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EUROPEAN COPD AUDIT

European COPD Audit: design, organisation of work and methodology

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ABSTRACT: Clinical audit has an important role as an indicator of the clinical practice in a given community. The European Respiratory Society (ERS) chronic obstructive pulmonary disease (COPD) audit was designed as a pilot study to evaluate clinical practice variability as well as clinical and organisational factors related to outcomes for COPD hospital admissions across Europe.

The study was designed as a prospective observational noninterventional cohort trial, in which 422 hospitals from 13 European countries participated. There were two databases: one for hospital's resources and organisation and one for clinical information.

The study was comprised of an initial 8-week phase during which all consecutive cases admitted to hospital due to an exacerbation of COPD were identified and information on clinical practice was gathered. During the 90-day second phase, mortality and readmissions were recorded. Patient data were anonymised and encrypted through a multi-lingual web-tool. As there is no pan-European Ethics Committee for audits, all partners accepted the general ethical rules of the ERS and ensured compliance with their own national ethical requirements.

This paper describes the methodological issues encountered in organising and delivering a multi-national European audit, highlighting goals, barriers and achievements, and provides valuable information for those interested in developing clinical audits.

KEYWORDS: Chronic obstructive pulmonary disease, clinical audit, exacerbation, hospital admission, outcomes

Chronic obstructive pulmonary disease (COPD) is a significant cause of morbidity and mortality in Europe and a major consumer of resources in both primary and secondary healthcare [1, 2]. The disease has an increasingly high profile with health authorities, health insurance companies and healthcare providers. In this regard, clinical audit is potentially a vital tool in assessing clinical practice in this chronic debilitating disease. Audits of patient care have been extended to measure the organisation of care and the resources dedicated to COPD care in acute units. Over the last 10 yrs, several audits have been carried out in individual countries highlighting important information about the delivery of care to COPD patients and the structure of the hospitals serving them. The first national COPD audit was developed in the UK in 1997 [3]. Others have followed, including Spain [4], Scandinavian countries [5] and Australia [6].

These audits provide growing evidence that the quality of COPD patient care varies widely between different hospitals and between different countries, and is frequently not consistent with published guidelines. Additionally, the organisation and resource provision for COPD varies considerably from unit to unit, and there is no mechanism for either identifying or disseminating examples of high-quality care or innovation in service delivery. In this context, it remains unknown which national systems deliver the best practice for different aspects of patients care. In all likelihood, we can all improve the care of COPD patients if we have better knowledge of our performance and gain understanding of the factors associated with better patient outcomes. However, there is not yet a culture of participation in audits across and within most European countries to provide a basis for such comparisons. Notwithstanding, the technology to facilitate an audit of this kind is available and large quantities of relevant data could be collected and reported to clinicians.

Being aware of this scenario, the European Respiratory Society (ERS) developed the first

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European COPD Audit as a pilot study to evaluate clinical practice as well as clinical and organisational factors related to outcomes for COPD admissions across Europe. In the present article, we describe the methodology used to perform this audit and the challenges of auditing across differing healthcare systems and countries.

METHODS

The audit was designed as a prospective, observational, non-interventional cohort trial over a defined time period, in which 13 European countries participated.

Governance

The ERS managed the audit, named a steering committee, which reported to the ERS executive committee, to oversee the process and assigned a project manager to help the steering committee develop the audit. The steering committee was formed by three respiratory physicians with expertise in COPD and clinical audits from three different countries: C.M. Roberts (UK), S. Hartl (Austria) and J.L. López-Campos (Spain). Each national society named one or two national experts to coordinate the audit in that particular country and to represent their views. Altogether, the steering committee, the project manager and all national experts formed the expert panel, an operational group that was responsible for ensuring the success of the data collection and which provided feedback on the process and suggested improvements through regular face-to-face meetings and teleconferences. Within each national participating society a number of investigators were appointed, each operating at an individual hospital level and responsible for local data collection on patients and organisation of care (fig. 1).

Funding

Central funding of the project was entirely granted by the ERS covering all costs at a European level. Expenses at a national level were not covered. The project gave freedom to national experts to raise funds to cover expenditure to develop the project in their own country according to their ethical regulations.

Selection of the participant countries

During 2009, contact with National Respiratory Societies across Europe was established by the steering committee with a proposal to participate. Those interested attended a meeting that took place during the 2009 ERS Annual Congress in Vienna, Austria. Subsequently, the steering committee provided information about the project to all members through the Forum of European Respiratory Societies. Two major conditions were set for national societies to participate: 1) the logistic capacity to provide the administrative structure for a national organisation of local investigators; and 2) the financial resource to support the national audit process. The national societies of 13 countries agreed to participate in the audit (table 1). A further 11 national societies that expressed an interest but were not in a position to participate were invited to meetings as observers. All participants were not-for-profit organisations with a legal status without profitable interests and were independent of industry, commercial and business or other conflicting interests. Participant national societies held the responsibility to organise data collection within their own territory following the decisions made by the expert panel. Each national society was responsible for selecting the participant hospitals in that particular country.

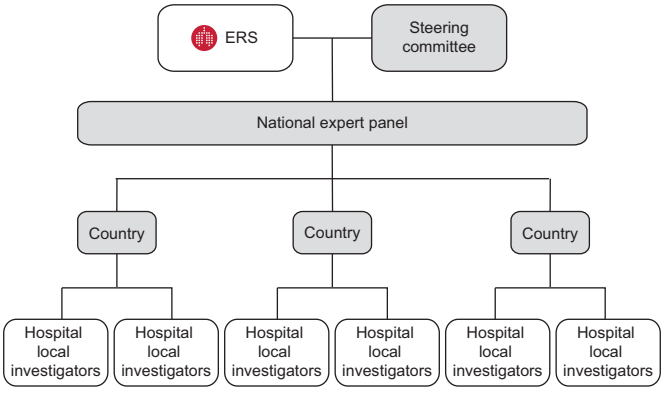

FIGURE 1. Governance of the audit. ERS: European Respiratory Society.

Data item selection

Items for the organisational database were selected by the steering committee based upon those that had previously been used and validated in the Spanish and UK national audits (table 2) [3, 5]. A number of terms had to be consensually defined, as there was no shared meaning across Europe and were considered key concepts for the audit.

Items for the clinical database were selected by the expert panel through a two-round modified Delphi process. The steering committee circulated a list of potential variables based upon items that had previously been used in the Spanish and UK national audits [3, 5], and included process issues matched to guidelines and those considered relevant by national experts. The aim was to select a relatively small group of items that were relevant to clinical practice and were easy to collect across the participating healthcare systems. All potential clinical variables were organised in a spreadsheet and sent to national experts for their evaluation. Each national expert graded items using one of three following options according to their importance: high relevance (five points), medium relevance (three points) or low relevance (one point). Thus, each item could be scored from 10 to 50 points. Those with >30 points were selected for the second round of the Delphi process. In the second round, the initial scoring was fed back to participants as a group mean allowing for a second voting round before a final list was determined (table 3). Items that scored >30 points in the second round were selected as variables for the clinical audit tool.

Web-tool development

A software company (IDCode, Lausanne Switzerland) was commissioned to design a web-based collection tool encompassing both the organisation and clinical databases. Data were entered remotely at each participant site to a centrally controlled server. Patient data were anonymised and encrypted. The web-tool was established as a multilingual database to allow each country to document the data in their own language.

The web-tool was organised as a hierarchical tool with different levels of responsibilities and rights to process data. Only the ERS and steering committee had full access to all data and the right to process them. At the national level there was a hierarchy for country administrators down to the local level hospital managers and doctors or research nurses coordinating the local data collection.

TABLE 1 Participant countries and hospitals

Country	Population density# inhabitants·km^{-2}	Participant hospitals n	Hospital catchment population¶	Beds per 100000 inhabitants#,+
Austria	101.1	49	5637560	482.82
Belgium	356	24	7171000	193.07
Croatia	78.4	10	3900000	201.54
Greece	85.9	23	16976830	66.21
Ireland	65.2	11	3775739	126.47
Malta	1303.6	1	417608	203.54
Poland	121.9	40	22505802	78.09
Romania	93.6	10	3828413	64.75
Slovakia	110.3	4	6120000	53.87
Spain	90.8	94	30702592	162.71
Switzerland	191.2	19	3524177	173.80
Turkey	92.3	22	41346670	41.07
UK	250.8	125	39908232	186.68
Total	226.2	432	185814623	127.39

#: data obtained from Eurostat database; ¶: as referred by the centre; +: beds per 100,000 inhabitants of catchment population.

Each participating country received training from the steering committee on COPD audit practice through teleconferences, local meetings and workshops before starting the definite data collection. Subsequently, each country trained hospital managers and doctors/nurses responsible for the data collection.

Inclusion–exclusion criteria

As there is no operational European definition for a COPD exacerbation case admission, the Global Initiative for Chronic Obstructive Lung Disease recommendation for diagnosing an exacerbation exclusively on the clinical presentation of the patient was adopted [7]. Thus, two inclusion criteria based on clinical grounds were established. 1) Patients who were admitted to hospital for $\geqslant$12 h with a senior clinician-made diagnosis of COPD exacerbation or any other synonym, confirmed at discharge as judged by the investigator/audit lead. 2) Patients who were admitted to hospital for $\geqslant$12 h with a respiratory cause of admission as indicated by the discharge report and a history compatible with COPD.

Exclusion criteria were defined to distinguish other primary conditions that might produce symptoms similar to those of a COPD exacerbation where COPD exacerbation was not the primary cause for admission (table 4). Critically, patients admitted with a senior clinician-made diagnosis of COPD exacerbation and treated as such were included within the audit, regardless of the findings on the chest radiograph.

Protocol of study

The study was comprised of two phases. During the first, all consecutive cases admitted to hospital due to an exacerbation of COPD were identified during an 8-week period and registered in the clinical database. Local investigators had to identify all COPD admissions on a daily basis according to the local hospital protocol. There was no intervention by the audit team to the care provided by the medical staff in charge of the patient. At discharge, the local investigator accessed the discharge report and evaluated whether COPD exacerbation remained the cause of admission. If this was the case, all clinical data were extracted from the medical record, uploaded to the database and the case was entered to the second phase.

During the second phase, data on patient outcomes of death and readmission at 90 days were sought from various sources, including hospital records, primary care practitioners or from the patient and carers. The date of death was recorded and the cause of death or readmission was classified as either COPD-related or not COPD-related.

The 8-week collection period was planned to start on November 2010, but a number of countries asked for a later start date either because of their milder climate or because of delays in obtaining ethical approval for data collection. Thus, there were two inclusion periods, as follows. Group 1 (Austria, UK, Slovakia and Poland), begun on October 25, 2010 and ended on December 19, 2010; and group 2 (Belgium, Greece, Spain, Switzerland, Croatia, Romania, Malta, Turkey and Ireland) recorded clinical cases from January 3, 2011 until February 27, 2011. The 90-day follow-up period ended on March 18, 2011 and May 28, 2011 for groups 1 and 2, respectively. After these periods, investigators had an extended time to complete the databases of the clinical cases that were pending for a few weeks more. Final closing of the databases for both groups was on June 22, 2011.

Ethics

The European audit followed the European ethical requirements for scientific studies. All partners of the project accepted the general ethical rules of the ERS, particularly the rules on conflict of interests and relationships with the tobacco industry, which was an exclusion criterion for individual participation as a national representative. As there is no European Ethics Committee for audits, national societies ensured compliance with European and national ethical requirements. Some countries needed complex ethics agreements. Grants at the national level to support the audit had to be given as unrestricted grants to the national society without any further influence or interference of the sponsor on future results. The Steering Committee produced a standard patient consent form

TABLE 2 List of resources and organisational variables selected

Hospital data
Number of beds
Population the hospital attends
Teaching/university hospital
Does your hospital belong to the national health service or is it a private company?
Does your hospital have an ICU?
Does your hospital have spirometry available?
Is there a respiratory physician on call every day of the year?
Respiratory unit or department
Does your unit have a respiratory outpatient clinic available?
Does your unit have an outpatient clinic for COPD?
How many emergency admissions for any cause did your unit take in 2009?
How many respiratory specialists are there in your unit?
How many medical trainees are there in your department?
How many chest physiotherapists/respiratory therapists are there in your unit?
How many nurse specialists are there in your unit?
How many lung function technicians are there in your unit?
Does your unit have a respiratory ward?
If yes, what percentage of COPD patients admitted during a year are managed on the respiratory ward?
How many ward rounds by the admitting specialist are there in the first 24 h of a COPD admission in a working day?
Does your unit operate a system of specialty triage for COPD?
Does your unit have an emergency department?
Does your unit have an admissions ward in which some/all COPD patients are treated?
Does your unit have a high dependency unit that admits COPD patients?
If yes, how many beds?
Does your unit have an ICU that admits COPD patients?
If yes, how many beds?
What percentage of COPD patients are seen by a physiotherapist or respiratory nurse specialist during an admission in your unit?
What percentage of COPD patients are seen by a respiratory medical specialist during an admission in your unit?
Does your unit offer noninvasive mechanical ventilation for acidotic respiratory failure patients?
If yes, do you have the capacity to treat all eligible patients?
Does your unit offer invasive mechanical ventilation for acidotic respiratory failure patients?
If yes, do you have the capacity to treat all eligible patients?
Does your unit have access to a pulmonary rehabilitation programme for discharged COPD admissions?
If yes, what type of programme do you carry on?
If yes, what percentage of eligible discharges receive pulmonary rehabilitation within 6 months?
Does your unit operate an early/supported discharge programme for COPD admissions?
If so, what percentage of admissions enter this programme?
Does your unit have access to a palliative care service for end-of-life COPD admissions?
Does your unit take care of long-term oxygen patients?
Does your hospital take care of home-ventilated patients?

ICU: intensive care unit; COPD: chronic obstructive pulmonary disease.

and an outline ethics application proforma for those countries that required a formal ethics research application. In the case of ethical dilemmas, the Ethics Committee of the ERS was consulted.

Statistical analysis

Statistical computations were performed by a data analysis team located in Seville, Valencia and Madrid, Spain. A preliminary data description was made to identify extreme values and inconsistencies. Thus, the database entered a data cleaning process starting on June 22, 2011. Those values considered extreme or found to have inconsistencies with other related variables were sent to local investigators to check and sent back the correct value. Once the database was completed, reports at a national and hospital level were created for the national experts, with their national information benchmarked against the rest of the countries or hospitals and the European average value. Median and interquartile range was used for quantitative variables, and the absolute and relative frequencies were used for qualitative ones using SAS 9.2 software (SAS Institute Inc., Cary, NC, USA). A multilevel multivariate analysis controlling for national and hospital clustering of cases will subsequently be performed.

DISCUSSION

There is increasing evidence and awareness that patients with various health problems do not consistently receive recommended care despite the proliferation of clinical practice

TABLE 3 List of clinical variables selected

Patient data
Patient audit number
Birth date
Age
Sex
Previous history
Pack-years
Current smoking status
Comorbidities: Charlson index
Number of admissions in the previous 12 months for COPD exacerbation
Spirometry results available?
Spirometry results: FVC %
Spirometry results: FEV_1 %
Spirometry results: FEV_1/FVC %
Current admission
Ward
Admission date
Dyspnoea increase?
Sputum increase?
Sputum colour change?
Body mass index
Any treatment for the exacerbation before admission?
Arterial blood gas result?
If yes, enter the actual arterial blood gas results
Any relevant abnormality on chest radiograph?
Treatments given for the exacerbation during admission?
Oxygen given during admission?
Ventilatory support given?
Clinical data upon discharge
Inhaled long-acting bronchodilators given at discharge?
Inhaled corticosteroids given at discharge?
Oxygen given at discharge?
Noninvasive mechanical ventilation given at discharge?
Length of stay
Death during current admission?
Readmission within 90 days?
Death within 90 days?
Date of death
Death caused by COPD?

COPD: chronic obstructive pulmonary disease; FVC: forced vital capacity. FEV_1: forced expiratory volume in 1 s.

TABLE 4 Exclusion criteria

A patient admitted as a clinical case of COPD exacerbation that is later judged to have another primary diagnostic reason for admission, *e.g.* the subsequent diagnosis is changed from COPD to heart failure
Any other primary cause of deterioration and hospital admission, such as:
Pneumonia
Pulmonary embolism
Pulmonary oedema
Pneumothorax
Thoracic trauma
Pleural effusion
Asthma
Pulmonary fibrosis
Sleep apnoea with no treatment
Kyphoscoliosis
Obesity-hypoventilation syndrome
Neuromuscular pathology
Tracheal or upper airway stenosis
Severe bronchiectasis
Severe tuberculosis sequelae
Bronchogenic carcinoma or any other thoracic neoplasm
Extrapulmonary diseases as the primary diagnosis for admission that may produce similar symptoms, such as:
Extensive cancer
Hepatic insufficiency
Renal insufficiency
Cardiac failure
Any other condition as judged by the investigator

COPD: chronic obstructive pulmonary disease.

guidelines. In the USA, it has been reported that only 33% of hospitalised patients with COPD receive guidelines-specified care [8]. Given the actual burden of COPD in both the population and healthcare systems worldwide, the failure to apply managed care guidelines is a major concern for respiratory professional societies [9]. Thus, there is a growing interest of managers in the development of specific measures on the performance of clinicians to improve healthcare. In this context, clinical audits have an important role as a reference of the quality of clinical practice in a given community.

Although the design of this audit is similar to previous ones [3–6], different factors, such as the varied health systems, the different provision of material and human resources, and the fact that there is no clinical audit system in most of Europe, make the present audit unique. The key component of a clinical audit is habitual performance, providing a framework to enable improvements to be made [10]. In this regard, it is of outstanding importance to supportively use the data obtained to bring about clinical practice improvement rather than to criticise the practice of one particular hospital or country.

The potential for the European COPD Audit Project is to raise the profile of COPD, provide an opportunity to promote respiratory medicine across Europe, inform the next COPD management guideline with the addition of recommendations about organisation of care, and develop educational resources to support improved clinical practice in areas identified as both good and poor practice. Additionally, a European audit may allow formal documentation of where management practice differs from evidence-based best practice guidelines and thereby identify areas of need for national and international improvement strategies.

Clinical features of severity of the disease are key factors influencing outcomes [11, 12]. However, there are also organisational aspects that may influence outcomes. The UK COPD audit described how resources may be of importance for the outcome from an admission [13–15]. A recent retrospective observational

study evaluated the impact of nurse staffing on in-hospital mortality [16]. These authors found that lower levels of nurse staffing were associated with increased mortality. Furthermore, in Ontario, Canada, higher spending has been recently associated to better clinical outcomes [17]. Together, these articles together strongly suggest hospital resources as an important factor influencing in-hospital outcomes.

Although our project was prospective in nature, the data gathering was retrospective, as all the information was extracted from the medical records. This has two main consequences. First, this could lead to missing values in some cases. Secondly, the project relied on the extraction of data from different types of hospitals with different data extractors, and different types of documents were checked. The use of electronic health records, a potential solution to these difficulties, is now much debated [18]. For these reasons, our database will have to undergo a process of data cleaning to ensure data accuracy.

The variability of the population included in the study from every participant country was a source of discussion. As this was a pilot study an estimation of the sample size for a representative homogeneous distribution of the population screened was not calculated. Relying on the experience from the UK and Spain audits, we initially intended to include 50 patients per centre of at least 10 participating centres in the country in order to gather a comparable sample size between countries. However, during the training workshops it became clear that the size of hospitals varies considerably in the participating European countries and that this could become a limitation for some countries with small service populations covered by smaller units. Therefore, the steering committee gave freedom to national experts to select as many hospitals as they could recruit in their own countries, to include all cases during an 8-week period, and to compare the catchment population of all centres with the total population of the country to evaluate the representative value. Consequently, this led to a differential contribution of the two countries with an audit history (UK and Spain) and a predominance of larger specialist hospitals taking part. As a consequence, patients are clustered within hospitals/countries and data at national and European levels will have to be interpreted in the context of these clusters.

In accordance with current guidelines [7], COPD exacerbations were defined as diagnosed by a senior clinician on clinical grounds. Subsequent analysis of included cases against spirometry will be used to assess the accuracy of diagnosis within the audit.

Two options were discussed to define the inclusion period. First, a time-fixed inclusion criterion for all cases admitted during a certain period would potentially under-represent smaller hospitals, and thus include fewer cases. Secondly, a fixed number of cases over a variable time period would reduce the impact of hospital size but limit recruitment. In our case, time was fixed during two different periods and the number of cases was open.

Not all interested countries were able to take part. In some cases, this was due to a lack of the national funding needed to establish the administrative structure, and in others this was due to barriers, including reservations about contribution of data to an external source. Although no country was excluded for ethical issues, ethical permission became a key factor as there is no clinical audit system in most of the participant countries with which to approve this kind of study and there is no mechanism for a pan-European ethical consent. There is also no comprehensive documentation of patient outcomes beyond discharge from hospital in many countries. To obtain this information in these cases, patients or caregivers had to be contacted, prompting a major ethical concern that needed formal ethical consideration.

Accuracy of mortality figures was thoroughly evaluated by the expert panel. In-hospital mortality was assumed to be accurate, but the post-discharge mortality registration method varied depending on the country. Some countries, such as the UK, have a system of notifying hospitals when a patient dies. In other countries, data on patient outcomes such as death and readmission were sought from various sources, including hospital records, primary care practitioners or from the patient and caregivers at 90 days after the admission.

The European audit has the potential to gather large-scale data on numerous patients from differing healthcare systems. The pilot study has proven feasibility although revealing a number of difficulties and weaknesses to overcome across different healthcare systems. Clinicians working across national boundaries will be able to promote better processes of care that are difficult to identity in smaller scale audit programmes and will improve the future system of audit by their feedback.

STATEMENT OF INTEREST

A statement of interest for S. Hartl can be found at www.erj.ersjournals.com/site/misc/statements.xhtml

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