

Appendix II: Blinded audit and audit diagnostic criteria.

Final diagnosis

The final diagnosis in both groups is established by partly by blinded audit and partly by the result of diagnostic imaging. Two physicians, independent of each other, perform audit of the patients' entire stay at the hospital. The physicians use the diagnostic criteria listed below. For each patient the physician performing the audit fills out a registration form containing the diagnostic criteria below and performs registration of which criteria / diagnosis are meet and which are not meet. When the two physicians, independent of each other, agree on a diagnosis, then this diagnosis is considered to be the final diagnosis of the hospital stay. When there is a disagreement of the final diagnosis, then a third physician will make a consensus agreement about the final diagnosis.

Blinded audit diagnostic criteria

The following criteria are used:

COPD with exacerbation:

All of the following criteria must be present:

- Patient diagnosed with COPD according to GOLD guidelines (132)
- Symptoms compatible with COPD exacerbation, with a worsening in one or more of the following: dyspnoea, sputum production or cough.

Asthma with exacerbation:

All of the following criteria must be present:

- Patient diagnosed with asthma according to GINA guidelines (233)
- Symptoms compatible with asthma exacerbation with a progressive worsening in one or more of the following: dyspnoea, wheezing or cough at night.
- Clinical examination with signs compatible with asthma exacerbation (prolonged expiration, wheezing, PEF lower than personal best)

Interstitial lung disease:

The patient has, either previously or during the hospital stay, been seen by a specialist in pulmonary medicine and diagnosed as having an interstitial lung disease according to the ERS guidelines (334).

Pneumonia:

The diagnostic criteria are based on the BTS definition of community acquired pneumonia (435). The exception being that the BTS criteria which states that “No other explanation for the illness, which is treated as CAP with antibiotics” is omitted. Pneumonia is defined as the presence of all of the following:

- Symptoms of an acute lower respiratory tract illness (cough and at least one other lower respiratory tract symptom).
- New focal chest signs on examination.
- At least one systemic feature (either a symptom complex of sweating, fevers, shivers, aches and pains and/or temperature of 38°C or more)
- New radiographic shadowing for which there is no other explanation (eg, not pulmonary oedema or infarction).

Parapneumonic effusion:

All of the following must be present:

- Pleural effusion diagnosed by either radiological examination (chest X-ray, CT of the chest, sonography by radiologist) or by thoracentesis
- Co-existing infection in the lung on the same side as the effusion (e.g. diagnostic criteria for pneumonia met)
- Diagnostic criteria for empyema not met

Empyema:

The presence of purulent / turbid / cloudy pleural fluid or a positive Gram stain / culture of pleural fluid.

Pulmonary embolism:

Pulmonary embolism diagnosed by:

- CT of the chest

- MR of the chest
- Angiography
- Ventilation perfusion scan (examination with a high risk of pulmonary embolism)

Pneumothorax:

Pneumothorax diagnosed by a radiological examination (chest X-ray, CT of the chest)

Heart failure:

Diagnosed when either the criteria for systolic or non-systolic heart failure are met.

Systolic heart failure: The criteria used are based on Task Force for Diagnosis and Treatment of Acute and Chronic Heart Failure 2008 of European Society of Cardiology guidelines (536). All of the following criteria must be present:

- Symptoms typical of heart failure (breathlessness at rest or on exercise, fatigue, tiredness, ankle swelling)
- Signs typical of heart failure (tachycardia, tachypnoea, pulmonary rales, pleural effusion, raised jugular venous pressure, peripheral oedema, hepatomegaly)
- Objective evidence of a functional abnormality of the heart at rest, defined as echocardiography with reduced left ventricle ejection fraction (< 45%)
- Diagnostic echocardiography performed by a cardiologist

Non-systolic heart failure: The criteria are based on recommendations by European Society of Cardiology Study Group on Diastolic Heart (637). All of the following criteria must be present:

- Signs or symptoms of congestive heart failure: Exertional dyspnoea, eventually objective evidence by reduced peak exercise oxygen consumption, orthopnea, gallop sounds, lung crepitations, pulmonary oedema.
- Normal or mildly reduced left ventricular systolic function
- Evidence of abnormal left ventricular relaxation, filling, diastolic distensibility and diastolic stiffness (Slow isovolumic left ventricular relaxation and / or slow early left ventricular filling and/or reduced left ventricular diastolic distensibility and/or increased left ventricular chamber or muscle stiffness)
- Diagnostic echocardiography performed by a cardiologist

Pulmonary oedema:

2 or more of the following criteria must be present:

- Signs of pulmonary oedema defined as the presence of increased respiratory rate, hypoxemia and auscultation with bilateral lung crepitations.
- Radiological examination with signs of pulmonary oedema (Chest X-ray, CT of the chest)
- Elevated B-type natriuretic peptide (BNP) or elevated N-terminal fragment BNP (NT-pro-BNP).

Acute myocardial infarction:

Diagnosed according to the consensus document of The Joint European Society of Cardiology/American College of Cardiology Committee for the Redefinition of Myocardial Infarction (738).

Criteria for acute, evolving or recent MI: Either one of the following criteria satisfies the diagnosis for an acute, evolving or recent MI:

(1) Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following:

- ischemic symptoms
- development of pathologic Q waves on the ECG
- ECG changes indicative of ischemia (ST segment elevation or depression)
- Coronary artery intervention (e.g., coronary angioplasty).

(2) Pathologic findings of an acute MI.

Criteria for established MI: Any one of the following criteria satisfies the diagnosis for established MI:

(1) Development of new pathologic Q waves on serial ECGs. The patient may or may not remember previous symptoms. Biochemical markers of myocardial necrosis may have normalized, depending on the length of time that has passed since the infarct developed.

(2) Pathologic findings of a healed or healing MI.

Pericardial effusion:

Diagnosis confirmed by echocardiography performed by a cardiologist.

Deep vein thrombosis:

Diagnoses confirmed by one of the following:

- Sonography performed by a radiologist
- Intravenous venography (conventional or computed tomography)

Anemia:

Diagnosed according to the WHO diagnostic criteria (839). The anaemia's are subdivided into light, moderate and severe, according to the following:

Men:

- Light anemia: $6 \text{ mmol/l} < \text{Hb} < 8.1 \text{ mmol/l}$
- Moderate anemia: $4 \text{ mmol/l} < \text{Hb} < 6.1 \text{ mmol/l}$
- Severe anemia: $\text{Hb} < 4.1 \text{ mmol/l}$

Women:

- Light anemia: $6 \text{ mmol/l} < \text{Hb} < 7.5 \text{ mmol/l}$
- Moderate anemia: $4 \text{ mmol/l} < \text{Hb} < 6.1 \text{ mmol/l}$
- Severe anemia: $\text{Hb} < 4.1 \text{ mmol/l}$

Malignancy:

Diagnosis confirmed by either histology or cytology. The extent of the disease estimated by radiological examination (computed tomography, magnetic resonance imaging, positron emission tomography, chest X-ray etc).

No diagnostic criteria meet:

If the patient does not fulfil any of the above mentioned criteria, final diagnosis is made by the auditor. The auditor reaches the final diagnosis by clinical judgement based upon the patient's previous medical history and all information from the hospital.

References

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