COPD MANAGEMENT PROTOCOL
STANFORD COORDINATED CARE

I. PURPOSE

To establish guidelines for the collaborative management of patients with a diagnosis of chronic obstructive pulmonary disease (COPD) who are not adequately controlled and to define the roles and responsibilities of the collaborating clinical pharmacist and pharmacy resident following this protocol.

II. POLICY

The clinical pharmacist and pharmacy resident, under this protocol, are authorized to initiate therapy, adjust dosages, change medication and authorize refills to the listed medications. All modifications to therapy must follow the detailed protocol and will be documented in the medical record.

III. PROCEDURE

Clinical pharmacist or pharmacy resident may make changes to inhaled bronchodilators, inhaled or systemic corticosteroids, and combination therapy of these inhaled agents (see Appendix).

Under this protocol, the clinical pharmacist or pharmacy resident will have the authority to order labs to assess treatment and to monitor for adverse events from the drug therapy.

Medication Therapy Management NOT covered in protocol:

- Methylxanthines (theophylline), antibiotics, antiviral agents, and oxygen therapy
- Conditions other than COPD
- Frequent infections and/or possible bronchiectasis, frequent exacerbations, acute COPD exacerbations, or post hospital discharge for COPD exacerbations
- Assessment for hypoxemia and hypercapnia

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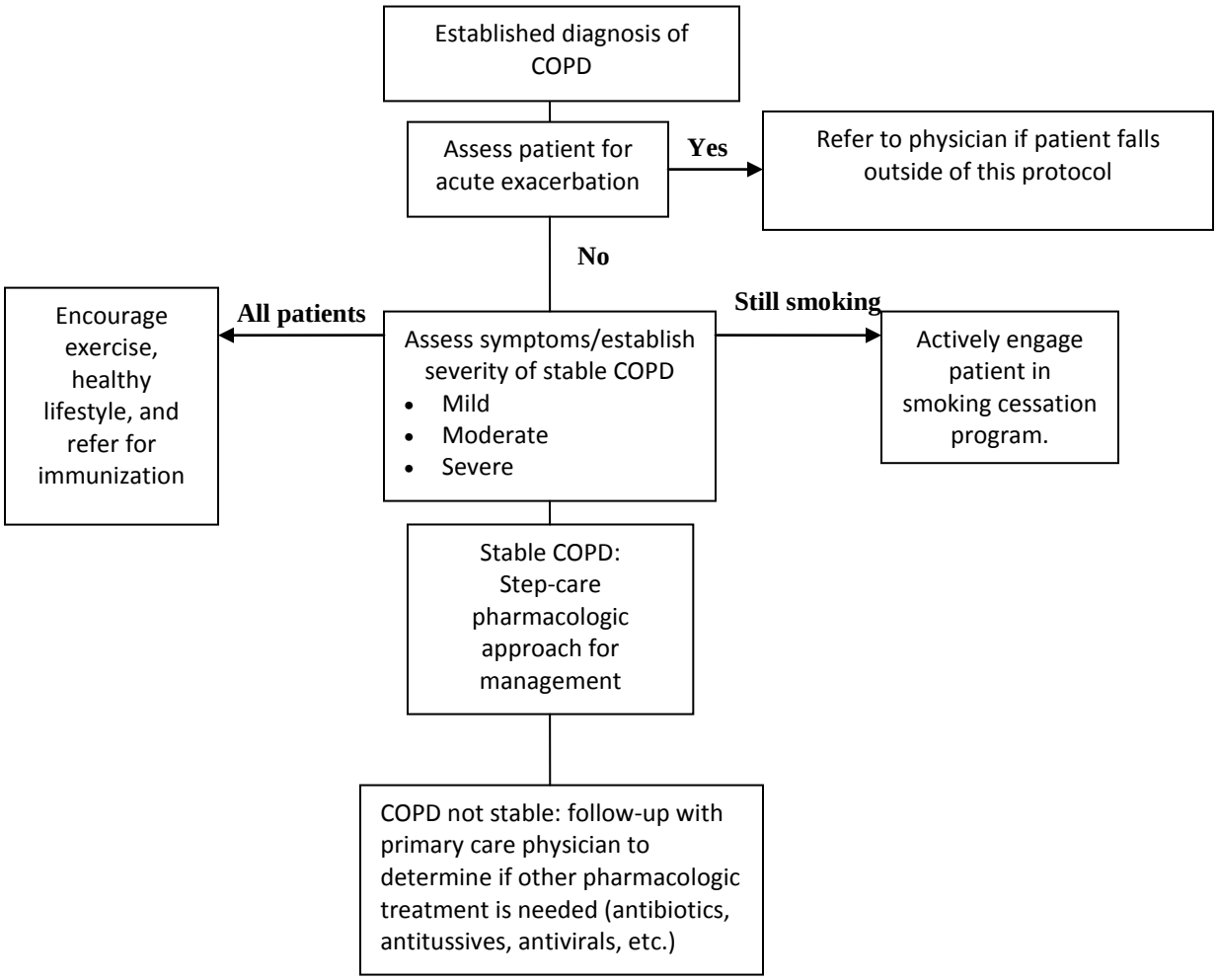
IV. PROTOCOL

COPD Treatment Algorithm



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Initial Visit Protocol

The patient's medical record will be reviewed and the following information will be gathered and discussed during the initial visit using the COPD workup form (Appendix 1):

- Blood pressure and pulse
- Complete medication history regarding COPD therapy, treatments, ER visits, hospitalizations and intubations secondary to COPD within the past year
- Assess COPD symptoms (cough, wheeze, dyspnea) and symptoms with exertion
- Review or order oximetry at SCC, if < 90 refer back to referring or primary provider
- Review or order spirometry at SCC, if not done at diagnosis
- Assess and classify severity of COPD (Appendix 3)
- COPD medications will be initiated, discontinued or adjusted as needed (Appendix 4 and 5)
- Assess social history, work/environmental exposure, and functional status
- Assess and educate inhaler technique and compliance
- Provide patient with patient education
- Follow-up within 1-4 weeks following initial visit

Follow-up Visit Protocol

Follow-up visits will be established between the clinical pharmacist or pharmacy resident. Follow-up appointments will be scheduled approximately every 1-6 months depending on severity of symptoms. The number of follow-up visits will be determined by the clinical pharmacist and pharmacy resident. Appendix 2 will be used to gather information for follow-up visits.

Assess at follow-up:

- Obtain an updated medication history, including both COPD and non-COPD medications
- Frequency of signs and symptoms of COPD
- History of COPD exacerbations
- Pharmacotherapy: effectiveness, adverse effects, compliance
  COPD medications will be initiated, discontinued or adjusted as needed (Appendix 4 and 5)
- Review or order spirometry if there is a substantial increase in symptoms or a complication
- Review inhaler/spacer technique; have patient demonstrate technique

Health Maintenance

- Spirometry should be performed annually on all COPD patients. Spirometry is needed to make a firm diagnosis of COPD and helps stage COPD severity. Can be used to guide treatment steps.
- All patients should receive annual influenza vaccination – influenza vaccines reduce serious illness and death in COPD patients by 50%.
- All patients should receive a Pneumovax vaccination – recommended for patients 65 years and older, and has been shown to reduce community-acquired pneumonia in those under 65 with FEV1 <40% predicted.
- Encourage and assist with smoking cessation in all patients with COPD.

V. DOCUMENTATION

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APPENDIX 1

COPD HISTORY WORK UP

1. What worries you most about your COPD? _____
   _____
2. What do you want to accomplish at the visit? _____
   _____
3. Symptoms:
   - Chronic cough with/without sputum? YES / NO Intermittently Every day
   - Wheezing? YES / NO Most days or nights? YES / NO
   - Dyspnea? YES / NO Worsens over time? YES / NO Worse on exercise or rest? YES / NO Present every day? YES / NO?
4. History of exposure to risk factors:
   - Does anyone smoke in the home (tobacco, other inhaled substances which produce fumes)? YES / NO
   - Do you smoke? YES/ NO If yes, how much per day? _____
     - Are you willing to quit at this time? YES / NO (If yes, refer to smoking cessation program)
   - Any exposure to occupational, chemicals, or smoke from home cooking and heating fuels? YES / NO
5. Have you ever gone to the emergency department for a COPD exacerbation? YES / NO
   If yes, how many times in the last 6 months? _____
6. Have you ever been hospitalized for COPD? YES / NO How many times? _____ Intubated? YES / NO
7. How many days of work have you missed in the past 3 months due to COPD? _____
8. Are you able to keep up with your friends and family during routine activities? YES / NO
9. Does your coughing or breathing keep you from doing things that you used to do and enjoy? YES / NO
10. Has your exercise capacity decreased over the years more than it has in your peers? YES / NO
11. Have you used any medications that help you breathe better? YES / NO
    Name of medication (inhalers/pills, prescriptions/OTC):_____
12. What other medication have you used for COPD? _____
    _____

13. Has your COPD medicine caused you any problems? YES / NO
    - If yes, what problems? shakiness nervousness bad taste sore throat cough upset stomach fast heartbeat other_____
    - Which medication caused this problem? _____

14. Are there any other factors that may affect your ability or desire to take your medications as directed?
    _____
    _____

APPENDIX 2

COPD FOLLOW-UP WORK UP

1. Since your last visit:
   - Has your COPD been any worse? YES / NO
   - Any changes in home or work environment? YES / NO
   - Any exacerbations? YES / NO
     - What do you think caused the symptom to get worse? _____
     - What did you do to control the symptom? _____
       _____
     - ER visits? YES / NO
     - Hospitalized? YES / NO
     - Intubated? YES / NO
   - Missed work? YES / NO
     If yes, how much? _____
   - How and when are you taking your COPD medications? _____
     _____
     _____
     _____
   - Have you missed any doses of your medications? YES / NO
     - If yes, how much?_____ How often? _____
     - Why? _____
   - Has your COPD medicine been effective in controlling your symptoms? YES / NO
   - Has your COPD medicine caused you any problems? YES / NO
     - If yes, (circle) shakiness nervousness bad taste sore throat cough
       upset stomach fast heartbeat other_____
     - Which medication caused this problem? _____

2. If patient is a smoker: Have you continued to stay off cigarettes? YES / NO
   - If not, how many cigarettes per day are you smoking? _____
   - Would you like to quit smoking? YES / NO (If yes, refer to smoking cessation programs)

APPENDIX 3

COPD Classification Scheme: Based on clinical features before treatment *

	Symptoms	FEV_1 (% predicted)
GOLD 1: Mild	• No abnormal signs • Cough ± sputum	• ≥ 80%
GOLD 2: Moderate	• Breathlessness ± wheeze on moderate exertion • Cough ± sputum • Variable abnormal signs (general reduction in breath sounds, presence of wheezes) • Hypoxemia may be present	• Between 79% and 50%
GOLD 3: Severe	• Dyspnea with any exertion or at rest • Wheeze and cough often	• Between 30% and 49%
GOLD 4: Very Severe	• Lung hyperinflation; cyanosis, peripheral edema and polycythemia in advanced disease	• < 30%

***The presence of one of the features of severity is sufficient to place a patient in that category. An individual should be assigned to the most severe grade in which any feature occurs.

APPENDIX 4
Pharmacologic Therapy for Managing COPD

	Recommended First Choice	Alternative Choice
GOLD 1: Mild	SA anticholinergic prn or SA $beta_2$-agonist prn	LA anticholinergic or LA $beta_2$-agonist or SA $beta_2$-agonist and SA anticholinergic
GOLD 2: Moderate	LA anticholinergic or LA $beta_2$-agonist	LA anticholinergic and LA $beta_2$-agonist
GOLD 3: Severe	ICS + LA $beta_2$-agonist or LA anticholinergic	LA anticholinergic and LA $beta_2$-agonist or LA anticholinergic and PDE-4 inhibitor or LA $beta_2$-agonist and PDE-4 inhibitor
GOLD 4: Very Severe	ICS + LA $beta_2$-agonist and / or LA anticholinergic	ICS + LA $beta_2$-agonist and LA anticholinergic or ICS + LA $beta_2$-agonist and PDE-4 inhibitor or LA anticholinergic and LA $beta_2$-agonist or LA anticholinergic and PDE-4 inhibitor

Adapted from the GOLD report 2013 (www.goldcopd.org)

APPENDIX 5

Comparative Daily Dosages of Inhaled Corticosteroids for Adults

Drug	Low Dose	Medium Dose	High Dose
Beclomethasone HFA (QVAR) 40 mcg/puff 80 mcg/puff	80-240 mcg	>240-480 mcg	>480 mcg
Budesonide DPI (Pulmicort) 90 mcg/puff 180 mcg/puff 200 mcg/puff	180-600 mcg	>600-1200 mcg	>1200 mcg
Fluticasone HFA (Flovent HFA) 44 mcg/puff 110 mcg/puff 220 mcg/puff **DPI (Flovent Diskus)** 50 mcg/puff 100 mcg/puff 250 mcg/puff	88-264 mcg 200 mcg		>440 mcg 1000 mcg
Mometasone DPI 220mcg/puff	220 mcg	440 mcg	>440 mcg
Combination Product: Fluticasone/Salmeterol DPI (Advair)	100/50 mcg	250/50 mcg	500/50 mcg
Budesonide/Formoterol (Symbicort Turbuhaler)	160/9 mcg	>160/9 – 320/18 mcg	320/18 mcg

Notes:

- The most important determinant of appropriate dosing is the clinical pharmacist's and pharmacy resident's judgment of the patient's response to therapy.
- The clinical pharmacist and pharmacy resident will monitor the patient's response on several clinical parameters and adjust the dose accordingly.
- The stepwise approach to therapy emphasizes that once control of COPD is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effect.