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The 2017 Update to the COPD Foundation COPD Pocket Consultant Guide

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Abstract

The COPD Foundation Pocket Consultant Guide (PCG) was first released in 2007 as a practice tool for use at point of service for clinicians, especially primary care clinicians diagnosing and treating patients with chronic obstructive pulmonary disease (COPD). Over the years, the PCG has been supplemented with a mobile app that presents the tool in an online smart phone accessible version that also allows the clinician to enter patient specific data for guidance to next steps of diagnosis or management.

In November 2016, a new update of the PCG was released that incorporates a flow diagram for stepped care that includes the newest recommendation for diagnosis, assessment and treatment; including the broad use of dual bronchodilator therapy and consideration of asthma COPD overlap syndrome (ACOS). The current controversy regarding when to add inhaled corticosteroids (ICSs) is addressed to support clinical decision making.

The PCG comes in 2 versions, one with generic names for COPD drugs available in the United States and one with trade names for those drugs. The update continues to recommend spirometry for those at highest risk, also emphasizing the need to assess symptoms, exacerbation risks and comorbidity before selecting appropriate non-pharmacological as well as pharmacological therapy. The tool is designed to facilitate COPD management in daily practice.

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Introduction

Chronic obstructive pulmonary disease (COPD) continues to be a common condition among primary care patients and has risen to become the third leading cause of death in the United States.[1] Yet it is still often diagnosed late and may be under or even untreated when it is recognized.[2] For many practicing physicians and other clinicians, aggressive diagnosis and management of COPD was not a significant part of their training. Spirometry remains underused as a diagnostic and follow-up assessment and is often not easily accessible to primary care clinicians and patients.[3-5]
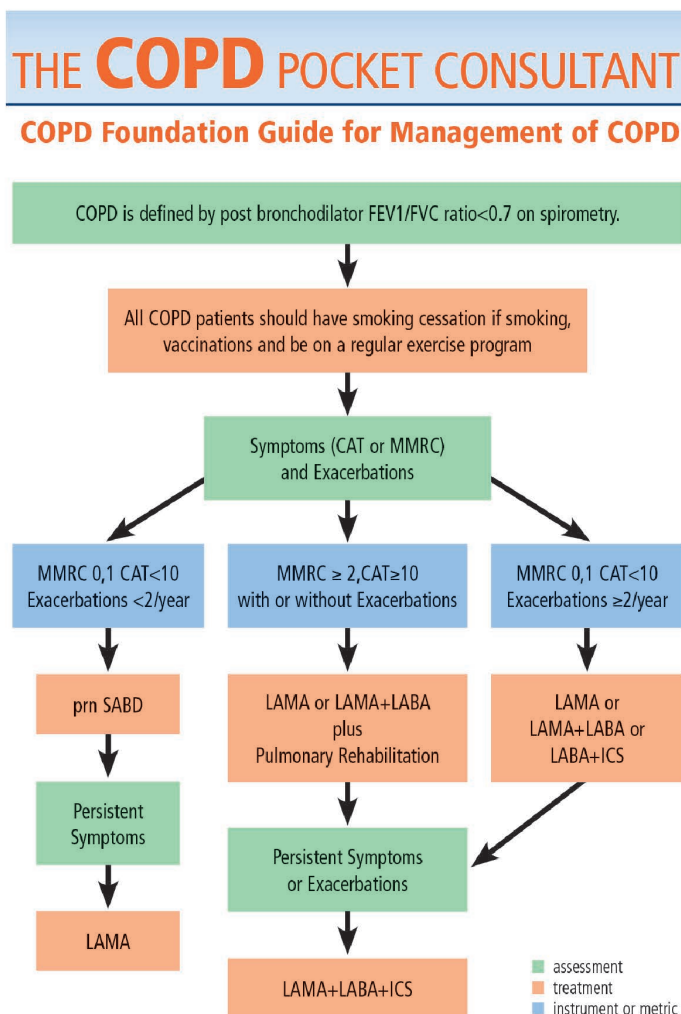
To supplement limited COPD-focused training and provide updated information, guidelines and care recommendations have been produced by both national and international organizations. These recommendations and guidelines are often not in a format to facilitate implementation or point-of-care use. For example, the 132 page 2017 Global initiative for chronic Obstructive Lung Disease (GOLD) recommendations[6] provide an important update and review of the evidence and recommendations for COPD management, but are lengthy.

The COPD Foundation produced its first brief, point-of-care COPD Foundation Pocket Consultant Guide (PCG) in 2007 with major updates in 2012[7] and in November 2016. The new PCG is a 4″ by 6″ tri-fold card to be used at the point of care (office, emergency department or hospital) and is supplemented with online versions (www.copdpraxis.com) and a phone-friendly app for Apple products (search "COPD Foundation" in the App Store). An app for Android users will be released later in 2017. This tool is an expert opinion, consensus document that relies on published evidence but is not an evidence-based review of all elements of COPD diagnosis and management. It is designed to incorporate best practices and serve as a short summary to guide major clinical decisions during visits to the office, emergency department or hospital. It is the work of the authors with input from many primary care health professionals who have reviewed and commented on its content.

Highlights of the 2017 Update

The new PCG begins with a practice flow diagram (Figure 1) to illustrate steps in diagnosing, assessing and grading COPD for management and ongoing care. Additionally, the PCG stresses that optimal COPD

Figure 1. COPD Care Algorithm

FEV$_1$=Forced expiratory volume 1 second; FVC=Forced vital capacity; CAT=COPD Assessment Test; MMRC=Dyspnea assessment test; SABD=Short acting bronchodilator – includes SABA=Short acting beta-2 agonist, SAMA=Short acting muscarinic agent, and combined SAMA/SABA; LAMA=Long acting muscarinic agent; LABA=Long acting beta-2 agonist; ICS = Inhaled corticosteroid

Figure 2. COPD Required Assessment for Therapy Guidance

Assess Severity Domains
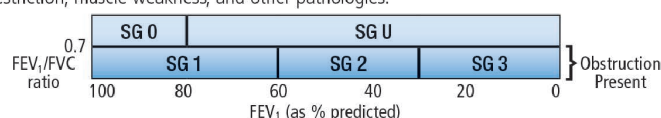### Each domain may have therapeutic implications.

Spirometry Grades:
SG 0 Normal spirometry does not rule out emphysema, chronic bronchitis, asthma, or risk of developing either exacerbations or COPD.
SG 1 Mild: Post bronchodilator FEV_1/FVC ratio<0.7, $FEV_1 \geq 60\%$ predicted.
SG 2 Moderate: Post bronchodilator FEV_1/FVC ratio<0.7, $30\% \leq FEV_1 < 60\%$ predicted.
SG 3 Severe: Post bronchodilator FEV_1/FVC ratio<0.7, $FEV_1 < 30\%$ predicted.
SG U Undefined: FEV_1/FVC ratio$\geq$0.7, $FEV_1 < 80\%$ predicted. This is consistent with restriction, muscle weakness, and other pathologies.

Regular Symptoms: dyspnea at rest or exertion, cough, sputum. Use COPD Assessment Test (CAT) or mMRC Breathlessness Scale to follow course of disease.

Exacerbations: two or more in the past year, especially if $FEV_1 < 50\%$ predicted suggests high risk.

Oxygenation: severe hypoxemia: resting O2 sat$\leq$88% or arterial pO2<55 mmHg episodic hypoxemia: exercise or nocturnal desaturation.

Emphysema: reduced density on CT scan, can be localized, abnormal high lung volumes, abnormal low diffusion capacity.

Chronic bronchitis: cough, sputum most days for at least 3 months in at least 2 years.

Comorbidities: defining and treating comorbid conditions, particularly cardiovascular, anxiety and depression, are critical components of COPD care.

The presence of eosinophilia may help select those exacerbators who could benefit from addition of ICS.

For those with recurrent exacerbations despite inhaled regimen consider:
a. Adding PDE4 Inhibitor Roflumilast (if chronic bronchitic) and/or
b. Adding Macrolide (if not active smoker) as immune modulator.

COPD patients with $FEV_1 < 60\%$ should have O2 saturation assessed.
a. Resting O2 sats$\leq$88% merit assessment for Oxygen therapy.
b. COPD patients with O2 sats$\leq$88% should have arterial blood gas tested and if significant hypercapnea consider for sleep study and potential noninvasive ventilation.

COPD patients with FEV1$\leq$ 45% should undergo Chest CT scanning and evaluation for Lung Volume Reduction Surgery or if FDA approves, bronchoscopic Lung Volume Reduction.

Annual low-dose CT scan for lung cancer screening - ages 55-79 years with 30 packyears and cigarette smoking in the last 15 years.

care requires evaluation of all the severity domains: spirometry, symptoms, exacerbation frequency, oxygen requirements, presence of emphysema, chronic bronchitis and comorbidities (Figure 2). The flow diagram is color coded (blue for assessments, green for available tools or metrics and orange for therapies) to remind clinicians that several important tools and tests are available for comprehensive COPD assessment. Furthermore, repeated re-evaluation of patients is key and may be used to guide both pharmacotherapy and other COPD treatment decisions. The chart highlights the importance of smoking cessation, vaccinations,

exercise, pulmonary rehabilitation, testing for Alpha-1 antitrypsin deficiency and again, evaluating comorbid conditions.

Spirometry is the basis for confirmation of a COPD diagnosis. The PCG continues to provide guidance for categorizing spirometry results, which fall into 3 major groups: normal, spirometry grade 0 (SG0); obstructive lung disease, spirometry grades 1-4 (SG1-4); and reduced lung function without obstruction, spirometry grade undefined (SG-U) (Figure 2). This panel also highlights the other roles of spirometry: to identify those with lower forced expiratory volume in 1 second (FEV_1) who may benefit from evaluation of hypoxemia at rest or with exercise (FEV_1 below 60% of predicted are candidates for pulse oximetry evaluation) and for those with $FEV_1 < 45\%$ predicted in whom you should consider computed tomography (CT) evaluation for emphysema that may be treatable with lung volume reduction surgery.

While not all patients fit into any 1-page algorithm, the simplified PCG fits most patients by grouping them into those with lower and higher symptom and functional status burdens using the modified Medical Research Council (mMRC) and the COPD Assessment Test (CAT)[8] scales which are short and feasible additions to routine primary care practice. The mMRC is a quick way to determine the activity and functional capacity of patients. The CAT incudes a broad range of questions across 8 domains including activity, sleep, fatigue, and symptoms such as daily cough. The care flow diagram adds the frequency of exacerbations to the symptom burden with the caveat that before diagnosis, COPD exacerbations are often referred to as recurrent and prolonged "bad" colds or episodes of "bronchitis."[9]

The flow chart (Figure 1) recognizes that COPD is progressive and that therapy is not static, requiring updates and enhancements as the patient's status changes. The medications can be thought of as a hierarchy centered around the current mainstay of COPD therapy, bronchodilators. Steps go up from "as needed short-acting bronchodilator" to "daily long-acting bronchodilators." Dual bronchodilator therapy is acknowledged as a newly recommended, optional starting choice for all COPD patients requiring daily therapy and a likely appropriate starting choice for those who are more symptomatic (e.g., mMRC >2 or CAT >10). The presence of 2 or more exacerbations a year is addressed by use of dual bronchodilator therapy plus consideration of the addition of daily inhaled

corticosteroids (ICSs) if needed (e.g., "triple therapy"). The current controversy regarding when to start and continue ICS therapy for prevention of exacerbations is noted at the bottom of the list of domain assessments (Figure 2). Specifically, the presence of eosinophilia may help select those whose exacerbations are most amenable to ICS therapy.

Both of the first 2 panels of the PCG note that spirometry must be accompanied with assessment of symptom, exacerbations and functional status burden plus the other domains of severity (oxygenation, emphysema, chronic bronchitis and comorbidities) to determine the best diagnostic and therapeutic approaches. While symptoms and exacerbations drive most therapeutic decisions, the presence of significant emphysema or the presence of chronic bronchitis could raise possible roles for other specialized treatments such as lung volume reduction or a phosphodiesterase 4 (PDE-4) inhibitor, respectively.

The COPD drugs available in the United States are all listed as individual drugs and combinations with doses and available routes of administration—oral, inhaler and nebulized solutions. The list includes not only the mainstays of therapy, bronchodilators and corticosteroids, but also specialized therapy such as PDE-4 inhibitors for individuals with chronic bronchitis and refractory exacerbations and less commonly used add-on therapies such as methylxanthines and mucolytics. These treatment options are included in both the blue colored generic drug classification (Figure 3) and the orange trade name versions (Figure 4) of the PCG. The drugs listed include those approved for COPD treatment as well as some approved only for asthma such as ICS inhalers since they may be combined with dual long-acting muscarinic antagonists (LAMA) plus long-acting beta2-agonists (LABA) inhalers to facilitate triple therapy (ICS+LAMA+LABA). We have not included azthromycin in the flow chart since it is not in common use in primary care and its long-term use remains unclear.[10] However, in the bullet points accompanying the flow chart, we have stressed that for those with recurrent exacerbations despite inhaled regimen, the following be considered: "Adding macrolide (if not active smoker) as immune modulator." (Figure 2)

Currently, diagnosis and management of COPD requires consideration of asthma and COPD overlap syndrome (ACOS) for individuals with a history of previous asthma, significant atopy or seasonal allergies such as allergic rhinitis.[11] For these individuals who also have significant reversibility on post-bronchodilator spirometry testing, a diagnosis of ACOS may be appropriate requiring that baseline therapy includes both ICSs and long-acting bronchodilators. These are individuals for whom triple therapy may be the initial treatment of choice. The algorithm for ACOS consideration is found on the same panel as the detailed mMRC scoring. (Figure 5.)

The final panel of the PCG includes the detailed CAT questions to facilitate quick assessment for those practices unable to embed the CAT within their electronic medical records. The panel provides all of the questions and the scoring algorithm to facilitate its use at each visit to monitor a patient's progress. (Figure 6)

The PCG can also be linked to the mobile app for Apple iOS which is found by searching for "COPD Foundation" in the App store. This app allows health care professionals to individualize a patient's therapy by filling in a symptoms assessment, spirometry results and exacerbation history. The app highlights further testing and/or therapy, based on the specific patient's information.

Treatment of the COPD patient requires consideration of more than lung function and pulmonary symptoms. Much of the morbidity, mortality, and hospitalization risks experienced by those with COPD occurs due to the presence of comorbid conditions, particularly cardiovascular disease, depression, and anxiety.[12] These may change the selection of therapy, as well as guide the need for adherence support and high priority of non-pharmacotherapies, such as pulmonary rehabilitation, that are effective for treating the depression and anxiety commonly accompanying COPD.

Individuals 50 years and older with a 20+ pack year history and less than 10 years of smoking abstinence are candidates for low dose CT scans to screen for lung cancer.[13] (Figure 2) This U.S. Preventive Services Task Force recommendation is especially important to follow in individuals with COPD since COPD,[14] and particularly the emphysematous form, is an independent risk factor for developing lung cancer.[15]

Comparing the PCG 2017 to GOLD 2017

The 2017 GOLD recommendations are an important desk reference and resource for in-depth review

Figure 3. Generic Version of COPD Drugs: Highlighted in Blue in the COPD Foundation Pocket Consultant Guide

Drug	Inhaler (mcg)	Solution for Nebulizer (mg)	Oral	Duration of Action (hours)
Beta 2 Agonists - Short Acting (SABA)				
Albuterol	90 (HFA-MDI)	0.63/3 ml 1.25/3 ml 2.5/3 ml		4-6
Levalbuterol	45 (HFA-MDI)	0.63/3 ml 1.25/3 ml		6-8
Beta 2 Agonists - Long Acting (LABA)				
Salmeterol	50 (DPI)			12+
Arformoterol		15 mcg/2ml		12+
Formoterol Fumarate		20 mcg/2ml		12+
Indacaterol Maleate	75 (DPI)			24
Olodaterol	5 (SMI)			24
Anticholinergics - Short-Acting (SAMA)				
Ipratropium Bromide	17 (HFA-MDI)	0.5/2 ml		4-6
Anticholinergics - Long-Acting (LAMA)				
Tiotropium	18 (DPI)			24
Tiotropium	5 (SMI)			24
Aclidinium Bromide	400 (DPI)			12
Glycopyrrolate Bromide	15.6 (DPI)			12
Umeclidinum	62.5 (DPI)			24
Long-Acting Anticholinergic plus Long-Acting B2-Agonist (LAMA/LABA)				
Umeclidinium / Vilanterol	62.5/25 (DPI)			24
Tiotropium / Olodaterol	5/5 (SMI)			24
Glycopyrrolate / Formoterol Fumarate	18/9.6 (MDI)			12
Glycopyrrolate / Indacaterol	15.6/27.5 (DPI)			12
Short Acting Anticholinergic plus B2-Agonist (SAMA/SABA)				
Ipratropium Bromide / Albuterol	20/100 (SMI)	0.5/2.5/3 ml		4-6

Drug	Inhaler (mcg)	Solution for Nebulizer (mg)	Oral	Duration of Action (hours)
Methylxanthines				
Theophylline (SR)			100-600 mg (Pill)	Variable, up to 24
Mucolytic				
N-acetylcysteine (NAC)			600mg	12
Inhaled Glucocorticosteroids (ICS)				
Beclomethasone*	40, 80 (HFA-MDI)			12
Budesonide*	90, 180 (DPI)	0.25/2 ml 0.5/2 ml		12
Fluticasone Propionate*	44-220 (HFA) 100, 250 (DPI)			12
Fluticasone Furoate*	100, 200 (DPI)			24
Mometasone*	220 (DPI)			24
Ciclesonide*	80, 160 (HFA)			12
Inhaled Glucocorticosteroid plus Long Acting B2-Agonists (ICS/LABA)				
Budesonide / Formoterol	80/4.5* 160/4.5 (HFA)			12
Fluticasone / Salmeterol	100/50* 250/50 500/50* (DPI)			12 12 12
Fluticasone / Salmeterol*	45/21 115/21 230/21 (HFA)			12 12 12
Mometasone Furoate / Formoterol Fumarate Dihydrate*	100/5 200/5 (HFA)			12
Fluticasone Furoate / Vilanterol	100/25 (DPI)			24
Approved for Reducing COPD Exacerbations				
Fluticasone / Salmeterol	250/50 (DPI)			12
Fluticasone Furoate / Vilanterol	100/25 (DPI)			24
Tiotropium	18 (DPI)			24
Tiotropium	5 (SMI)			24
Roflumilast (PDE4 Inhibitor)			500 mcg	24

*FDA approved for Asthma
HFA=Hydrofluoroalkane   MDI=Metered Dose Inhaler   DPI=Dry Powder Inhaler   SMI=Soft Mist Inhaler

of evidence, references and the resulting care recommendations.[16] At 132 pages with a 45-page executive summary, these are references that few practicing clinicians will have time to review. The PCG summarizes much of the same care recommendations in one short pocket guide that is intended to be a quick reference used at the point of care.

There are other differences also. GOLD 2017 continues to use the 4 grades of COPD based on FEV_1 values from post bronchodilator spirometry to categorize mild, moderate, severe and very severe COPD (Table 1). The PCG uses 5 grades to include normal (SG0) and a category of undefined which is reduced lung function without criteria for chronic obstruction (SGU). The other 3 categories are redefined to more closely fit with the American College of Physicians, American College of Chest Physicians, American Thoracic Society, European Respiratory Society Consensus Statement recommendations[16] that identified high levels of evidence to support using an FEV_1 <60% of predicted (labelled moderate COPD) as the cut off for increased risk of exacerbation and another important change at an FEV_1 <30% of predicted where hypoxemia is more likely to require continuous oxygen therapy. (Table 1)

The PCG authors believe the evidence from the COPD Genetic Epidemiology study and the SPIROMICS

Figure 4. Trade Name Version of COPD Drugs Highlighted in Orange in the COPD Foundation Pocket Consultant Guide

Drug	Inhaler (mcg)	Solution for Nebulizer (mg)	Oral	Duration of Action (hours)
Beta 2 Agonists - Short Acting (SABA)				
Albuterol	90 (HFA-MDI)	0.63/3 ml 1.25/3 ml 2.5/3 ml		4-6
Proair	90 (HFA-MDI)			4-6
Proventil	90 (HFA-MDI)			4-6
Ventolin	90 (HFA-MDI)			4-6
Xopenex	45 (HFA-MDI)	0.63/3 ml 1.25/3 ml		6-8
Beta 2 Agonists - Long Acting (LABA)				
Serevent	50 (DPI)			12+
Brovana		15 mcg/2ml		12+
Perforomist		20 mcg/2ml		12+
Arcapta Neohaler	75 (DPI)			24
Striverdi Respimat	5 (SMI)			24
Anticholinergics - Short-Acting (SAMA)				
Atrovent	17 (HFA-MDI)			4-6
Ipratropium Bromide		0.5/2ml		4-6
Anticholinergics - Long-Acting (LAMA)				
Spiriva Handihaler	18 (DPI)			24
Spiriva Respimat	5 (SMI)			24
Tudorza Pressair	400 (DPI)			12
Seebri Neohaler	15.6 (DPI)			12
Incruse Ellipta	62.5 (DPI)			24
Long-Acting Anticholinergic plus Long-Acting B2-Agonist (LAMA/LABA)				
Anoro Ellipta	62.5/25 (DPI)			24
Stiolto Respimat	5/5 (SMI)			24
Bevespi Aerosphere	18/9.6 (MDI)			12
Utibron Neohaler	15.6/27.5 (DPI)			12
Short Acting Anticholinergic plus B2-Agonist (SAMA/SABA)				
Ipratropium Bromide / Albuterol		0.5/2.5/3 ml		4-6
DuoNeb		0.5/2.5/3 ml		4-6
Combivent Respimat	20/100 (SMI)			4-6

Drug	Inhaler (mcg)	Solution for Nebulizer (mg)	Oral	Duration of Action (hours)
Mucolytic				
NAC			600 mg	12
Methylxanthines				
Theophylline (SR)			100-600 mg (Pill)	24
Theo 24			100-400 mg (Pill)	24
Uniphyl			400-600 mg (Pill)	24
Inhaled Glucocorticosteroids (ICS)				
Qvar*	40, 80 (HFA-MDI)			12
Pulmicort*	90, 180 (DPI)	0.25/2 ml 0.5/2 ml		12
Flovent*	44-220 (HFA) 100, 250 (DPI)			12
Arnuity Ellipta*	100, 200 (DPI)			24
Asmanex*	220 (DPI)			24
Alvesco*	80, 160 (HFA)			12
Inhaled Glucocorticosteroid plus Long Acting B2-Agonists (ICS/LABA)				
Symbicort	80/4.5* 160/4.5 (HFA)			12
Advair Diskus	100/50* 250/50 500/50* (DPI)			12 12 12
Advair*	45/21 115/21 230/21 (HFA)			12 12 12
Dulera*	100/5 200/5 (HFA)			12
Breo Ellipta	100/25 (DPI)			24
Approved for Reducing COPD Exacerbations				
Advair	250/50 (DPI)			12
Breo Ellipta	100/25 (DPI)			24
Spiriva Handihaler	18 (DPI)			24
Spiriva Respimat	5 (SMI)			24
Daliresp (PDE4 Inhibitor)			500 mcg	24

*FDA approved for Asthma
HFA=Hydrofluoroalkane   MDI=Metered Dose Inhaler   DPI=Dry Powder Inhaler   SMI=Soft Mist Inhaler
COPD patients should be tested for alpha-1 antitrypsin deficiency, the genetic form of COPD. www.alpha-1foundation.org

trial[17,18] warrants the reintroduction of the SG0 and SGU classifications within this pocket guide. Data from high resolution CT scans has shown that people with normal spirometry can have simple forms of chronic bronchitis and/or emphysema.[17,18] Additionally, these individuals appear to experience considerable morbidity and may be at risk for disease progression. Symptomatic individuals with these spirometry grades should be evaluated for other signs of illness using other diagnostic tests and spirometry should be repeated periodically to assess possible progression. These individuals may be candidates for referral to a lung specialist.

In the PCG, we have chosen to present a summary of COPD management in a simple flow sheet defining a hierarchy of therapies that mirror practice decisions. The flow sheet, supplemented by the assessment of all of the COPD severity domains presented, as well as assessment of ACOS, should allow for a clear and uniform approach to COPD management, monitoring and repeated assessments that are so important for the care of individuals with a chronic progressive condition. The PCG suggests dual bronchodilator therapy for symptomatic patients regardless of exacerbation risk,
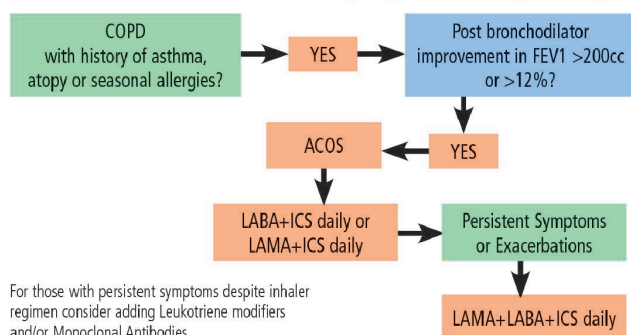
Figure 5. Modified Medical Research Council Dyspnea Scale and Asthma-COPD Overlap Syndrome

mMRC Breathlessness Scale

Grade	Description of Breathlessness
0	I only get breathless with strenuous exercise
1	I get short of breath when hurrying on level ground or walking up a slight hill
2	On level ground, I walk slower than people of the same age because of breathlessness, or have to stop for breath when walking at my own pace
3	I stop for breath after walking about 100 yards or after a few minutes on level ground
4	I am too breathless to leave the house or I am breathless when dressing

Chris Stenton. The MRC breathlessness scale. Occup Med (Lond)(2008)58(3): 226-227 doi:10.1093/occmed/kqm162, Table 1. By permission of Oxford University Press on behalf of the Society of Occupational Medicine.
A mMRC score of 1 or more suggests significant symptoms.

Asthma COPD Overlap Syndrome (ACOS)

For those with persistent symptoms despite inhaler regimen consider adding Leukotriene modifiers and/or Monoclonal Antibodies

National Quit Smoking Line: 1-800-Quit NOW (784-8669)
COPD Foundation Information Line: 1-866-316-COPD (2673)
COPD 360: http://copd360social.org

Free Consultant Guide App- search "COPDFoundation" on App store

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Figure 6. The COPD Assessment Test

COPD Assessment Test (CAT)

- A CAT score of 10 or more suggests significant symptoms.
- A change in CAT score of 2 or more suggests a possible change in health status.
- A worsening CAT score could be explained by an exacerbation, poor medication adherence, poor inhaler technique, or progression of COPD or comorbid conditions. An adjustment in therapy may be needed.

suggesting maximal bronchodilator therapy may be required prior to significant exacerbation risk.[19]

The COPD Foundation Pocket Consultant Guide was designed to be a readily accessible, practical guide for the assessment and management of the COPD patient at the point of care. It represents the opinion of the authors and is presented as a statement of the Board of Directors of the COPD Foundation but not that of any corporation or government body. As the understanding of COPD evolves and therapies advance, we expect the PCG to continue to evolve.

Declaration of Interest

Table 1. Comparison of Levels of COPD as Presented in Global Initiative for Chronic Obstructive Lung Disease 2017 and the 2017 COPD Pocket Consultant Guide

GOLD 2017	**GOLD 1** – Mild FEV_1 is ≥80% predicted **GOLD 2** – Moderate FEV_1 is 50%-79% predicted **GOLD 3** – Severe FEV_1 is 30%-49% predicted **GOLD 4** – Very Severe FEV_1 is <30% predicted
PCG 2017	**SG 0** – Normal spirometry does not rule out emphysema, chronic bronchitis, asthma, or risk of developing either exacerbations or COPD. **SG 1** – Mild FEV_1 is >60% predicted **SG 2** – Moderate FEV_1 is 30-60% predicted **SG 3** – Severe FEV_1 is <30% predicted **SG U** Undefined: FEV_1/FVC ratio >0.7, FEV_1 <80% predicted. This is consistent with restriction, muscle weakness, and other pathologies.

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