Protocol 2010

Index

Rationale, background and need

Chronic Obstructive Pulmonary Disease (COPD) is a significant cause of morbidity and mortality in Europe and a major drain on resources in both primary and secondary healthcare. The disease has an increasingly high profile with health authorities, health insurance companies and healthcare providers.

Evidence is growing that COPD patient care varies widely between different hospitals and between different countries, and is frequently not consistent with published guidelines. Nevertheless, it remains unknown which national systems deliver the best results for patients and which can be improved. In all likelihood, we can all improve the care we give to COPD patients if we have better knowledge of our own performance and a greater understanding of what factors may help.

It is the intention of this COPD audit to develop a core data set that can be used to audit COPD in acute hospital admissions across Europe with a view to raising the standards of care to a level consistent with the European management guidelines. The European Health and Consumer Protection Directorate General (DG SANCO) supports programs that improve European health promotion. The general objectives of the programme are: - to improve citizens' health security; - to promote health, including the reduction of health inequalities and - to generate and disseminate health information and knowledge. The primary intention is to create European Networks that can provide information on European standards of care to allow comparisons of health care systems. Applicants have to be non-profit making and independent of industry, commercial and business or other conflicting interests.

Both the Spanish Thoracic Society and the British Thoracic Society partnered by the Royal College of Physicians of London (RCP) have designed and delivered comprehensive national audit programmes using web based audit tools. These audits have provided valuable information about clinical processes of care and patient outcomes that have been used to benchmark individual hospitals against regional and national performance and against national guidelines (Roberts 2001, 2002, 2003, Price 2006, Hosker 2007, Quantrill 2007). Audits of patient care have been extended to measure the organisation of care and the resources dedicated to COPD care in acute units. Understanding these factors has helped interpret data collected on clinical processes and outcomes. Sharing of good practice and feedback of results to individual providers and national governments has provoked much discussion around health inequalities. A consistent pattern of improvement in organisation and provision of care has been observed between the two UK national audits of 2003 and 2008. More recently the UK 2008 audit extended data collection to primary care and from patients on their symptoms and use of health care resources prior to admission (RCP 2009).

Large scale national audits of these kinds are possible and have demonstrated enormous enthusiasm amongst clinical colleagues with over 98% of all eligible UK acute NHS Hospital Trusts participating in the 2008 audit round. In Spain, the COPD National Audit (AUDIPOC) recorded information on cases admitted to any unit of the participant hospitals due to an exacerbation. Every region in the country participated in the study with 158 participant hospitals, a studied population close to 37 million people, and an initial recruitment of 12,896 cases admitted to hospital.

It is evident that the technology to facilitate audit of this kind is available and that participation by clinicians is good and large quantities of relevant data can be collected and fed back to

participants. Recently the UK audit data has been used to engage the Departments of Health in the four component countries (England, Wales, Scotland and Northern Ireland) in positive discussions about improving health care delivery to COPD patients and as a basis for a COPD service specification. In Spain the Government has funded a national audit programme, whilst in Austria there are ongoing discussions between Government agencies and the Austrian Society of Pneumology to develop a COPD chronic disease programme that includes audit.

At a European level there is no current respiratory audit programme of any kind but the European Cardiac Society (ECS) does have a limited audit programme that has collected data on a variety of specific cardiac areas of clinical practice e.g. cardiac catheterisation procedures. This work has been partially funded by the EU and the ECS.

Audit across differing health care systems and in countries without a tradition of clinical audit will pose a number of challenges and this proposal attempts to address those identified by the applicant team and the referees of the initial submission.

Potential for the European COPD Audit Project:

1. Raise the profile of COPD
2. Provide an opportunity to promote respiratory medicine across Europe
3. Development of numerous research elements
4. Development of the next COPD management guideline with the addition of recommendations about organisation of care
5. Development of educational resources to support improved clinical practice on account of identification of both good and poor practice

Proposal

Objectives, expected outcomes and measurable performance indicators

This respiratory project proposal is designed to produce a European web-based audit tool that can be used at local, regional, national and international levels to provide data on performance that will be used to improve service delivery and ultimately patient care. The clinical audit data collection will initially focus on acute admissions to hospitals. The data items will include process issues matched to guidelines e.g. 'Were arterial blood gases taken on admission?', data items e.g. 'What were the blood gas measurements for pH?', and also patient outcome measures e.g. length of stay and mortality. This audit survey tool will be made available to national societies to deploy as appropriate within their own countries and spheres of influence but with the intention of making it available to all acute hospital units admitting COPD patients.

The experience from prior audit programmes is that such a data set should be relatively small and contain items that are relevant and easy to collect across the participating healthcare systems.

For this audit about 25 items of process of care are selected from the current ERS/ATS COPD guidelines. In addition basic anthropomorphic data, with outcome measures of death, length of stay and readmissions at 90 days (as used in both the Spanish and UK audits) are captured. The process for selecting data items involved a modified Delphi technique in which a list of possible items was presented to the participating national societies and each was asked to prioritise the items until a consensus list of the most important is derived. Two rounds were used in which the initial prioritisation was fed back to participants as a group mean allowing for a second 'voting' round before a final list was determined.

Items will be collected retrospectively from health care records in patients identified prospectively over a defined time period of the year e.g. November to January. Data will be entered remotely via the web to a centrally controlled server database and patient data will be anonymised. The software programme held on the server is enabled to provide real time data analysis that can give pre-determined comparative feedback to the participant sites. For example mean and SD age of patients of participant unit compared to that health region or compared to the national database or even across Europe. This analysis will be extended to markers of severity e.g. admission arterial pH, and to outcomes e.g. length of stay. The information provided will allow benchmarking of individual units and allow adjustment for confounding factors e.g. co-morbidities, to be measured and analysed too. Such data will in the initial phase be relayed back to participating national societies and the individual participating units as 'unit performance' and 'national performance' against the European average and inter-quartile ranges.

Beyond the collection of patient clinical data it is decided that additional information about the organisation and support for clinical COPD services is also collected. There is a huge potential for European health care providers to learn from good and innovative practice in alternative health care systems. The data from the resources and organisation of care aspects can be summarised and posted on a web site that will allow colleagues elsewhere to enter a dialogue and to learn from each other's experience.

It is well appreciated that data collection of this kind will prove challenging in some national environments and therefore it is decided to begin with a pilot feasibility study that will identify some of these factors either common to or specific within national circumstances. A call for volunteer national societies that are aware of the resources and practical issues will be made first. Success in this pilot phase will then provide evidence with which to extend the programme to other ERS member societies. It is anticipated from early enquiries that between 6 and 10 national societies will commit to enter this pilot audit project.

For a comparable reflection of the treatment practice of COPD admissions to hospitals within each country, it will be necessary to include a representative sample of hospitals (10-20 hospitals per country) of different size and different population treated by them in a random way. Each hospital will collect every COPD case within a certain period. This will ensure that the comparison between European countries will not be biased. The sample size will be 50-100 cases per hospital depending on the frequency of COPD admissions.

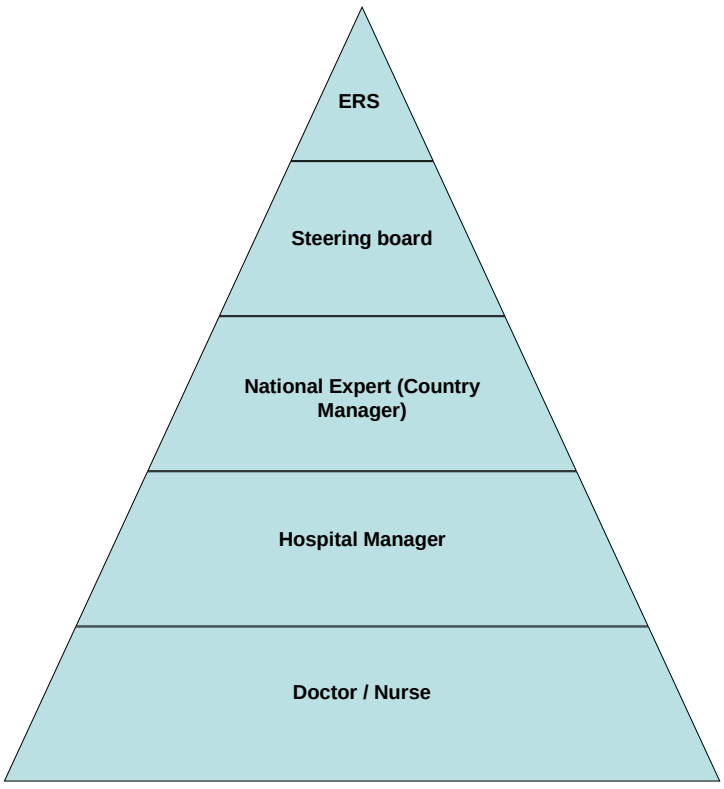
The core data set will be set up in a multilingual data base to allow each country to document the data in their own language. The data processing and the hosting of the server will be done by ERS, but national Societies will have access to their own data, but cannot publish them internationally without permission of ERS.

Each participating country received training from the Steering board on COPD Audit practice (supervision of data collection, feedback letters, usage of the database) before starting the definite data collection. Subsequently every country has to train the hospital managers and doctors/nurses responsible for the data collection in their hospital.

Data collection shall start by the 25th of October 2010 for two months (± 19th of December) followed by a 90 days follow-up period after which reports will be created (2011).

Method

This COPD audit is a cross-sectional, multicenter research. The anonymised data collection is specified to patients experiencing an acute COPD exacerbation and therefore admissioned to the hospital. All data will be stored into a centralised data base.



The structure of the database (webtool) will be multilingual web-based. It is organised as hierarchical tool with different levels of responsibilities and rights to process data: only the ERS and Steering board will have full access to all data and the right to process them. At the national level there will be a certain hierarchy for country administrators (country managers/national expert) down to the local level hospital managers and doctors or research nurses coordinating the local data collection. All patient related data will be anonymised at the level of data collection and the original ID will not be stored at the database but on the local server.

Due to this hierarchy a case will be open for changes until it is submitted. After that it will only be open to statistical processing at the European level.

The study comprises different stages:

1. Web-tool creation: the dataset are established according to guideline recommendations of treatment of COPD exacerbation and outcome markers are added. The two questionnaires (regarding organisational data and patient data) are validated in a Delphi process by all participants and reduced to a core pilot dataset that includes a significant and achievable number of items.

2. Establish and train local teams: to guarantee the same level of understanding and the best achievable structure at the national level it's necessary to create teams with certain responsibilities and an organised form of communication with the European team. A specific memo of understanding has to be signed by all participants. All hospital administrators have to identify every case either with the diagnosis of COPD or with the suspicion of COPD from their medical record. The consequent follow up has to allocate the right case at the end. This needs specific training of all study doctors/nurses.

3. Pilot phase: 5 month of data collection (2 month for entering cases and 90 days follow-up) with the aim of documentation of every COPD case admitted to a partnering hospital. In this case the supervision of the terminated cases from the European level is very important.

4. Data processing and report creation: after closure of case submission the data will have to be processed and a list of reports according to questions and results will be published. The ownership of European data is at the ERS and COPD audit Steering group, national data are owned by the National Experts (representatives of the national scientific societies). Within the group of partners there will be a defined procedure to submit new proposals for data analysis with the right for authorship to the executive panel. All national publications will have to be agreed with the ERS Headquarter

5. European Union: the general pilot report will be used to apply to the European Union for a grant to extend this audit to all European countries.

Participants

The COPD audit project is leaded by the European Respiratory Society ERS and Steering board. They collaborate with several national scientific societies organised within the Forum of Respiratory Societies in Europe (FERS).

The following partners are assigned to this pilot COPD audit project:

Austrian Society of Pneumology	Prof	Otto Burghuber
	Dr	Robab Kohansal
Belgian Society of Pneumology	Prof	Renaud Louis
	Dr	Vincent Heinen
British Thoracic Society	Dr	Sally Welham
	Dr	Christine Bucknall
	Dr	Sheila Edwards
Croatian Respiratory Society	Prof	Neven Miculinic
	Dr	Hrvoje Puretic
Hellenic Respiratory Society	Prof	Nikos Tzanakis,
	Dr	Epameinondas Nontas Kosmas,
Institutul National de Pneumologie M. Nasta	Prof	Florin Mihaltan
	Prof	Miron Alexandru Bogdan
Irish Thoracic Society	Dr	Suzanne McCormack
	Dr	Terry O'Connor
Macedonian Respiratory Society	Prof	Dejan Dokic
Polish Society of Pneumology	Dr	Joanna Chorostowska
	Dr	Piotr Boros
Slovak Pneumological Society	Prof	Ivan Solovic MD PhD.
	Prof	Ruzena Tkacova
Spanish Society of Pneumology and Thoracic Surgery	Dr	Francisco Pozo-Rodríguez
Swiss Society for Pulmonary Medicine	Prof	Daiana Stolz
	Dr	Sibylle Hofmeier
	Dr	Lucas Boeck
Turkish Thoracic Society	Dr	Feyza Erkan
	Dr	Mehmet Polatli

Ethical requirements

All participants are non-for-profit organisations with a legal status without any profitable interests. There is no funding from pharmaceutical companies on the European Project of the COPD Audit. All data publications or analysis of data for third parties have to be agreed by the Executive panel of the Study group.

Participant centers will care for local ethical agreement as needed for their national legal requirements. The European Audit will follow the European ethical requirements for scientific studies.

Budget European Respiratory Society

Detailed Budget:

Budget 2010	**EURO**	
Steering Travels	€ 7'000	
Development of database	€43'000	
Maintenance of database	€ 3'000	
Staff cost equivalent of 5 days per week	€72'000	
Staff cost equivalent of 2.5 days/week for 4 months	€12'000	
Contingency reserve	€15'000	
Meeting in Barcelona commissioned from RCP	€ 4'000	
Total 2010		**€156'000**

Budget 2011	**EURO**	
Steering Travels	€ 3'000	
Staff cost equivalent of 5 days per week	€72'000	
Statistical support	€8'000	
Total 2011		**€83'000**
Total		**€239'000**

Dataset:

Clinical cases:

- No. of audit
- Birth date
- Age
- Gender
- 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: FEV1 (%)
- Spirometry results: FEV1/FVC (%)
- Ward
- Admission date
- Dyspnea increase?
- Sputum increase?
- Sputum colour change?
- BMI
- Treatment for the exacerbation before admission?
- Arterial blood gas results on admission
- Any relevant abnormality on Chest X Ray
- Treatments for the exacerbation during admission
- Oxygen?
- Ventilatory support
- Inhaled long-acting bronchodilators at discharge
- Inhaled corticosteroids at discharge
- Oxygen at discharge
- Non-invasive mechanical ventilation at discharge?
- The date of discharge for calculation of LOS
- Death during current admission?
- Discharge date
- Length of stay
- Readmission within 90 days

- Death within 90 days
- Date of death
- Death due to COPD

Hospital data:

- Number of beds
- Total number of beds in the hospital
- How many people may have access to your hospital
- 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 an intensive care unit that admits COPD patients
- If yes, how many beds
- Does your hospital have spirometry available?
- Is there a respiratory physician on call every day of the year?
- Does your hospital have a respiratory ward
- Does your hospital have a respiratory team

- 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 team
- 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 (miss this Q if previously answered no respiratory nurse nor chest physiotherapist)
- 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 project 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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