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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. This European Respiratory Society 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 non-interventional cohort trial, in which 422 hospitals from 13 European countries participated. There were two databases one for hospitals' resources and organization and one for clinical information. The study comprised a first 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 multilingual 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.
The present paper describes the methodological issues encountered in organising and delivering a multi-national European audit, highlighting goals, barriers and achievements, and providing valuable information for those interested in developing clinical audits.
Key words: chronic obstructive pulmonary disease, clinical audit, exacerbation, hospital admission, outcomes

Introduction

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 years, 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 United Kingdom in 1997 [3]. Others have followed including Spain [4], the 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 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 all can 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 audit of this kind is available and large quantities of relevant data could be collected and reported to clinicians.

The European Respiratory Society (ERS) aware of this scenario developed the first 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 manuscript we describe the methodology used to perform this audit and the challenges of auditing across differing health care 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 (SC) to oversee the process which reported to the ERS executive committee, and made a project manager available to help the SC develop the audit. The SC was formed by three respiratory physicians with expertise in COPD and clinical audits from three different countries, United Kingdom (CMR), Austria (SH) and Spain (JLLC). Each national society named one or two national experts to coordinate the audit in that particular country and to represent their views. Altogether, the SC, 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 meetings and teleconferences. Within each national

participating society a number of investigators were appointed each operating at individual hospital level and responsible for local data collection on patients and organisation of care.

Funding.

Central funding of the project was entirely granted by the ERS covering all costs at 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 SC with a proposal to participate. Those interested attended a meeting that took place during the 2009 ERS Annual Congress (Vienna, Austria). Subsequently, the SC 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 interest but were not in a position to participate were invited to meetings as observers. All participants were non-for-profit organisations with a legal status without profitable interests and 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.

Data item selection

Items for the organisational database were selected by the SC based upon those that had previously been used and validated in the Spanish and United Kingdom national audits [3, 5] (table 2). A number of terms had to be consensually defined, since 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 SC circulated a list of potential variables based upon items that had previously been used in the Spanish and United Kingdom national audits [3, 5] and including process issues matched to guidelines and those considered relevant by national experts. The aim was to set a relatively small group of items relevant to clinical practice and easy to collect across the participating healthcare systems. All potential clinical variables were organised in a spread sheet and sent to national experts for their evaluation. Each national expert graded items using one of three options according to their importance: high relevance (5 points), medium relevance (3 points), or low relevance (1 point). Thus, each item could be scored from 10 to 50 points. Those with more than 30 points were selected for the second round of the Delphi process. In this 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 more than 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 data bases. 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 data base to allow each country to document the data in their own language.
The web was organised as a hierarchical tool with different levels of responsibilities and rights to process data. Only the ERS and SC 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.
Each participating country received training from the SC 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.

Since there is no operational European definition for a COPD exacerbation case admission, the GOLD 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:

- Patients admitted to hospital for 12 hours or longer with a senior clinician made diagnosis of COPD exacerbation or any other synonym, confirmed at discharge as judged by the investigator/audit lead.
- Patients admitted to hospital for 12 hours or longer 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 X-ray.

Protocol of study

The study comprised 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 daily identify all COPD admissions 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 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. Group 1 (Austria, United Kingdom, Slovakia and Poland) started on October 25th 2010 and ended on December 19th 2010. Group 2 (Belgium, Greece, Spain, Switzerland, Croatia, Romania, Malta, Turkey and Ireland) recorded clinical cases from January 3rd 2011 until February 27th 2011. The 90-day follow-up period ended on March 18th 2011 and May 28th 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 22nd 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. Since 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. An informed consent for the patients was created by the SC and an outline ethics committee protocol for those countries needing them. 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 at 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 22nd 2011. Those values considered extreme or found to have inconsistencies with other related variables were sent to local investigators to check and send back the correct value. Once the database was completed, reports at a National and hospital levels 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, with SAS 9.2 (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 guidelines. In the United States it has been reported only 33% of hospitalized patients with COPD receive guidelines-specified care [8]. Given the actual burden of COPD in both the population and the health 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 health care. 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, 4, 5, 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 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, 14, 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. Further, in Ontario higher spending has been recently associated to better clinical outcomes [17]. These papers 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 since all the information was extracted from the medical records. This has two main consequences. Firstly, 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. Since 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 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 vary 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 SC gave freedom to national experts to select as many hospitals as they could recruit in their own countries and all cases during an 8 week period were to be included and the catchment population of all centres was compared to 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 (United Kingdom 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 level 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. A time fixed inclusion criterion for all cases admitted in that period would potentially underrepresent smaller hospitals which will include fewer cases. Secondly, a fixed number of cases over a variable time period reduces the impact of hospital size but limits 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 due to lack of national funding that needed to establish the administrative structure, in others 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 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 post discharge mortality registration method varied depending on the country. Some countries like the UK have a system of notifying hospitals when a patient dies. In other countries data on patient outcomes like 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 health care systems. The pilot study has proven feasibility although revealing a number of difficulties and weaknesses to overcome across different health care 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.

Tables and figures.

Table 1. Participant countries and hospitals.

Country	Population density (inhab/Km^2)*	Number of participant hospitals.	Hospital catchment population†	Beds / 100,000 inhabitants*‡
Austria	101.1	49	5,637,559	48.28
Belgium	356	23	7,170,999	19.31
Croatia	78.4	10	3,900,000	20.15
Greece	85.9	23	16,976,830	6.62
Malta	1303.6	1	417608	20.35
Ireland	65.2	11	3,775,739	12.65
Poland	121.9	40	22,505,802	7.81
Romania	93.6	10	3,828,413	6.48

Slovakia	110.3	3	6,120,000	5.39
Spain	90.8	94	30,702,592	16.28
Switzerland	191.2	19	3,524,177	17.38
Turkey	92.3	22	41,346,670	4.11
United Kingdom	250.8	117	39,118,232	18.75
Total	**226.2**	**422**	**185,024,623**	**12.73**

* Population data obtained from Eurostat database. † As referred by the centre. ‡ Beds per 100,000 inhabitants of catchment population.

Table 2. List of resources and organisational variables selected.

Hospital data
Number of beds
Population the hospital attends
Teaching/University hospital
Does your hospital belongs to the National Health Service or is it a private company?
Does your hospital have an intensive care unit?
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 hours 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 % of COPD patients are seen by a physiotherapist or respiratory nurse specialist during an admission in your unit
What % of COPD patients are seen by a respiratory medical specialist during an admission in your unit
Does your unit offer non-invasive 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 program you carry on?
If yes, what % of eligible discharges receive pulmonary rehabilitation within 6 months
Does your unit operate an early /supported discharge programme for COPD admissions?
If so, what % 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?

Table 3. List of clinical variables selected.

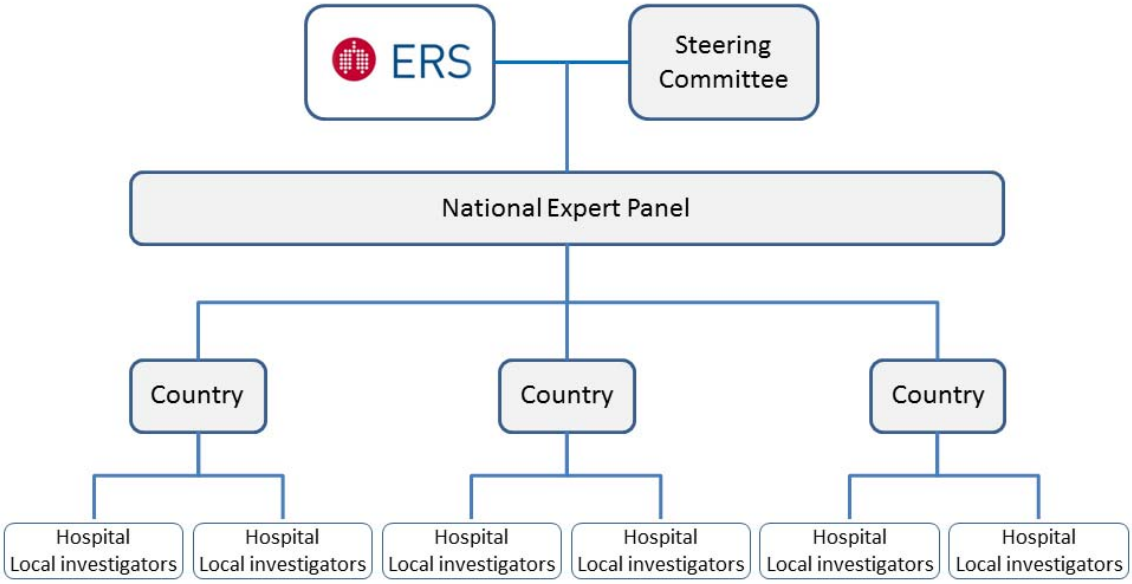
Patient data
Patient audit number
Birth date
Age
Gender
Previous history
Pack-years
Current smoking status
Comorbidities: Charlson index
Number of admissions in the previous 12 months for COPD exacerbation
Spirometry results available?
Spirometry results: FVC (%)
Spirometry results: FEV_1 (%)
Spirometry 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 X-ray
Treatments for the exacerbation during admission
Oxygen during admission?
Ventilatory support
Clinical data upon discharge
Inhaled long acting bronchodilators at discharge
Inhaled corticosteroids at discharge
Oxygen at discharge
Non-invasive mechanical ventilation at discharge?
Length of stay
Death during current admission?
Readmission within 90 days
Death within 90 days
Date of death
Death caused by COPD?

Spirometry results: FVC: forced vital capacity. FEV_1: forced expiratory volume in the first second.

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 apnea 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.

Figure 1. Governance of the audit.



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