system, the cardiovascular system, and the respiratory system, through physiotherapy, occupational therapy and speech therapy, which bear a direct relationship with a pathological process being treated by the National Health System, as well as technical methods (orthoprosthesis).

1.6. Methodology

In the same way as strategies already approved in 2006, 2007 and 2008 by the Interterritorial Council in the National Health System (cancer, ischemic cardiopathy, diabetes, mental health, palliative care and stroke), two elements have been the basis for the preparation of this Strategy:

- 1.** The analysis of COPD situation in Spain and in the international setting, in order to know the background, the current status of organization for care provided for this disease, critical points, and evidence available about best practices. To this end, COPD plans currently in place in the Autonomous Communities have been taken into account.
- 2.** The selection of a scientific coordinator and the setting up of two committees to write the Strategy:
 - a)** A Technical Committee formed by representatives of the Pulmonology and Thoracic Surgery Societies, Primary Care, including physicians as well as nurses, E.R. unit, rehabilitation, as well as social workers, physiotherapists, pharmacologists, experts in smoking, and by other associations such as the Spanish Internal Medicine Society, as well as the Spanish Patient Forum.
 - b)** An Institutional Committee formed by representatives appointed by the Regional Ministries of Health from the Autonomous Communities. One of its main functions has been the assessment of the adequacy and feasibility of the proposed objectives, as the Autonomous Communities themselves and their health services will be responsible for setting up and achieving said objectives.

On behalf of the Ministry of Health and Social Policy, the Directorate-General for the National Health System Quality and Innovation Agency, through the Health Planning and Quality Office, has been responsible, together with the technical coordinator, for directing the project, supported by the Health Information Institute.

These two committees have worked in a joint and interactive manner, both in face-to-face meetings, and through emails and other software tools.

During a first stage, critical issues in COPD care were identified. To this end, the Autonomous Communities established priorities to be addressed, and based on these and on their own experience, the technical committee pointed out those aspects which showed greater deficits or disparities within the care process.

These objectives and recommendations have been prepared upon these deficiencies, and in order to achieve the highest quality and equity in the system; and they have been approved by the Interterritorial Council in the National Health System.

With support by the Health Information Institute, indicators were identified for the whole set of proposed strategic lines, which will allow to conduct a systematic and on-going assessment. This will enable the follow-up and assessment of the Strategy throughout its execution process, through an information system feasible for the whole National Health System and the set of COPD plans and programs already established in the Autonomous Communities.

1.6.1 Document Structure

This document is divided into five parts:

- First part: *General aspects*, including justification, COPD definition, its risk factors, epidemiology, costs and burden of the disease and its situation in Spain, legal framework and work methodology.
- Second part: *Development of strategic lines*, where objectives and recommendations are detailed. The following strategic lines were defined:
 - Strategic Line 1: Prevention and early detection.
 - Strategic Line 2: Chronic patient care.
 - Strategic Line 3: Patient care during exacerbation.
 - Strategic Line 4: Palliative care.
 - Strategic Line 5: Training of professional staff.
 - Strategic Line 6: Research.

Strategic lines open out into general and specific objectives, with their corresponding technical recommendations. The order in which the strategic lines are presented is dictated by the theoretical relevance of the healthcare planning approach and the Strategy's internal coherence.

Third part: *Assessment and information system for the Strategy*, which collects descriptive information, indicators, and a qualitative report.

Fourth part: *Examples of best practices*, developed within the Spanish setting, which have shown their efficacy and effectiveness.

Fifth part: *Appendixes*, where different specific aspects in the Strategy are discussed in depth.

Summing up, based on available information and evidence, this document intends to establish a set of objectives to achieve and a set of recommendations that, realistically and according to available resources and the scope of competence of Autonomous Communities, may help to improve the quality of interventions and outcomes in COPD.

2. Development of Strategic Lines

2.1. Prevention and early detection

2.1.1. Analysis of the situation

Introduction

The theoretical Public Health model states that health causes and decisive factors in individual patients do not always necessarily coincide with health causes and deciding factors in the general population. The former refer to the reason why an individual contracted that disease in a specific moment and circumstance, while the latter refer to the incidence and prevalence of the disease in the whole population. Only those interventions intended to modify the causes and decisive factors for the general population will be effective and efficient in the fight against the disease⁵³. Effective health policies are those designed from the population point of view.

Prevention

According to the Spanish National Health Survey (2006), 26.44% of the population over 16 years of age (31.56% of males and 21.51% of females) smoke every day. These figures are lower than those in the former Survey (2003): 28.1% prevalence of daily smoking (34.2% in males and 22.4% in females).

The average age of initiation in daily use of tobacco is 14.2 years, and it is 13.1 for occasional smoking. In any case, the last data obtained show a decrease in smoking within this age group, from 21.5% in 2003 to 14.8% in 2006; that is to say, a 6.7-point reduction.

The tables below show the evolution in prevalence and use of tobacco:

Table 12. Evolution of Prevalence of Tobacco Use according to the National Health Survey 2003-2006

Prevalence	2003	2006
Overall	31 %	29.5 %
males	34.2 %	31.6 %
females	22.4 %	21.5 %

Note: Overall prevalence included daily smokers + occasional smokers.

Source: National Health Survey, 2006. Available at: www.msc.es/estadEstudios/estadisticas/encuesta-Nacional/home.htm. Last access: April, 2008

Table 13. Evolution of Tobacco Use during the last 2 years

Modification of use	NO	INCREASED*	REDUCED**
Overall:	49.38 %	22.73 %	32.90 %
males	46.71 %	19.40 %	33.89 %
females	41.09 %	27.41 %	41.09 %

*In both gender, there is an increase in tobacco use among the youngest: 16-24-year old. A higher proportion of females has increased their use.

** The highest proportion of smokers (no difference by gender) who have reduced their use can be observed in the 35-44-year group.

Source: National Health Survey, 2006. Available at: www.msc.es/estadEstudios/estadisticas/encuesta-Nacional/home.htm. Last access: April, 2008

Undoubtedly, the evolution of tobacco use in our country has been clearly influenced by the new legal framework represented by the enforcement of Law 28/2005 (a law regulating sale, supply and advertising of tobacco products). The approval by Parliament of this law in December, 2005, has represented the introduction of a new legal framework for the implementation of health measures in smoking control.

Law 28/2005, dated December, 26th, on health measures against smoking (Ley de medidas sanitarias frente al tabaquismo)

This rule, which came into force on January, 1st, 2006, regulated the sale, supply, use and advertising of tobacco products. The objective of this rule is to prevent younger persons from acquiring this habit, and help those who want to quit smoking to do it in an easier way. All citizens are enforced to obey the law, and lack of knowledge does not release from this duty. However, the primary responsibility for upholding the law falls upon the owner of the center or establishment. The Public Administrations also have the duty to uphold the law.

Tobacco can only be sold in “estancos” (tobacconist’s shops) and vending machines, which must be located in centers or areas where smoking is allowed. Tobacco cannot be sold in establishments where smoking is forbidden, such as shopping centers, petrol stations, or cafe areas, if any, even if the space assigned for tobacco sale is physically separated from the rest of the establishment. Tobacco can still be sold in those “estancos” that were located in a shopping centre before the promulgation of this law, until their franchise expires.

The law allows to establish smoking areas in premises over 100m², under certain conditions (it cannot represent more than 30% of the surface assigned for customer service), but it is not compulsory to establish said areas. The owner of the establishment will decide whether to provide a smoking

area, or declare the whole establishment as smoke-free. If the owner decides to provide a smoking area, there must be a signal at the entrance to the premises, showing that it is forbidden to smoke in the establishment, except in those areas provided. If after 8 months (moratorium for bars and restaurants), areas have not been provided according to the criteria stated by law, smoking will be forbidden throughout the premises.

In those centers and buildings where the law establishes smoking is completely forbidden (working and teaching places, shops, or others) tobacco cannot be used or sold, not even in those spaces assigned for catering (cafeterias, diners, etc.). The law states that the owner or his employees are responsible for taking all reasonable measures to prevent the use of tobacco. At least, they must warn the person who is smoking to put out their cigarette or leave the premises or the non-smoking area. The Autonomous Communities have the power to inspect and sanction, in order to ensure that Law 28/2005 is obeyed.

The last data from the Government Survey about use of drugs in secondary education (2006-2007) point out that 14.8% of the population between 14 and 18 years of age smoke daily, with a higher prevalence among girls (16.9% vs. 12.5%).

Since this law has come into force, different entities, scientific societies, administrations, associations and organizations have been issuing different assessments. They all coincide that this new legal framework has represented a major qualitative step forward, and it is, undoubtedly, the highest advance in Public Health that has taken place in Spain during the two past decades.

One aspect to highlight is that this law was approved by all Parliament Groups in the Chamber of Deputies, without any exception, and that it also had a wide social support from the beginning. According to surveys by the Sociological Research Centre in 2005⁵⁴, 77% of the population considered this law was positive, and almost one year after its enforcement, support remained at 68%⁵⁵.

In order to analyze the impact this law has had upon the general Spanish population, the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) has conducted two surveys on a representative sample of the general Spanish population. The first one was conducted in 2005, some months before the law approval and implementation, and the second one in 2007, 12 months after its enforcement.

These were epidemiologic, observational and transversal surveys, targeted to a random sample, representative of the general Spanish population, in two different years, 2005 and 2007, with the objective of measuring the impact that the implementation of the law with healthcare measures against smoking might have had upon the prevalence of passive smoking. The primary outcomes show that the prevalence of overall expo-

sure to air contaminated by tobacco smoke was reduced from 49.5% in 2005 to 37.9% in 2007. That is to say, it can be considered that there was a 22% reduction due to the impact of this law. The higher reductions in prevalence due to the impact of this law can be found in school (from 29.7% in 2005 to 18.8% in 2007, a reduction of 49.8% due to the impact of the law) and in working places (from 25.8% in 2005 to 11% in 2007, a reduction of 58.8% due to the impact of the law). On the other hand, less noticeable reductions happened at home (from 29.5% in 2005 to 21.4% in 2007, a reduction of 27% due to the impact of the law) and in places of entertainment (from 37.4% in 2005 to 31.8% in 2007, a reduction of 8% due to the impact of the law).

Summing up, the conclusion is that reductions in tobacco use in public places due to the impact of the law in Spain have ranged between 49.5% and 8%, with working places and schools as those places where the impact has been higher, and entertainment places those where the impact has been less noticeable.

In terms of tobacco use, it was observed that around 1 million persons quit smoking during 2007, even though when the reason for this increase of ex-smokers is analyzed (19% in that year), only 10% reports having quit as a consequence of the law coming into force, though the law had an influence in 22% of those who made an effort.

One aspect to highlight is the analysis of the evolution of prevalence during the last five years, where a lower number of smokers can be observed, at the expense of a reduction in the incorporation of the younger population.

Environmental Pollution

There is no evidence in developed or developing countries that environmental pollution is a major cause for COPD⁵⁶. The White Book of European Health states literally that “the role of environmental pollution as a cause for COPD is not clear”⁵⁷. Even though periods of high contamination may affect the respiratory health of persons with an established COPD, tobacco continues being the most relevant causal factor for COPD, with its attributable fraction quantified in 80-90%, all of it avoidable. The same studies quantify the attributable risk of COPD to pollution, exposure in the working place, and other factors, in around 10%. High environmental pollution, particularly the urban type with fine particles, SO₂ and NO₂, has been associated with an increase in respiratory symptoms, as well as an increase in hospital admissions due to COPD exacerbations⁵⁸. The effect of home pollution, that is to say, the one caused within the home by the use of wood and coal stoves and heaters, has not been widely studied, but it may probably also have a minor effect upon the population.

Early Diagnosis

Given that COPD is a chronic and progressive disease, its detection at early stages, together with smoking cessation, might result in a better prognosis. Various studies have shown a delay in diagnosing COPD and a high rate of underdiagnosis. Higher awareness among healthcare professionals and the general population about the importance of chronic respiratory symptoms should facilitate an earlier detection of this condition. The main causes for this lack of an early diagnosis are:

- COPD symptoms are not very relevant until the disease is well established.
- Affected persons are typically smokers with little motivation to quit.
- There is lack of knowledge about the characteristics of the disease and its treatment, by the general public and healthcare professionals.
- There is a confirmed lack of knowledge by Primary Care Physicians (PCPs) about morbidity and mortality caused by COPD.
- Lack of easy access to spirometry in Primary Care⁵⁹.

Campaigns conducted to sort out these deficiencies have shown the high benefits of early detection by spirometry in smokers with respiratory symptoms^{60, 61}, and even though there are contradictory results, it seems that COPD detection is associated with a higher probability of smoking cessation.

Programs of massive screening in the population searching for COPD patients are expensive, and not always yield the desired results. In fact, no test can be used with a 100% sensitivity and specificity. Maybe that is why the most efficient alternative (cost-effective) would be to select high risk populations and conduct diagnostic tests which meet the minimal criteria for sensitivity, reproducibility and validation.

The most accepted proposal consists in combining the presence of the main risk factor (smoking) with age (as age increases, the disease prevalence increases) and conducting a high consistency test, such as spirometry⁶². In this sense, it has been observed that COPD prevalence can be over 30% in persons over 40 years of age and a smoking history of more than 10 packages/year¹. These data suggest that the use of active search programs in high risk population may offer interesting results in terms of detecting new cases. However, these initiatives must be accompanied by efficacious therapeutic interventions.

In this sense, when the screening program is accompanied by a simple therapeutic measure, such as advice against smoking, results improve from a

1 Currently, the packet-year unit is used as a measure of tobacco use intensity, which provides information about the time a person has been smoking and the intensity of his use during most of that time, in one single piece of data. One package-year is equivalent to smoking one package of cigarettes every day during the last year. Example: a 66 packages-year smoker. This patient has smoked the equivalent to two packages per day during 33 years.

therapeutic point of view, and this encourages to a great extent an early search for this type of patients⁶³.

Besides the preventive strategy against smoking, early detection also encourages physical exercise, the prevention of exacerbations by means of the adequate vaccinations, and an early initiation of pharmacological treatment, whenever indicated, capable of improving the quality of life of these patients.

COPD must be suspected in all individuals over 40 years of age, who have risk factors, such as exposure to tobacco smoke (>10 packages/year), and who present symptoms compatible with disease (coughing, expectorating, effort dyspnea). This diagnosis must be confirmed through a spirometry which shows an airflow limitation.

Forced spirometry is essential to diagnose the disease and assess its severity. It also allows us to establish its prognosis, to guide its treatment, and to facilitate the control of therapeutic response and disease evolution.

In forced spirometry, the patient is asked, after a maximal inspiration, to expel all air in the shortest time possible. The maximal volume blown out during the first second of a forced spirometry is called VEMS in Spanish (though it is recommended to use the English acronym, FEV₁). Forced Vital Capacity (FVC) is the total volume of air expelled during a forced spirometry. The forced spirometric manoeuvre is conducted before and after bronchodilator treatment.

There is COPD when the relationship between FEV₁/FVC is lower than 0.70 after the bronchodilator treatment⁹. The severity of this limitation is assessed through the value of FEV₁ expressed as a percentage of a reference value (which, in turn, depends on each individual's ethnic group, age, gender, and height). FEV₁ is a simple indicator of lung function, which is valid, reliable, and sensitive to change⁶⁴.

The GOLD committee and the SEPAR-ALAT guidelines have established some levels of airflow limitation severity based on FEV₁, which can be used as guidance for therapy and are related to disease evolution, survival, and quality of life of the person affected (table 14)⁹. Their characteristics are:

- Stage I: Mild COPD
 - Mild airflow limitation (FEV₁/FVC < 0.70, FEV₁ ≥ 80% of the reference value).
 - Typically, but not always, accompanied by chronic coughing and increase in expectoration.
 - The individual may ignore that his lung function is abnormal.

- Stage II: Moderate COPD
 - Higher deterioration of airflow limitation (FEV₁/FVC < 0.70, 50% ≤ FEV₁ < 80% of the reference value).

- Progression of symptoms and dyspnea, characteristically during exercise.
 - The persons affected typically ask for medical care due to dyspnea or an exacerbation.
- Stage III: Severe COPD
 - Major airflow limitation ($FEV_1/FVC < 0.70$, $30\% \leq FEV_1 < 50\%$ of the reference value).
 - Higher dyspnea and reduction of capacity for exercise, with frequent exacerbations and reduction of quality of life.
 - Stage IV: Very severe COPD
 - Severe airflow limitation ($FEV_1/FVC < 0.70$; $FEV_1 < 30\%$ of the reference value or $FEV_1 < 50\%$), accompanied by respiratory impairment (defined as a reduction in the partial pressure of oxygen (PaO_2) under 60 mmHg with or without hypercapnia CO_2 partial pressure ($PaCO_2$) over 45 mmHg, measured at sea level, breathing environmental air.
 - Health-related quality of life is significantly reduced, there are frequent exacerbations.

Table 14. COPD Classification (FEV1/FVC < 0.7*)

Level of severity	FEV1 after bronchodilator ()
Mild	>80%
Moderate	>50% and < 80%
Severe	>30% and < 50%
Very Severe	< 30% or <50% with CRI**

* Below the inferior level of normality in subjects over 60 years.

** CRI (Chronic respiratory insufficiency): $PaO_2 < 60\text{mmHg}$ with or without hypercapnia ($PaCO_2 \geq 45\text{ mm Hg}$) at sea level, breathing environmental air. Source: Peces-Barba G, Barbera JA, Agusti AGN, Casanova C, Casas A, Izquierdo JL, Jardim J, López-Varela V, Montemayor T, Monsó E y Viejo JL. SEPAR-ALAT Guidelines for COPD diagnosis and treatment. Arch Bronconeumol. 2008; 44(5): 271-81

2.1.2. Objectives and Recommendations

General Objective 1

To reduce COPD incidence

Specific Objectives for Primary Prevention:

- 1.1.** To reduce, at a national level, the prevalence of smoking among the adult population ($>$ or $=$ 16 years of age) up to 23.4% (27.6% in males and 19.5% in females) during 2011.

- 1.2.** To reduce, at a national level, the prevalence of smoking in young people (16 to 24-year old) up to 23% (21% in males and 25% in females) during 2011.
- 1.3.** To delay by half a year the age of smoking initiation in the 14 to 18-year old population in 2011.
- 1.4.** To conduct inspections and other measures for the strict obedience of the law against smoking, as well as in terms of the levels of atmospheric contaminants and contaminants in the working place, as appear in current guidelines.
- 1.5.** To increase awareness among population and professionals about the relationship between tobacco, environmental contamination, exposure at the working place and COPD, and the consequences of this disease.
- 1.6.** To establish smoking cessation programs in primary care centers.

Recommendations:

- To include in the annual evaluation of objectives or in annual management agreements the carrying out of prevention, promotion and health education activities, in order to obtain the commitment by the whole group of Primary Care professionals for said purpose.
- In collaboration with teaching authorities:
 - To train the group of teaching professionals about tobacco effects in health and the prevention of smoking in the school setting.
 - To develop specific programs for control and follow-up of tobacco use, involving the whole educational community.
- To conduct interventions in communication media, to get them involved in the promotion of healthy lifestyles.
- To encourage the use of new educational technologies, in order to reach the target population: adolescents, smoking youth.
- To protect the right of people working in catering and hotel management services, and other closed spaces, to work in an environment free of smoke.
- To increase information among the population about the effects of tobacco use in the health of smoking people, as well as in the health of those exposed to environmental tobacco smoke, promoting informative campaigns adapted to specific population groups, according to age, gender and role, prioritizing young people and females, and insisting on smoke-free homes and the model role of parents and care givers.
- To facilitate the access of users to smoking cessation programs which will include, whenever deemed necessary, pharmacologic treatment, psychological support and/or techniques for smoking cessation.

- To develop, within the patient's clinical history, adequate and homogeneous registration systems, which will be the drivers of identification mechanisms of the smoking population, in order to have relevant information for the primary prevention of COPD.
- To encourage the role of Primary Care nurses in the promotion of healthy lifestyles.
- To conduct activities about health advice against smoking in all primary care centers.
- To adopt all necessary measures, including population surveys, in order to learn periodically the prevalence of tobacco use, particularly among the school population and adolescents, teachers, healthcare professionals and pregnant females.
- To watch that Law 28/2005, dated December, 26th, is adequately obeyed, using all tools necessary to this end. This law includes healthcare measures against smoking, and regulates the sale, supply, use and advertising of tobacco products.
- To include in the Primary Care's patient record all working aspects which show exposure to substances that might irritate the airways.
- To assess the exposure to risk factors in the working place of persons diagnosed with COPD.

General Objective 2

To improve the early diagnosis of persons with COPD.

Specific Objectives for Early Detection:

- 2.1. To have all structural, material, and organizational materials adequate for COPD diagnosis in primary care centers.
- 2.2. To conduct, within preventive activities in adults, an early detection of COPD for persons over 40 years of age who present a history of smoking (current or in the past) superior to 10 packets/year¹ (which is equivalent to smoking 20 cigarettes per day during 10 years) and with respiratory symptoms.
- 2.3. To establish monitoring systems so that forced spirometries can be accessible and conducted with the adequate quality according to established criteria² (see appendix IV).

¹ Currently, the packet-year unit is used as a measure of tobacco use intensity, which provides information about the time a person has been smoking and the intensity of his use during most of that time, in one single piece of data. One package-year is equivalent to smoking one package of cigarettes every day during the last year. Example: a 66 packages-year smoker. This patient has smoked the equivalent to two packages per day during 33 years.

² These monitoring systems will be implemented within 2 years.

Recommendations:

- To conduct interventions in order to capture the risk population, particularly if they present respiratory symptoms (chronic coughing, dyspnea and expectoration).
- To conduct pilot experiences to assess the efficacy of early detection programs in smoking persons without respiratory symptoms.
- To evaluate the implementation in certain geographical areas of alternative initiatives, such as mobile units or telemedicine.
- To count with referral criteria from emergency services to primary care centers for those patients who arrive with conditions compatible with COPD and who have not been previously diagnosed.
- To use / encourage the use of computer alert systems which will help professionals to identify those persons who must be included in the screening.
- To include COPD detection within preventive activities in the Occupational Health programs.
- Protocols, clinical pathways or guidelines of action for COPD will include prevention and early detection activities.

2.2. Chronic Patient Care

2.2.1. Analysis of the Situation

Justification

COPD is a chronic and complex disease, in which many other dimensions are involved, besides the airflow limitation itself. Some of these dimensions are symptomatology, air entrapment, exacerbations, the perceptive scope, comorbidity, or extra-pulmonary involvement. These not only have an impact on the clinical aspects of COPD, but also on its management.

Multidimensional Assessment

We can summarize COPD assessment with the following key items:

Stage	Characteristics
I Mild COPD	FEV ₁ Dyspnea Quantification (MRC scale) Simple nutritional assessment (BMI) Comorbidity

II Moderate COPD	FEV ₁ Dyspnea Quantification (MRC scale) Simple nutritional assessment (BMI) Exacerbations Comorbidity Assessment of inhalatory technique Assessment of adherence and treatment compliance Psychosocial factors
III and IV Severe / Very severe COPD	FEV ₁ Dyspnea Quantification (MRC scale) Nutritional assessment (body composition) Exacerbations Comorbidity Stress test Hyperinsufflation assessment Assessment of inhalatory technique Assessment of adherence and treatment compliance Psychosocial factors
Special Situations:	Patient candidate for respiratory rehabilitation: FEV ₁ Dyspnea Quantification (MRC scale, Börg scale) Stress test (six-minute walk) Nutritional assessment Comorbidity Arterial gasometry / Arterial Oxygen Saturation Assessment in the final stage of life: Advance Directives Dyspnea Quantification (visual analogic scale) Psychological and social assessment Pain scale Assessment by care giver
BMI: Body Mass Index Source: Modified from British Medical Research Council.	

Clinical Assessment of COPD

- COPD patients typically smoke or have been smoking during a prolonged time, and report coughing, expectoration and/or dyspnea symptoms.
- Any subject over 40 years of age with a history of exposure to tobacco smoke or bio-mass combustion or any other source of exposure, who presents respiratory symptoms, might be suffering COPD; therefore, a spirometry test must be conducted.

Assessment of the Pulmonary Component

Airflow Limitation

- Forced spirometry is an essential element in managing this disease, as it allows establishing a diagnosis, quantifying its severity, monitoring its evolution, and assessing the severity of exacerbation episodes.
- Bronchodilator test is useful for initial assessment, and in order to rule out asthma. During follow-up, it is recommended to conduct a spirometry test after bronchodilation.
- There is COPD when the relationship between FEV_1/FVC is lower than 0.70 after the bronchodilator treatment⁹. The severity of this limitation is assessed through the value of FEV_1 expressed as a percentage of a reference value which, in turn, depends on each individual's ethnic group, age, gender, and height (Figure 5). FEV_1 is a simple indicator of lung function, which is valid, reliable, and sensitive to change⁶⁴.

Hyperinsufflation

One of the main determining factors for dyspnea in a person suffering COPD is pulmonary hyperinsufflation, which becomes particularly accentuated during exercise. Inspiratory capacity (IC), a measurement also obtained during spirometry, has proven to be useful as an indirect measurement of dynamic pulmonary hyperinsufflation; this is an interesting parameter, particularly in order to monitor therapeutic response. Pulmonary volume determination, through plethysmography, helium dilution or nitrogen washout, provides more accurate functional data about air entrapment. An increase in residual volume (RV) or in functional residual capacity (FRC) and the reduction of IC relative to total lung capacity (TLC), are some of the parameters indicating static hyperinsufflation. A Spanish study has shown that those people with COPD with higher hyperinsufflation, expressed as $IC / TLC < 25\%$, present a higher mortality rate⁶⁵.

Static pulmonary volume determination is particularly indicated for patients with $FEV_1 < 50\%$ or in those who present dyspnea out of proportion with their level of airflow limitation⁶⁶.

Exercise Tolerance

Exercise capacity can be affected by important and complex factors, some of which are ventilation, gas exchange, circulation, muscular function, nutritional status and symptoms. The majority of these aspects have been described as prognostic variables, therefore it is logical to anticipate that exercise capacity might be one of the most potent prognostic indicators. There are various stress tests, from simple methods (6 or 12-minute walk test, shuttle test) to more complete methods (ergometer bicycle). Among them, the distance walked during the six-minute walk has gained popularity due to its

simplicity, its closeness to daily physical activity, and because it has been included in the BODE index.

It is recommended to assess exercise tolerance, particularly in severe or very severe patients⁶⁶. Its use is also recommended for the multidimensional assessment of patients candidate for respiratory rehabilitation (Table 15).

Gas Exchange

Arterial gasometry at rest is indicated if $FEV_1 < 50\%$ of the reference value, and in home oxygen therapy prescription.

Other Respiratory Tests

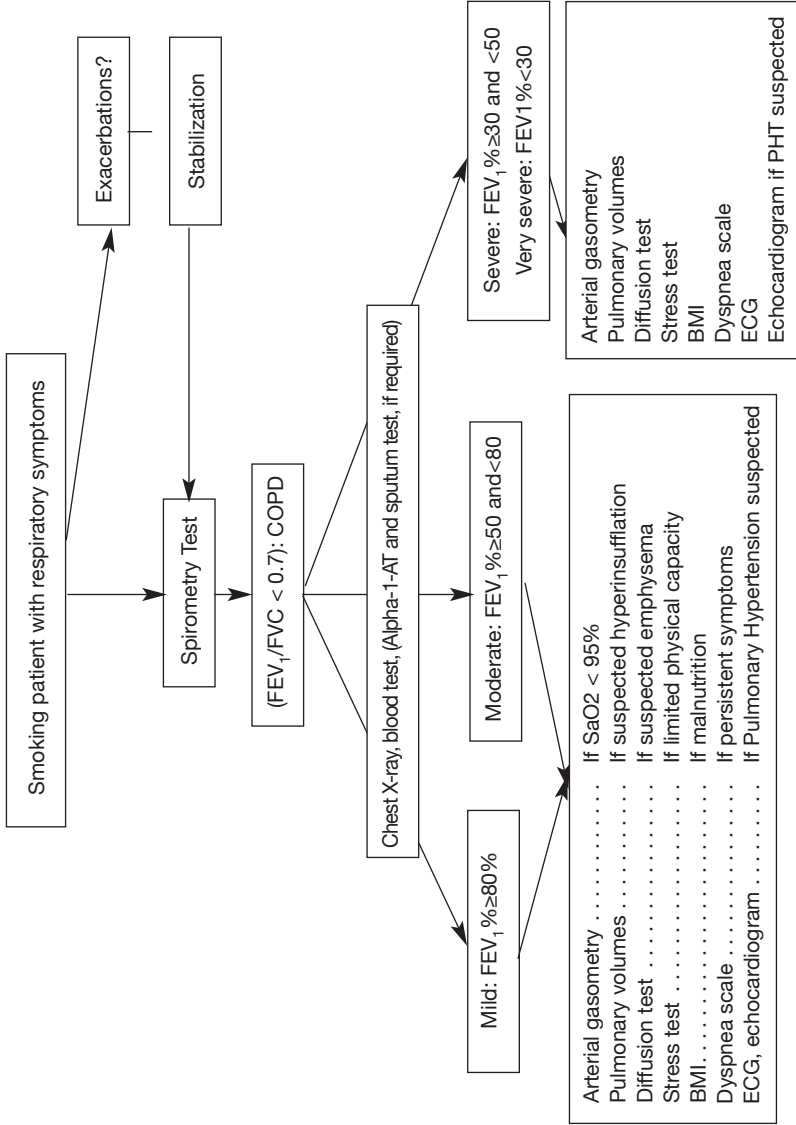
- Diffusing Capacity of the Lung for Carbon Monoxide (DLCO): Indicated if $FEV_1 < 50\%$ of the reference value, and if emphysema is suspected, and for preoperative evaluation of candidates for pulmonary resection.
- Sleep studies: Indicated if concomitant sleep apnea syndrome is suspected.
- Respiratory muscular function. Only if respiratory muscular dysfunction or diaphragmatic paralysis are suspected, or if the level of dyspnea is out of proportion with FEV_1 .
- Compliance Test: Not routinely indicated.
- Imaging Techniques: A chest X-ray must be conducted for initial assessment, and if symptoms appear during follow-up. A thoracic high-resolution computerized tomography (CT) is recommended for evaluation of surgical treatments, and for diagnosis of concomitant conditions (neoplasias, associated bronchiectasis, etc.)

It is recommended to complete the initial assessment with a blood test and an electrocardiogram (ECG). Other diagnostic tests are reserved for selected cases. Initial assessment and follow-up must be conducted in a coordinated manner between the healthcare levels of Primary Care and Pulmonology.

Assessment of the Perceptive Component

There is a current increasing interest to know the opinions of people who suffer COPD, their concerns and preferences. Many times, this perception is not adequately captured by the functional or biologic indicators used to monitor the disease. Therefore, it is necessary to develop tools capable of collecting this type of information, the so called “patient-reported outcomes” (PROs). A “patient-reported outcome” is defined as a disease dimension which is obtained from the patient, without the need to conduct biologic or functional tests. Dyspnea scales or quality of life questionnaires are some examples of widely known PROs. However, other dimensions such as impact on physical activity, mood, social or familiar impact, are being explored in recent years.

Figure 5. Proposed Algorithm for Initial Assessment of a Smoking Patient with Respiratory Symptoms



Source: Pece-Barba G, Barbera JA, Agusti AGN, Casanova C, Casas A, Izquierdo JL, Jardim J, López-Varela V, Montemayor T, Monsó E y Viejo JL. Diagnosis and management of chronic obstructive pulmonary disease: joint guidelines of the Spanish Society of Pulmonology and Thoracic Surgery (SEPAR) and the Latin American Thoracic Society (ALAT). Arch Bronconeumol. 2008; 44(5): 271-81

Dyspnea

Dyspnea is the main symptom of COPD, even though it can be perceived in different ways by patients with the same level of airflow limitation. It is worth taking into account that people with COPD often reduce their physical activity to minimize the impact of dyspnea, therefore the latter must always be investigated within the context of the level of physical activity tolerated by the person who suffers COPD compared with other subjects of the same age.

There are various tools for dyspnea measurement and assessment. The scale put forward by the British Medical Research Council (See Table 1) is the most widely used and recommended, even though it is relatively insensitive to slight changes in time. The Börg dyspnea scale is widely used for patients included in respiratory rehabilitation programs, as it allows assessing changes before and after exercise. During the final stage of life, dyspnea is the most incapacitating and prevalent symptom. It is recommended to measure it combining a simple scale, such as the visual analogic scale, with a specific or multidimensional instrument of quality of life, which incorporates psychosocial information and caretaker's distress. Guidelines about COPD management in the final stage of life have been recently presented, which widen this information, besides pointing out other aspects required for clinical evaluation in this stage of life (candidate identification, advance directives, etc...)⁶⁷.

Assessment of the extra-pulmonary component

In recent years, many extra-pulmonary manifestations of the disease have been described. These manifestations have an undoubted impact in the clinical situation of persons who suffer COPD, and some of them even affect the prognosis, regardless of the functional severity of the obstruction. Weight loss, loss of muscle mass, anemia or, for example, osteoporosis, are some of the most prominent ones.

Nutritional Study

Nutritional status is an independent prognostic factor associated to the survival of persons with COPD. Body Mass Index ($BMI = \text{weight [Kg]} / \text{height [m}^2\text{]}$) is the anthropometric parameter most widely used for its assessment. However, BMI does not consider possible differences in body composition. Body weight consists of fat mass, extracellular water and body cell mass (BCM). The latter shows the amount of metabolically active and contractile tissue. Approximately 60% of BCM is muscle. There is no method in clinical practice capable of measuring BCM, and therefore the parameter which better shows nutritional state is fat-free mass. There are different methods to assess fat-free mass, the most widely used of which is bioelectrical impedance.

Comorbidity Assessment

Generally speaking, people with COPD have higher comorbidity than other subjects with the same risk factors. This comorbidity may condition their treatment, the presence of exacerbations, the use of resources, and the disease prognosis; therefore, it is recommended to collect detailed data about these aspects in their assessment. This circumstance requires a change of the traditional approach, more targeted to the treatment of the specific condition, and a new orientation with a comprehensive perspective focused on the treatment of the patient with comorbidity.

For example, scientific literature shows unacceptable re-admission rates (over 30% at 2 months of hospital discharge) in chronic patients with cardiac and respiratory diseases, which tells us that these patients' care must be improved, within a scheme focused on the person rather than on the disease (disease-oriented management vs. patient-oriented management)⁶⁸.

The most frequent comorbidities are arterial hypertension, ischemic cardiopathy, heart failure, diabetes, or anxiety-depression. Recent observational studies suggest that an adequate comorbidity treatment may be beneficial, even in terms of survival⁶⁹.

Registry of Exacerbations

Exacerbation assessment is an essential aspect, which affects all disease components. Exacerbations cause deterioration in the health status of persons who suffer COPD⁷⁰, they favor disease progression, and even have an impact on prognosis⁷¹. Some of COPD's extra-pulmonary manifestations get worse during as well as after the exacerbation, and the same happens with certain comorbidities. Due to all this, collecting the frequency of exacerbations, their severity and their possible etiology are very useful elements in COPD management.

Multidimensional Scales

COPD complexity has led to think about assessment scales capable of integrating some of the disease dimensions. The most widely known is the BODE Index¹¹. This scale includes nutritional assessment through body mass index, degree of obstruction (FEV_1), dyspnea and exercise capacity, assessed through the 6-minute walk test. Each of these variables is divided into ranges which are then assigned a value (Tables 2 and 3), so that the final score is between 0 and 10 points. The BODE Index has shown superiority vs. FEV_1 as a mortality predictor, and has also shown its usefulness in predicting exacerbations or differentiating health status. Some modifications for this index have been recently proposed, such as BOD¹⁸ or BODE_x¹⁹.

Pharmacological Treatment

- In patients with occasional symptoms, treatment with short-acting bronchodilators reduces symptoms and improves stress tolerance (Evidence A).
- In patients with permanent symptoms, the use of long-acting bronchodilators provides a higher control of symptoms, improves quality of life and lung function, and reduces the number of exacerbations (Evidence A).
- In patients with moderate and severe COPD, the combination of long-acting B₂-agonists and inhaled corticosteroids causes an additional improvement in lung function, symptoms, quality of life and exacerbations (Evidence A).
- During exacerbations, systemic corticotherapy is the treatment of choice for severe COPD exacerbations. For mild/moderate exacerbations, its use is recommended when initial evolution is not favorable.
- Theophylline may be added to treatment for those patients who continue being symptomatic with an optimal treatment, or for those where it is necessary to use oral administration (Evidence D).
- The use of mucolytics and/or antioxidants may be considered for patients with habitual expectoration and/or frequent exacerbations (Evidence B).
- Replacement use of Alpha 1-Antitrypsin is indicated for selected patients who have a deficit of this enzyme (Evidence B).
- There is currently no evidence to recommend the use of cough suppressants, antileukotrienes, prophylactic antibiotics or respiratory stimulants.

Note: See Table 4 about Evidence Categorization.

Oxygen Therapy

- Treatment with continuous home oxygen therapy (HOT) increases survival in persons with severe COPD and respiratory impairment (Evidence A).
- Criteria for HOT indication require a $\text{PaO}_2 < 55$ mmHg, or between 50-60 mmHg when it is accompanied by polyglobulia or signs of right heart failure, while breathing environmental air at sea level (Evidence A). The objective is to maintain a $\text{PaO}_2 > 60$ mmHg or $\text{SaO}_2 > 90\%$ (Evidence D).
- Values of arterial gases are necessary to determine the indication, and provide information about the acid-base balance.
- The effect of oxygen therapy depends on the duration of its administration. With 18 hours/day, effects are superior to those obtained with 15 or 12 hours/day (Evidence A). It is not recommended to use it for less than 12 hours per day.

- When there are no HOT criteria, oxygen therapy during sleep is indicated if, besides prolonged desaturations, there are signs of right heart failure or polyglobulia.

Note: See Table 4 about Evidence Categorization.

Respiratory Rehabilitation

- Respiratory Rehabilitation (RR) improves dyspnea, exercise capacity, and health-related quality of life (Evidence A).
- RR reduces the use of healthcare services and hospital admissions (Evidence B), it is cost-effective (Evidence B) and improves the BODE Index.
- Rehabilitation programs including exercise and limb training are most effective (Evidence A).
- Implementation of home maintenance programs is a valid alternative option to rehabilitation conducted in hospital since the initial stages of the disease (Evidence B).
- Activity and daily physical exercise are beneficial for persons with COPD (Evidence B).
- Rehabilitation must be recommended to all COPD patients who, after receiving optimized treatment, are still limited by dyspnea when conducting their daily activities (Evidence A).

Note: See Table 4 about Evidence Categorization.

Home Ventilation

- There is no scientific evidence to justify the chronic use of non-invasive ventilation (NIV) in patients with stable COPD.

Surgical Treatment

- There are surgical procedures that may provide clinical improvement in highly selected patients with very severe COPD.
- Lung transplant provides functional and symptomatic improvement (Evidence C).
- This option may be considered for patients under 65 years of age and highly advanced disease, who meet the general criteria for transplantation.
- Lung Volume Reduction Surgery (LVRS) provides functional and symptomatic improvement in patients with heterogeneous emphysema with upper lobe predominance and low tolerance to stress (Evidence A).
- In these patients, LVRS increases survival (Evidence B).
- LVRS is contraindicated in patients with homogeneous emphysema, $FEV_1 < 20\%$ or $DLCO < 20\%$ (Evidence A).

- In highly selected patients, bullectomy may improve lung function and dyspnea (Evidence C).

Note: See Table 4 about Evidence Categorization.

2.2.2. Objectives and Recommendations

General Objective 3

To reduce the morbi-mortality in persons with COPD and improve health-related quality of life.

Specific Objectives for Secondary Prevention:

Pulmonology departments / units will have sufficient technology in order to conduct an adequate multidimensional assessment of persons with COPD (spirometry, lung volumes, diffusion capacity of carbon monoxide, arterial gasometry, stress tests, nutritional assessment, co-oximetry, etc.)

- 3.1.** To conduct a multidimensional COPD assessment to patients with moderate / severe disease (see table 15).
- 3.2.** Patients diagnosed with COPD will have from the beginning a nursing care plan which will increase their training and autonomy for an effective management of the therapeutic regimen, and favor the prevention of complications, according to the criteria included in the table.

The care plan will include at least:

- Comprehensive and overall assessment of the patient's care needs.
- Formulation of those detected care needs.
- Formulation of objectives in order to solve those problems identified. These objectives must be agreed upon with the patient, and be realistic in terms of working conditions and care continuity.
- Formulation of interventions in order to achieve those objectives formulated.
- Assessment of the family structure of the severe patient, with special focus upon the main caretaker. Special emphasis will be made in case of elderly spouses and persons with little social support.
- For assessments, formulations of care problems, objectives and interventions, nursing models and validated taxonomical classifications will be used.

- 3.3.** To recommend all active smoking persons with a COPD diagnosis to quit smoking, offering smoking cessation programs at their pri-

mary care centre and/or referring them to specialized smoking cessation units.

- 3.4.** To assess and, if needed, facilitate the reimbursement or co-payment of pharmacological treatment for smoking cessation to any COPD patient.
- 3.5.** To determine, based upon clinical practice guidelines, quality criteria for the care process, and to conduct measurements upon it according to the criteria included in the table.

These criteria will include at least the monitoring of:

- Inclusion in follow-up programs.
- Percentage of COPD patients who receive influenza vaccination (in order to reach 90% coverage) and antipneumococcal vaccination.
- Inclusion in respiratory rehabilitation programs for the whole group of patients with moderate / severe COPD.
- Physical exercise adapted to their functional capacity
- Use of continuous home oxygen therapy and its adequate compliance
- The correct referral to Pulmonology for symptomatic patients.
- Treatment compliance.
- Multifunctional assessment and nursing care plan mentioned in objectives 3.1 and 3.2
- The number of COPD patients included in smoking cessation programs, and the number of patients who have quit smoking.

- 3.6.** To establish measures for monitoring pharmacological treatment adequacy. These should aim at:
 - Increasing the use of long-acting bronchodilators for COPD treatment, replacing the regular use of short-acting bronchodilators, according to clinical practice guidelines.
 - To adapt to clinical practice guidelines the use of inhaled corticosteroids in combination.
- 3.7.** To implement in a progressive manner measures for oxygen therapy and other home respiratory therapies which will allow patient's mobility and travels within and outside their Autonomous Community.
- 3.8.** To set up structured programs for respiratory rehabilitation.

Recommendations:

- To establish coordinated programs between Primary and Specialized Care and other centers and nursing homes in order to facilitate the comprehensive management of COPD patients (treatment, follow-up, patient recovery, and end of life).

- To promote computerized patients' records shared by Primary and Specialized Care, encouraging interconsultation between these care levels as a training tool, as well as collaborative tools.
- Access to COPD patient's records must be possible from both care levels; where, besides an overall assessment, the results of spirometry/s and other respiratory functional tests can be looked up.
- To encourage an active role by severe patients and involvement by their caregivers, training them in basic COPD care, elementary physiotherapy, and verification of the inhalation technique, as well as in early detection of signs and symptoms of exacerbation, and an adequate control of different comorbidities.
- To conduct campaigns targeted to encouraging physical exercise in old age people.
- To conduct satisfaction surveys among patients and caregivers about care received in different care levels.
- To boost home care by nursing professionals for moderate-severe COPD patients.
- To promote accessibility through the following measures:
 - To favor overall care in a single clinical act.
 - To widen care through telematic applications or telephone consultations.
 - To design coordination and care circuits between the health system and the social system (social services, nursing homes...) in order to provide adequate care to patients who require nursing care due to their social status.
- To boost the role of patient associations, by informing about their existence.
- To involve supply companies in therapy adequacy and compliance (oxygen therapy, nebulizer therapy, ventilation, and others).
- Educational materials will be available for persons diagnosed with COPD from the beginning, and these will be based upon scientific evidence and agreed upon in terms of their severity.
- Multidisciplinary oxygen therapy consultations will be promoted, with the possibility to conduct arterial gasometry and pulse oximetry.
- To assess establishing the role of Liaison Nurse for capture and follow-up of hospital discharges, as well as the role of Advisor Pulmonologist, which will allow a comprehensive care for COPD patients.
- To increase the number of COPD patients who receive training and respiratory physiotherapy programs in Primary Care.

2.3. Care for Patients with Exacerbations

2.3.1. Analysis

Justification

The clinical evolution of COPD is frequently affected by transitory episodes of symptom increase, typically defined as exacerbations. Initially, these instability manifestations were considered epiphenomena in the natural history of COPD. However, recent evidence indicates that, on the contrary, these obviously contribute to deterioration in the state of health⁷⁰, create a high demand for care, affect disease progression and increase the risk of death⁷².

In Spain, it is estimated that COPD exacerbations represent 10 -12% of Primary Care consultations, between 1 and 2% of all visits to hospital emergency units, and around 10% of medical admissions⁷³. The economic implications of this are enormous. Around 60% of the overall cost for COPD can be attributed to exacerbations. However, beyond their economic impact, current interest is focused on recent scientific evidence which highlight the strong clinical impact of exacerbations upon the health status of patients, their repercussion upon certain extra-pulmonary aspects, and their influence upon disease progression and even upon prognosis^{71,74,75,76,77}.

A COPD exacerbation is an acute change in the basal clinical situation of the patient, beyond daily variability, which involves an increase in dyspnea, in expectoration, purulent expectoration, or any combination of these three symptoms, and which requires a therapeutic change.

Frequencies

Exacerbation distribution is not homogeneous among COPD patients. Some cases seldom present these events, while others suffer them repeatedly. The latter represent a high risk group, with higher morbid-mortality. Patients with frequent episodes are defined as those who suffer 3 or more exacerbations per year. These exacerbations must be separated by an interval of at least 2 weeks after the end of the preceding exacerbation, so that the new exacerbation can be differentiated from the concept of therapeutic failure or relapse.

Assessment

Assessment of a patient with a potential COPD exacerbation must focus on assessing the episode severity and rule out other causes of symptom deterioration. A complete patient's record and physical examination are essential elements. It is particularly important to know the basal situation of the pa-

tient, specifically the level of dyspnea, history of previous exacerbations, the degree of bronchial obstruction, and the presence of comorbidities. During physical examination, respiratory function must be assessed, respiratory frequency must be considered, as well as the use of accessory muscles and the presence of signs suggesting respiratory failure, including cyanosis, asterixis, mental alterations and peripheral edema. The most relevant types of differential diagnosis appear in Table 16.

Table 16. Differential Diagnosis for Symptom Deterioration in COPD Patients

Respiratory Causes

- COPD exacerbation
- Pneumonia
- Pneumothorax
- Pulmonary embolism
- Pleural effusion
- Bronchogenic carcinoma
- Rib fracture

Cardiac Causes

- Heart failure
- Cardiac arrhythmias

Other:

- Upper airway obstruction
- Drugs (sedatives, narcotics, non-selective b-blockers, etc.)

Source: 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: 532-555.

Exacerbation Severity

The combination of clinical data and complementary examinations will lead to define the exacerbation severity, a key element in order to decide the type of treatment and the place where to conduct it. However, the classification of exacerbation severity is not well defined, as it can be categorized based on clinical presentation (particularly symptoms) or by use of resources. Table 17 shows a joint proposal by the European and American Respiratory Medicine Societies (quote 1), including clinical data and physical findings which help to define exacerbation severity and the most adequate care level. Other authors define exacerbation severity as: mild, when patients have a higher need for medication but can control themselves; moderate, in cases where the patient has a higher need for medication and feels the need for additional medical care; and severe, when the patient/caregiver acknowledges an obvious and fast deterioration in his condition, which requires hospitalization⁷⁸.

Table 17. Classification of Exacerbation Severity

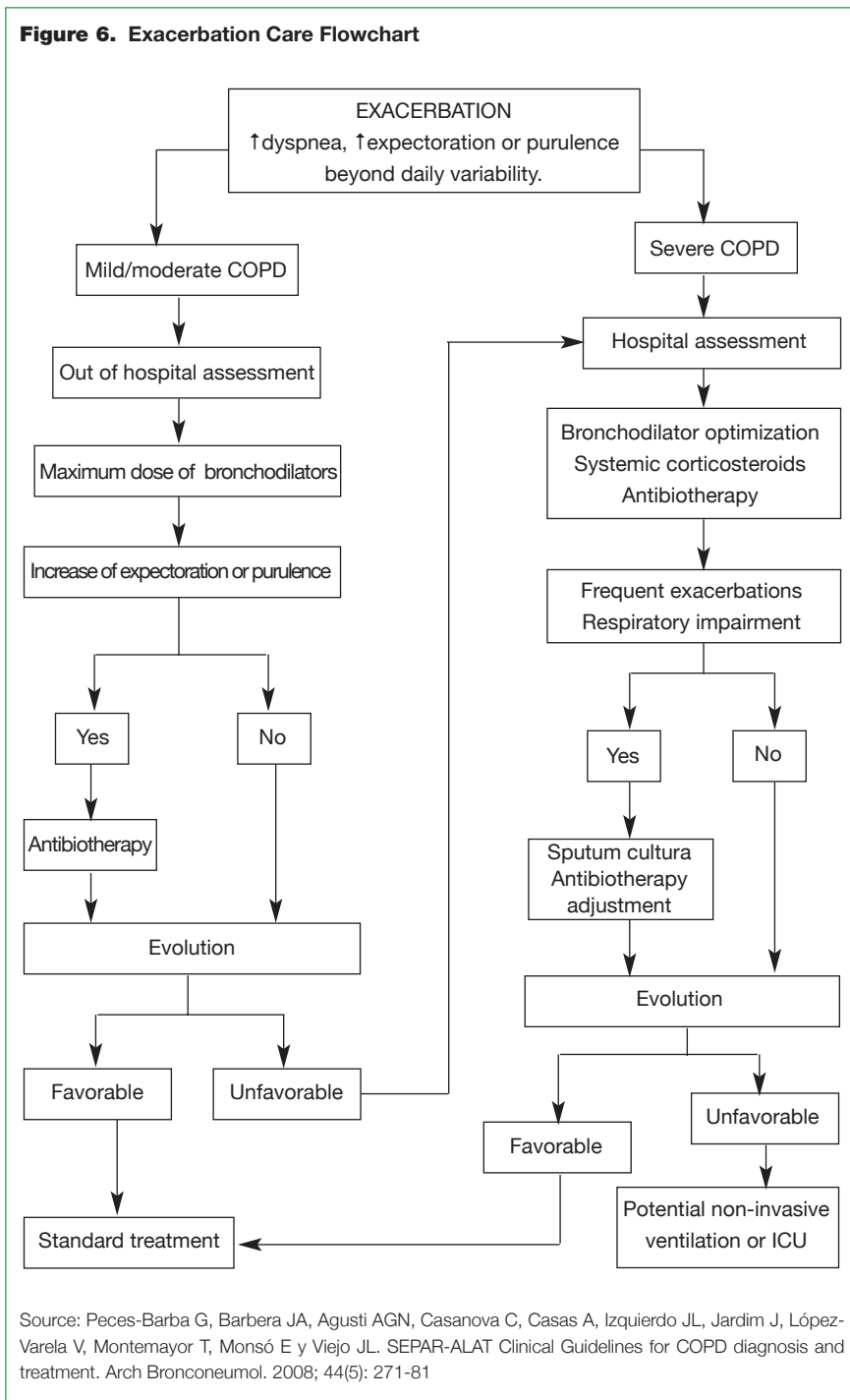
	Level I	Level II	Level III
Patient's Record:			
- Significant comorbidity	+	+++	+++
- History of frequent exacerbations	+	+++	+++
- Basal severity of COPD	Mild/Moderate	Moderate/Severe	Severe
Physical Examination:			
- Haemodynamic assessment	Stable	Stable	Stable /Unstable
- Use of accessory muscles / tachypnea	Not present	++	+++
- Persistent symptomatology after the initial treatment	No	++	+++
<p>Level I: Exacerbation which can be controlled out of hospital; Level II: Exacerbation which requires hospital care; Level III: Exacerbation which requires intensive care. +: unlikely to be present; ++: likely; +++: very likely. #: Comorbidities most frequently associated with bad prognosis are: congestive heart failure, ischemic cardiopathy; diabetes mellitus and renal impairment (with permission).</p> <p>Source: 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.</p>			

Exacerbation Treatment

- Mild-moderate COPD exacerbations can be treated out of hospital as first option.
- During exacerbation, bronchodilator treatment with a short-acting beta-2 agonist and/or ipratropium bromide will be preferred (Evidence A).
- Systemic corticotherapy is the treatment of choice for severe COPD exacerbation. In mild/moderate COPD exacerbations, its use is recommended when the initial evolution is not favorable. (Evidence A)
- In 50-75% of COPD exacerbations, an infectious bacterial agent is isolated in sputum in around half of the cases, and a viral agent in one third of cases. Antibiotherapy is recommended for those exacerbations which present, besides dyspnea, an increase in the amount of usual expectoration and/or purulence.
- In a patient with frequent exacerbations, or an exacerbation requiring assisted ventilation, infection may be caused by *Pseudomonas aeruginosa*.
- Criteria for hospital discharge are based on clinical and gasometry stabilization, and the ability of the patient to control the disease at home.
- Home hospitalization can be an option for treatment of COPD exacerbations, with an efficacy equivalent to conventional hospitalization.

Note: See Table 4 about Evidence Categorization.

Figure 6. Exacerbation Care Flowchart



Source: Peces-Barba G, Barbera JA, Agusti AGN, Casanova C, Casas A, Izquierdo JL, Jardim J, López-Varela V, Montemayor T, Monsó E y Viejo JL. SEPAR-ALAT Clinical Guidelines for COPD diagnosis and treatment. Arch Bronconeumol. 2008; 44(5): 271-81

Non-pharmacological Exacerbation Treatment

Oxygen Therapy in COPD Exacerbations

- The objective is to reach a figure of $\text{PaO}_2 \geq 60$ mm Hg without causing respiratory acidosis (Evidence C).
- FiO_2 between 24 and 35% is usually enough.
- Initially, oxygen must be supplied through a Venturi-type mask, and later on through nasal cannula.
- In cases where there is acidosis or hypercapnia, therapeutic monitoring must be conducted with gasometry, and it is recommended to conduct the first control 30 minutes after initiating the therapy. Gasometry is also recommended whenever there are deterioration signs.
- Pulse oximetry will help in monitoring and subsequent adjustment of FiO_2 levels.

Note: See Table 4 about Evidence Categorization.

Mechanical Ventilation in COPD

- Mechanical ventilation is indicated when, despite pharmacological treatment and oxygen therapy, the patient continues presenting a $\text{pH} < 7.35$ (Evidence A).
- It can be applied non-invasively (NIV), or invasively (IV) as endotracheal ventilation.
- The survival of patients with COPD exacerbations requiring IV is not inferior to survival when IV is required for other reasons.

Note: See Table 4 about Evidence Categorization.

2.3.2. Objectives and Recommendations

General Objective 4

To provide adequate treatment, based on the best scientific evidence, to COPD patients who present exacerbations, either at home or at the most appropriate care level.

Specific Objectives:

- 4.1.** To implement clinical pathways, protocols or procedures for COPD exacerbation care, based on the best scientific evidence.
- 4.2.** To conduct an assessment and monitoring of pharmacological and non-pharmacological treatment for patients with exacerbations.

- 4.3. To establish systems which will allow Primary Care Centers to receive a report with treatment and care plan when COPD patients are discharged from hospital.
- 4.4. To reduced the percentage of unplanned hospital re-admissions and/or visits to hospital emergency units at 30 days of hospital discharge.
- 4.5. Hospitals must have, preferably in specific areas, non-invasive mechanical ventilation equipment, monitoring devices, and staff trained in the adequate use of these devices, adapted to the real possibilities of each center.
- 4.6. Hospitals will implement Smoking Cessation Units or programs for those hospitalized COPD patients who smoke.
- 4.7. To provide a short-term care continuity by the Primary and/or Specialized Care team, after a severe exacerbation.

Recommendations:

- To develop specific comprehensive programs for patients with frequent exacerbations, because this is a high risk group (morbidity and mortality) and presents a high assistential burden.
- Any patient with disease exacerbation will undergo strict clinical controls, and a visit by Primary Care within 72 hours is recommended. In cases requiring hospitalization, patients must have specialized control within 15 days.
- To include in the annual evaluation of objectives or in annual management agreements the implementation of quality standards for COPD care, in order to obtain the commitment by the whole group of professionals for said purpose.
- To implement instruments which will allow continuity of care in acute patients (for example, e-consultation).
- To develop programs for early hospital discharge / home hospitalization.

2.4. Palliative Care

2.4.1 Analysis of the Situation

Justification

COPD is one of the conditions considered when making an estimation of patients who require palliative care in the population, at any level of care. The great majority of deceased people go through an advanced and terminal stage with great need for symptom relief, particularly for dyspnea, as well as emotional support and continuous planning for comfort care.

Palliative Care has the essential objective of suffering relief, and improving as much as possible the quality of life of patients in a terminal stage. Their care presents a series of emotional and ethical considerations and special characteristics of care for patients as well as for caretakers and relatives.

The Palliative Care Strategy, approved by the National Health System Inter-territorial Council on March, 14th, 2007, and published on July, 2007, establishes a series of objectives to achieve in order to help to improve the quality of interventions and results related to the disease in advanced or terminal stage, in a realistic way, and according to available resources and the scope of competence of Autonomous Communities, and in consistency with available scientific evidence.

One of the critical issues pointed out by the committees who prepared the Palliative Care Strategy is a specific palliative coverage, limited to patients with cancer, and even more limited for non-oncological patients; and, consequently, sometimes late interventions by the palliative care teams. Therefore, one of the priority areas highlighted by that Strategy was the need to promote palliative care for non-oncological patients. The Palliative Care Strategy is structured around five major lines:

- A continuous assistential process, as patient care in advanced and terminal stages cannot be an isolated event, but has to be part of a care process conducted in a continuous and coordinated way between Primary and Specialized Care, with a single and inter-disciplinary therapeutic plan, which involves all care levels.
- Organization of Care: Patients with advanced or terminal disease must receive care based on the best practices and scientific evidence available, and in a continuous and coordinated way between the different care levels. Primary Care teams, in collaboration and sharing responsibility with Specialized Care Resources, are key elements in their role as palliative care managers for patients in advanced or terminal stage, supported by specific palliative care teams in complex situations.
- Patient's Autonomy: It is essential to apply bio-ethical principles, and involve the patient in the process according to principles, values and contents in the Patient's Autonomy Law. Patients and their families have a right to the inclusion of general measures about end of life care in healthcare services, as well as access to specific palliative care teams.
- Healthcare staff training: Continuous and specific training programs, as well as support programs for healthcare professionals, are essential in order to adequately attend to the bio-psycho-social needs of these patients and their families.

- **Research:** The Ministry of Health and Social Policy has funded and promoted lines of research for palliative care, through their inclusion in the official invitations to tender for research projects.

The Strategy is assessed two years after its approval, in order to prepare a report where the degree of achievement for the proposed objectives is analyzed, in order to determine whether these are still appropriate, and also to include new objectives based on new scientific evidence.

Final Stages of the Disease

- A plan of action should be agreed upon by patients and caregivers in case of patients with highly advanced disease.
- Planning for a correct therapeutic management of patients with COPD in a very advanced stage must take into account the clinical and social dimensions around it.

2.4.2. Objectives and Recommendations

General Objective 5

To provide special care to patients with COPD in advanced terminal stage, as well as to their relatives and/or caregivers, according to the National Health System Palliative Care Strategy.

Specific Objectives:

- 5.1.** To encourage the application of bioethical principles and involve the COPD patient in the process according to principles, values and contents in the Patient's Autonomy Law, and the legislation currently in force in different Autonomous Communities.
- 5.2.** To establish procedures for identification, action and assessment of the palliative care process in patients with COPD in advanced terminal stage, which include information and registration systems.
- 5.3.** Patients with COPD in advanced or terminal stage will receive care in the palliative care system in their basic area and health zone, at home and/or specialized, and with such support teams as they require according with their needs and in the adequate moment, adapted to different situations and geographical areas.
- 5.4.** To implement in a progressive way a system of specific access to psychological and socio-familial support for patients and relatives, which shall be specialized and adapted to their needs.

- 5.5. To establish support programs for caregivers, providing information about care services, resources and materials, which will facilitate and speed up bureaucratic proceedings within what has been established by the National Health System Palliative Care Strategy.
- 5.6. To carry out awareness and information activities for general population and professionals, about palliative care objectives, principles and resources.
- 5.7. To establish continuous and specific training programs for Primary and Specialized Care professionals, so that they can meet adequately the needs of patients with disease in advanced / terminal stage and their families.

2.5. Professional Training

2.5.1 Analysis of the Situation

The White Book of the Medicine Degree by the National Agency for Quality Evaluation and Accreditation (ANECA) establishes that Medicine students must know how to order and interpret in a competent way (routinely and without supervision) a simple spirometry test; they should also have practiced under supervision how to interpret complete respiratory function tests⁷⁹.

Care for COPD patients is included in all curricula for the current University Nursing Degree, due to its epidemiological relevance, and because nurses play a relevant role in disease prevention, and for follow-up of patients already diagnosed.

COPD represents a major chapter within care of persons with respiratory conditions, which are addressed in the core subject called Medical-Surgical Nursing, and appears in all nursing texts about this subject. Besides, Primary Care health plans, including COPD patient care, are addressed in Community Nursing, which is also a core subject. The proportion of practical-clinical credits for these subjects is approximately 50%, therefore students also acquire those abilities and attitudes required for taking care of people in this situation, both in the Specialized Care setting and in the Primary Care setting.

It can be expected for new Nursing Degree curricula to address as well training in care for this type of patients, according to competences stated by Order CIN/2134/2008, dated July, 3rd, which determines the criteria for verification of official university degrees for the practice of the Nursing profession, one of which is: "To plan and provide nursing care for persons, families or groups targeted to health results, assessing their impact through clinical

and assistential guidelines, which describe the procedures to diagnose, treat or manage a health problem”.

However, the reality is different, even at European level. In recent years, numerous clinical guidelines and manuals have been published in scientific literature. Many of them have been published by scientific societies and others by supranational organizations. Among them, we can highlight the GOLD and SEPAR-ALAT Guidelines, already mentioned in this documents, as well as others such as the one by the American Thoracic Society, and by the European Respiratory Society, etc.^{80,81,82}

Even though this information has been widely spread and easy to access, and even though it always discusses in depth the same COPD aspects, such as prevention, early diagnosis and clinical management, studies continue reporting difficulties in implementing clinical guidelines, often derived of lack of training and specific knowledge about the disease, particularly in Primary Care setting, on both physician and nursing levels.

We can point out the study by Rutschmann *et al*⁸³, where 455 primary care physicians and 255 hospital physicians completed a survey. Even though 75% of participants assumed an increase in COPD prevalence and incidence, and even one third of them acknowledged it as a public health issue, only 55% of them used spirometry as a criterion to define COPD, and only one third of them were aware of the GOLD indications published so far.

More recently, Glaab *et al*⁸⁴ received a questionnaire completed by 486 Primary Care Physicians and 359 Pulmonologists. The current COPD classification described in GOLD for moderate and severe was only used by 36.2% and 23.4% of Pulmonologists, and by 32.1% and 20.2% of primary care physicians, respectively.

In Spain, out of 13 scientific societies which typically manage COPD patients, 53.8% report having work groups about the disease, and only 30.8% report having specific training programs in COPD within their educational offer.

This is particularly important if we take into account that COPD patients usually access the National Health System through the Primary Care level. A brief course lasting 13 hours about COPD and its diagnosis through spirometry increased the referral of persons with suspected COPD (with FVC and FEV₁ information) from 9% to 56%.⁸⁵

Another indicator of the development degree for training in COPD can be found in the awarding system for continuing training activities by the Committee for Healthcare Professional Continuing training, by the Ministry of Health and Social Policy. This awarding system shows that, since 1998, 111 training activities with the term COPD in their title have been assessed.

Out of these, 56 were targeted to medical staff, 23 to nursing staff, and 16 were targeted to both professional levels at the same time. Seven courses for

pharmacists were assessed, as well as eight for Specialized Care nurses, and another one for all types of healthcare staff within the Specialized Care level.

Also, 83 training activities in which the term “spirometry” appeared on the title were assessed. 26 were targeted to medical staff, 28 to nursing staff, and the remaining 29 were targeted to both levels without distinction.

2.5.2. Objectives and Recommendations

General Objective 6

To promote training for healthcare professionals in order to adequately meet the needs of COPD patients, and to encourage a comprehensive and integrated approach to the disease, and coordination between Primary and Specialized Care.

Specific Objectives

- 6.1.** To have a Continuing training Plan in Autonomous Communities for all professionals who take care of COPD patients.

Training Contents

This plan will include some minimum contents, which will depend upon the group of professionals it is targeted to.

- Primary Care Nursing Professionals, as well as those working in Nursing Homes:
 - Promotion of healthy lifestyles, smoking prevention, and conducting smoking cessation programs.
 - COPD early detection and adequate conduction of forced spirometry tests.
 - Assessment of COPD patients’ needs, as well as those by their relatives, and implementation of a care plan through the use of conceptual models and validated taxonomical classifications.
 - Exacerbation prevention according to COPD stage and comorbidities.
 - Health education for patients and relatives, and increase in their autonomy.
 - Training in inhalation technique.
 - Respiratory care.
 - Review of therapeutic compliance and inhalation technique.
 - Management during end of life (palliative treatment, final decisions, support for grief and bereavement, etc.).

- Specialized Care Nursing Professionals who are involved in the care process for COPD patients:
 - Non-invasive mechanical ventilation.
 - Multidimensional assessment.
 - Assessment of COPD patients and relatives’ needs, and implementation of the care plan through the use of conceptual models and validated taxonomical classifications.
 - Treatment for smoking cessation.
 - Overall assessment of complex patient, working plan, coordination, and assessment of results.
 - End of life management (palliative care, final decisions, etc.).
 - Management of acute events.
- Primary Care Physicians
 - Complementary training in COPD.
 - Prevention and management of exacerbations.
 - Smoking prevention, and treatment for smoking cessation.
 - Early diagnosis of the disease.
 - Interpretation of forced spirometry.
 - Treatment in stable and acute stages.
 - End of life management (palliative care, final decisions, etc.)
- Emergency Unit Physicians:
 - Early diagnosis of the disease.
 - Interpretation of forced spirometry.
 - Treatment in stable and acute stages.
 - Complementary training in COPD.
- Specialized Care Physicians who are involved in the care process for COPD patients:
 - Non-invasive mechanical ventilation.
 - Multidimensional assessment.
 - Treatment for smoking cessation.
 - End of life management (palliative care, final decisions, etc.)
- Rehabilitation and physiotherapy professionals
 - This plan will at least include contents of peripheral musculature training programs.

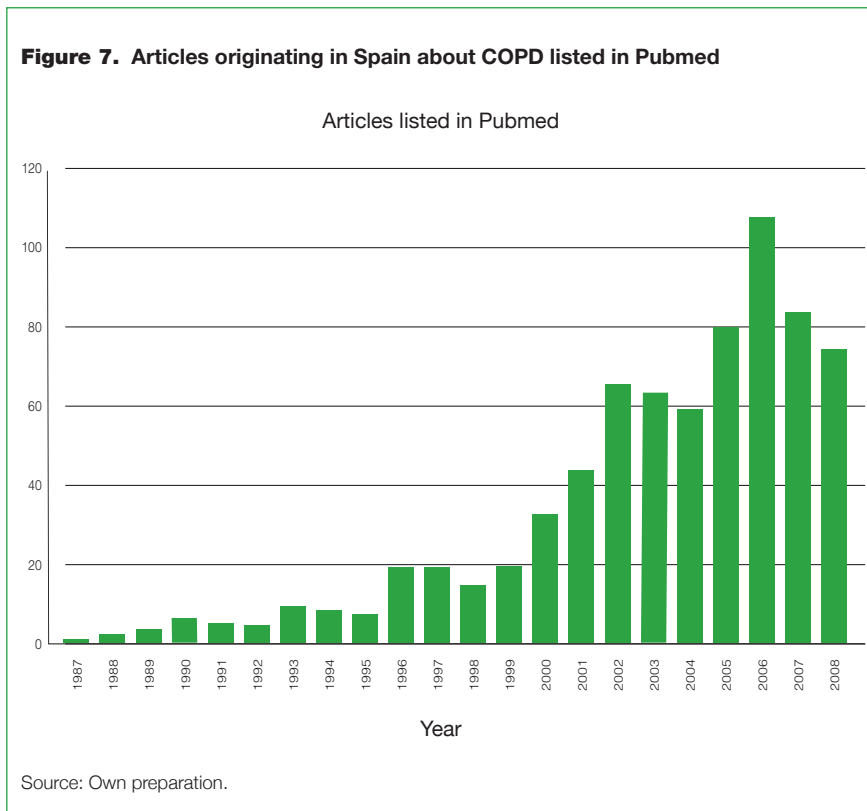
Recommendations:

- To conduct a study about COPD training needs in the Autonomous Communities.

2.6. Research

2.6.1. Analysis of the Situation

In recent years, the number of articles listed in Pubmed with the acronym EPOC (COPD, in English) originating in Spain has been increasing, with a total number of 757 articles. This increase has been observed in a more significant way since the beginning of the new millennium (Figure 7).



During 2006, SEPAR awarded 37 grants, 12 of which had COPD as study matter. This represented 32.4% of all projects presented. Studies focused on cancer represent 18.9%, the second most researched disease.

From 2004 to 2007, CIBERES received 96 requests for projects, and 38 of these were funded. During these 3 years, funded projects associated with COPD reached the total sum of 2,533,443 €. Their allocation can be observed in the following table:

Table 18. Amount funded by CIBERES and number of COPD research projects

Autonomous Community	Amount funded	No of projects
Andalusia	104,544	2
Balearic Islands	419,970	5
Canary Islands	98,033	2
Castile and Leon	108,100	1
Catalonia	1,334,086	19
Madrid	263,033	5
Basque Country	205,678	4
Total	2,533,444	38

Source: ISCIII

During the years 2006 to 2008, the Instituto de Salud Carlos III funded 47 research projects associated with COPD, for a total amount of 2,379,153 euros.

The following table is intended to compare the total number of projects funded in said years for healthcare research and healthcare technology assessment, vs. those specifically for COPD.

Table 19. Research Projects funded by the ISCIII

HEALTHCARE RESEARCH PROJECTS 06-08				
PI TOTAL	REQUESTED	FUNDED	% SUCCESS	AMOUNT + %
2006	1,840	586	31.85	51,972,533
2007	1,123	539	48.00	53,534,066
2008	1,981	637	32.16	70,615,528
TOTAL	4,944	1,762	35.64	176,122,128
HEALTHCARE TECHNOLOGY ASSESSMENT PROJECTS (HTAs) 06-08				
ETES TOTAL	REQUESTED	FUNDED	% SUCCESS	AMOUNT + %
2006	424	124	29.25	5,087,741
2007	559	162	28.98	7,702,824
2008	576	198	34.38	8,812,091
TOTAL	1,559	484	31.05	21,602,656
HEALTHCARE RESEARCH PROJECTS 06-08 COPD				
PI COPD	REQUESTED	FUNDED	% SUCCESS	AMOUNT + %
2006	22	7	31.82	349,297
2007	10	5	50.00	392,436
2008	18	6	33.33	834,416
TOTAL	50	18	36.00	1,576,148
HEALTHCARE TECHNOLOGY ASSESSMENT PROJECTS (HTAs) 06-08 COPD				
ETES COPD	REQUESTED	FUNDED	% SUCCESS	AMOUNT + %
2006	13	10	76.92	330,028
2007	11	8	72.73	318,049
2008	14	11	78.57	154,928
TOTAL	38	29	76.32	803,004
TOTAL COPD PROJECTS 06-08				
TOTAL COPD	REQUESTED	FUNDED	% SUCCESS	AMOUNT + %
2006	35	17	48.57	679,324
2007	21	13	61.90	710,484
2008	32	17	53.13	989,344
TOTAL	88	47	53.41	2,379,153

Source: ISCIII

2.6.2. Objectives and Recommendations

General Objective 7

To promote epidemiological, basic, clinical and translational research in terms of prevention and comprehensive care for COPD.

Specific Objectives:

- 7.1.** To promote, through their inclusion in official invitations to tender for research projects, interdisciplinary lines of research prioritizing COPD.
- 7.2.** To implement measures to promote the creation of reputable networks of research centers and groups highly qualified in COPD.
- 7.3.** To promote Primary Care research about COPD care.

Priority Lines

- Research about new models of care for COPD exacerbation (continuity of care, telemedicine, Chronic Program or similar ones, etc.).
- Research about innovative models of care and results in quality of life, dependence, safety, accessibility and emotional aspects.
- Programs of improvement in quality of care.
- Consequences focused on patients (Patient-reported outcomes).
- Repair mechanisms in COPD.
- Study of etiopathogenic mechanisms in exacerbation.
- Etiopathogenesis of COPD extra-pulmonary manifestations.
- Biomarkers.
- Ageing, COPD and comorbidity.
- Lung development and COPD.
- Cancer and COPD.
- COPD and cardiovascular alterations.
- Research for alternative models in COPD diagnosis.
- Oxygen therapy with portable device in COPD.
- Role of home respiratory rehabilitation.
- Pharmacoeconomics. Cost-efficacy and cost-utility studies for various alternative options in pharmacological and non-pharmacological treatment.
- Alternative options to conventional COPD treatment. Models of care. Identification of patient groups.
- Research about COPD prevention.

3. Evaluation and Information Systems for the Strategy

Introduction

Evaluation, understood as a systematic and continuous process which designs, obtains and provides information which is scientifically valid, reliable, and useful for decision making, represents an essential element within the National Health System COPD Strategy, and is considered an integral part of it, in order to improve the quality of the National Health System.

The person who suffers COPD is, undoubtedly, the great beneficiary of this evaluation, as this contributes to favor, encourage and improve the comprehensive care for COPD, through control and optimization of the objectives put forward by this strategy, which include:

- Epidemiological situation of COPD.
- Resources available in every Autonomous Community in order to face this disease.
- Any actions developed at regional level for strategy implementation.

The correct and timely conduction of the evaluation allows checking the level of achievement of those proposed objectives, to establish any adequate correct guidelines, to know the progress made by each Autonomous Community, and to verify the Strategy's efficacy. The evaluation must show the road being covered, with its failures and successes, until an improvement plan may finally be drafted.

In order to achieve all this, this Strategy counts on the essential commitment by all Autonomous Communities; besides, different indicators have been prepared by consensus, which will allow collecting and processing all necessary information for its consequent evaluation.

The sources of information available to this Strategy are: the Health Information Institute, which will be actively involved through its standardized registry (CMDB), the Primary Care Information Service, and the National Health Survey. As an additional tool for data collection, in order to compare what has been achieved vs. what has been proposed, we will have a questionnaire for data collection self-completed by the Autonomous Communities.

What the National Health System and the Autonomous Communities intend to achieve with all this is: efficacy, efficiency and effectiveness of the

Strategy in COPD. To this end, all necessary data must be collected through measurement of indicators, which allows comparing them with the desired results, and finally correcting deviations, if any, through improvement programs.

A) Quantitative Indicators

Specific Objective of Primary Prevention 1.1

Percentage of smokers in persons over 15-year of age

- Formula: $[a / b] * 100$
 - a) Number of persons studied who are over 15 years of age, and who declare they smoke at the time of the interview.
 - b) Total number of persons studied who are over 15 years of age.
- Definitions:
Any person who uses tobacco daily, regardless of quantity, will be considered a smoker.
- Source of Information:
National Health Survey. MHSP Breakdown:
By Autonomous Community and gender.
- Periodicity:
Triennial

Specific Objective of Primary Prevention 1.2

Percentage of smokers within the 16-to-24 age range

- Formula: $[a / b] * 100$
 - a) Number of persons studied who declare they smoke at the time of the interview, with ages within the 16-to-24 range.
 - b) Total number of persons studied with ages within the 16-to-24 range.
- Definitions:
Any person who uses tobacco daily, regardless of quantity, will be considered a smoker.
- Source of information:
National Health Survey. MHSP
- Breakdown:
By Autonomous Community and gender.
- Periodicity:
Triennial.

Specific Objective of Primary Prevention 1.3

Average age of initiation in smoking

- **Formula:**
Median of ages declared as initiation in smoking, by persons studied who are over 15 years of age, and who declare they smoke at the time of the interview.
- **Definition:**
Any person who uses tobacco daily, regardless of quantity, will be considered a smoker.
- **Source of information:**
National Health Survey (ENSE).
- **Breakdown:**
By Autonomous Community and gender
- **Periodicity:**
Triennial

Specific Objective of Primary Prevention 1.6

Healthcare centers with smoking cessation programs

- **Formula:** $[a / b] * 100$
 - a) Number of healthcare centers where there are programs for smoking cessation.
 - b) Number of healthcare centers.
- **Source of information:**
Autonomous Community and SIAP (Primary Care Information System)
- **Breakdown:**
Autonomous Community.
- **Periodicity:**
Annual.

Specific Objective of Early Detection 2.1

Primary Care Centers with Spirometer

- **Formula:** $[a / b] * 100$
 - a) Number of Primary Care centers where there is a spirometer.
 - b) Total number of Primary Care Centers.

- Note: The number of centers where there is at least one spirometer will be included.
- Source of information:
Autonomous Community.
- Breakdown:
Autonomous Community.
- Periodicity: Annual.

Primary Care Centers with a responsible person and spirometry circuit

- Formula: $[(a) / (b)] * 100$
 - a) Number of Primary Care Centers where there are a responsible person and a circuit.
 - b) Total number of Primary Care Centers.
- Definition:
Number of Primary Care Centers where there is a spirometry circuit in written and the identification of the person responsible for it.
- Source of information:
Autonomous Community.
- Breakdown:
Autonomous Community.
- Periodicity:
Annual.

General Objective 3

Overall mortality rate by COPD

- Formula: $[(a) / (b)] * 100$
 - a) Number of persons who die due to COPD in one year.
 - b) Population in that year.
- Definition:
It includes deaths codified with references J40 - J47 from the International Classification of Diseases (ICD) versión 10.
Rates adjusted by age will be estimated, using the European population as standard population.
- Source of information:
Deaths according to their cause (INE) and own preparation (MHSP).
- Breakdown:
Autonomous Community.

- Periodicity:
Annual.

Rate of early mortality by COPD

- Formula: $[a / b] * 100$
 - a) Number of persons under 75 years of age who die due to COPD in one year.
 - b) Population under 75 years of age.
- Definition:
It includes deaths codified with references J40 - J47 from the International Classification of Diseases (ICD) versión 10.
Rates adjusted by age will be estimated, using the European population as standard population.
- Source of information:
Deaths according to their cause (INE) and own preparation (MHSP)
- Breakdown:
Autonomous Community.
- Periodicity:
Annual.

Specific Objective for Secondary Prevention 3.8

Hospitals with respiratory rehabilitation programs

- Formula: $[a / b] * 100$
 - a) Number of hospitals with a respiratory rehabilitation program.
 - b) Total number of hospitals.
- Source of information:
Autonomous Communities.
- Breakdown:
Autonomous Communities.
- Periodicity:
Annual.

Specific Objective for Care in Acute Stage 4.4

Percentage of hospital re-admissions due to COPD

- Formula: $[b / a] * 100$
 - a) Number of patients aged 15 and over, who are re-admitted to

hospital within one year, after one hospitalization episode with a primary diagnosis of COPD.

b) Total number of patients aged 15 and over who are discharged from hospital with a primary diagnosis of COPD.

- **Definition:**

It includes any of 491, 494 and 496 categories from the International Classification of Diseases (ICD), version 9-MC, as primary diagnosis. Any unexpected admission (emergency admission) after a previous discharge, within 30 days after the previous discharge, will be considered a re-admission. This can be due to any reason (excepting those diagnosis included in diagnostic categories MDC 21: Injuries, poison and toxic effect of drugs; MDC 22: Burns, MDC 25: Multiple Trauma).

- **Source of information:**

Registry of hospital discharges (CMBD). MHSP

- **Breakdown:**

By Autonomous Community.

- **Periodicity:**

Annual.

- **Note:**

The condition of re-admission for the same patient in the same hospital is based on the identification of patients for that hospital and year, based on patient's record number, hospital code, date of birth, and gender. A series corresponding to a whole year is based upon the index hospitalizations occurred during the first 11 months of the year.

Specific Objective of Care in Acute Stage 4.5

Hospitals with non-invasive mechanical ventilation

- **Formula:** $[a / b] * 100$

a) Number of hospitals with non-invasive mechanical ventilation.

b) Total number of hospitals.

- **Definition:**

Number of hospitals with non-invasive mechanical ventilation equipment, monitoring devices, and staff trained in the adequate use of said devices.

- **Source of information:**

Autonomous Communities.

- Breakdown:
Autonomous Communities.
- Periodicity:
Annual.

Specific Objective of Care in Acute Stage 4.6

Hospitals with smoking cessation units or programs

- Formula: $[(a) / (b)] * 100$:
 - a) Number of hospitals with smoking cessation units or programs.
 - b) Total number of hospitals.
- Definition:
Number of hospitals which include smoking cessation within their portfolio of services.
- Source of information:
Autonomous Communities.
- Breakdown:
Autonomous Communities.
- Periodicity: Annual.

Specific Objective of Research 7.1

Number of research projects about COPD with public funding.

- Formula: Number of research projects about COPD with public funding in one year.
- Definition:
It includes all those projects developed through official funding systems by Health Authorities, either by the Central Government (through the ISCIII) or by the Autonomous Communities.
All new projects approved each year will be included, regardless of their funding terms.
- Source of information:
ISCIII, MHSP and Information Systems by the Autonomous Communities
- Breakdown:
None. NHS as a whole.
- Periodicity:
Annual,

Specific Objective of Research 7.3

Number of research projects about COPD in Primary Care with public funding

- **Formula:** Number of research projects about COPD in Primary Care with public funding in one year.
- **Definition:**
It includes all those projects developed through official funding systems by Health Authorities, either by the Central Government (through the ISCIII) or by the Autonomous Communities.
All new projects approved each year will be included, regardless of their funding terms.
- **Source of information:**
ISCIII, MHSP and Information Systems by the Autonomous Communities
- **Breakdown:**
None. NHS as a whole.
- **Periodicity:**
Annual.

B) Qualitative Indicators

Prevention and early detection					
Specific objectives	Included in healthcare plan	N.º conducted	N.º On-Going	N.º Assessed	Brief Description
1.4. To conduct inspections and other measures for the strict obedience of the law against smoking, as well as in terms of the levels of atmospheric contaminants and contaminants in the working place, as appear in current guidelines.					
1.5. To increase awareness among population and professionals about the relationship between tobacco, environmental contamination, exposure at the working place and COPD, and the consequences of this disease.					

Specific objectives	Included in healthcare plan	Included in management objectives	Measurement System	Assessed	Results (Include formula and data source)
1.6. To establish smoking cessation programs in primary care centers.					
2.2. To conduct, within preventive activities in adults, an early detection of COPD for persons over 40 years of age who present a history of smoking (current or in the past) superior to 10 packets/year (which is equivalent to smoking 20 cigarettes per day during 10 years) and with respiratory symptoms.					
2.3. To establish monitoring systems so that forced spirometries can be accessible and conducted with the adequate quality according to established criteria (See Appendix IV).					

Chronic patient care

Specific objectives	Included in healthcare plan	Included in management objectives	Measurement System	Assessed	Results (Include formula and data source)
3.1. To conduct a multidimensional COPD assessment to patients with moderate / severe disease.					
3.2. Patients diagnosed with COPD will have from the beginning a nursing care plan which will increase their training and autonomy for an effective management of the therapeutic regimen, and favor the prevention of complications, according to the criteria included in the table.					
3.3. To recommend all active smoking persons with a COPD diagnosis to quit smoking, offering smoking cessation programs at their primary care centre and/or referring them to specialized smoking cessation units.					

Specific objectives	Included in healthcare plan	Achieved	Description of measures		
3.4. To assess and, if needed, facilitate the reimbursement or co-payment of pharmacological treatment for smoking cessation to any COPD patient.					
Specific objectives	Included in healthcare plan	Included management objectives	Measurement System	Assessed	Results (Include formula and data source)
3.5. To determine, based upon clinical practice guidelines, quality criteria for the care process, and to conduct measurements upon it.					
3.6. To establish measures for monitoring pharmacological treatment adequacy.					
Specific objectives	Included in healthcare plan	Achieved	Description of measures		
3.7. To implement in a progressive manner measures for oxygen therapy and other home respiratory therapies which will allow patient's mobility and travels within and outside their Autonomous Community.					
Specific objectives	Included in healthcare plan	N.º of hospitals with rehabilitation program	N.º of centers with extension to primary care	N.º of centers with home care	Types of programs*
3.8. To set up structured programs for respiratory rehabilitation.					
* CSE will later conduct a categorization of said programs.					
Acute patient care					
Specific objectives	Included in healthcare plan	Achieved	Description of measures		
4.1. To implement clinical pathways, protocols or procedures for COPD exacerbation care, based on the best scientific evidence.					

Specific objectives	Included in healthcare plan	Included management objectives	Measurement System	Assessed	Results (Include formula and data source)	
4.2. To conduct an assessment and monitoring of pharmacological and non-pharmacological treatment for patients with exacerbations.						
4.3. To establish systems which will allow Primary Care Centers to receive a report with treatment and care plan when COPD patients are discharged from hospital.						
4.7. To provide a short-term care continuity by the Primary and/or Specialized Care team, after a severe exacerbation.						
Palliative care						
Specific objectives	Included in healthcare plan	Achieved	Description of measures			
5.1. To encourage the application of bioethical principles and involve the COPD patient in the process according to principles, values and contents in the Patient's Autonomy Law, and the legislation currently in force in different Autonomous Communities.						
Specific objectives	Included in plan		Included in management objectives			Brief description of actions conducted, dates of implementation and, if any, measurement systems, assessment and results
	Health care	Specific	2009	2010	2011	
5.2. To establish procedures for identification, action and assessment of the palliative care process in patients with COPD in advanced terminal stage, which include information and registration systems.						

Specific objectives	Included in plan		Included in management objectives			Brief description of actions conducted, dates of implementation and, if any, measurement systems, assessment and results
	Health care	Specific	2009	2010	2011	
5.3. Patients with COPD in advanced or terminal stage will receive care in the palliative care system in their basic area and health zone, at home and/or specialized, and with such support teams as they require according with their needs and in the adequate moment, adapted to different situations and geographical areas.						
5.4. To implement in a progressive way a system of specific access to psychological and socio-familiar support for patients and relatives, which shall be specialized and adapted to their needs.						
Specific objectives	Included in healthcare plan		Achieved			Description of measures
5.5. To establish support programs for caregivers, providing information about care services, resources and materials, which will facilitate and speed up bureaucratic proceedings within what has been established by the National Health System Palliative Care Strategy.						
5.6. To carry out awareness and information activities for general population and professionals, about palliative care objectives, principles and resources.						
5.7. To establish continuous and specific training programs for Primary and Specialized Care professionals, so that they can meet adequately the needs of patients with disease in advanced / terminal stage and their families.			Complete Appendix 1-A Palliative Care Training			

Specific objectives	Included in healthcare plan	Achieved	Description of measures
6.1 To have a Continuing training Plan in Autonomous Communities for all professionals who take care of COPD patients.			Complete Appendix 1-B
Research			
Specific objectives	Included in healthcare plan	Achieved	Description of measures
7.1. To promote, through their inclusion in official invitations to tender for research projects, interdisciplinary lines of research prioritizing COPD.			Complete Appendix 1-C
7.2. To implement measures to promote the creation of reputable networks of research centers and groups highly qualified in COPD.			Complete Appendix 1-C
7.3. To promote Primary Care research about medical and nursing care for COPD.			Complete Appendix 1-C

Appendix 1-A: Continuing education activities in palliative care

Assessed period:

Please state the total number of activities (courses, workshops, conferences) approved by the national body or by the relevant Autonomous Community, the total amount of credits granted by the Agency, and the total number of participants.

Targeted to	Number	Credits	Participants
Primary Care Nurses			
Specialized Care Nurses			
Primary Care Physicians			
Emergency Unit Physicians			
Specialized Care Physicians			
Rehabilitation Professionals			
Other professionals			
Multidisciplinary Teams			

Appendix 1-B: Continuing education activities in COPD

Assessed period:

Please state the total number of activities (courses, workshops, conferences) approved by the national body or by the relevant Autonomous Community, the total amount of credits granted by the Agency, and the total number of participants.

Targeted to	Number	Credits	Participants
Primary Care Nurses			
Specialized Care Nurses			
Primary Care Physicians			
Emergency Unit Physicians			
Specialized Care Physicians			
Rehabilitation Professionals			
Other professionals			
Multidisciplinary Teams			

Appendix 1-C: Research activity report form

For projects associated with any of the objectives in this Strategy, the following data must be presented:

1. Specific Strategy objective the Project is associated with.
2. Project title.
3. Principal Investigator.
4. Total budget.
5. Source of funding (if managed by the ISCIII, state the file code).
6. On-going / completed / published and reference.

4. Good Practices

4.1. Primary Care activities for smoking prevention

Objective:

- To help preventing the initiation of smoking habit in school students.
- To inform the educational community (students, professors and families) about the problem represented by smoking, as well as about the resources available for smoking cessation in the basic zone healthcare center.
- To encourage the involvement by the educational community in smoking cessation groups.

Target population: Educational community in secondary education centers: students, families and professors.

Setting: Healthcare area.

Description: Activities are conducted in the educational center, by healthcare center professionals, with the collaboration of education professionals. These activities are divided into:

- Information activities: informative sessions, workshops with students, and conferences.
- Intervention activities: Offer of help to quit smoking at individual and group level. Co-oximetries. Assessment and referrals.
- Contest offers: Poster contest, comic strip and short story contest.

Evaluation:

	2005-06	2006-07	2007-08
Healthcare centers involved	19	17	22
Educational centers involved	25	14	32
Activities conducted in the educational center	197	60	125
Workshops	132	34	91
Educational centers involved	25	11	27
Healthcare staff involved		21	56
Students involved	3,853	1,011	2,896
Participant teachers		46	91
Information tables	28	12	30
Educational centers involved	19	10	24
Healthcare staff involved		22	48
Co-oximetries	1,472	654	1,681
Selection Process	9	7	10
Educational centers involved	5	5	7
Students involved	27	11	36

Institution and centers responsible for the intervention or program: Majorca Primary Care Management. Servei de Salut de les Illes Balears (Ib-Salut). Conselleria de Salut i Consum i Conselleria d'Educació.

Bibliographic references:

- David Medina Bombradó, Bartomeu Seguí Prat. Pla sobre el tabaquismo a les Illes Balears 2003-2007. Conselleria de Salut i Consum. Govern de les Illes Balears. 2003
- Ángel Arturo López González. Guía para un abordaje integral del tabaquismo en la empresa. Conselleria de Salut i Consum. Govern de les Illes Balears. 2005
- José Manuel Valverde, Jesús Milán, Helena Girauta, Begoña Uriarte. Guía de intervención grupal para el abordaje del tabaquismo en Atención Primaria. Conselleria de Salut i Consum. Govern de les Illes Balears. 2005

Contact: hgirauta@ibsalut.caib.es

Helena Girauta Reus.

Technical Department Nurse. Coordinator of Mallorca P.C. Smoking Cessation. Responsible for Primary Care Smoking Cessation. Ib-Salut

4.2. Efficacy of a Screening Program for COPD Diagnosis

Objective: To assess the efficacy of an active search plan (ASP) for people with COPD in the primary care setting, and in people with high risk of suffering this disease.

Target population: Patients over 40 years of age and a cumulative smoking history (>10 packages/year) who visit their PCP for any other reason, in the Primary Care Setting.

Setting: Healthcare area.

Description: Prospective case-control study, on a cohort of patients who attended consecutively, for any reason and during a 6-month period, a Primary Care Center. Four PC center physicians took part in the ASP. A spirometry test was conducted to those patients ≥ 40 years and a history of smoking ≥ 10 packages/year (cases). The control group involved patients who met the same inclusion criteria, who were requested a spirometry test during the same period of time by the remaining physicians in the center ($n=4$), who were not recruited in the ASP. COPD was defined as a $FEV_1/FVC < 0.70$ after bronchodilator. Previous COPD diagnosis were excluded. Results are analyzed in terms of spirometry quality.

Evaluation: 244 patients are included, 210 of which met the inclusion criteria (190 (90.5%) cases and 20 (9.5%) control), out of which 171 (81.4%) were males and 39 (18.6%) were females, with an average age of 60±11 years and a tobacco use of 36±22 packages/year. Both groups showed no differences in age or smoking habits, however the control group presented higher symptomatology (p<0.001) and higher previous pharmacological treatment (p<0.001). The ASP achieved 55 (28.9%) new COPD diagnosis, out of which only 4.8% were receiving previous treatment. On the other hand, 12 (60%) COPD cases were detected in the control group, and 60% of them were already using inhalers. Only 104 (54.8%) spirometry tests were considered to have moderate-high quality. This table shows the proportion of COPD patients, according to age groups, within persons involved to the ASP.

	Age groups				Total	P
	40-49y	50-64y	65-79y	≥80y		
No. Of COPD						
(All spirometry tests, n=190)	10	18	21	6	55	
n = 190)	(22.2%)	(25.0%)	(32.8%)	(66.7%)	(28.9%)	0.021
No. Of COPD						
(Good quality spirometries, n=104)	7	12	16	5	40	
	(35.0%)	(27.9%)	(45.7%)	(83.3%)	(38.5%)	0.038

Conclusions: The COPD ASP multiplies by almost 5 times the number of COPD diagnosis in Primary Care. In patients with ≥40 years of age and ≥10 packages/year, the prevalence of not previously diagnosed COPD is 38.5%. However, only slightly over half of spirometry tests are considered to be of good quality.

Note: These are preliminary results. Currently, a publication is expected which includes two Primary Care centers and a higher number of assessed cases.

Institution and centers responsible for the intervention or program: Department of Health 08 in the Community of Valencia (Pulmonology Unit-Internal Medicine Department in the Hospital General de Requena) and Primary Care Center in Requena, Valencia.

Contact:

Juan José Soler Cataluña.

Pulmonology Consultant.

Pulmonology Unit. Internal Medicine Department. Hospital General de Requena

jjsoler@telefonica.net

Bibliographic references:

- Soler-Cataluña JJ, Martínez-García MA, Quiles L, Masmano C, Santos V, Fortea J. Eficacia de un plan de cribado para el diagnóstico de la EPOC. Arch Bronconeumol 2007; 43 (Espec Congr):46-47.

4.3. To detect the degree of COPD Clinical Guidelines implementation in our setting

Objective: To assess whether COPD diagnosis and treatment have been modified in our setting since clinical practice guidelines were published.

Target population: Population with COPD diagnosis seen in Primary Care and Pulmonology.

Setting: Autonomous Community.

Description: Many Clinical Practice Guidelines (CPG) which focus specifically on COPD diagnosis and treatment have been developed during the last 5 years. However, their degree of application and efficacy have not been proved. This study is based on a comparative analysis of two observational transversal studies, conducted in the year 2000 (IDENTEPOC) and in the year 2005 (VICE). The main clinical guidelines have been published between these two dates, therefore it is possible to analyze their impact upon real life, upon COPD diagnosis as well as COPD treatment in our setting. A comparative analysis between outcomes was conducted to this end.

Evaluation:

- *IDENTEPOC Study:* During the year 2000, in Primary Care, 38.6% of patients were initially diagnosed with COPD by clinical and/or radiologic criteria, without any functional confirmation, vs. 10.2% in the Pulmonology setting ($p < 0.001$). In 2005, 31% of those subjects who had been diagnosed with COPD through a spirometry test in Primary Care, and 14% in Pulmonology, did not show an obstructive pattern.
- *VICE Study:* In 2005, only 4.1% of patients were receiving a specific treatment for smoking, and the implementation of rehabilitation programs was not very relevant. No major differences were observed in terms of pharmacological treatments between both studies. The main difference in 2005 was a wide use of tiotropium and combinations of beta2agonists with inhaled corticosteroids. Even though both series show a slight adaptation of treatment according to severity, prescription habits are not adjusted to criteria established in the guidelines.

Conclusions: The outcomes of this analysis show that, even though Clinical Practice Guidelines might be useful tools to improve the clinical management of COPD, the lack of relevant qualitative changes in COPD management after their publication suggests that their current impact upon clinical practice is not very relevant, which justifies taking specific measures for their implementation.

Institution and centers responsible for the intervention or program: Pulmonology Department. Hospital Universitario Guadalajara.

Contact: Dr José Luis Izquierdo Alonso. Head of the University Hospital Pulmonology Department. jlizquierdo@sescam.org

Bibliographic references:

- Izquierdo JL, De Miguel J. Economic Impact of pulmonary drugs on direct costs of stable Chronic Obstructive Pulmonary Disease. *Journal of COPD*. 2004; 1: 215-223.
- De Miguel Díez J, Izquierdo Alonso JL, Rodríguez González Moro JM, De Lucas Ramos P, Molina París J. Tratamiento farmacológico de la EPOC en dos niveles asistenciales. Grado de adecuación de las normativas recomendadas. *Arch Bronconeumol* 2003; 39: 195-202.
- Izquierdo JL, Rodríguez JM, de Lucas P, Martín Centeno A, Gobartt E. ¿Ha cambiado el manejo de la EPOC en España? Resultados de un estudio multicéntrico comunitario (VICE). *Rev Clin esp*. 2008; 208: 18-25.
- Izquierdo Alonso JL, Rodríguez González-Moro JM. Tratamiento de la enfermedad pulmonar obstructiva crónica leve. *Medicina Clínica*. 2008; 130; 661-665.
- Peces Barba G, Barberá JA, Agustí A, Casas A, Casanova C, Izquierdo JL, et al. Guía clínica SEPAR_ALAT de diagnóstico y tratamiento de la EPOC. *Arch Bronconeumol*. 2008; 44: 271-281.

4.4. Respiratory Rehabilitation in COPD. Pilot Study in the Hospital Virgen del Camino, Pamplona

Objective: To increase the use of respiratory rehabilitation in the hospital setting with existent structures, exporting the program used in the Hospital Virgen del Camino (HVC) to those patients who meet the inclusion criteria in the rest of public hospitals in Navarre.

Target Population: Initially targeted to the HVC reference population.

Setting: Autonomous Community.

Description: Development of the pilot stage of a rehabilitation program for patients with stable (without exacerbations) moderate-severe COPD, with grade II, III dyspnea and motivated, who have quit smoking or are in process of joining a smoking cessation program. Exclusion criteria were also described.

Patients were recruited in the Pulmonology office, where diagnostic tests for inclusion and exclusion were conducted.

Consequently, patients were assessed at the HCV Medical Rehabilitation Unit, a quality of life questionnaire was completed, and a group education session was conducted on the first day of treatment.

Sessions were conducted in groups of 6 patients during 8 weeks, 3 weekly one-hour sessions, or 12 weeks with 2 weekly one-hour sessions. Aerobic resistance and stress exercises were conducted (isotonic exercises), for lower as well as upper limbs.

Evaluation: *Evaluation of each patient after the sessions:* Patients were asked to complete again the quality of life questionnaire, and they are assessed again at the Pulmonology Office, including a new walk test and Respiratory Frequency Tests (RFTs).

Training Maintenance at Home: Each patient is provided with a personalized program prepared by HVC Rehabilitation, which is included in the department's discharge report for control and supervision by their PCPs.

Evaluation of the pilot stage (5-12 months after initiation): Required for the pilot stage to become a NHS ordinary activity.

INDICATOR	2008	2009	2010
– Number of patients included in the Respiratory Rehabilitation Program	40	75	100
– % of COPD patients with a Physical Activity personalized program.	10%	20%	30%
– % of patients who comply with the physical activity program.	40%	40%	40%
– COPD patients who have received recommendations for Physical Activity within a structured program	100	150	200
– % of patients with improvement in the 6-minute walk test	50%		
– % patients with improvement in the QLC (quality of life questionnaire)	50%		

Institution and centers responsible for the intervention or program: Pulmonology and Rehabilitation Departments Hospital Virgen del Camino

Contact:

Javier Hueto.

Head of the Pulmonology Department.

jhueto@cfnavarra.es

4.5. Multidisciplinary program coordinated between Primary Care and hospitals, for an improvement in COPD care: COPD Procedure

Objective:

- To improve the quality of healthcare for COPD patients, by means of a more effective coordination between Primary Care and Specialized Care.
- To unify criteria for assessment, treatment and follow-up, regardless of the area or healthcare center involved.
- To rationalize the application of available material and human resources.
- To promote healthy life habits among the non-affected population, in order to prevent new cases from appearing.

Target population: Patients with COPD or at risk of suffering COPD from the PCS Right area (reference hospital, Hospital de la Santa Creu i Sant Pau)

Setting: Healthcare area.

Description: *The COPD Procedure Project* is a set of actions agreed upon by consensus in a multidisciplinary way by all healthcare professionals of said area in Barcelona who see COPD patients. Specifically, it includes: hospital and area Pulmonologists, Primary Care physicians, Internal Medicine, Hospital Emergency, palliative care, hospital and Primary Care nurses, as well as liaison nurses, pharmacists and clerical staff. The project consists of:

1. Consensus by all professionals about the main diagnostic and therapeutic actions. A guideline book was edited, as well as a reduced pocket-sized version with the essential items, one specifically for hospital professionals and another one for Primary Care.
2. Creation of specific care circuits for specific actions (frequent hospital admissions, patient with home ventilation, respiratory rehabilitation program, coordination between care levels after hospital discharge), with mixed participation by professionals from both care levels.
3. Specific training program for Primary Care physicians and nurses, and hospital physicians (Pulmonology, Emergency, and Internal Medicine).
4. Program for training, follow-up and quality control for spirometry in Primary Care, based on the Pulmonary Function Unit in the Hospital Pulmonology Department.
5. A common education program for patients in primary and specialized care.
6. An agreement for drug prescription by all professionals, including hospital pharmacists and Primary Care.

7. Setting up a software program for COPD patients' follow-up by Primary Care, incorporated to the usual software used by PCPs throughout Catalonia (e-CAP).
8. Inclusion of the project within those objectives with economic incentives (Direction by Objectives –DPO–) in Primary Care (physicians and nurses).

Evaluation:

Its objective is to determine the efficacy and impact caused by the intervention upon said healthcare area. This is a quasi-experimental study, with an evaluation or data collection, before and after the intervention, at two years of its implementation. A sample of COPD patients is used as control group; these have been randomly selected, but they come from another healthcare area in Barcelona, the "Mountain PCS", where the COPD Procedure has not been implemented.

Information is collected at two levels:

- Based on the clinical-administrative systems in those healthcare centers involved.
- Prospective data collection in a cohort of 416 randomly selected COPD patients.

The primary variables in the study are: use of healthcare services, particularly hospital resources (frequent visits to Emergency and hospitalization by exacerbation) and patient's quality of life (assessed through the CRDQ questionnaire).

Data for the first analysis previous to intervention have currently been collected, and their analysis has begun.

Institution and centers responsible for the intervention or program: Hospital de la Santa Creu i de Sant Pau, Barcelona. 17 basic areas from the Dreta de l'Eixample PCS, Barcelona.

Contact: Dra Ingrid Solanes. Pulmonology Department in the Hospital de la Santa Creu i de Sant Pau, Barcelona. isolanes@santpau.cat.

Bibliographic references:

- V. Plaza, A. Antón, I. Bolibar, R. Güell, JA. de la Fuente, MA. LLauger, K. Naberán, J. Sanchis, I. Solanes y P. Valverde. PROCÉS MPOC. Programa multidisciplinar entre la Atención Primaria y el Hospital de la Santa Creu i Sant Pau de Barcelona para la mejora asistencial de la enfermedad pulmonar obstructiva crónica (EPOC). Ed. Servei Català de la Salut. 2006. Barcelona. ISBN: 84-393-7280-9. Depósito legal: B-44.329-2006.
- Bolibar I, Plaza V, Llauger MA, Amado E, Antón PA, Espinosa A, Domínguez L, Fraga MM, Freixas M, de la Fuente JA, Liguerra I, Medrano C, Peiro M, Pou MA, Sanchis J, Solanes I, Valero C, Valverde P, and the corp process study group. Assesment of a primary and terciary care integrated management model for chronic obstructive pulmonary disease. BMC Public Health 2009, 9: 68. <http://www.biomedcentral.com/1471-2458/9/68>.

4.6. Efficacy of a specific program for COPD patients with frequent exacerbations

Objective: To assess the efficacy of a specific program (SP) for COPD patients with frequent exacerbations.

Target population: COPD patients who suffer multiple exacerbations / hospitalizations.

Setting: Healthcare area.

Description: Prospective, randomized and controlled study at one year, comparing the SP efficacy vs. standard treatment (ST) in a group of patients with frequent exacerbations (3 or more episodes per year). This program involves conducting comprehensive and frequent clinical controls, accompanied by an educational program targeted to optimizing treatment, improving compliance, and encouraging self-care. Comparisons within and between groups are conducted for various parameters of care, dyspnea, health-related quality of life (HRQL), inhalation technique and pulmonary function.

Evaluation:

26 patients (all male) are included, with a median age of 73 ± 8 years and $43 \pm 15\%$ FEV1(%). Exacerbations requiring hospital care (visits to Emergency and/or hospitalizations) were reduced in both groups, by 24.4% ($p=NS$) in the ST group and 44.1% ($p=0.071$) in the SP group. Hospitalizations were reduced by 73.3% in the intervention group, while they were increased by 22% in the ST group ($p<0.001$). Hospitalization days were reduced by 77.3% in the SPG group, while they increased by almost twice in the ST group ($p=0.014$). Dyspnea, HRQL and inhalation technique were improved in both groups. FEV1 presented one out of 46 ml/year in the ST group, while it increased 10 ml/year for the SP group ($p=D/K$).

Therefore, using a simple program entails a significant reduction in number of hospitalizations, higher HRQL, and maybe better prognosis.

Institution and centers responsible for the intervention or program: Department of Health 08 in the Community of Valencia (Pulmonology Unit – Internal Medicine Department in the Hospital General de Requena).

Contact:

Juan José Soler Cataluña (see GP 4.2)

Bibliographic reference:

- Soler JJ, Martínez MA, Román P, Orero R, Terrazas S, Martínez-Pechuán A. Eficacia de un programa específico para pacientes con EPOC que presentan frecuentes agudizaciones. Arch Bronconeumol 2006; 42:501-508.

4.7. Home Care Program for Respiratory Patients (ADER)

Objective: To provide home treatment for chronic respiratory diseases with exacerbations after an early hospital discharge, so that patients can be more comfortable and the average hospital stay is reduced (increasing bed availability at hospital).

Target population: Patients with an exacerbation of chronic respiratory diseases, particularly COPD, which require hospitalization.

Setting: Healthcare area.

Description: In patients with COPD exacerbation, standard treatment is prescribed according to national and international guidelines. Once patients are stabilized, and no longer require intravenous treatment, 2-4 days after admission they are discharged from hospital (early), and they continue treatment at home until the acute episode is over. Patients are visited daily by a nurse, and in case of worsening, there is a consultation with the Pulmonologist. If worsening is severe, it will be decided to re-admit the patient to hospital. Once the exacerbation episode is over, a hospital Pulmonologist will discharge the patient, and refer him to hospital outpatient services or Primary Care.

Evaluation: Hospital stay was reduced (5.9 ± 2.8 versus 8.0 ± 5.1 days, $p < 0.001$). The re-admission rate was very low, 1%. Reduction in the average stay brought about higher bed availability.

Institution and centers responsible for the intervention or program: Pulmonology Department. Hospital Universitari Son Dureta. Palma Mallorca. Servei de Salut de les Illes Balears (Ib-salut). Conselleria de Salut i Consum.

Contact: Dr Ernest Sala

Bibliographic reference:

- Sala E, Alegre L, Carrera M, Ibars M, Orriols FJ, Blanco ML, Cárceles F, Bertran S, Mata F, Font I, Agustí AG. Supported discharge shortens hospital stay in patients hospitalized because of an exacerbation of COPD. *Eur Respir J* 2001; 17:1138-42.

4.8. National Clinical Audit of the Clinical Practice on Patients with exacerbations of COPD (AUDIPOC). Multicenter Pilot Study in seven Autonomous Communities

Objective: To describe the hospital mortality within 90 days in a cohort of patients admitted with COPD exacerbations (COPDe) and the variations among hospitals.

Target population: Hospital admission for COPD patients.

Setting: National study.

Description: Two approaches have been made in the studio. In the first one the admissions in the following hospitals were analyzed: Guadalajara, Clinic de Barcelona, 12 de Octubre de Madrid and Galdácano de Vizcaya. In the second approach the admissions in seven Autonomous Communities have been evaluated, among them Castile-La Mancha. Admissions for exacerbation of COPD have been studied between February, 5 and March, 16, 2007 in 30 public hospitals with admission of acute patients from six Autonomous Communities of Spain: Basque Country, Extremadura, Cantabria, La Rioja, Castile-La Mancha and Navarre, serving a population of 6,597,734 inhabitants.

Evaluation: 1203 patients were included: the average of age was 73.8 ± 9.7 years of age (range 27-96). The 89.3 % are male. The 5.74 % are not smokers and a in a 14.6 % data were not collected. The 93% were admitted from the Emergency Unit and the 55.6% were hospitalized in the Unit of Pneumology, and the 38.6% in the Unit of Internal Medicine. The co-morbidity was frequent, with a median average of Charlson Index of 2-5% (medium 2) and the researcher considered that a 43.1% of patients showed clinically relevant co-morbidity. The 9.9% of cases received ventilation support, the 60.5% of cases in conventional units of hospitalization.

A number of 57 patients (4.74%) died during the hospital stay. Mortality within 90 days was 9.62%. There were important differences among hospitals, with a range of mortality within 90 days between 0 and 26.7%, medium 9.4. The readmission rate was 37.1%, a range among hospitals from 15 to 80%, and 75% of the hospital readmissions were due to a new exacerbation of COPD. The conclusion is that the rate of mortality within 90 days of a 10% and readmissions 37% is high and the variations of mortality and readmissions among hospitals justify a national clinical audit.

Institution and centers responsible for the intervention of program: Unit of Pneumology. Hospital Universitario de Guadalajara.

Bibliographic References:

- Pozo P, Fernández-Francés J, Hueto J, Izquierdo JL, Melero C, Alvarez J. The Spanish national clinical audit. On COPD exacerbations (eCOPD). Pilot study: selection of study subjects. *European Respiratory Journal* 2008; supl 52. A543

Contact:

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4.9. Clinical Pathway for care of patients with COPD exacerbation who require hospitalization

Objective: To assess the initial performance of a clinical pathway (CP) for care of patients hospitalized due to COPD exacerbation.

Target population: Patients admitted due to COPD exacerbation to a first care level hospital.

Setting: Healthcare area.

Description: During a first stage, a CP was prepared for EPOC exacerbation (E-EPOC), adjusted to scientific evidence, adapted to the center, and by consensus with all participants. This CP consisted of the following:

a) a standardized (diagnostic and treatment) protocol, called “clinical guidelines”, b) temporary action patterns to rule care; c) sheet of variations; d) informative note for the patient, and e) satisfaction questionnaire. Every COPD patient who requires hospitalization due to E-EPOC should follow this CP. Exacerbations due to pneumonia, pulmonary embolism, pleural effusion and pneumothorax were excluded. A prospective study is conducted during the first 6 months since CP implementation. There is a record of number of deaths and intubations, ICU admissions, hospital stay and re-admissions (<30 days). Treatment received is also analyzed, its variations and the level of satisfaction by the patient. Results are compared vs. a retrospective series (RS) of all hospitalizations due to COPD seen in our hospital during the 6 months before PC implementation.

Evaluation: The prospective series includes 50 admissions generated by 45 patients, all of them male, with a median age \pm SD of 74 ± 8 years. The CP was followed in 19 admissions (38%), guidelines were applied in 8 cases (16%), and no protocol was followed in 23 cases (46%). The RS includes 81 admissions corresponding to 66 patients, one female (1.5%) and the rest of them males (98.5%) aged 73 ± 11 years. One patient (5.3%) died in the CP group, while there were 6 deaths (7.4%) in the RS group (NS). Seven (8.6%) patients were admitted to ICU, and five (6.3%) required intubation in the RS. In the CP group, no intubation or ICU admission were required (NS). The length of hospitalization was shorter in the CP group, but without reaching significant levels (5.8 ± 3.3 vs 6.5 ± 4.6 days). Among discharged cases, the re-admission rate was similar in both groups (5.5% in CP vs. 5.7% in RS, NS). In the CP group, antibiotic and inhaler use was reduced by 20.5% and 13.5%, respectively, though no statistical signification was achieved. The total number of variations was 108, most of them attributable to healthcare staff (57.5%). The satisfaction level was high, with a global score of 85.4%.

Conclusions: The initial application of a CP for patients hospitalized due to COPD, in our center, seems to be associated (though no significant rates were achieved) with a lower number of major complications (intubations and admissions to ICU), with a shorter hospital stay, a lower use of antibiotics and inhalers, and a high level of satisfaction. However, compliance rate is still very low, and there is a high proportion of variations; therefore, the procedure is still far from being established.

Institution and centers responsible for the intervention or program: Department of Health 08 in the Community of Valencia (Pulmonology Department – Internal Medicine Unit in the Hospital General de Requena)

Contact: Juan José Soler Cataluña (see BP 4.2)

Bibliographic reference:

- Soler JJ, Donat Y, Haya C, Martínez MA, Román P. Vía clínica para la atención del paciente con EPOC agudizado que precisa ingreso hospitalario: resultados iniciales. Arch Bronconeumol 2003; 39 (Supl 2): 66.

4.10. Pulmonology Day Clinic

Objective: To create a new hospital unit, the Pulmonology Day Clinic, to provide fast care within the hospital setting for patients with chronic respiratory conditions with exacerbation, particularly COPD.

Target population: Patients with chronic respiratory disease already diagnosed by the Pulmonology Department, and with an open patient's record in the hospital, who present exacerbation without any signs of severity (RF > 30 bpm, use of accessory musculature, hypotension, alteration of level of consciousness, etc.)

Setting: Healthcare area.

Description: Creation of a unit where patients are seen from Monday to Friday, from 8 a.m. to 3 p.m., within the hospital, adjacent to the standard hospitalization area, and formed by two rooms (office and examination room, and treatment room). A full-time nurse and a part-time Pulmonologist will see patients in this unit. Patients can be referred to it (always through telephone contact) in two ways: the Primary Care Physician who sees patients regularly can refer them for assessment, or patients themselves can request an appointment, through a contact telephone number that will be provided to all chronic respiratory patients who are typically seen at the Pulmonology Department.

Before initiating any activity in the unit, there were meetings with Primary Care physicians, in order to explain its operation and criteria for referral.

Evaluation: Retrospective analysis, describing the first 168 consecutive patients seen at the unit.

Median age was 67 ± 14 years (range: 13-91). Thirty-eight patients had not been admitted within the last five years, the rest had an average of 3.5% hospital admissions during this period (27 patients had been admitted five or more times during the last five years). Sixty-one patients had not visited Emergency during the last year, the rest had visited Emergency an average 2.3 times during this period of time (22 subjects were seen three or more times in the Emergency Unit).

The most frequent diagnosis (64%) was chronic airflow obstruction (COPD or asthma). Patients stayed in the unit for a median 1.4 ± 0.9 hours (0.5 to 5 hours) (138 patients stayed in the unit less than three hours). 19% of cases presented $\text{SaO}_2 < 90\%$ at arrival. The most commonly used treatments were bronchodilators (generally administered by nebulization) and oxygen therapy.

After being seen at the unit, 158 patients were discharged and sent home, and the remaining 10 were admitted to hospital. In this second group, the most frequent diagnosis at discharge from the unit was chronic airflow obstruction (CAO) (six cases), followed by respiratory failure with unspecified cause (two cases), pneumonia (one) and amyotrophic lateral sclerosis (one). Seven out of 10 hospitalized patients had not visited Emergency during the last year, and six had not been hospitalized during the past five years.

In conclusion, the majority of patients seen in the unit presented a previous profile of high use of hospital resources. The most frequent condition is CAO. The high majority of cases are solved in less than 3 hours, and 94% of patients are discharged and sent home. Hospitalized patients are not, overall, those who present a past history of higher use of hospital resources. Summing up, this is an effective system to manage chronic respiratory conditions, which allows outpatient management for most cases seen, despite a quite significant proportion of respiratory failure at arrival.

Institution and centers responsible for the intervention or program: Pulmonology Department. Complejo Hospitalario Xeral-Calde (Lugo)

Contact:

M^a Camino Muñiz Fernández.

Pulmonology Department. Complejo Hospitalario Xeral-Calde (Lugo)

ma.camino.muñiz.fernandez@sergas.es

Bibliographic reference:

- López Villapún ME, Golpe Gómez R, Pérez de Llano LA. Hospital de día en neumología. Experiencia de un programa piloto. *Pneuma* 2008;4(3):132.

4.11. Continuity of Care Program for Advanced Chronic Respiratory Patients. RESC Program

Objective:

- To aim for a comprehensive and multidisciplinary care, continuity of care, and coordination between different care levels for advanced COPD.
- To improve quality of life in advanced COP, and patients' autonomy through dyspnea improvement, exercise capacity, patients' education about their disease, and the optimal use of healthcare resources and technologies: respiratory rehabilitation program.
- To preserve continuity of care and access to the most adequate resources through the Day Hospital Unit, the Liaison Nurse, and support to home care through a team of Respiratory-ESAD.
- To protocolize the approach to smoking habits, not only with the objective of smoking cessation, but also for reduction of use and damages, according to the cases.
- During the terminal stage of the disease, to address patients' needs, as well as the needs of those around them, from the perspective of palliative care programs.
- To record the characteristics of patients and care activity, and evaluate them in order to gain a higher knowledge of advanced COPD and its assistential needs.

Target Population: Advanced COPD patients who are highly dependent and frequent users of healthcare services, and who meet one or more of the following criteria:

- Requiring two or more hospitalizations during the last year.
- With chronic respiratory failure and home oxygen, or requiring any other healthcare technology: non-invasive ventilation, aerosol therapy, etc.
- Patients with persistent dyspnea, despite following standard treatment.
- Requiring special or individualized physiotherapy techniques.
- Terminal stages of the disease. Palliative care.

Setting: Autonomous Community.

Description: The RESC Program is a hospital-based continuity of care program conducted at the Hospital Joan March, which receives patients referred from the acute hospitals in Majorca, who have been previously assessed by hospital support teams (UVASS). Those who meet the inclusion criteria are invited to take part in the RESC Program,

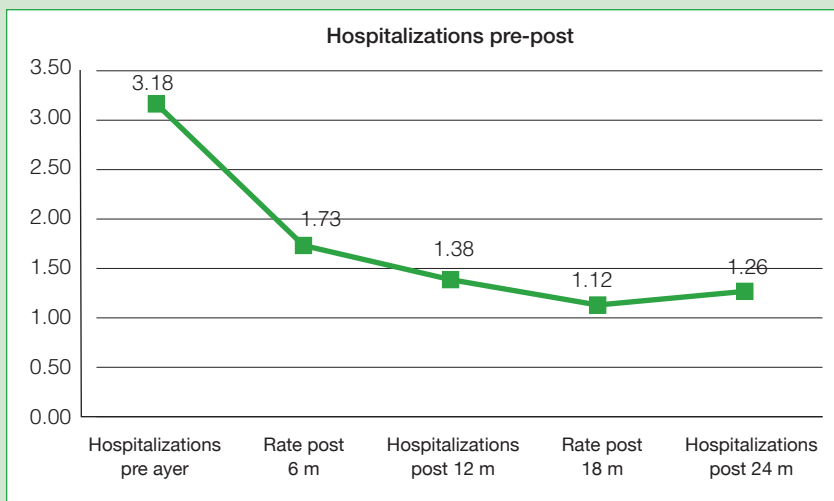
The program is designed with the intention of meeting the needs of those respiratory patients with a strong dependence from healthcare resources, out of hospital whenever possible, through external medical consultation and frequent nurse, offering outpatient respiratory rehabilitation, telephone access through the liaison nurse, coordination between levels of care, and patient's home care through the Respiratory-ESAD support team.

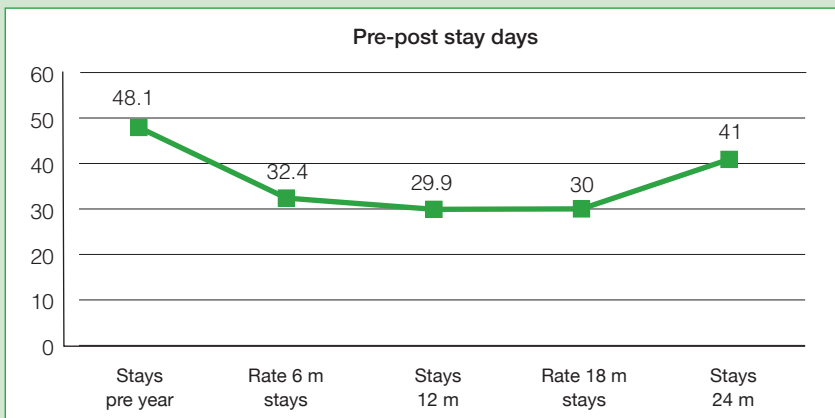
All activity is based upon the search for comprehensive care through an interdisciplinary team.

Evaluation: When the patient is recruited for the program, a comprehensive evaluation is conducted, including: anamnesis, functional tests, evaluation of knowledge, quality of life and others. Said evaluation is repeated every five months, recorded and processed through SPSS.

Since the program implementation in 2002, evaluations have been conducted for many of the areas considered most interesting:

- Care Plan: Significant improvement ($p < 0.05$) is verified in four dependence areas (Virginia Henderson) and respiratory quality of life (SGQR) after application of the care plan.
- Consultation with nurse and liaison nurse: It achieves a significant improvement in therapeutic device management, compliance, specific quality of life and reduction of hospitalizations.
- Program of outpatient respiratory rehabilitation: In 72 patients with severe and very severe COPD. Significant improvements ($p < 0.05$) are verified before and after RHB in: BODE Index, six-min walk test, dyspnea according to Borg and CRQ scales, quality of life in all CRQ areas, number of hospitalizations, hospital stay length, and exacerbations.
- Follow-up of 120 COPD patients who were included in the program because they required two or more hospitalizations during the last year (median 3.2) and an average 48.12 days of hospital stays. The evolution during two years of RESC program follow-up appears in the figures below.
- According to current bibliography, hospitalization costs for those 120 patients on the previous year (third level hospitals), was 2 million euros, and during the two following years (second level hospital) one million euros per year.





Institution and centers responsible for the intervention or program: Hospital Joan March (Mallorca), Gestió Sanitaria de Mallorca (GESMA). Servei de Salut de les Illes Balears (Ib-salut). Conselleria de Salut i Consum.

Contact:

Feliu Renom Sotorra Head of the Respiratory Department. RESC Program Coordinator. frenom@gesma.caib.es

Bibliographic references:

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4.12. Spirometry Workshop in a Rural Health Center in Ávila

Objective:

General Objective:

- To improve recruitment and management of patients with respiratory conditions in the basic health area of Arenas de San Pedro (Ávila).

Specific Objectives:

- To implement a continuous service for conducting spirometry tests in the health center.
- To facilitate the adequate training in spirometer management and interpretation of test results for the professionals in the center.
- To facilitate access to those patients in the area who require said diagnostic test.

Target Population: Healthcare staff in the health center (13 physicians and 9 nurses).

Setting. Basic zone.

Description: The workshop is included within a wider plan for quality improvement which was prepared with the aim to improve care for COPD patients in the basic health area. It involves the implementation of a diagnostic test useful for capture and follow-up of patients with respiratory conditions, which was seldom used.

Material and human resources:

A spirometer, a physician, and a Specialized Care nurse who were experienced in conducting and interpreting said test; both professionals played the role of monitors.

Duration: 3 months (March–July, 2008) two days a week, one hour during working hours.

Development of Activities:

The workshop involved having, during three months, a centralized service for conducting spirometry tests, to be used by the healthcare staff in the center; as well as a series of complementary teaching activities:

- Providing a practical dossier for test results interpretation, as well as another about how to use the spirometer supplied.
- Programming and conducting various teaching sessions in order to present the workshop to the whole staff.
- Establishing a centralized system of appointments to conduct spirometry tests to center patients during the three months of the workshop.
- Conducting practical sessions divided into three parts, with an approximate duration of 20 minutes each. Spirometries were conducted by the monitors to those patients invited. On the other hand, students also conducted their own spirometry, guided by monitors or by other students, as any other patient.

Currently, the spirometry service in the center is still running. Each physician-nurse team conducts spirometries for patients in their quota. A physician is responsible for registration, analysis of those results obtained, and analysis of any potential technical and organizational improvements. A nurse is responsible for material maintenance and use of the spirometer, together with the assistant staff in the lab.

Evaluation: Out of 22 members of the healthcare staff team, 15 members were involved (seven physicians and eight nurses), that is to say, 68.18% of the team, as well as two specialized care nurses.

The theoretical section was completed by all 15 (100%).

15 members took part at least once in the practical section, observation of spirometries conducted in patients, and comments about outcomes; but only nine of them completed the 5 minimally required practices or sessions. 13 students conducted spirometries acting as patients, and only three completed three practices.

During the 3 months of the workshop, 64 patients were studied, 46 males and 18 females. A total of nine graphs (eight males and one females) were considered not acceptable, because of the whole manner of conduction.

Institution and centers responsible for the intervention or program: Health center in Arenas de San Pedro (Ávila)

Contact: Pablo Blázquez Crespo. Coordinator.

4.13. COPD Group in the Research Unit

Objective: To develop multidisciplinary research about the physiopathology of COPD inflammatory mechanisms.

Target Population: COPD patients in any categories.

Setting: Healthcare area

Description: This is a research group created in the year 2000, and formed by different healthcare professionals with different medical specialties (Pulmonology, Immunology, Clinical Tests, Anatomopathology), Biologists and Nurses. There are different projects recruiting COPD patients who meet the inclusion criteria. In most studies, biomarkers are assessed, with a potential interest in pathogenesis and disease treatment. There are also projects to assess epidemiological and clinical aspects, and new technologies.

The following tasks are worth highlighting:

1. Recruitment, signature of informed consent forms, fieldwork.
2. Lab work: Processing of biological samples (blood, serum, induced sputum, bronchoalveolar lavage, bronchial and pulmonary biopsies), sample storage and filling, cellular cultures, cellular-molecular biology techniques (ELISA, nephelometry, oxidative stress analysis, Western-Blot, polymerase chain reaction, duplicate flow cytometry).
3. Intellectual work: Database preparation and update, statistical analysis, discussion and drafting of publications and communication materials, theoretical sessions, bibliographical review, preparation of new projects, preparation of doctoral thesis.

Evaluation: Number of projects approved and published articles.

Projects approved:

1. Endothelial dysfunction in COPD (FIS, PI04/1946).
2. FIS, PI 04/214 Molecular mechanisms in inflammatory response during COPD exacerbations.
3. EPOC and autoimmunity Evaluation of potential self-antigens. Conselleria Economia, Hisenda i Innovació, Illes Balears. (PRIB-2004-10072).
4. Autoimmunity and inflammation systemic in phenotypic characterization and COPD evaluation. (FIS, PI052082).
5. FIS, PI05/1463- Study about COPD exacerbations in Spain (ECOS).
6. Emerging Group for the study of Malalties Respiratòries approved in 2006. Project: "Resistance exercise reduces the inflammation which is a characteristic of chronic obstructive pulmonary disease (COPD)" Govern de les Illes Balears.
7. Antiinflammatory effects of home oxygen therapy in COPD. FIS EC07/90250. IP: Dr J. Sauleda.
8. Transversal action in lung cancer: "COPD and lung cancer, a biologic synergy model" ISCIII CIBERES 2007.
9. Pilot study of the efficacy of statins in COPD treatment. SEPAR-2007.
10. SEPAR 2007- Effects of smoke upon skeletal muscle regeneration and remodelling.
11. FIS, PI07/90721. AUDIPOC: National clinical audit about COPD exacerbations. Coordinated Project. AUDIPOC Islas Baleares.
12. FIS, PI080673. Similarities and differences in inflammatory response to tobacco between lung cancer and chronic obstructive pulmonary disease.
13. FIS, PI080696. Study of the erythropoietin receptor on pulmonary tissue and on bone marrow stem cells in patients with pulmonary emphysema.
14. FIS, PI080780, Relationship between systemic inflammation and bone marrow in COPD patients.

Published articles:

- Agustí AGN, M. Morlá, J. Sauleda, C. Saus, X. Busquets. NFkB activation and iNOS upregulation in skeletal muscle of patients with COPD and low body weight. *Thorax* 2004; 59:483-487
- Noguera, E. Sala, A. R. Pons, J. Iglesias PhD; W. MacNee, Agustí AGN. Expression of Adhesion Molecules During Apoptosis of Circulating Neutrophils in COPD. *Chest*, 2004; 125:1837-1842
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- Cosio BG, Iglesias A, Rios A, Noguera A, Sala E, Ito K, Barnes PJ, Agusti A.. Low-dose theophylline enhances the anti-inflammatory effects of steroids during exacerbations of COPD. *Thorax.* 2009 May; 64(5):424-9. Epub 2009 Jan 21.

Institution and centers responsible for the intervention or program: Pulmonology Department and Research Unit. Hospital Universitari Son Dureta. Palma Mallorca. Servei de Salut de les Illes Balears (Ib-salut). Conselleria de Salut i Consum.

Contact: Dr B. Cosio, Dr E. Sala, Dr J. Sauleda

4.14. Development of a continuing quality improvement project at the COPD unit in the Piedrahita (Ávila) Health Center

Objective:

- To know the baseline status of COPD patients in the basic health area, in terms of age, gender, smoking, and diagnostic criteria.
- To increase coverage in the COPD unit as a measure for diagnosis and capture of patients.
- To achieve that 80% of those patients considered as COPD sufferers are diagnosed according to spirometric diagnostic criteria.

- To implement a service for conducting and interpreting spirometries in the health center, through previous appointment at the desk, and in charge of persons who have received specific training.
- To create in the center a registration system for spirometries conducted and their result.
- To reduce the number of patients considered as suffering COPD who don't have a past history of smoking.
- To establish a relationship between the COPD unit and the smoking cessation unit.
- To improve the registration about smoking history in the patient's record.
- To diagnose COPD as early as possible.

Target Population: Population ≥ 40 (3,660) years from the basic health area of Piedrahita (Ávila), who are likely to suffer COPD.

Setting: Basic zone.

Description: The problem is addressed through the continuing quality improvement methodology. To this end, a first cycle of improvement is initiated, the problem is formulated, its causes are analyzed, quality criteria are established, objectives are set out, and interventions are decided upon, stating who will be responsible for each and its timetable. Indicators for the evaluation are specified, the intervention is carried out and evaluated. According to the results, a second cycle of improvement is initiated, with new objectives, intervention and evaluation.

Activities Developed:

- Review of the 307 service lists (COPD) by CIAS (Health Area Identification Code).
- Registry of existing patients not previously included by any cause.
- Review of records of registered patients, and record of who meet and who does not meet the inclusion criteria; exceptions will be considered as meeting the criteria.
- To program two training sessions, in collaboration with the person in charge of continuing education.
- A practical spirometry workshop for the whole team, and specific training for those in charge of the unit.
- A theoretical session about COPD: diagnosis and treatment.
- Training activity in Asthma / COPD differential diagnosis.
- Four team sessions by the person responsible for this improvement project.
- To establish a team of two physicians and two nurses to conduct spirometries in the health center. These will be conducted in the community only in exceptional cases.
- To examine and calibrate the spirometer by the PCM technical team. Collaboration by the clinical assistant.
- To determine a timetable and an appointment system for this service.

- To conduct spirometry to those patients who have not undergone this test, unless they are exceptions.
- To delete from the lists those patients without a past history of smoking and symptoms compatible with asthma.
- To create a census of smokers, together with the person in charge of the smoking cessation unit.
- To establish a protocol in the center for detecting and referring to spirometry all smokers over 40 years of age.
- To file a copy of spirometries where results can be verified.

Evaluation: A systematic sample has been chosen by computerized system, based on the automated list of patients included in the unit by November, 15th, 2006. Said list has been generated by the Primary Care Management. Sample size: 40 patient records (n=40).

Criterion 1. Coverage

Standard: To increase patient coverage by the COPD unit by 12%, from 91 to 122.

Correcting measures demanded a previous deletion of patients from the list.

Achieved: We have moved from 67 after patient deletion to 172, which represents a 19.3% increase (criterion achieved: 160.8% from standard)

Criterion 2. Diagnosis through spirometry, that is to say, meeting the inclusion criterion in a documented unit.

Standard: In 80% of patient records, a diagnostic spirometry must be included, or diagnosis by specialist stated, or whether it is an exception meeting clinical criteria.

Achieved: Out of 40 histories evaluated, 28 meet the inclusion criterion while 12 do not. It is met in 70% of cases, while it is not met in 30% (87% of proposed standard).

Criterion 3. Training of the team.

Standard: 70% of healthcare professionals in the team have received training in spirometry technique and result interpretation.

Achieved: 73% of healthcare professionals receive spirometry training, and 85.7% of physicians receive COPD management training (standard is met in over 100%).

Criterion 4. Spirometry record in PR.

Standard: A diagnostic spirometry is registered or filed in 90% of patient records.

Achieved: Patient record with filed or registered spirometry: 67.5% (75% of standard).

Criterion 5. Patient age

Standard: To reduce by two points the average age of patients in the unit in 2006, vs. the average age in 2005.

Achieved: The average age in 2006 is 74.55 years, while the average age in 2005 was 76.59 years (standard met by 100%).

Criterion 6. Patients under 70 years of age.

Standard: To increase by 10% the number of patients <70 years.

Achieved: There are 46 patients under 70 years in 2006, vs. 28 in 2005 (standard met by 100%).

Criterion 7. Smoking record

Standard: 90% of COPD patients must have a record of past smoking.

Achieved: In 39 patient records (97.5%) there is a record of past history of smoking. (Standard met by 100%).

Criterion 8. Spirometry record

Standard: There is a record book for spirometries in the center, where results appear (50%)

Achieved: 169 appointments and 109 recorded (standard met by 100%).

There is a stable unit for conducting spirometries in the Health Center, with previous appointment and working hours (one day per week, four hours), and people in charge who have received specific training.

During the intervention period, we have conducted 169 spirometries, noting acceptability, reproducibility and whether diagnostic or not, tested before and after bronchodilation.

Institution and centers responsible for the intervention or program: Piedrahita (Ávila) Health Center

Contact: M^ª Concepción Ledesma Martín.

5. Appendixes

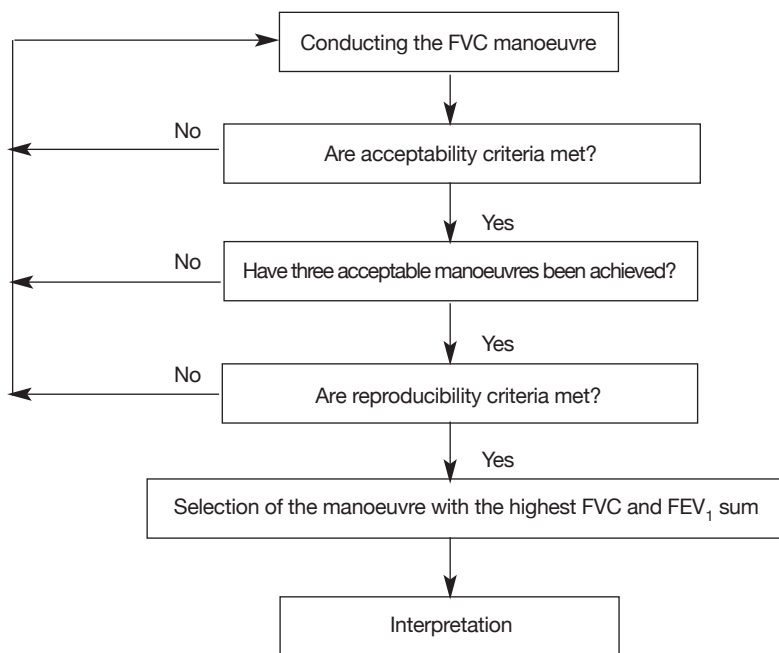
I. Basic Criteria for Spirometry Standardization

Table 20. Basic criteria for spirometry standardization

Calibration	Calibration must be conducted daily, and even more frequently for those spirometers where the manufacturer requires so.
Acceptability Criteria:	For an expiratory manoeuvre to be considered acceptable, all criteria below must be met:
Start	It must be sharp with obvious deflection. Extrapolated volume under 150 ml or lower than 5% of the forced vital capacity.
Slope	It must be gentle and without gaps No coughing during the manoeuvre No glottic closure No leaks No mouthpiece obstruction No intercurrent inspirations
Finalization	It must be asymptotic. There are two criteria for finalization: 1. The patient cannot continue with the expiration. The technician must try to achieve the maximum effort. 2. The volume-time curve does not show changes in volume (0.025 L) within one second.
Duration	Expiratory time over 6 seconds.
Number of Attempts	At least three acceptable curves must be obtained. If not achieved, new attempts must be conducted, with 8 manoeuvres maximum.
Reproducibility Criteria	Less than 150 ml difference between the two best values for FEV ₁ and FVC, of acceptable curves.
Organizative Criteria	<ol style="list-style-type: none">1. There must be a nurse in charge of spirometries in all health centers.2. The nursing staff must have a specific training plan for conducting spirometries.3. All medical and nursing staff must have enough knowledge in order to interpret results.

Source: Own elaboration.

Figure 8. Diagram for application of acceptability and reproducibility criteria in spirometry



Source: Own preparation.

II. Coordination between Primary and Specialized Care

Initial Assessment and Follow-up⁷

For initial assessment of a COPD patient, a spirometry is required to establish the diagnosis, and the study must be completed also with:

- Bronchodilator test. It detects bronchial hyperreactivity or complete obstruction reversibility, which would rule COPD out.
- Blood test. Useful for detecting anaemia or polyglobulia.
- Alpha-1 antitrypsin (AAT) test.

- Chest X-ray. It can be normal, or show signs of lung hyperinflation, vascular attenuation or radio-transparent areas suggesting emphysema. Bulla, radiolucent areas or arterial hypertension signs may also be detected.

If the patient presents mild disease, or moderate disease without complications or associated severe comorbidities, the treatment and follow-up plan must be determined in Primary Care, according to the established strategic plan. In these cases, it will be enough to conduct at least one spirometry with annual periodicity. For the remaining cases, collaboration by the Pulmonologist is advisable, according to what is stated in the next section.

Referral and Return Criteria for Stable Patients

Clinical follow-up of mild COPD patients and a large group of moderate COPD patients can be conducted by Primary Care. Study and follow-up shared with a pulmonologist is advisable in certain cases which present diagnostic doubts, failed attempts of smoke cessation^{29,86}, presence of complications, and need for more complex treatments in severe or very severe COPD. The following list shows some clinical scenarios where it is recommended to consult a Pulmonology Specialist⁸⁷.

- Initial differential diagnosis in special cases or cases with doubtful diagnosis (asthma, bronchiectasis, etc).
- Periodical evaluation of patients with severe or very severe disease, or poorly controlled moderate disease.
- Smoking assessment and treatment in patients with previous failures, comorbidities, and/or adverse effects with potential pharmacological interactions.
- Presence of right cardiac failure.
- Indication of continuous home oxygen therapy.
- Prescription of respiratory rehabilitation.
- Patients with predominant emphysema.
- Disease in young subjects, or those with suspected alpha-1-AT deficit.
- Presence of bulla.
- Assessment of long-term disability.
- Assessment of potential surgical treatments.

- Dyspnea out of proportion with a moderate condition.
- Frequent bronchial infections.
- Associated polymorbidity with impact upon the respiratory process.
- Fast reduction in FEV₁ (> 50 ml/year).
- Diagnostic or therapeutic doubts during the disease evolution.

Faced with these situations, the pulmonologist must assess the patient referred by Primary Care, and conduct all complementary tests required. After this, he must recommend the most adequate treatment, and determine the need to continue a coordinated follow-up program, agreed upon by consensus between Specialized Care and Primary Care. Whenever there is clinical stabilization, and lack of those criteria listed above, follow-up must be conducted exclusively by Primary Care.

Outpatient Treatment for Exacerbations

Exacerbations are defined as acute changes in the patient's basal clinical situation, beyond daily variability, where there is an increase in dyspnea, in expectoration, sputum purulence, or any combination of these three symptoms^{78,87}.

The patient with mild or moderate COPD will be treated as an outpatient as first option, even though all episodes require follow-up during the first 72 hours. During exacerbation, the treatment commonly used by the patient shall not be interrupted, but inhaled therapy must be optimized in order to obtain maximum bronchodilator effect.

Antibiotics will only be used for those exacerbations which present, besides dyspnea, an increase in volume of the usual expectoration and/or purulence, according to the list of antibiotics recommended below^{88,89}.

It is recommended to administer oral glucocorticoids (initial doses not superior to 40 mg/day of prednisone or equivalent during 10 days maximum) in severe COPD exacerbations, and in those mild or moderate COPD cases with unfavorable initial evolution⁹⁰.

Exacerbation treatment. Mild or moderate COPD (outpatient treatment)

- To optimize inhaled treatment with short-acting bronchodilators: anticholinergic (ipratropium bromide up to 0.12 mg every 4-6

hours) and/or short-acting beta-2 agonist (salbutamol up to 0.6 mg or terbutaline up to 1.0 mg, every 4-6 hours).

- Antibiotic therapy, if there is an increase in expectoration and/or purulent sputum, besides dyspnea: Amoxicillin/Clavulanic Acid, Azithromycin, Cefditoren, Levofloxacin or Moxifloxacin).
- To assess evolution at 72 hours.

In those cases where there is no improvement at 72 hours, treatment modification or referral to hospital must be considered.

Criteria for hospital referral when there is a COPD exacerbation^{87,91,92}

1. Severe COPD ($FEV_1 < 50\%$) with comorbidity, frequent reinfections or poor clinical evolution.
2. Any grade of COPD with:
 - Respiratory failure.
 - Tachypnea (>25 breaths per minute).
 - Use of accessory muscles.
 - Signs of a new or worsening right cardiac failure.
 - Hypercapnia.
 - The condition is impossible to control at home.
 - Severe associated comorbidity.
 - Reduction of the consciousness level or confusion.
 - Poor evolution of clinical condition.
 - The need to rule out other diseases, as those listed below, which cannot be ruled out by Primary Care means:
 - Pneumonia.
 - Pneumothorax.
 - Left cardiac failure.
 - Pulmonary thromboembolism.
 - Bronchopulmonary neoplasia.
 - Upper airways stenosis.

To assess the intervention on smoking in hospitalized smoking patients: from a minimal systematized intervention to pharmacological treatment (intensive interventions and multicomponents).

III. Respiratory Rehabilitation

The American Thoracic Society and the European Respiratory Society (ATS/ERS)⁹² published a document in 2006 defining respiratory rehabilitation as a “multidisciplinary and overall intervention which has proven to be effective from an evidence-based medicine perspective, for patients with chronic respiratory diseases who are symptomatic and have often reduced their daily life activities.”

The three key concepts in respiratory rehabilitation are: individualized treatment, of a multidisciplinary nature, and demanding the joint work of different healthcare professionals paying attention to physical and social functions.

Respiratory Rehabilitation Programs (RRPs) may vary in design and operation, but they all share common objectives^{93, 94}, such as the highest possible control, relief and reversal of symptoms, and of the physiopathological process of patients. Also to optimize pulmonary function, improve exercise capacity, and increase independence in daily life activities. Other objectives are improvement in health-related quality of life, control of psychosocial factors involved in the disease, life prolongation and reduction of the use of healthcare resources, and reduction of the disability caused by chronic respiratory disease.

The components of RRP⁹⁵ are: education for patients and relatives, respiratory physiotherapy (airway permeability and respiratory re-education techniques), muscular training (lower and upper limbs, and respiratory muscles), emotional and nutritional support, occupational therapy (measures for energy saving). It is also worth considering that patients joining a respiratory rehabilitation program must have access to optimal pharmacological treatment, and ideally must have quit smoking or be in the process to smoking cessation.

Levels of evidence about the efficacy of respiratory rehabilitation (ATS)^{96,97} are:

Lower limb training: A

Upper limb training: A

Respiratory muscle training: B

Education, Physiotherapy: B⁹⁸

Psychosocial support: C

Note: See Table 4 about Evidence Categorization.

Some of the benefits of rehabilitation⁹⁹ are improvement in dyspnea, exercise capacity and HRQL (A). RR reduces the use of healthcare services and hospital admissions (B), it is cost-effective (B) and it improves the

BODE Index¹³. The most effective types of RR are those including exercise and limb training (A). Implementation of home maintenance treatments is a valid option to rehabilitation conducted in hospital from the initial stages of the disease (B). Daily activity and physical exercise are beneficial for COPD patients (B). Finally, rehabilitation must be recommended to any COPD patient who, after an optimized treatment, continues being limited by dyspnea to carry out daily activities (A)^{81,100}.

RRPs can be adapted to any person with chronic respiratory disease. Neither age nor level of condition can be considered limitations for rehabilitation.

Traditionally, RRP have been designed for COPD, but other persons suffering different respiratory conditions may also benefit¹⁰¹. Overall, a motivated and collaborative patient is required, with a reduced exercise capacity, persistent dyspnea, coughing and/or expectoration, and impact on DLA. Patients must have optimal pharmacological treatment. The GOLD Strategy recommends RR initiation from Stage II.

The most relevant contraindications are cognitive or psychiatric alterations that prevent involvement in training programs, and uncontrolled severe diseases (cardiac failure, advanced pulmonary hypertension...).

Rehabilitation's scope of action involves mainly the comprehensive care of patients with invalidating processes. For this comprehensive care, it is required to have material and human resources that must belong to a specific unit, the Respiratory Rehabilitation Unit, coordinated by a physician specialized in rehabilitation, and formed by physiotherapists, nurses, clinical assistants, occupational therapists and social workers.

The team must be in close contact with the Pulmonologist responsible for diagnosis and optimal pharmacological treatment, and with other departments, which may potentially refer patients, such as Paediatrics, Thoracic Surgery, ICU, Internal Medicine. They must also be in contact with Nutrition, Palliative Care, the Smoking Cessation Unit, Psychology, etc.

The multidisciplinary team and types of program may vary, depending on the center and healthcare resources. The ideal material resources appear in Table 21.

Rehabilitation programs can be organized at three levels: hospital, outpatient and home. Hospital programs in our setting are limited to treatment for COPD with exacerbations. Outpatients programs including effort training are the cornerstone of RR. Home programs have also been described, generally as maintenance after attending the RR program^{102,103}. A good coordination among these three levels of care will allow offering a multidisciplinary respiratory rehabilitation program which is effective, safe, and provides clinical benefits for the whole adequate population.

Table 21. Material Resources in Respiratory Rehabilitation

Respiratory Room

- Individualized physiotherapy treatments (bronchial drainages)
- Group Gym treatments
- Muscular training
- Cycle ergometers and treadmills

Materials

- Oxygen
- Pulse Oximeters
- Instruments to aid physiotherapy (IMP2 devices, Flutter, etc)
- Ins-exufflator
- Secretion aspiration
- Basic system for cardiopulmonary resuscitation
- Materials for Lower Limb Training (cycle ergometers and treadmills) and Upper Limb Training (dumbbells, elastic bands).
- Materials for respiratory muscle training (Theshold)

Source: Own elaboration.

A correct assessment of respiratory rehabilitation will require adequate patient's record and clinical examination, as well as a detailed analysis of those complementary tests ordered by the Pulmonologist or other specialists, including: clinical tests, gasometry, pulse oximetry, chest X-ray, CT scan, electrocardiogram, pulmonary function studies, spirometry, diffusion, measurement of MIP (maximum inspiratory pressure) and MEP (maximum expiratory pressure), etc. Detecting the presence of associated conditions is important, as these could make unfeasible certain therapeutic measures typically included in rehabilitation programs.

Functional assessment is essential in order to determine the objectives of the rehabilitation treatment and measure its results once completed. Following Celli, three areas must be considered from a rehabilitation perspective:

1. Functional deterioration: It is assessed by Forced Expiratory Volume during the first second (FEV_1). It determines disease severity and respiratory obstruction. It allows group classification, measuring exacerbation frequencies, pharmacological cost, and mortality quantification.
2. Systemic impact: With simple tests such as the 6-minute walk¹⁰⁴ (6mm) which is the most widely used rehabilitation test. The following evaluations are also used: shuttle test, cardiopulmonary ef-

fort tests, daily life activity monitoring, body mass index, peripheral muscle assessment. Respiratory muscle assessment is conducted through maximum inspiratory and expiratory pressure (MIP and MEP).

3. Patient's perception: The most important parameters to be assessed are dyspnea and quality of life. Dyspnea is an independent predicting factor, and allows the assessment of rehabilitation programs. It is well correlated with health-related quality of life. The most typically used dyspnea scales are the Medical Research Council (MRC) Scale and the Borg Scale

Health-related quality of life questionnaires mostly used in respiratory rehabilitation are: SF-36 (generic), and the Chronic Obstructive Disease Questionnaire (CRDQ) by Guyatt and the Saint George Questionnaire (both of them specific). It is recommended to use the BODE Index as prognostic and evolution index for COPD.

In terms of COPD programs, physical training is RR's cornerstone. It is indicated for all those chronic respiratory diseases which cause a reduction in exercise tolerance, dyspnea, effort fatigue and impact on DLA (Activities of Daily Life), or all of these. In terms of RR's duration and frequency, it has been proven that longer programs cause wider and longer-lasting effects. The usual recommendation is attending two or three times per week, for at least 20 sessions.

On the other hand, low intensity exercise causes symptomatic and quality of life improvement, but greater results are achieved with high intensity exercise. Intensities > 60% of exercise capacity or fatigue perceptions of 3-6 in Borg Scale seem to be adequate.

In terms of training specificity, lower limbs have traditionally been trained with bicycle or treadmill, but there are many DLAs which involve arms, therefore the upper limbs must also be trained, with a clear improvement in dyspnea and ventilation requirements.

To train resistance through cycling or walking is the most frequent type of training. Its limitation is low tolerance to high exercise loads. That is why the interval resistance mode is winning adepts. In this modality, patients carry out brief peaks of higher workload, followed by lower workload stages, during which patients recover from the previous peak. Strength training (lifting dumbbells) achieves an increase in muscular mass and strength, and is well tolerated. Typically, 2-4 series of 6-12 repetitions are conducted with intensities between 50-80% of the maximum weight patients are able to lift in one repetition.

Other strategies to improve exercise are: using bronchodilators before exercise, and using oxygen to allow training intensification, but there is still no clear consensus about this.

There is also non-invasive mechanical ventilation, which can improve exercise tolerance in those patients already using it. There is no clear consensus about this measure.

Respiratory muscle training is also mentioned, particularly for those patients with confirmed respiratory muscle weakness. Neuromuscular electric stimulation is useful for bed-ridden patients, or those who suffer extreme weakness in striated muscles.

Even though rehabilitation program components may vary from one program to another, these appearing in Table 22 are accepted as basic:

Table 22. Program Components

1. Education

2. Nutrition

3. Pulmonary Physical Therapy

- a) Respiratory Physiotherapy
- b) Respiratory Exercises

4. Muscular training

- a) Lower limb training
 - I. Resistance training
 - II. Strength training
 - III. Combined training
- b) Upper limb training
- c) Respiratory muscle training

5. Occupational therapy

- a) Simplification of work
- b) Energy saving techniques
- c) Treatment through basic daily life activities and technical help

6. Psychosocial and behaviour interventions

Source: Own preparation

Access to respiratory rehabilitation should be universal, for all COPD patients; however, this is not the case. In some Autonomous Communities, there is some type of outpatient respiratory rehabilitation service, or irregular home service^{105,106}. It is necessary to include the RR intervention in the COPD Strategy document by the MHSP, in order to develop high quality programs, and avoid disparities.

Regarding the necessary training for professionals working in these units (physicians specialized in Pulmonology, Rehabilitation and Physical

Medicine, Primary Care, physiotherapists, occupational therapists, nurses...), these require specific knowledge and experience, not only for initial assessment but also for prescription and application of rehabilitation, control and process follow-up techniques. Training in this field is non-existent, and there are no acknowledged qualifications.

On the other hand, our healthcare and legislative organization is very different from the Anglosaxon one, and those studies we manage usually come from this latter setting. It is essential to adapt RR procedures, which have proven to be effective, to our own reality, promoting a training offer by public organisms to those professionals involved, and legislating for a universal offer to patients who might have an improvement through RR.

IV. Care Plan. The Role of Nurses in Different Care Levels and in the Community

COPD treatment requires an interdisciplinary team to provide transversal coverage, with high quality and in an on-going manner, to patient needs in different settings, basing its interventions upon scientific evidence. Nurses play a key role as point of reference for patients and their families, and in order to ensure the correct treatment, follow-up and prevention of exacerbations.

The Community Nurse is the professional who provides care and better knows patients and their environment, and the Respiratory Specialist Nurse must act as support for Primary Care teams, and in follow-up and care of complex patients.

From the nursing perspective, these patients' approach must be based on three basic pillars:

- a) Interventions derived from WHO recommendations for chronic patients.
- b) National and international guidelines on COPD (GOLD¹⁰⁷, SEPAR-ALAT⁷...)
- c) The assessment of "human responses developed by each subject at the evolution of their health status" (nursing diagnoses)^{108,109}.

Once the human response has been assessed, the nursing professional will choose the most adequate intervention in order to achieve the desired results^{110,111}. The following table includes the most frequent problems, interventions and results in COPD patients^{112,113}.

Table 23. Most Frequent Diagnoses in COPD Patients

NANDA (North American Nursing Diagnosis Association)* Classification

00078	Ineffective management of therapeutic regimen
00079	Lack of treatment compliance
00031	Ineffective airway clearance
00092	No tolerance to activity
00052	Deterioration in social interaction
00069	Ineffective approach
00126	Insufficient knowledge
00070	Adaptation deterioration
00146	Anxiety
00120	Situational low self-esteem
00148	Fear
00032	Ineffective respiratory pattern
00147	Death anxiety

*Nursing diagnoses: 2007-2008 Definition and Classification – Publisher: Elsevier – 10/2007

OUTCOME CRITERIA

NOC (Nursing Outcomes Classification)**

1824	Knowledge: disease care
1808	Knowledge: medication
1811	Knowledge: Prescribed activity.
1609	Therapeutic behaviour.
1902	Risk control
0402	Respiratory status: gas exchange
0401	Respiratory status: airway permeability
2004	Fitness
0002	Energy conservation
1302	Overcoming problems.
2002	Welfare
1205	Self-esteem
1305	Psychosocial adaptation: lifestyle change
1302	Overcoming problems (coping)

** (CRE) (Nursing Outcomes Result) – Harcourt Publishing House - second edition- 2001

Table 23. Most Frequent Diagnoses in COPD Patients (continuation)

INTERVENTIONS – NIC

NIC (Nursing Interventions)* Classification**

5602	Training: Disease process.
5616	Training: Prescribed medication.
7400	Healthcare System Guidelines
4420	Agreement with patient
4360	Behaviour modification
4490	Help for smoking cessation
6610	Risk identification
3390	Ventilation assistance
3320	Oxygen therapy
3350	Respiratory control and follow-up
5820	Anxiety reduction
3230	Respiratory physiotherapy
0200	Promoting exercise
0180	Energy management
1800	Self-care assistance
5440	Encouraging support systems

*** (Nursing Intervention Classification) - - Harcourt Publishing House – third edition- 2001

Source: Self-prepared table.

Sharing information and knowledge among levels and among professionals is a key aspect in the whole process. Information technologies and e-learning initiatives can be a great help.

The main objectives must focus in preventing morbidity and its sequel, providing therapeutic education programs which encourage autonomy, compliance, early detection of exacerbations and their subsequent follow-up, not forgetting an adequate control of co-morbidities.

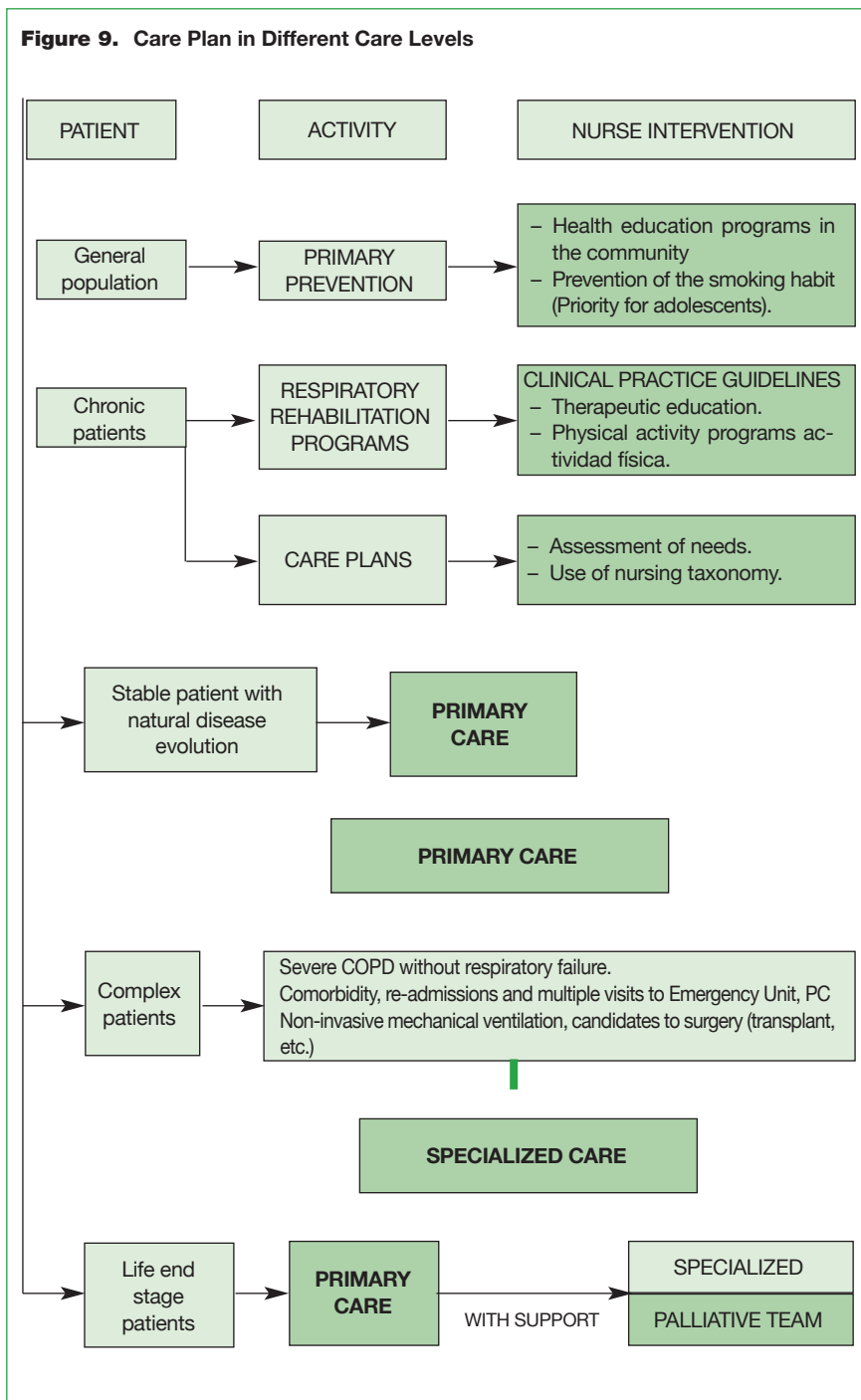
When preparing the care plan, the aspects which appear in the table below must be taken into account:

Table 24. Care Plan Aspects

To promote healthy lifestyles.	To prevent the initiation in the smoking habit. Subjects: smoking population.
Smoking cessation. Structured program targeted to smoking population.	Smoking cessation program according to regulations.
Annual good-quality forced spirometry as bronchodilator test.	Early diagnosis, follow-up according to regulations
Overall patient assessment according to severity. Validated questionnaires according to severity.	Risk factors; Comorbidities (number and type) (<i>anxiety-depression in severe patients</i>): Respiratory signs and symptoms. Dyspnea scale (MRC), coughing and expectorating (quantity and colour) in different stages; quality of life and daily life activities; physical activities; compliance of treatment (pharmacological and non-pharmacological). To detect poly-medicated patients; use of healthcare resources and control of oxygen saturation in severe patients.
Vaccination (influenza and antipneumococcal)	Preventive hygienic measures. Annual influenza virus. Information about potential adverse effects. Pneumococcal. Every five years. Information about potential adverse effects.
To ensure correct treatment compliance according to severity.	Therapeutic education programs, structured and programmed individually or in group. Educational material for patients and family (Controlling COPD or others)
Structured physical activity programs	According to regulations.
Individualized working plan adapted to each patient and situation. Reduction of morbidity associated to COPD and re-admissions to hospital.	Identification of patients and plans for individualized and on-going follow-up, coordinated among PC, specialized care and hospital. Early detection of exacerbations and rapid response at home Use of available resources (PC, hospital, socio-sanitary)
Severe exacerbation and/or severe COPD patient. Home visit.	Home follow-up for severe patients or during exacerbations (hospital at home) by expert nursing staff.

Source: Own preparation.

Figure 9. Care Plan in Different Care Levels



V. Hospitalization at Home and Early Discharges in Exacerbation

Hospitalization at home in COPD exacerbation

This is an out-of-hospital care program based on the structure of a “hospitalization at home” team, which can be specific to this process or general for the whole hospital. The program must only cover healthcare due to acute exacerbation, regardless of other potential programs for overall healthcare. It must replace the conventional hospital stay required for this process⁶⁸.

Patients must be selected in hospital emergency services or the day hospital unit, and later on transferred home under continuous care by a physician and a specialized nurse, and the adequate healthcare equipment, able to offer 24-hour-a-day coverage^{68,114}.

Home early discharge in COPD exacerbation

Program based on the structure of the same home hospitalization team, with the aim of reducing patients’ hospital stay. Patients will be selected from the Pulmonology and Internal Medicine hospitalization areas¹¹⁵.

In both cases, there is a higher level of satisfaction by patients and caret givers, as well as by healthcare professionals, direct costs are reduced, there is improvement in treatment compliance, and visits to Emergency and hospital admissions are reduced during the weeks following discharge.

Patient selection

COPD patients who require hospitalization due to exacerbation. During the program follow-up, patients must receive the same treatment and care than in hospital.

Inclusion Criteria

- Patients living in the program’s area of action.
- With 24-hour company.
- Telephone availability.
- Adequate understanding of the program.

Exclusion Criteria

- COPD severe exacerbation or presence of polymorbidity.
- Patient’s home outside the area, or lack of company or telephone.
- Difficulty to understand the program.
- Requiring more than two home visits per day.
- Severe social problems.

Structure of a home hospitalization unit

- A generally transversal unit, located in the hospital’s organization chart and depending on the management.
- In each case, a clerical admission will be created in charge of the hospital, with a virtual bed. The patient will be transferred home by ambulance, and will receive care by the team during the first 24 hours.
- A hospital team specialized in this care must be formed, coordinated with the Pulmonology Department for this process. The number of persons in the team will depend upon hospital type and needs.
- The required medication and saline therapy will be prepared and administered by the team, as well as sample extraction for tests.
- Supplying companies will be contacted for availability of oxygen therapy, nebulized therapy, home ventilators, etc.
- It must provide coverage 365 days per year, and have enough margin of manoeuvre to provide adequate care during “peaks and valleys” of demand.
- It must have a telephone call center easy to access by patients included in the program.
- It must be in permanent contact with the Primary Care team. When the program is completed, patients will have care continuity by their Primary and/or Specialized Care team, according to the existent strategic plan, and with special attention to fragile patients with a high rate of re-admissions.

VI. Guidelines for the Implementation of Non-Resuscitation Orders and Limitation of Therapeutic Efforts

Justification for Guidelines

Not everything technically possible is useful for patients or ethically justifiable. We must assess what we do to avoid damaging the patient without providing a potential benefit. Limitation of Therapeutic Efforts (LTE) have the same aims and ethical basis as Do Not Resuscitate (DNR) Orders, though they include more therapeutical aspects than cardiorespiratory arrest: the DNR order is a LTE.

LTEs are not motivated by those savings obtained by limiting resources, but by avoiding damage to the patient; it is not a form of euthanasia, as only useless or neutral treatments are limited, that is to say, those which are “futile”. We understand as futile^{116,117,118} anything which might be useful in theory, but predictably will not obtain the desired result, will only prolong the dependence situation, and has under 1% possibility of benefit.

Patients with very severe COPD, which in a stable stage present very severe respiratory failure despite correct treatment, may be candidates for some type of LTE, particularly if conventional measures or non-invasive mechanical ventilation are not enough.

Classification of Patients in terms of Therapeutic Effort and Types of Decisions

DNR orders are part of the LTE concept, in the section for non-implementation of measures, and it is adequate to classify COPD patients in various levels according to the current clinical status of their disease and comorbidity, in order to differentiate the intervention levels they are adequate for¹¹⁹:

- **Level A:** Patients in which treatment is expected to be satisfactory, and can be discharged by hospital, or those where the underlying disease prognosis is unknown (this often happens in Emergency Units). This would include all patients with stable COPD.
- **Level B:** Patients with chronic and debilitating diseases, where therapeutic intervention has uncertain results, or indication is doubtful. This would include all patients with advanced stage COPD.

- **Level C:** Patients with short-term fatal prognosis, for whom therapy has proven ineffective or is known to be ineffective. This would include patients with terminal stage COPD.

Table 25. Summary of recommended actions according to COPD level and clinical situation

Level	Definition	COPD Situation	Actions
A	Treatment is expected to be satisfactory, and patient may be discharged.	Stable	Initiate CPR
B	Therapeutic intervention has uncertain results or indication is doubtful.	Advanced	It is convenient to explore the patient's wishes directly or through his relatives. Record decision in patient's clinical record.
C	Short-term fatal prognosis	Terminal	CPR not indicated. To discuss the decision with patient or relatives, only if they request it. Record decision in patient's clinical record.

NOTE: In any level, the existence of living wills about no-CPR must be respected.

Recommendations: Formal aspects of DNR Orders and Decision Process

1. It is necessary to point out that the order must be issued by the highest-rank physician in charge of the patient, his treating physician. Decisions must not be taken by physicians in training, and they must always be intended to represent group decisions, in which the whole therapy team is involved; if individually issued, the order must be subsequently endorsed by the rest of the team. If orders are issued during patients' hospitalization by physicians on duty, they must be endorsed as soon as possible by the responsible physician.
2. DND Orders must include the name of the physician in charge of the patient, who must sign the order with the current date, and the medical reasons or patient's reasons for its issue.
3. The physician issuing the order must ensure that the rest of the team is aware of its implementation, and the nurse in charge of the

patient must ensure that the order is known by the rest of the nursing team.

4. DNR Orders must appear in a visible place within patients' records, as well as in nursing orders, so that the whole team involved in the patient's treatment (hospital physicians, resident physicians, on-duty staff, nurses) may be aware of them beforehand, or can identify them quickly in case of cardiac arrest warning.
5. DND Orders only affect CPR, and must not represent a reduction in the level of care or life support measures, which must be modified, if considered adequate, by different decision processes.
6. DNR Orders will be periodically reviewed by the physician responsible for the patient, and can be deleted, if deemed convenient due to changes in the patient's clinical situation.

Decision process

- I. The physician considers that the patient's clinical situation does not justify CPR (Level C patients):
 - a) To establish a consensus with the rest of the therapeutic team.
 - b) To issue the order justifying its reasons, and specifying the persons who take the decision.
 - c) To inform the family about the irreversibility judgment conducted and the decision to limit therapeutic efforts regarding CPR, looking for their agreement, using an easy terminology which will facilitate understanding the scope of the decision. Seldom to the patient.
 - d) To ensure the order is known by all persons treating the patient, and is accessible by on-duty teams.
- II. The patient states his wish to limit treatment in terms of DNR Orders directly or through previous instructions:
 - a) To ensure that the information provided to the patient and the competence level are adequate, as well as providing clear and understandable information.
 - b) To issue the order justifying its reasons, and specifying the persons who take the decision.
 - c) To ensure the order is known by all persons treating the patient, and is accessible by on-duty teams

- III. The physician believes it is convenient to consider a DNR Order for a Level B patient:
- a) To explore the wishes of the competent patient in terms of CPR, or indirectly through patient's representatives, if the patient is not competent.
 - b) To respect the negative by the competent patient to discuss this issue, exploring his wishes to name a representative.
 - c) To make the decision according to patient's preferences, either directly or indirectly through the representative.
 - d) If the decision is made to issue a DNR Order:
 - 1. To issue the order justifying the reasons for it, and specifying the persons making the decision.
 - 2. To ensure the order is known by all persons treating the patient, and is accessible by on-duty teams.

Glossary

ANECA	National Agency for Quality Evaluation and Accreditation
ASP	Active Search Plan
BCM	Body Cell Mass
BMI	Body Mass Index
BODE	Multidimensional index including information about B (body mass index), O (obstruction), D (dyspnea) and E (exercise capacity) BOD Does not include exercise capacity BODEx Number of exacerbations instead of exercise capacity
CAO	Chronic airflow obstruction
CC.AA.	Autonomous Communities
CI	Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
CP	Clinical pathway
CPG	Clinical Practice Guideline
CPR	Cardiopulmonary Resuscitation
CT	Computerized Tomography
DALY	Disability Adjusted Life Years
DLCO	Diffusion Capacity of the Lung for Carbon Monoxide
ECG	Electrocardiogram
ENS	National Health Survey
EPI-SCAN	Epidemiologic Study of COPD in Spain
FEV₁	Forced Expiratory Volume in the first second
FRC	Functional Respiratory Capacity
FVC	Forced Vital Capacity
GOLD	Global Initiative for Chronic Obstructive Pulmonary Disease
HOT	Home Oxygen Therapy
HRQL	Health-related Quality of Life
IC	Inspiratory Capacity
ICD	International Classification of Diseases
ICU	Intensive Care Unit
IV	Invasive Ventilation
LVRS	Lung Volume Reduction Surgery
MEP	Maximum Expiratory Pressure
MHSP	Ministry of Health and Social Policy
MIP	Maximum Inspiratory Pressure
NHS	National Health System
NIV	Non-invasive Ventilation

NRO	No Resuscitation Order
PC	Primary Center
SIAP	Primary Care Information System
PCP	Primary Care Practitioner/Physician
PROs	Patient-Reported Outcomes
RCT	Randomized Clinical Trial
RF	Respiratory Frequency
RR	Respiratory Rehabilitation
RRP	Respiratory Rehabilitation Program
RV	Residual volume
TEL	Limitation of therapeutic effort
TLC	Total Lung Capacity
WHO	World Health Organization
YLL	Years of Life Lost
YLD	Years Lived with Disability or Poor Health

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