COPD-X Summary of Changes V2.46, June 2016

Implications for Clinical Practice

The following changes have been identified as being the most significant and likely to have an impact on clinical practice:

O7.4 Falls in COPD

Addition of a new section on falls as a COPD co-morbidity. The section discusses risk factors for falls and advocates the benefits of generic falls prevention programs, as well as specific interventions for COPD patients.

O9.2 Lung volume reduction surgery and other techniques

Addition of wording advising that all patients being considered for lung volume reduction should be discussed by an expert panel that includes a radiologist, respiratory physician, interventional pulmonologist and thoracic surgeon.

X2.1 Confirm exacerbation and categorise severity

Addition of a paragraph discussing the use of arterial blood gas (ABG) samples versus venous blood gas (VBG) samples to determine the need for non-invasive ventilation (NIV). Using VBGs as an initial assessment cannot be recommended until it is prospectively shown to be safe and non-inferior to upfront ABG assessment. Caution is required due to the lesser precision with VBGs compared to ABGs.

X3.1 Controlled oxygen delivery

Addition of a paragraph discussing the use of high flow oxygen and including a positive recommendation for education programs administered to members of the ambulance service to reduce high concentration oxygen delivery to patients with acute exacerbations of COPD.

All Changes

C. Confirm diagnosis and assess severity

New wording added on the prevalence of the asthma and COPD overlap from a 2015 study by Alshabanat. Additional 2015 studies by Gibson and Nielsen found an increased frequency of exacerbations in patients with features of both asthma and COPD, compared to those with COPD alone.

C2.1 History

Addition of a sentence providing further description of the CAT (COPD Assessment Tool), as well as citation of a meta-analysis by Karloh 2016 which demonstrates the CAT to be useful for several aspects of COPD including a valid diagnosis, likelihood of exacerbations, depression, lung function and mortality.

C2.5 COPD case finding

Inclusion of a study by Haroon 2015 discussing COPD case finding and/or screening strategies. This found that active opportunistic case finding through primary care had greater success. The use of screening questionnaires in patients suspected to have COPD, followed by diagnostic assessment, had the best diagnostic yields. Widespread population screening is not recommended.

O. Optimise Function

O1.2.3 Long-acting bronchodilator combinations (LAMA/LABA)

Inclusion of wording from a 2015 meta-analysis by Horita showing significantly greater improvements in trough FEV_1, dyspnoea scores, as well as fewer exacerbations and pneumonia in the LAMA plus LABA group compared with the LABA plus ICS combination. However, frequencies of any adverse event, all-cause death and change of total score of SGRQ were not different between the two groups. It is noted that the results have to be interpreted with caution due to the high heterogeneity among studies.

Inclusion of wording from the FLAME trial comparing indacaterol/glycopyrronium, once daily to fluticasone/salmeterol, twice daily (Wedzicha 2016). This double blind RCT included over 3000 patients with moderate to severe COPD with a history of at least one exacerbation in the previous year. The study showed that patients in the indacaterol/glycopyrronium arm had an 11% lower annual rate of exacerbations and the rate of moderate to severe exacerbations was lower. Trough FEV_1 was 62mls higher at 52 weeks and SGRQ was 1.8 points lower. Whilst statistically significant, the clinical significance of these latter two measures was not clear. In COPD patients with frequent exacerbations, the LAMA/LABA combination was superior to the ICS/LABA combination, but it is not known if this is a class effect. This trial does not address the role of 'triple therapy' (ICS/LABA/LAMA) in this patient group.

Addition of evidence from a network meta-analysis of LAMA/LABA combinations compared with monotherapies (Oba 2016) which found that the fixed dose combinations provided benefits in lung function and quality of life, with no increase in adverse outcomes. Combination therapy reduced moderate to severe exacerbations compared with LABA but not compared with LAMA. Effects on severe exacerbations were similar with both combination and monotherapies.

O4.1 Inhaled corticosteroids and long-acting beta2-agonists in combination (ICS/LABA)

New wording added from a 2015 study by Pascoe regarding the benefits (reduction in exacerbation frequency) with the addition of fluticasone furoate to vilanterol, compared with vilanterol alone in patients with a higher blood eosinophil count. In patients treated with vilanterol alone, exacerbation rates increased progressively with increasing eosinophil count percentage category. However, prospective validation is required before routine clinical recommendations can be made.

Addition of wording from the SUMMIT study which randomised 16,590 COPD patients with post-bronchodilator FEV_1 50-70% predicted, and a history or increased risk of cardiovascular disease, to fluticasone furoate/vilanterol, fluticasone furoate, vilanterol or placebo (Vestbo 2016). No benefit for all-cause mortality (primary outcome) was seen with any of the active treatments, compared to placebo. Secondary outcomes included a clinically insignificant reduction in the rate of decline of FEV_1 with fluticasone furoate/vilanterol or fluticasone furoate vs placebo. There were potentially clinically relevant reductions in exacerbation rates with all three active treatment arms. Rates of pneumonia were similar between treatment groups.

O4.2 Inhaled corticosteroids and long-acting beta2-agonists and long-acting antimuscarinics in combination

Addition of wording drawing attention to the frequent over-prescribing of "triple" therapy in COPD patients without asthma, severe airflow obstruction or history of frequent exacerbations (Brusselle 2015). The study highlighted the importance of commencing bronchodilators as opposed to inhaled corticosteroids, as initial pharmacological therapy for patients with symptomatic COPD.

O5.1 Inhaler technique

Addition of wording from an Australian cross-sectional study (Sriram 2016) which found that the proportion of patients with COPD who made at least one error in inhaler technique ranged from 50% to 83%, depending on the device used.

O7.2 Cardiac disease

Inclusion of wording from a multicentre observational cohort study (Bhatt 2016) stating that the use of beta-blockers was associated with a significantly lower rate of total and severe exacerbations over a two year period in subjects with GOLD stage 2–4. However, the wording advises caution in interpreting these studies because of substantial differences in the comparator arms and also advises caution in the use of beta blockers in patients with airways disease with co-existing asthma.

O7.2.3 Stroke

Addition of a new section on stroke as a co-morbidity of COPD. The Rotterdam cohort study of 13,115 subjects, studied for up to 22 years, included 1566 patients with COPD, who had a 20% higher incidence of stroke during the study, particularly following an exacerbation of COPD (Portegies 2016). However, it was noted that this association was no longer significant after adjusting for smoking, indicating that smoking is a common risk factor for both conditions.

O7.4 Falls in COPD

Addition of a new section on falls as a COPD co-morbidity. A study by Johal 2009 notes COPD as the second most prevalent condition among patients presenting with hip fractures to emergency departments. A large cohort study (Yohannes 2016) demonstrated a higher risk of hip fractures in patients with COPD in comparison to a matched non-COPD sample and patients who used inhaled bronchodilators and corticosteroids had an even higher falls risk in comparison to those not using inhalers. A history of falls in the six months prior to hospital admission is the strongest predictor of all-cause mortality in patients with severe COPD. The section discusses risk factors for falls and advocates the benefits of generic falls prevention programs, as well as specific interventions for COPD patients.

O7.7 Gastro-oesophageal reflux disease (GORD)

Addition of a 2016 study by Busch stating that prospective data from users of inhaled medications has shown that GORD is a common risk factor for COPD exacerbations across all medication groups except for those using only short-acting bronchodilator medications.

O9.2 Lung volume reduction surgery and other techniques

Addition of a sentence advising that all patients being considered for lung volume reduction should be discussed by an expert panel that includes a radiologist, respiratory physician, interventional pulmonologist and thoracic surgeon (Herth 2016).

P: Prevent deterioration

P1.1 Smoking cessation

Addition of wording from a study by Jimenez-Ruiz (2015) stating that COPD patients often have barriers to smoking cessation such as lower self-efficacy and lower self-esteem, as well as co-existing depression.

D: Develop a plan of care

Addition of wording pointing out that not all disease management programs have shown benefit (Kruis 2014). A cluster RCT in 40 general practices in the Netherlands of an intervention comprising a multidisciplinary team of caregivers trained in motivational interviewing, setting up individual care plans, exacerbation management, implementing clinical guidelines and redesigning the care process, found no difference in HRQoL compared to usual care.

D4. Telehealth

Addition of wording based on a systematic review by Gregerson 2016 which examined the effects of telehealth on quality of life in COPD. Only three (of 18 suitable studies) demonstrated significant improvements in quality of life.

Inclusion of a study by Ho 2016, which showed that in patients utilising a telemedicine intervention, involving accessing a website to record a range of daily variables with clinician access and intervention depending upon certain "flags", time to readmission, was significantly greater in the telemedicine group compared with usual care.

D5. Treat anxiety and depression

Inclusion of a new paragraph from a retrospective cohort study (Singh 2016) stating that depression and anxiety are important predictors of readmission in COPD patients.

X: Manage eXacerbations

Inclusion of a paragraph based on a study by Guerrero 2016 which prospectively followed a Spanish cohort of (predominantly male) patients. Re-admission to hospital within 30 days following discharge for an acute exacerbation of COPD increased 12 month mortality rates.

Inclusion of wording based on a Turkish study by Gunen 2010 adding to the statement that a significant proportion of COPD patients who require hospitalisation for an acute exacerbation may have pulmonary embolism. A CT pulmonary angiogram on 138 consecutive patients admitted with an exacerbation of COPD found pulmonary embolism in 14% of patients.

Addition of wording based on a study by Donaldson 2015 stating that prolonged COPD exacerbations are associated with worse health status and the exacerbation that follows occurs sooner. A failure of airway function to return to pre-exacerbation levels is associated with symptoms of cold and sore throat (viral infections), and patients who have these events have a faster decline in FEV_1.

X2.1 Confirm exacerbation and categorise severity

Addition of a paragraph discussing the use of ABG versus VBG samples to determine the need for NIV. McKeever et al 2016 argued that all patients presenting with an exacerbation of COPD should initially be assessed with a VBG and only go on to an ABG if the VBG pH was ≤7.34. The primary reasons for preferring VBG samples cited were less pain and lower risk of bruising. However, the general applicability of these findings is limited by the fact that the cohort had relatively few patients with a pH <7.30. The authors did not propose that VBGs should replace ABGs to assess severity of respiratory failure or be used to monitor patient response to treatment/NIV. This algorithm cannot yet be recommended until it is prospectively tested. Caution is required due to the lesser precision with VBGs compared to ABGs.

X3.1 Controlled oxygen delivery

Addition of a paragraph discussing the use of high flow oxygen. This includes discussion of a retrospective Australian study in New South Wales (Susanto 2015); a Victorian retrospective case file emergency department audit of patients admitted to hospital with acute exacerbation of COPD (Chow 2015); and a New Zealand study (Pilcher 2015) in which significantly fewer patients received high concentrations of oxygen following an education program to reduce high concentration oxygen delivery to patients with acute exacerbations of COPD administered to members of the ambulance service.