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Original Article

Clinical Audit of Patients Admitted to Hospital in Spain due to Exacerbation of COPD (AUDIPOC Study): Method and Organisation

Francisco Pozo-Rodríguez[a,b,*], Carlos José Álvarez[a], Ady Castro-Acosta[b], Carlos Melero Moreno[a], Alberto Capelastegui[c], Cristobal Esteban[c], Carmen Hernández Carcereny[d], José Luis López-Campos[e], José Luís Izquierdo Alonso[f], Antonio López Quílez[g], Alvar Agustí[d,b] and Grupo AUDIPOC España◆

[a]*Neumología, Hospital 12 de Octubre, Madrid, Spain*
[b]*Centro de Investigación Biomédica en Red de Enfermedades Respiratorias (CIBERES), Spain*
[c]*Neumología, Hospital de Galdakao, Vizcaya, Spain*
[d]*Unidad Atención Integrada Hospital Clínic, Institut del Tòrax, Hospital Clínic, Barcelona, Spain*
[e]*Unidad Médico-Quirúrgica de Enfermedades Respiratorias, Hospital Universitario Virgen del Rocío, Sevilla, Spain*
[f]*Neumología, Hospital Universitario de Guadalajara, Guadalajara, Spain*
[g]*Departamento de Estadística e Investigación Operativa, Universidad de Valencia, Valencia, Spain*

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ABSTRACT

Background: There is little information regarding the clinical management of hospital inpatients diagnosed with exacerbation of Chronic Obstructive Pulmonary Disease (COPD). AUDIPOC is a clinical audit dealing with the clinical management of COPD in Spain.
Objectives: To examine the adequacy and validity of the instruments used to measure the variables proposed by AUDIPOC Spain (Preliminary Study) and to verify the viability of AUDIPOC in a complex environment with hospitals of different sizes, resources, and organizational layout (Pilot Study).
Materials and methods: The Preliminary Study took place in 4 hospitals and studied 213 cases. The Pilot Study took place in 30 hospitals of 6 Autonomous Communities (i.e. Regions) and studied 1203 cases.
Results: The results of both studies contributed to the improvement of the design, methods and organisation of the AUDIPOC work. Some of the improvements include better training of those responsible at a hospital level, a new classification of hospitals, the incorporation of new variables and the creation of a Panel for the Coordination and Management of the Project.
Conclusions: The AUDIPOC study is viable. It aims to recruit 10 000 patients across 142 hospitals from all the Regions of Spain.

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Auditoría clínica de los pacientes hospitalizados por exacerbación de EPOC en España (estudio AUDIPOC): método y organización del trabajo

Palabras clave:
EPOC
Exacerbaciones EPOC
Auditoría clínica
Mortalidad
Reingresos

RESUMEN

IAntecedentes: Existe poca información sobre el manejo clínico de pacientes ingresados en hospitales públicos españoles con un diagnóstico de exacerbación de enfermedad pulmonar obstructiva crónica. AUDIPOC es una auditoría clínica sobre el manejo de exacerbación de EPOC en España.
Objetivos: Validar la adecuación y validez de los instrumentos de medición de las variables propuestas en AUDIPOC España (estudio preliminar) y verificar su viabilidad en un medio complejo con hospitales de tamaño, recursos y organización diferentes (estudio piloto).

*Corresponding author.
E-mail address: fpozo@h12o.es (F. Pozo-Rodríguez).
◆The names of the authors from the Grupo AUDIPOC España are detailed in Attachment 1.

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Material y métodos: El estudio preliminar se realizó en 4 hospitales y 213 casos. El estudio piloto en 30 hospitales de 6 comunidades autónomas y 1.203 casos.
Resultados: Los resultados de ambos estudios contribuyeron a mejorar el diseño y los métodos y organización del estudio AUDIPOC, incluyendo un mejor entrenamiento de los responsables hospitalarios, una nueva clasificación de hospitales, la incorporación de nuevas variables y la creación de una oficina de coordinación y gestión del proyecto.
Conclusiones: El estudio AUDIPOC es viable y prevé reclutar 10.000 pacientes en 142 hospitales de todas las Comunidades Autónomas.
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Introduction

COPD patients frequently have episodes of exacerbation of the disease (eCPOD[1,2]), which are clinically relevant for being associated with a significant mortality rate.[3,4] They accelerate the deterioration of pulmonary function[5], reduce the quality of life of the patient[6] and cause most of the social, economical, and health costs of the disease.[2,7] Numerous guides for clinical practice are designed to systematise the treatment of eCOPD[1,8,9] developing standards of quality.[10] However, given the lack of information on the clinical management of these patients in Spain[2] the integrated research program (IRP) on CPOD by SEPAR[11] and CIBER on respiratory diseases (CIBERRD)[12] decided to push for a national clinical audit (AUDIPOC study) in order to analyse the medical attention given to hospitalised patients diagnosed with eCOPD. The objectives of the AUDIPOC study are described in table 1.

With the objective of evaluating and eventually improving the methods and organisation of the treatment, a preliminary study was performed to determine the adequacy and validity of the measuring instruments for the various proposed variables. A pilot study was also performed to verify the viability of this complex audit, with hospitals of different sizes, resources, and organisation systems.

In this paper, we present the initial methodological design of the AUDIPOC study, the most relevant results and conclusions from the preliminary and pilot studies, as well as the implications of both studies in AUDIPOC organisation and design.

Method

AUDIPOC Study, Spain

Initial generic design

AUDIPOC Spain was designed as an observational transverse study with prospective case recruitment. It is based on hospital stay and outpatient follow-up for three months after admission. Clinical data will come from the patients' medical records (medical history and related documents) and data regarding development and hospital materials will be obtained as the study takes place. The study will be performed at 142 public Spanish hospitals in each of the autonomous communities (ACs), which represents 65% of general public hospitals with emergency services[13] offering coverage to approximately 80% of the Spanish population (fig. 1). The sample population will be made up of patients hospitalised in participating health centres during the study period and diagnosed with eCPOD by the attending physician upon admission.

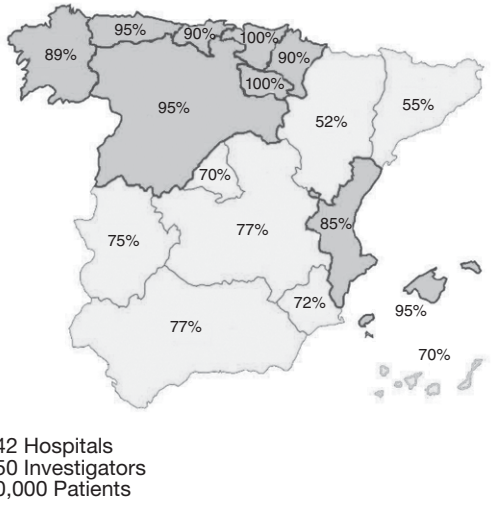

Figure 1. Population covered by the participating hospitals in the AC.

Table 1
Objectives of the AUDIPOC study

General objective
Describe the type of medical attention being given in Spain to patients hospitalised with a clinical diagnosis of CPOD exacerbations.
Specific objectives
1. Describe the clinical state of the patients upon admission
2. Describe the type, quality, and adequacy of the clinical attention given (Clinical Model, CM)
3. Describe the resources and organisation model of each hospital (Hospital Management Models, HMM)
4. Describe the available outpatient social and health devices (Out-patient Management Model, OMM)
5. Describe disease outcomes: duration of hospitalisation, deaths, and re-admittances
6. Describe the variation in clinical interventions, organisation and hospital; resources between regions, type of hospital and participating hospitals
7. Describe the variation in outcomes between regions, hospital type and participating hospitals
8. Describe latent variables for spatial distribution (SV) by patient place of residence
9. Examine the impact of CM, HMM, OMM, and SV vectors on outcomes

Organisation of the study

A Scientific Committee (SC) made up of pulmonologists, epidemiologists, and statisticians designed the study. The fieldwork will be directed by the SC, which will designate regional directors (RD) in the various participating ACs. A local manager (LM) will coordinate the study in the participating hospitals and supervise the collection of survey data.

Variables and measurement instruments

Data on 284 variables related to the participating hospitals and 471 variables on patient subjects will be collected *(online repository)*. The variables will be grouped into 5 categories: 1) available resources and work organisation or hospital model (HM); 2) clinical practice models (PM), with data on the clinical process; 3) outcomes: duration of hospital stay, and mortality rate, frequency of flare-ups and readmissions during hospital stay and 90 days following discharge; 4) analysis of spatial data: location of the hospital and patient's residence; and 5) audit evaluation: evaluating whether clinicians know the audit in progress and the quality of databases.

Analysis plan

The distribution for each variable will be described by national and regional levels, type of hospital and individual hospital and the position of each entity with respect to its category will be compared. The project will also evaluate the influence of the clinical condition of the patient, clinical practice models, hospital models and geographical variability on the outcomes via hierarchical Bayesian spatial models. Where applicable, the predictable spatial variability in the study will be taken into account in order to ascertain the determinants linked to geographical factors and isolate the effect of the variables under evaluation. To this end, random effects will be introduced with auto-regressive spatial structures. The analysis will be performed using Monte Carlo methods for Markov chains (MCMC) with Win BUGS computer programme.

Ethical aspects and conflict of interest

The AUDIPOC España project must be approved by ethics committees and the management of participating hospitals. The SC and LM will be responsible for the safety and confidentiality of the patient and participants' data. The WEB-based database will be dissociated and encrypted.

Preliminary study

The preliminary study was performed between March 13 and April 12 of 2006 in several hospitals: 12 de Octubre (Madrid), Guadalajara General, Galdakao (Vizcaya), and Clìnic (Barcelona), with an assigned population of 1,571,000 inhabitants. Two hundred twenty-one patients were recruited. The database was designed using Microsoft Access 2003.

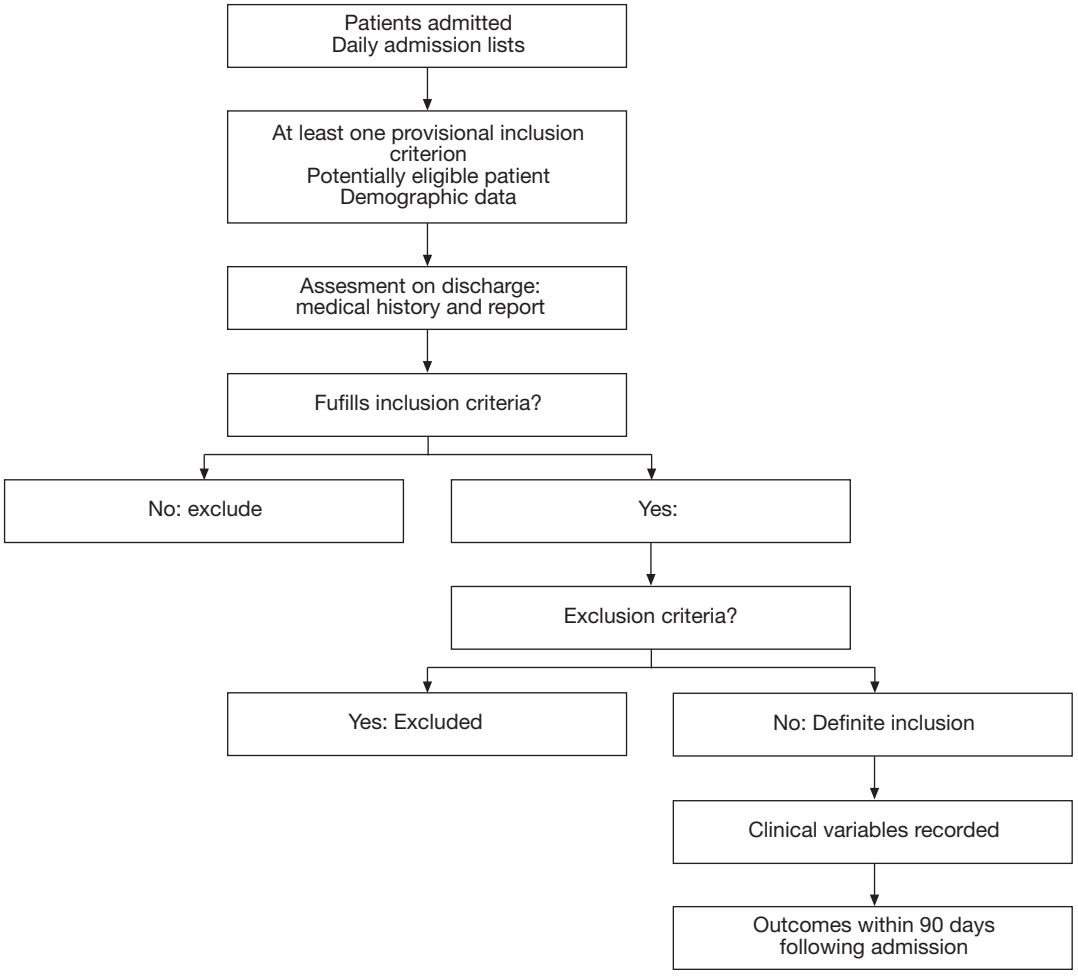

Figure 2. Patient acquisition system.

Table 2
Provisional inclusion criteria. Diagnostic criteria upon admission

Provisional inclusion of the patient upon admission
1. CPOD or chronic pulmonary obstructive disease
2. COB or chronic obstructive bronchitis
3. CB or chronic bronchitis
4. CAO or chronic airflow obstruction
5. CAL o chronic airflow limitation
6. Obstructive lung disease
7. Asthmatic bronchitis with or without reference to acuteness, exacerbations, dyspnoea, bronchospasms, or respiratory insufficiency
8. Respiratory infection, excluding pneumonia
9. Bronchial infection
10. Chronic, acute, or exacerbated respiratory failure, not associated with a causal effect other than CPOD
11. Filial, non-filial, or undetermined dyspnoea
12. Non-specific or non-filial respiratory pathology under study
13. Heart Failure IF acute pulmonary oedema is not explicitly mentioned and IF accompanied by any of the terms previously described

Table 3
Inclusion and exclusion criteria

a. Definitive inclusion criteria (at least one)
1. Admitted principally for eCPOD diagnosis
2. Admitted for "*respiratory pathology*" [respiratory infection without radiological infiltration or pleural effusion (OR) respiratory failure (OR) right heart failure (OR) bronchitis (OR) bronchospasms (AND) [*historical diagnosis of CPOD (OR*) a documented FEV1/FVC < 0.70 in the absence of other obstructive diseases such as asthma or bronchiolitis]
b. Definitive Exclusion Criteria (any of the following):
1. Specific diagnosis: pulmonary oedema, pneumonia, pulmonary embolism, pneumothorax, rib fractures, aspiration, pleural effusion, etc. upon admission
2. Other associated respiratory pathology that determines treatment: pulmonary fibrosis, kyphoscoliosis, obesity-hypoventilation, neuromuscular pathology, upper airway obstruction, bronchiectasis, extensive tuberculosis sequelae, asthma, bronchiolitis or uncontrolled brochogenic carcinoma
3. Pathology outside the lungs that determines treatment: major cardiopathy with chronic heart failure, evolved dementia, extended neoplasia, liver or kidney failure, or other situations at the discretion of the researcher

These criteria are evaluated on the discharge report and clinical history. The cases included are those that have at least one inclusion criteria and no exclusion criteria.

Pilot study

The pilot study was performed between February 5 and March 16 of 2007 in 30 hospitals from 6 ACs (Cantabria, Castilla La Mancha, Vasque Country, Extremadura, Navarra, and Rioja) with an assigned population of 6,597,734 inhabitants. In figure 2, the patient acquisition system is outlined, designed to systematise case definitions. Admission forms were reviewed upon hospital admission in order to identify the provisional inclusion criteria, indicators of acute or exacerbated pulmonary pathology (potentially eligible cases, table 2). Upon discharge, the patient's chart or clinical history was reviewed to see if he/she had a definite or possible diagnosis for eCPOD, non-CPOD respiratory pathology, or pathology outside lungs, which are definitive inclusion and exclusion criteria for the study (table 3).

Our group created a WEB-based information system for online data registration, with the necessary precautionary measures to minimise editing errors. The service was provided under the Windows 2003 Server platform, DELL servers, in an n+1 infrastructure that integrates AT and Rapier Switches from Allied Telesyn, HP Switches, APC Masterswitch, Etinc load balancers and firewalls and MS SQL Server 2003 database motor. The SC and LM were responsible for the security and confidentiality of participating patient and hospital's data. The database was dissociated and encrypted and the ethics committees formed by the participating hospital management approved the project.

Table 4
Some relevant characteristics for cases included in the preliminary and pilot studies

Variable	Preliminary Study (n: 213)	Pilot Study (n: 1203)
Age (years)	74.0	73.7
Males (%)	88.0	89.3
Active smokers (%)	20.6	19.1
Ex-smokers	66.0	60.6
Non smokers	6.2	5.7
Unregistered tobacco history	7.2	14.6
Previously documented spirometry	53.0	60.7
FEV1 (ml) and % over predicted (means)	1,225 (46)	1,167 (52)
FEV1/FVC means	50.0	52.0
Relevant co-morbidity as deemed by the researcher	–	43.2
Charlson Index (mean)	2.3	2.5
Admitted by Pulmonology	53.0	55.5
Admitted by Internal Medicine	37.0	38.6
Chest x-ray upon admission	98.1	97.6
Blood gases upon admission	94.8	93.2
Mean PaO_2 (mHMg)	58.3	55.6
Mean $PaCO_2$ (mHMg)	45.4	46.7
Acidosis (pH ≤ 7.35) upon admission	16.0	14.0
Frequency of treatment with MV (% NIMV)	12.7 (81.5)	10.2 (89)
NIMV at the hospital	63.3	60.5
Mean duration of stay (days)	9.0	9.8
Hospital mortality	4.3	4.7
Mortality following discharge (90 days from admission)	–	5.1
Re-admissions (until 90 days)	–	37

Values expressed as percentages unless otherwise specified.
MV: Mechanical Ventilation; NIMV: Non-Invasive Mechanical Ventilation.

Results

Preliminary study

There was substantial variation in the rates of recruitment between the four centres with respect to the assigned population (between 1.1 and 1.6/100,000). Table 4 presents some relevant data from the preliminary and pilot studies. The data obtained in the preliminary study allowed for the conclusions that: (i) the definition of case the was ambiguous and allowed for interpretations that produced greater variability in recruitment of patients; (ii) the majority of the variables were relevant to the objectives of the AUDIPOC and could be answered; (iii) the study lacked variables related to socioeconomic level, patient's lifestyle or social support and the follow-ups on clinical and vital states of each case; and (iv) there were mistakes in collecting information for some variables because they were too open to interpretation or lacking in guidelines, response limits and automatic internal checks in the database. Therefore, the definition of case was sharpened and a new WEB-based information system was designed. Both changes were implemented in the pilot study.

Pilot study

One thousand eight hundred and ninety-one potentially eligible cases were recruited. Ninety-five were rejected on the basis of improper case handling, and 593 for exclusion criteria (295 for non-CPOD chronic respiratory pathology, 195 or non-eCPOD acute respiratory pathology, and 103 for pathology outside lungs). Finally 1203 patients were included in the study. This constituted the first admission for eCPOD in 27% of cases. One hundred and fourteen patients (9.5%) died, 57 during admission (4.7%) and 57 following discharge within the 90-day follow-up period. During this follow-

up period, 424 patients (37.2%) were readmitted, 75% of them due to eCPOD. Of the 30 participating hospitals, 2 had active CPOD rehabilitation programs, 2 offered home care, and 2 had intermediate pulmonary care. 90% offered non-invasive mechanical ventilation and 2/3 of the emergency services did not have a medical protocol for normalised eCOPD care. Table 4 summarises some of the relevant data from the pilot study, along with information from the preliminary study. The results from this pilot study allowed for the following conclusions: (i) the WEB-based information system worked and allowed for real-time monitoring of the study; (ii) the patient acquisition system and the exclusion/inclusion criteria helped to standardise the recruitment process; (iii) a significant difference remained present in the provisional recruitment and definitive inclusion rates among hospitals and ACs; (iv) the definition of hospitals as primary, secondary, and tertiary did not appropriately classify the health centres in terms of resources, organisation, and health care offer; (v) a notable level of variability was observed in interventions and outcomes between hospitals and ACs (table 5); and (vi) the AUDIPOC España study was feasible.

Implications for the design of the AUDIPOC study

Based on the initial design and the results from the preliminary and pilot studies, the SC decided to: (i) maintain the provisional and definitive exclusion and inclusion criteria; (ii) reinforce the training of hospital representatives and survey assistants in order to homogenise recruitment and inclusion in the study; (iii) implement a better definition of hospital[14] (table 6); (iv) add variables that help to explain the variability in interventions and outcomes; (v) create a panel for the coordination and management of the project, and (vi) design a consistency study in order to document the reproducibility of data collection, which will be performed using 29 relevant variables (online repository) in 15% of the provisionally included patients, selected through a randomised sampling design stratified by centre.

Discussion

eCPOD episodes have a major clinical relevance.[2] However, little information is available on the clinical management of hospitalised patients diagnosed with eCPOD in Spain. In 1997, the British Thoracic Society and the Royal College of Physicians of London propelled the first audit on the subject, involving 38 hospitals and 1,400 patients.[15] The results suggested that the procedures and styles of clinical practice were not in line with recommendations and that there were big differences between hospitals.[15] A second study was performed in 2003, this time at a national level, with 234 hospitals and 7,529 patients.[16] The results from this second study confirmed the finding from the first study.

The British and Spanish studies shared the same objective: to understand the type and quality of assistance that patients admitted with the diagnosis of eCPOD in everyday medical practice, but they differ in various methodological aspects that deserve further exploration. Firstly, the existence of a positive diagnosis for eCPOD without further restrictions was the inclusion criteria for the British audit, which could have implicated the inclusion of patients without CPOD in such a large proportion that it could contaminate the results of the audit. In addition to the evidence published on infra and over-diagnosis of CPOD,[17,18] some results from the British study, such as the elevated representation of women (49%) or the proportion of cases without spirometry (45%[16]) suggest that the diagnosis of eCPOD upon admission lacked sufficient precision. Therefore, the SC of the Spanish study decided to use an entrance filter in the pilot study composed of criteria for inclusion/exclusion, without incorporating spirometry. This way, the study subjects were an adequate representation of the normal clinical practice, combining cases of sure diagnosis (with spirometry) with presumed

Table 5
Variability between hospitals and AC for several variables and outcomes

Variable	Range among hospitals (n = 30)	Range among AC (n = 6)
Co-morbility deemed relevant by the researcher	16.7-82.4	38.2-50.9
Documented spirometry frequency	25.6-94.2	41.7-81.7
% FEV1 over the reference value (mean)	30.4-56.7	43.6-51.9
Frequency of documented acidosis (pH ≤ 7.35)	0-40.9	4.9-23.9
Frequency of treatment with mechanical ventilation	0-27.8	3.7-13.6
Admitted by pulmonology	0-100	21.9-78
Mean duration of stay (days)	4-13	7-10
Hospital mortality	0-20	2.5-7.9
Total 90-day mortality	0-26.7	5.7-13.9
90 day re-admissions	15-80	20.9-45.2

Values expressed as percentages unless otherwise specified.

Table 6
Hospital types. Classification of public Spanish hospitals performed by the Department of Quantitative Methods in Economy and Management at the University of Las Palmas.[14] (2007) as requested by the Ministry of Health and Social Policy

Hospital types	
Group 1	Small county hospitals with less than 150 beds (mean), little high-tech equipment, few doctors, and low level of complexity
Group 2	Basic general hospitals, smaller than 200 beds (mean), minimal technological endowment, adequate share of doctors, and a greater complexity
Group 3	Area hospitals, mid-sized with around 500 beds. Over 50 internal medicine residents and 269 doctors (mean). Mid-level complexity (1.5 departments and 1.01 case mix)
Group 4	Large hospitals with greater heterogeneity in size and activity. High-intensity faculty (over 160 internal medicine residents) and elevated complexity (mean of 4 complex departments and case mix above 1.2)
Group 5	Very large and highly active hospitals. Offers complete services in all departments. Over 680 doctors and around 300 internal medicine residents. Includes large complexes

diagnoses (without spirometry). Indeed, in the pilot study, spirometry was documented in only 68% of cases. Other data from the pilot study showed the efficiency of the filter in excluding cases that were unlikely to be CPOD and retain cases that were likely to be CPOD: 75% of cases included compared to 23% of cases excluded had been diagnosed with markers specifically for CPOD (table 7). The excluded cases (fig. 3) tended to be older, with a greater proportion of women (46%) that was far superior to the group of included cases (11%) and the described rates for the Spanish CPOD population.[19] These data aided the SC in making the decision to maintain the entrance filter in the AUDIPOC study.

Secondly, the British audit[15,16] assigned a fixed number of cases to each participating hospital, whereas the AUDIPOC recruited each emergent case during the study period. This allowed for the aggregated estimators at the national, regional, and hospital levels, to be pondered for the weight of health care at each hospital.

Table 7
Distribution of the provisional inclusion criteria among the cases that were definitely included in the pilot study and those excluded. Some cases could meet various criteria

Criteria for the basis of provisional inclusion	Cases included (n = 1203)	Cases excluded (n = 593)
COPD COB, CB, CAO, CAL, obstructive pneumopathy	74.4	23.1
Bronchial or respiratory infection	32.3	55.7
Chronic respiratory failure	14.1	19.1
Non-filial dyspnoea	7.6	11.6
Heart failure	2.7	6.4
Asthmatic bronchitis	1.3	3.9

Values expressed as percentages.
CB: chronic bronchitis; COB: chronic obstructive bronchitis; CPOD: chronic pulmonary obstruction disease; CAL: chronic airway limitation; CAO: chronic airway obstruction.

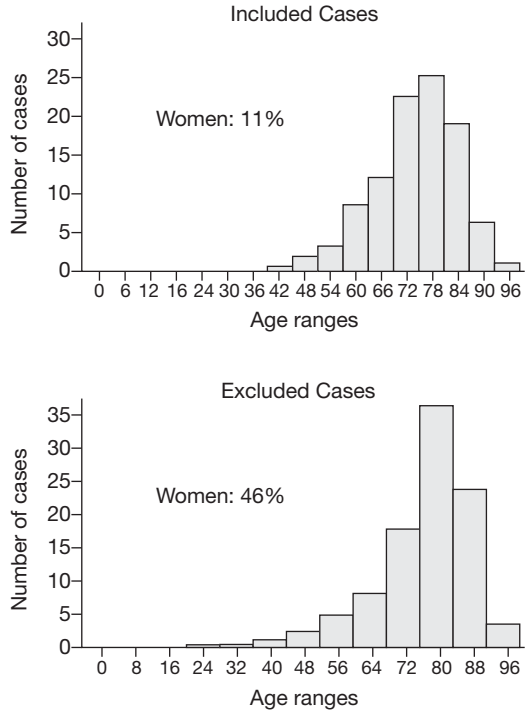

Figure 3. Differential distribution of the cases included and excluded according to sex and age.

Also, in relation to the variability in interventions and outcomes between hospitals and regions that was reported both by the British studies and the pilot study, the SC decided that in the AUDIPOC, in addition to adjusting for the clinical condition of each patient and the structure and organisation of the hospital, they would use spatial analysis techniques to determine the impact of determinants linked to geographical factors.

Finally, AUDIPOC will incorporate diverse mechanisms for quality control of the data collected. In order to control for a potential information bias, data will also be collected on the involvement and knowledge of the responsible doctor for each patient in relation to the audit process. Furthermore, the management panel for the project will perform a daily supervision of the progress of the study and the quality of the data collected by performing an exhaustive review of a randomly selected group of cases and periodical intermediate analysis to identify impossible values and other inconsistencies.

The types of health practice identified in the AUDIPOC study will be assessed with external and internal standards. The first to be used will be the GOLD[1] and SEPAR[8,10] standards, as well as quality controls proposed by the CPOD strategy of the National Health System;[2] the comparison will be performed on national, regional, hospital type, and individual hospital levels. The next analysis will be performed on the central tendency data from each level of the AUDIPOC. The results from these comparisons will be used to make recommendations for clinicians and health management in order to improve the medical attention for patients hospitalised with eCPOD in Spain. The evaluation of the grade and quality of compliance with these recommendations will be verified with another clinical audit project on CPOD exacerbations at European level. This involves a pilot study sponsored by the European Respiratory Society (ERS), coordinated by British and Spanish researchers, with 13 countries participating in the field work through their respective national health societies.

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Attachment 1. Grupo AUDIPOC España

Coordinator: POZO RODRIGUEZ, Francisco. Neumología, Hospital 12 de Octubre. Madrid. **Coordination panel:** CASTRO ACOSTA, Ady Angélica. Médico Investigador CIBERES Unidad de Epidemiología Clínica, Hospital Universitario 12 de octubre. Madrid. BOUKICHOU ABDELKADER, Nisa Lic. CC y TT. Estadísticas. Investigador CIBERES Unidad de Epidemiología Clínica, Hospital Universitario 12 de octubre. Madrid. JIMENEZ ARANDA, Guillermo Estadístico Investigador CIBERES Unidad de Epidemiología Clínica, Hospital

Universitario 12 de octubre. Madrid. **Scientist and management commitee:** POZO RODRÍGUEZ, Francisco. Coordinador del estudio AGUSTÍ, Alvar. Neumología, Instituto Cardiotorácico Hospital Clinic, Barcelona. ÁLVAREZ MARTÍNEZ, Carlos José. Neumología, Hospital 12 de Octubre. Madrid. CAPELASTEGUI SAIZ, Alberto. Neumología, Barakaldo. Bilbao. ESTEBAN GONZÁLEZ, Cristobal. Neumología, Hospital de Galdakao. Vizcaya. HERNÁNDEZ CARCERENY, Carme. Neumología, Hospital Clinic. Barcelona. IZQUIERDO ALONSO, José Luis. Neumología, Hospital de Guadalajara. LOPEZ CAMPOS, José Luís. Neumología, Hospital Universitario Virgen del Rocío. Sevilla. MELERO MORENO, Carlos. Neumología, Hospital Universitario 12 de octubre. Madrid. **ANDALUSIA:** REGIONAL MANAGER: José Luís López Campos. Neumología, Hospital Universitario Virgen del Rocío. **Almería:** Complejo Hospitalario Torrecárdenas. LOCAL MANAGER: José Calvo Bonachera. **Cádiz:** Hospital de La Línea de la Concepción. LOCAL MANAGER: Armando Falces Sierra. Hospital General de Jerez de la Frontera. LOCAL MANAGER: Gregorio Soto Campos. Hospital Puerta del Mar. LOCAL MANAGER: Fernando Romero Valero. Hospital Puerto Real. LOCAL MANAGER: Jesús Sanchez Gomez. Hospital Universitario Reina Sofía. LOCAL MANAGER: Maria Jesús Cobos Ceballos. **Granada:** Hospital Universitario San Cecilio. LOCAL MANAGER: Alicia Conde Valero. **Huelva:** Hospital Infanta Elena. LOCAL MANAGER: Rosa Vázquez Oliva. Hospital Juan Ramón Jiménez. LOCAL MANAGER: Rut Ayerbe García. **Jaén:** Centro Hospitalario Ciudad de Jaén. LOCAL MANAGER: Bernardino Alcázar Navarrete. E.P.H.A.G. Alto Guadalquivir (Andujar). LOCAL MANAGER: Juan Manuel Bravo Santervás. **Málaga:** Hospital Costa del Sol. LOCAL MANAGER: José Fernández Guerra. Hospital Regional Carlos Haya. LOCAL MANAGER: José Luís de la Cruz Ríos. Hospital Serranía de Ronda. LOCAL MANAGER: Francisco José Cabello Rueda. Hospital Virgen de la Victoria. 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Hospital Universitario de Tenerife. LOCAL MANAGER: José Antonio Gullón. **CANTABRIA:** REGIONAL MANAGER Ramón Agüero Balbín. Neumología, Hospital Marqués de Valdecilla. **Cantabria:** Hospital de Laredo. LOCAL MANAGER: Miguel Zabaleta Murguiondo. Hospital Marqués de Valdecilla. LOCAL MANAGER: Ramón Agüero Balbín. Hospital Sierrallana LOCAL MANAGER: Mar García Pérez. **CASTILLA LA MANCHA:** REGIONAL MANAGER Jesús Fernández Francés. Neumología, Hospital de Guadalajara. **Albacete:** Hospital de Albacete. LOCAL MANAGER: Ana Isabel Tornero. **Ciudad Real:** Hospital La Mancha Centro (ALCAZAR). LOCAL MANAGER: Gloria Francisco. Hospital Manzanares. LOCAL MANAGER: Fernando Pedraza and Marisi Verdugo. **Cuenca:** Hospital de Cuenca. LOCAL MANAGER: María José Peirón. **Guadalajara:** Hospital de Guadalajara. LOCAL MANAGER: Jesús Fernández Francés and JL Izquierdo. **Toledo:** Hospital de Talavera. LOCAL MANAGER: José Celdrán. Hospital de Toledo. LOCAL MANAGER: Encarna López Gabaldón. **CASTILLA Y LEÓN:** REGIONAL MANAGER Jesús Reyes Hernández Hernández. Neumología, Hospital Nuestra señora de Sonsoles. **Ávila:** H Nuestra señora de Sonsoles. LOCAL MANAGER: Eugenio Trujillo Santos. **Burgos:** Complejo Hospitalario de Burgos. LOCAL MANAGER: Luís Rodríguez Pascual. Hospital Santiago Apostol de Miranda de Ebro. LOCAL MANAGER: Esteban Pascual Pablo. Hospital Santos Reyes Aranda de Duero. LOCAL MANAGER: Pedro Cancelo Suárez. **León:** Complejo Asistencial de León. LOCAL MANAGER: Ana José Seco García. Hospital del Bierzo. LOCAL MANAGER: Juan Ortiz De Saracho y Bobo. **Palencia:** Complejo Asistencial de Palencia. LOCAL MANAGER: Maria Ángeles Fernández Jorge. **Salamanca:** Complejo hospitalario de Salamanca. LOCAL MANAGER: Rosa Cordovilla Pérez. **Segovia:** Hospital General de Segovia. LOCAL MANAGER: Graciliano Estrada Trigueras. **Soria:** Complejo Asistencial de Soria, Hospital Santa Bárbara. 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Hospital Fundación Alcorcón. LOCAL MANAGER: Barbara Steen. Eva De Higes Martinez. Mercedes Izquierdo Patron and Ángela Ramos Pinedo. Hospital Gomez Ulla. LOCAL MANAGER: Javier Jareño, Ignacio Granda Uribe and Sergio Campos Tellez. Hospital Gregorio Marañón. LOCAL MANAGER: Jose De Miguel Rodriguez Gonzalez Moro. Hospital Infanta Cristina, Parla. LOCAL MANAGER: Maria Teresa Rio. Ramirez. Hospital Infanta Sofía. LOCAL MANAGER: Blas Rojo Moreno Arrones and Raul Moreno Zabaleta. Hospital La Paz. LOCAL MANAGER: Sergio Alcolea Batres. Hospital Puerta de Hierro. LOCAL MANAGER: Antolin López Viña. Hospital Ramón and Cajal. LOCAL MANAGER: Esteban Perez Rodriguez. Hospital Sureste Arganda del Rey. LOCAL MANAGER: Sergio Salgado Aranda. **COMUNIDAD FORAL DE NAVARRA:** REGIONAL MANAGER. Javier Hueto Perez de Heredia. Neumología, Hospital de Navarra de Pamplona. **Navarra:** Hospital De Navarra De Pamplona. LOCAL MANAGER: Jalil Abú-Shams, Victor Manuel Eguía Astibia. Hospital Garcia Orcoyen De Estella. LOCAL

MANAGER: Idoya Pascal Martínez. Hospital Reina Sofia De Tudela. LOCAL MANAGER: José Antonio Cascante Rodrigo and Jose Javier Lorza Blasco. Hospital Virgen Del Camino De Pamplona. LOCAL MANAGER: Joan Boldú Mitgans and Pilar Cebollero Rivas. **COMUNIDAD VALENCIANA:** REGIONAL MANAGER Juan José Soler Cataluña. Neumología, Hospital de Requena. **Alicante:** Hospital de Elda. LOCAL MANAGER: Alejandro Muñoz. Hospital de Orihuela. LOCAL MANAGER: Jose Manuel Querol. Hospital de San Joan. LOCAL MANAGER: Adaluz Andreu Rodríguez. Hospital de Torrevieja. LOCAL MANAGER: Esther Pastor. **Castellón de la Plana:** Hospital de la Magdalena. LOCAL MANAGER: Khaled Bdeir Egnayem Hospital de La Plana. LOCAL MANAGER: Luis Miravet. Hospital General de Castellón. LOCAL MANAGER: Margarita Marin Royo. **Valencia:** Hospital Clinico Valencia. LOCAL MANAGER: Maria Cruz Gonzalez Villaescush. Hospital de Requena. LOCAL MANAGER: Juan Jose Soler Cataluña. Hospital Dr Peset. LOCAL MANAGER: Alberto Herreron Silvestre and Alfonso Martinez Martinez. Hospital Frances de Borja, Gandia. LOCAL MANAGER: Concha Pellicer Ciscar. Hospital Rivera. LOCAL MANAGER: Elsa Naval Sendra. Hospital Sagunto. LOCAL MANAGER: Eva Martinez Moragon. Hospital Universitario la Fe. LOCAL MANAGER: Montserrat Leon Fabregas. **EXTREMADURA:** REGIONAL MANAGER Juan Antonio Riesco Miranda. Neumología, Hospital de Cáceres. **Badajoz:** Hospital de Badajoz. LOCAL MANAGER: Jose Antonio Gutiérrez Lara. **Cáceres:** Hospital de Cáceres. LOCAL MANAGER: Juan Antonio Riesco Miranda. Hospital de Plasencia. LOCAL MANAGER: Miguel Angel Hernández Mezquita. **GALICIA:** REGIONAL MANAGER Juan Suárez Antelo. Neumología, Complejo Hospitalario Universitario A Coruña. **La Coruña (A Coruña):** Complejo Hospitalario Universitario A Coruña. LOCAL MANAGER: Juan Suarez Antelo. FPH Barbanza. LOCAL MANAGER: Emilio Manuel Padin Paz. Hospital de Conxo-Santiago de Compostela. LOCAL MANAGER: Jesús Suarez Martinez. **Lugo:** Hospital Comarcal Burela. LOCAL MANAGER: Sonia Paredes Vila. Hospital Xeral. LOCAL MANAGER: Rafael Golpe Gomez. **Orense (Ourense):** CH Ourense. LOCAL MANAGER: Carlos Vilariño Pombo and Jose Manuel García Pazos. **Pontevedra:** Hospital do Meixoero, Vigo. LOCAL MANAGER: Manuel Nuñez Delgado. Hospital Povisa. LOCAL MANAGER: Maria Dolores Corbacho Abelaira. Hospital Xeral, Vigo. LOCAL MANAGER: Marta Nuñez Fernandez. **ISLAS BALEARES:** REGIONAL MANAGER Borja García Cosio. Neumología, Hospital Son Dureta. **Palma de Mallorca**: Hospital Comarcal de Inca. LOCAL MANAGER: Elena Laserna Martinez. Hospital de Manacor. LOCAL MANAGER: Rosa Maria Irigaray Canals. Hospital de San Llatzer. LOCAL MANAGER: Salvador Pons Vivas. Hospital Son Dureta. LOCAL MANAGER: Borja Garcia Cosio. **Menorca**: Hospital Mateu Orfila. LOCAL MANAGER: Jordi Guerrero. **Ibiza:** Hospital Can Misses, Ibiza LOCAL MANAGER: Alvaro De Astorza and Antonio Cascales García. **LA RIOJA:** REGIONAL MANAGER Manuel Barrón Medrano. Neumología, Hospital de la Rioja. **La Rioja:** Fundación Hospital de Calahorra. LOCAL MANAGER: Susana Chic Palacin and Manuel Barron Medrano. Hospital De La Rioja. LOCAL MANAGER: Carlos Ruiz Martínez and Manuel Barron Medrano. **PAIS VASCO:** REGIONAL MANAGER Cristóbal Esteban González. Neumología, Hospital de Galdakao. **Álava:** H de Santiago. LOCAL MANAGER: Mª Ines Carrascosa. H Txagorritxu. LOCAL MANAGER: Laura Tomas. **Gipuzcoa (Guipuzkoa):** H Bidasoa. LOCAL MANAGER: Mª Asunción Celaya and Silvia Dorronsoro. H Donostia. LOCAL MANAGER: Mª Rosa Berdejo and Monica Rayon. Hospital de Mendaro. LOCAL MANAGER: Iñaki Royo and Nicolás Gurrutxaga. H de Mondragón. LOCAL MANAGER: Iñaki Peña and Mikel Temprano Gogenola. H Zumarraga. 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LOCAL MANAGER: Hortencia Canto Argiz. **REGION DE MURCIA:** REGIONAL MANAGER. Juan Miguel Sánchez Nieto. Neumología, Hospital General Universitario Morales Meseguer. Hospital de los Arcos. LOCAL MANAGER: Damian Malia Alvarado, Jose A Ros Lucas and Nuria Castejon Piña. Hospital General Universitario Morales Meseguer. LOCAL MANAGER: Juan Miguel Sanchez Nieto, Maria Loreto Alemany Frances and Roberto Bernabeu Mora. Hospital Santa Maria Rosell. LOCAL MANAGER: Ines Bernal Belijar, Jose Javier Martinez Garceran, Mercedes Guillamon Sanchez and Pilar Berlinches Acin. Hospital U Reina Sofía. LOCAL MANAGER: Carlos Orts Arqueros, Maria Jesus Aviles Ingles and Pedro Mendez Martinez.

Attachment 2. Supporting information

Supplementary data associated with this article can be found in the online version on the web at doi:10.1016/j.arbres.2010.04.004.

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