Dear Moniek, as we agreed in the last TConference I'm sending you some thoughts about the Inclusion/Exclusion criteria for the ERS │copd audit.

My concern with I/E criteria is grounded on the very fact that they are not recorded in the WEB tool. So, if "reasons for withdrawn" are given in any sort of "narrative form" instead of a list of comprehensive options there may be room for misunderstanding and misclassification; this would make difficult the characterization of cases dropped out and the comparison with those retained.

Selection of cases in the Spain AUDIPOC study was done in two steps:

1.- Upon admission, when patients are transferred to (in hospital) wards. The admission forms contain a list of provisional diagnoses given by the emergency room doctors. Local investigators review every morning these forms to pinpoint potential cases (see the list of provisional inclusion criteria) and mark them as PROVISIONAL (interim) study subjects. At this point the (potential) case is entered in the main database (WEB tool) and demographics and provisional criteria for inclusion registered as well.

2.- At discharge. Local investigators check discharge forms and clinical records looking for definite I/E criteria (see the list of criteria). At this point they enter in the main database the Definite Inclusion criteria for those retained in the study and the Definite Exclusion criteria for those who have been withdrawn.

In doing so we produce information that allow us to compare both subsets of study subjects with regard to demographics and some clinical attributes.

In Spain the selection of cases for the ERS copd audit is being done the same way that in the Spanish AUDIPOC study. The criteria are quite similar in both studies and the Spanish doctors are familiar with the AUDIPOC ones.

What we are doing here is creating a simple excel database to keep track of the inclusion and exclusion criteria. I´m sending it you.

AUDIPOC España

Provisional inclusion criteria upon admission. Assessed from admission forms. One or more.

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
8. dyspnoea, bronchospasms, or respiratory insufficiency
9. Respiratory infection, excluding pneumonia
10. Bronchial infection
11. Chronic, acute, or exacerbated respiratory failure, not associated with a diagnosis other than CPOD
12. Undetermined dyspnoea
13. Non-specific or non-filiated respiratory pathology under study
14. Heart Failure IF acute pulmonary oedema is not explicitly mentioned and IF
15. accompanied by any of the terms previously describe
16. Others

Definite Inclusion/Exclusion criteria at discharge. Assessed from discharge forms.

1.- Inclusion (one of them)

1. Principal diagnosis of (e)CPOD at discharge
2. Admitted for "respiratory pathology" [respiratory infection without radiological infiltration or pleural effusion (OR) respiratory failure (OR) right heart failure (OR) bronchitis (OR) bronchospasm (AND) [historical diagnosis of CPOD (OR) a documented FEV1/FVC < 0.70 in the absence of other obstructive diseases such as asthma or bronchiolitis]

2.- Exclusion (any of the following):

1. Primary diagnosis AT DISCHARGE:
    a. pulmonary edema,
    b. pneumonia,
    c. pulmonary embolism,
    d. pneumothorax,
    e. rib fractures (Thoracic trauma),
    f. aspiration,
    g. pleural effusion,
2. Other associated respiratory conditions that determine treatment:
    a. pulmonaryfibrosis,
    b. kyphoscoliosis,
    c. obesity-hypoventilation,

   d. neuromuscular pathology,
   e. upper airway obstruction,
   f. bronchiectasis,
   g. extensive tuberculosis sequelae,
   h. asthma,
   i. bronchiolitis
   j. uncontrolled brochogenic carcinoma
3. Extrapulmonary conditions that determine treatment:
   a. major cardiopathy with chronic heart failure,
   b. evolved dementia,
   c. extended neoplasia,
   d. liver failure
   e. kidney failure,
   f. other situations at the discretion of the researcher

ERS | copd audit

Inclusion criteria

1. 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.

2. Patients admitted to hospital for 12 hours or longer with a respiratory cause of admission as referred by the discharge report and a history compatible with COPD.

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:

1. Pneumonia.
2. Pulmonary embolism.
3. Pulmonary oedema.
4. Pneumothorax.
5. Thoracic trauma.
6. Pleural effusion.
7. Asthma.
8. Pulmonary fibrosis.
9. Sleep apnea with no treatment.
10. Kyphoscoliosis.
11. Obesity-hypoventilation syndrome.

12. Neuromuscular pathology.
13. Tracheal or upper airway stenosis.
14. Severe bronchiectasis.
15. Severe tuberculosis sequelae.
16. Bronchogenic carcinoma or any other thoracic neoplasm.
17. Extrapulmonary diseases as the primary diagnosis for admission that may produce similar symptoms, such as:
    a. Extensive cancer.
    b. Hepatic insufficiency.
    c. Renal insufficiency.
    d. Cardiac failure.
    e. Any other condition as judged by the investigator.

Note: a patient with a primary diagnosis of COPD exacerbation may also have comorbidities that include conditions taken from the list above. The key to exclusion or inclusion is to determine the primary diagnostic cause for admission