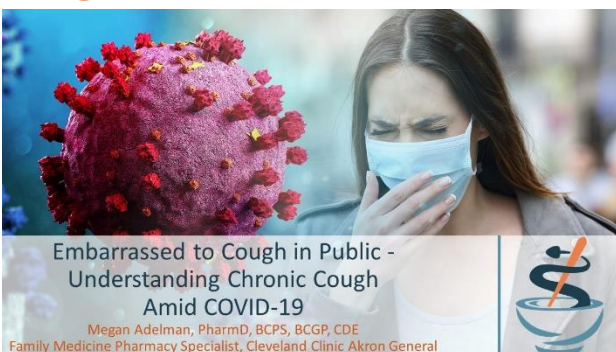




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Embarrassed to Cough in Public - Understanding Chronic Cough Amid COVID-19



Faculty
Megan Adelman, PharmD, BCPS, BCGP, CDE,
Family Medicine Pharmacy Specialist,
Cleveland Clinic Akron General

The already cumbersome burden and social limitations associated with chronic cough have been amplified during COVID-19. The heightened awareness of and concern associated with cough has made any errand or public appearance more difficult for those with chronic cough. Now, more than ever, patients with chronic cough are seeking effective treatments to minimize symptoms and improve quality of life. Current treatment strategies for cough fall short of meeting the needs of all patients with cough, particularly those patients who experience refractory or unexplained cough, so this is an area of unmet need. This educational session will summarize the current treatment landscape for chronic cough, as well as highlight the ways that current management falls short of meeting the needs of all patients. The purpose of this session is to equip pharmacists and nurses to provide appropriate counseling and treatment recommendations for patients with chronic cough. It is critical that healthcare providers understand not only the mechanism of chronic cough and current treatments, but also the receptors involved and their relationship to the rationale of new pipeline agents in development. Pharmacists and nurses will leave this session better able to care for and meet the needs of patients who suffer from this frustrating and stigmatizing condition.

Learning Objectives

Pharmacist

1. Describe the pathophysiology of cough
2. Define the types and characteristics of chronic cough and review clinical implications
3. Identify current treatment options for chronic cough including benefits and limitations with use
4. Recognize innovative, pipeline treatment approaches to cough and associated mechanisms

Pharmacy Technician

1. Describe the pathophysiology of cough
2. Define the types and characteristics of chronic cough and review clinical implications
3. Identify current treatment options for chronic cough including benefits and limitations with use
4. Recognize innovative, pipeline treatment approaches to cough and associated mechanisms

Nurse

1. Describe the pathophysiology of cough
2. Define the types and characteristics of chronic cough and review clinical implications
3. Identify current treatment options for chronic cough including benefits and limitations with use
4. Recognize innovative, pipeline treatment approaches to cough and associated mechanisms

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Target Audience

Pharmacists, Pharmacy Technicians, Nurses

Universal Activity Number

Pharmacist

0798-0000-20-213-H01-P

Pharmacy Technician

0798-0000-20-213-H01-T

Nurse

0798-0000-20-213-H01-N

Credit Hours

1.0 Hour

Activity Type

Knowledge-Based

CE Broker Tracking Number

20-718181

Activity Release Date

October 8, 2020

Activity Offline Date

April 8, 2021

ACPE Expiration Date

October 1, 2023

Educational Support Provided By

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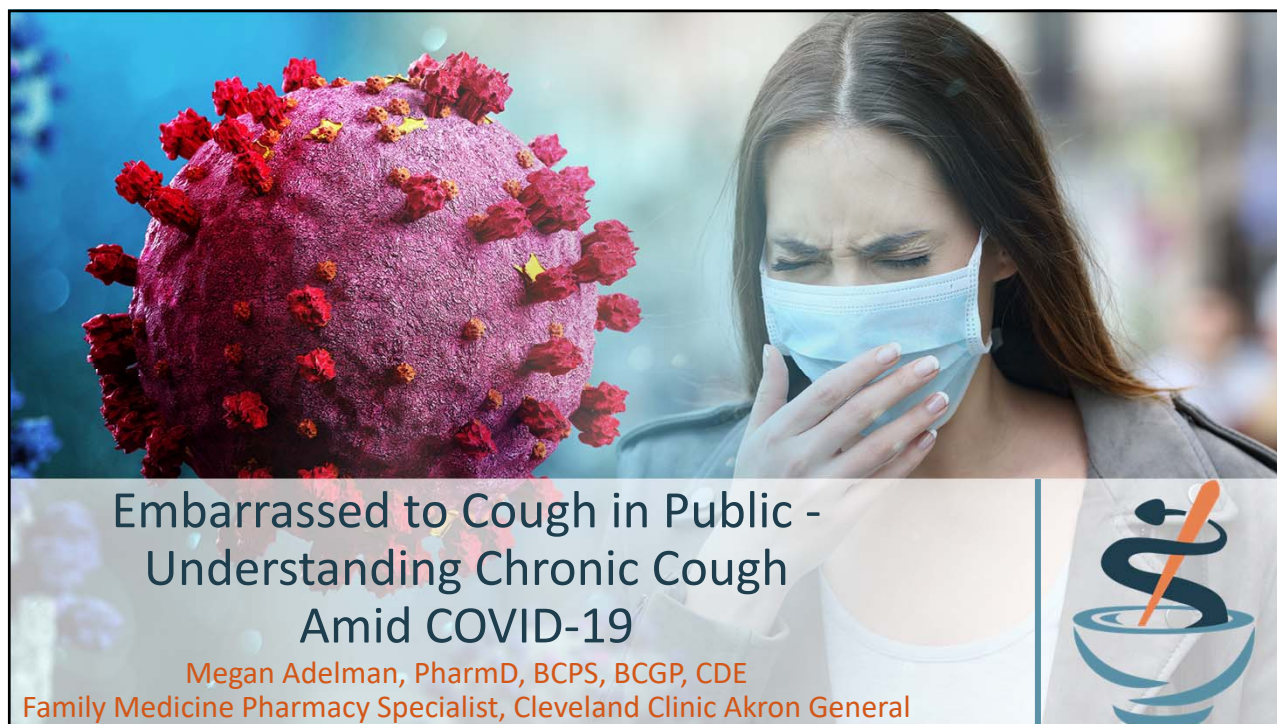
Consult full prescribing information on any drugs or devices discussed.

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Family Medicine Pharmacy Specialist, Cleveland Clinic Akron General



1

Faculty Disclosure

- Megan Adelman declares no existence of a financial interest in any amount related to the content of this activity.
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2

Learning Objectives

At the conclusion of this activity, participants should be better able to:

- Describe the pathophysiology of cough
- Define the types and characteristics of chronic cough and review clinical implications
- Identify current treatment options for chronic cause including benefits and limitations with use
- Recognize innovative, pipeline treatment approaches to cough and associated mechanisms

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3

Social Stigma

- Outbreaks like COVID19 can cause fear and anxiety, leading to social stigma about people, places, or things. These stigmas can directly impact an individual's mental health
 - Some people who may be experiencing social stigma during COVID:

How to Prevent Coronavirus Stigma. [Internet]. RevereHealth. (updated: 2020; accessed: Aug 2020).

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4

Social Stigma

- Outbreaks like COVID19 can cause fear and anxiety, leading to social stigma about people, places, or things. These stigmas can directly impact an individual's mental health

- Some people who may be experiencing social stigma during COVID:

Healthcare workers and emergency responders

People who have travelled

Large families

How to Prevent Coronavirus Stigma. [Internet]. RevereHealth. (updated: 2020; accessed: Aug 2020).

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Social Stigma

- Outbreaks like COVID19 can cause fear and anxiety, leading to social stigma about people, places, or things. These stigmas can directly impact an individual's mental health

- Some people who may be experiencing social stigma during COVID:

Healthcare workers and emergency responders

People who have travelled

Large families

*People with chronic conditions – like allergies, asthma,
chronic cough – which mimic symptoms of COVID*

How to Prevent Coronavirus Stigma. [Internet]. RevereHealth. (updated: 2020; accessed: Aug 2020).

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6

In a Crunch: Let's Talk Cough

Early studies have found that up to 60% of people with **COVID-19** have a **dry cough**.

- Symptoms of Coronavirus. [Internet]. Centers for Disease Control and Prevention. (updated: May 2020; accessed: Jul 2020).
- Koo HK, Jeong I, Lee SW, et al. Medicine (Baltimore). 2016;95(37):e4595

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In a Crunch: Let's Talk Cough

Early studies have found that up to 60% of people with **COVID-19** have a **dry cough**.

Studies indicate that chronic cough can occur at minimum 2.5% of the adult population

- Symptoms of Coronavirus. [Internet]. Centers for Disease Control and Prevention. (updated: May 2020; accessed: Jul 2020).
- Koo HK, Jeong I, Lee SW, et al. Medicine (Baltimore). 2016;95(37):e4595

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8

In a Crunch: Let's Talk Cough

Early studies have found that up to 60% of people with **COVID-19** have a **dry cough**.

Studies indicate that chronic cough can occur at minimum 2.5% of the adult population

*....In the United States this would estimate
~8.2 million who suffer from chronic cough*

- Symptoms of Coronavirus. [Internet]. Centers for Disease Control and Prevention. (updated: May 2020; accessed: Jul 2020).
- Koo HK, Jeong I, Lee SW, et al. Medicine (Baltimore). 2016;95(37):e4595

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9

Overview: By the Numbers



30 M



40%



\$4 B

- Irwin et al. Chest. 2006;129:15.
- Irwin et al. Am Rev Respir Dis. 1990;141:640.
- Caley. Nothing to sneeze at: cough-cold products shift to meet trends. [Internet]. Drug Store News. (updated: 2019; accessed: 2020).

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10

Overview: By the Numbers

~6.2% of US adults have chronic obstructive pulmonary disease

~7.7% of US adults have asthma

- Wheaton AG, Liu Y, Croft JB, et al. MMWR Morb Mortal Wkly Rep. 2019;68(24):533-8.
- Asthma Facts and Figures. [Internet]. Asthma and Allergy Foundation of America. (updated: 2020; accessed Sept 2020)
- Song WJ et al. Eur Resp J. 2015;45:1479-81.

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11

Overview: By the Numbers

~6.2% of US adults have chronic obstructive pulmonary disease

~7.7% of US adults have asthma

~9.6% of adults may have chronic cough!

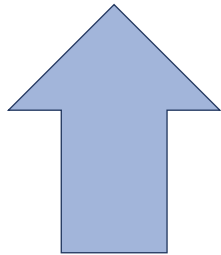
- Wheaton AG, Liu Y, Croft JB, et al. MMWR Morb Mortal Wkly Rep. 2019;68(24):533-8.
- Asthma Facts and Figures. [Internet]. Asthma and Allergy Foundation of America. (updated: 2020; accessed Sept 2020)
- Song WJ et al. Eur Resp J. 2015;45:1479-81.

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12

Coughing Up a Lung: Not Just the Physical Impact



Dysfunction in
Daily Activities

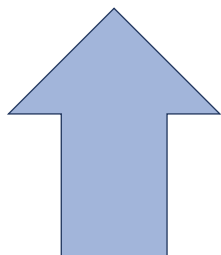
French et al. JAMA Int Med. 1998;158(15):1657-61.

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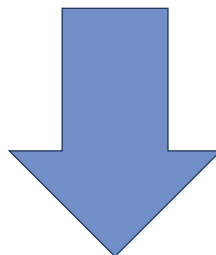


13

Coughing Up a Lung: Not Just the Physical Impact



Dysfunction in
Daily Activities



Feeling of
Exhaustion

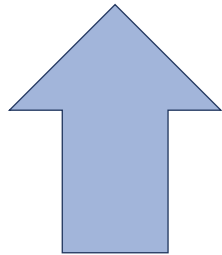
French et al. JAMA Int Med. 1998;158(15):1657-61.

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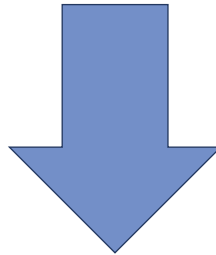


14

Coughing Up a Lung: Not Just the Physical Impact



Dysfunction in
Daily Activities



Feeling of
Exhaustion



Quality of Life
Measures

French et al. JAMA Int Med. 1998;158(15):1657-61.

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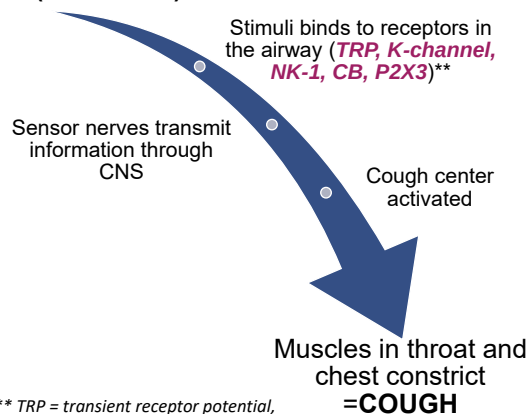


15

Pathophysiology

- Protective / survival mechanism
 - Clears the upper airway of secretions (i.e. mucus, foreign particles, etc.)
- Process:
 - Inspiration with epiglottis closure
 - Opening of the epiglottis with rapid expiration >> **creation of sound**

**Cough stimuli
(ex: irritant)**



• Irwin et al. CHEST. 2006;146(4):885-9.

• Shah MD, Shah SM. Indian J Pediatr. 2001;68(2):53-10.

** TRP = transient receptor potential,
K=potassium, NK=neurokinin,
CB=cannabinoid

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Definitions

Classification	Duration	Potential Etiology
Acute	< 3 weeks	Upper respiratory tract infection Pneumonia Asthma and COPD exacerbation Heart failure exacerbation
Subacute	3-8 weeks	Post-infectious cough Bacterial sinusitis
Chronic	> 8 weeks	GERD COPD / chronic bronchitis Drug-Induced Lung cancer Smoking Allergies / asthma

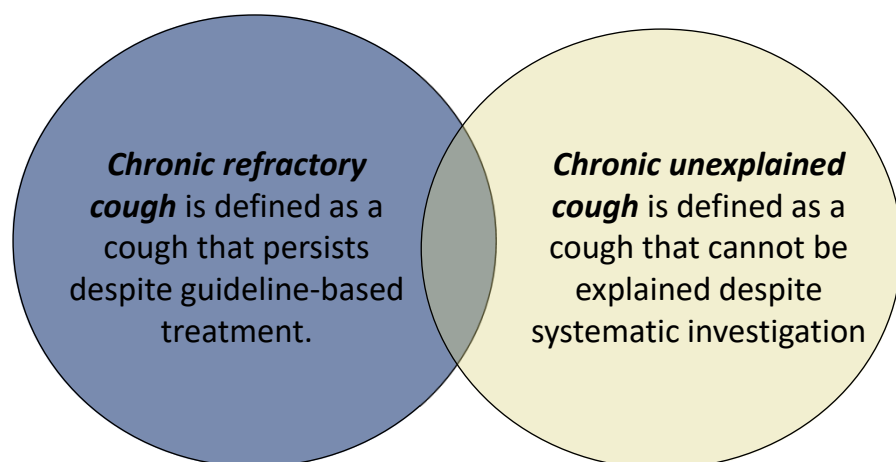
- Irwin et al. CHEST. 2006;146(4):885-9.
- Gibson et al. CHEST. 2016;149(1):27-44.

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17

Chronic Cough: Terminology



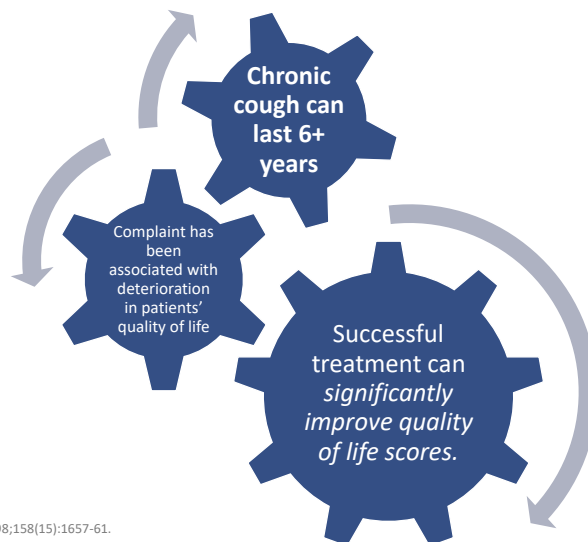
- Irwin et al. CHEST. 2006;146(4):885-9.
- Gibson et al. CHEST. 2016;149(1):27-44.

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18

Why Does This Matter?



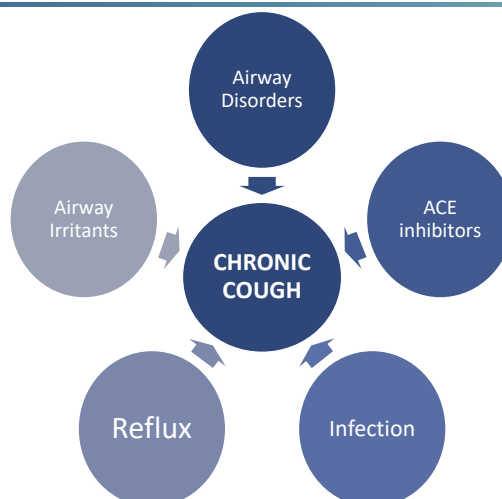
French CL et al. Arch Intern Med. 1998;158(15):1657-61.

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Contributing Factors



Gibson P, et al. BMJ. 2015;351.

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20

Differential Diagnosis



Other workups: sputum eosinophil tests, esophagostomy, bronchoscopy

Kardos P, Pneumologie. 2010;7:122-33.

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21

Patient Inquiry



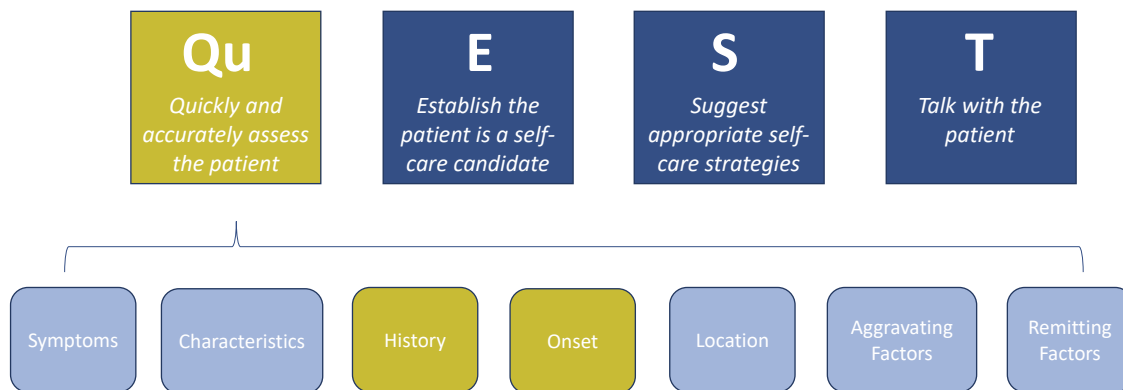
Berardi et al. Handbook of Nonprescription Drugs, 18th edition.

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Patient Inquiry



Berardi et al. Handbook of Nonprescription Drugs, 18th edition.

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Clinical Presentation

Classifications	Characteristics	Potential Etiology
Productive	- Wet / "Chesty" Cough - Effective - Non-Effective	Bronchitis Bacterial infection
Non-Productive	Dry / hacking cough	Viral and Atypical Bacterial Infections Reflux Disease Cardiac Disease Drug-Induced Cancer Unexplained / refractory cough*

* Most commonly presents as a dry cough

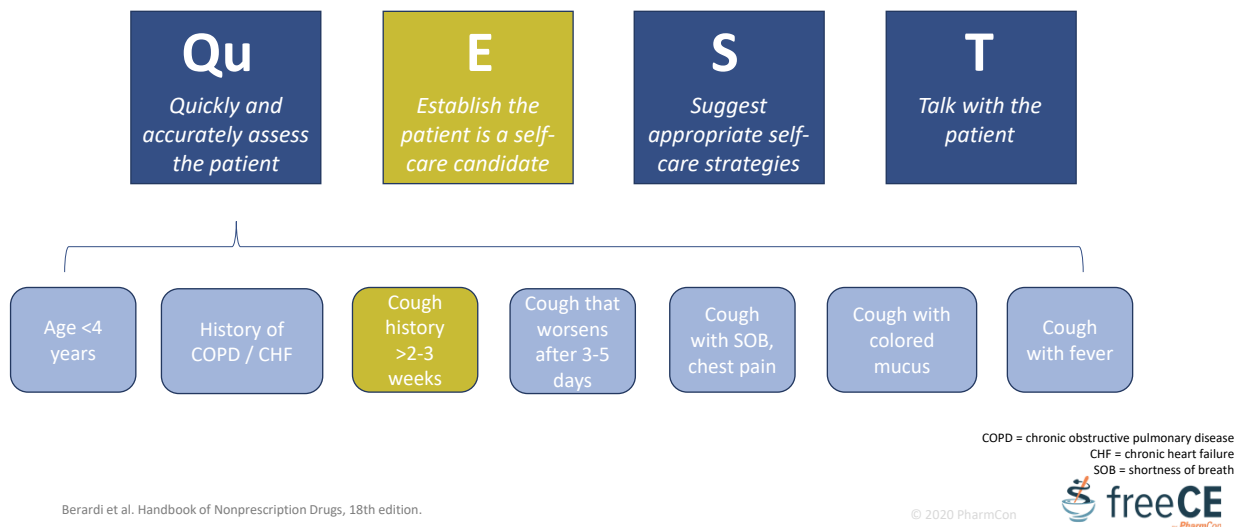
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Patient Inquiry



25

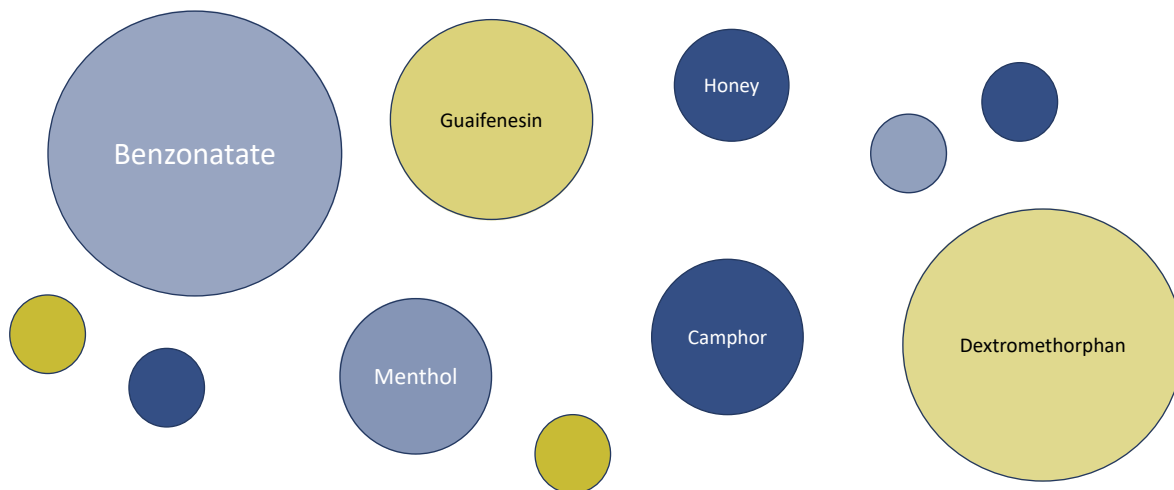
Non-Pharmacologic Therapies

- Speech pathology and physiotherapy
 - Education
 - Symptom control techniques
 - Reducing laryngeal irritation
 - Psychoeducational counseling
- *Clinical Pearls*
 - Coverage is insurance specific
 - Medicare – covered under part B with patient responsible for 20% of copay

- Gibson et al. CHEST. 2016;149(1):27-44.
- Centers for Medicare and Medicaid. [Internet]. CMS. (updated: 2020; accessed: 2020).

26

Hacking Our Way into Treatment



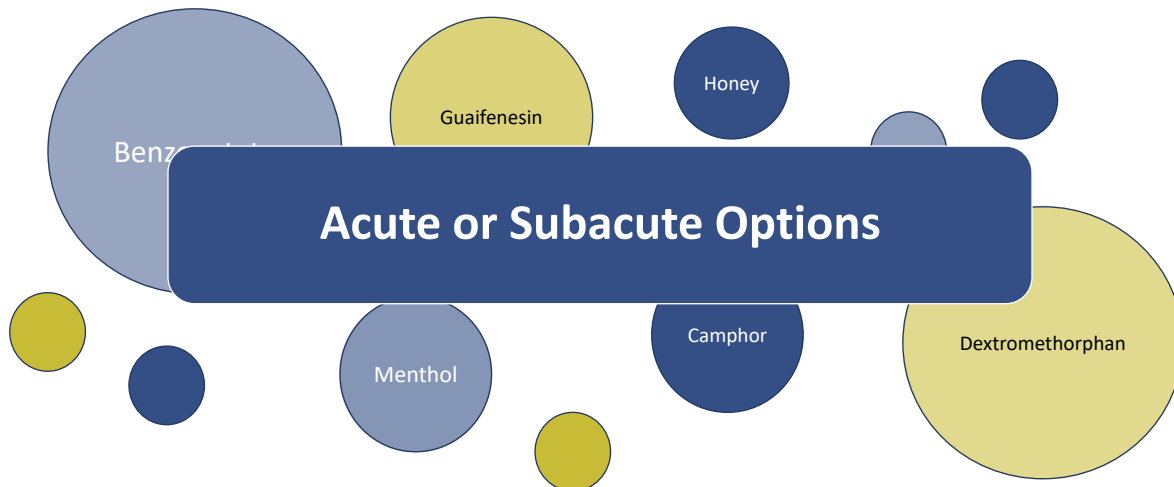
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Hacking Our Way into Treatment



Berardi et al. Handbook of Nonprescription Drugs, 18th edition.

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Hacking Our Way into Treatment: Chronic Cough

	CHEST (2016, 2018)	ACCP (2006)	CICADA (2010)	AAFP (2007)	BTS (2006)
Neuromodulators (ex: Gabapentin)	✓				
Inhaled Corticosteroids	✓	✓	✓	✓	✓
Proton Pump Inhibitors	✓	✓	✓	✓	✓
Antihistamine with Decongestant	✓	✓		✓	✓

ACCP = American College of Chest Physicians
 CICADA = Cough in Children and Adults
 AAFP = American Academy of Family Physicians
 BTS = British Thoracic Society

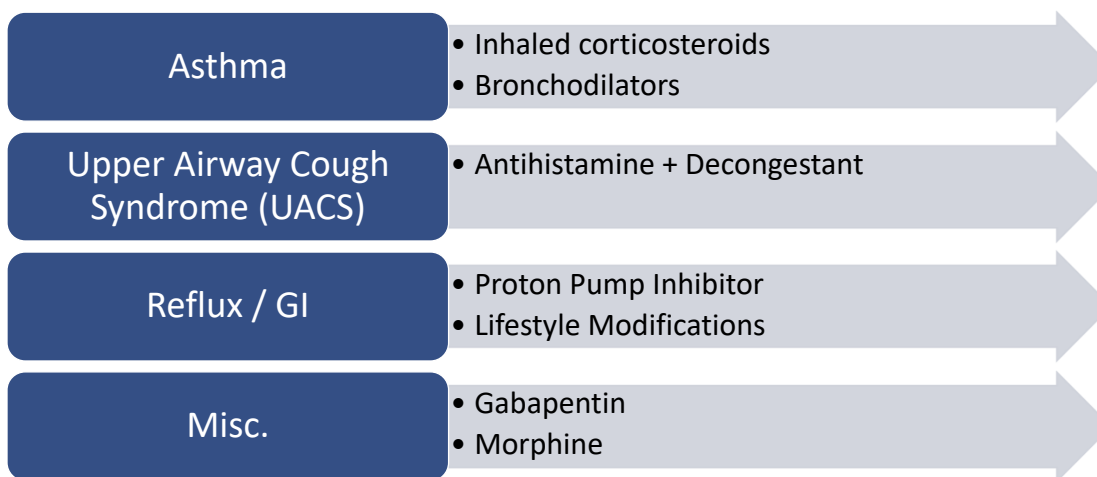
- Adapted from: Gibson et al. CHEST. 2016;149(1):27-44.
- Irwin et al. CHEST. 2018; 153(1):196-209
- Irwin et al. CHEST. 2006;146(4):885-9.
- Gibson et al. MJA. 2010;192(5):165-71.
- Morice AH et al. Thorax. 2006;61(1):11-24.
- Coughlin. Am Fam Physician. 2007;75(4):567-75.

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29

Hacking Our Way Through an Algorithm



- Irwin et al. CHEST. 2006;146(4):885-9.
- Coughlin. Am Fam Physician. 2007;75(4):567-75.

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30

Antihistamine-Decongestant

- AAFP (2007): initial treatment option in patients without clear cause or specific disease
 - Combination: diphenhydramine + pseudoephedrine
- ACCP (2006): recommend an antihistamine/decongestant for UACS (grade B)

- Morice AH et al. Thorax. 2006;61(1):i1-24.
- Coughlin. Am Fam Physician. 2007;75(4):567-75.

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Antihistamine-Decongestant

- AAFP (2007): initial treatment option in patients without clear cause or specific disease
 - Combination: diphenhydramine + pseudoephedrine
- ACCP (2006): recommend an antihistamine/decongestant for UACS (grade B)

First generation antihistamine used in cough because needs to cross the blood brain barrier to target medulla (note difference from allergic rhinitis)

Second-generation antihistamines (e.g., loratadine, fexofenadine) **lack antitussive activity.**

- Morice AH et al. Thorax. 2006;61(1):i1-24.
- Coughlin. Am Fam Physician. 2007;75(4):567-75.

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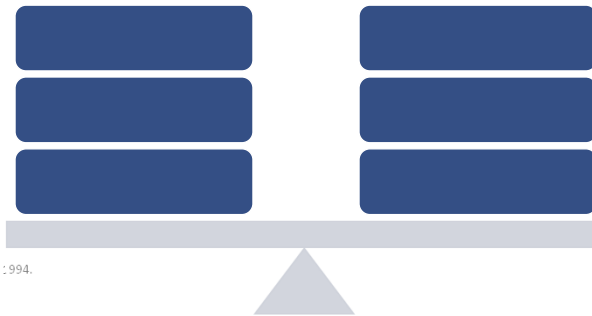
32

Inhaled Corticosteroids

Mechanism: reverses the capillary permeability to prevent and control inflammation

Negative bronchial hyper-responsiveness and eosinophilia – ICS not recommended (CHEST)

Cough variant asthma responds to treatment with corticosteroids (BTS)



- Boulet LP et al, Am J Respir Crit Care. : 994.
- Evald T et al, Allergy. 1989.
- Gibson et al, CHEST. 2016.
- Irwin et al, CHEST. 2006.

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33

Inhaled Corticosteroids

Fluticasone

Mometasone

Budesonide

Beclomethasone

Recommendation:
400 mcg per day of
budesonide equivalent

Johnstone KJ et al. Cochrane Library and Database of Systematic Reviews. 2013:1-71.

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Corticosteroid Comparisons

	Low	Medium	High
Beclomethasone	≤ 240	>240 – 480	>480
Budesonide	≤ 600	>600 – 1200	>1200
Fluticasone HFA	≤264	>264 – 440	>440
Fluticasone DPI	≤300	>300 – 500	>500
Mometasone	≤220	>220 – 440	>440

NHBLI EPR3. 2012.

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Proton Pump Inhibitors (PPI)

ACCP (2006):

- *In adult patients with chronic cough suspected to be due to reflux-cough syndrome,. We recommend that treatment include 1) diet modification to promote weight loss... 2) head of bed elevation and avoiding meals within 3 hours of bedtime and 3) **in patients who report heartburn and regurgitation, PPI (Grade 1C)***
- *In adult patients with suspected chronic cough due to reflux-cough syndrome but without heartburn or regurgitation, we recommend against using PPI therapy alone (Grade 1C)*

Irwin et al. CHEST. 2006;146(4):885-9.

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36

Proton Pump Inhibitors

- Guidelines do **not** indicate optimal dosing or duration
 - Most studies include *high dose PPI*



- Irwin et al. CHEST. 2006;146(4):885-9.
- Gibson et al. CHEST. 2016;149(1):27-44.
- Park et al. PLoS One. 2017;12(10):e0185397.

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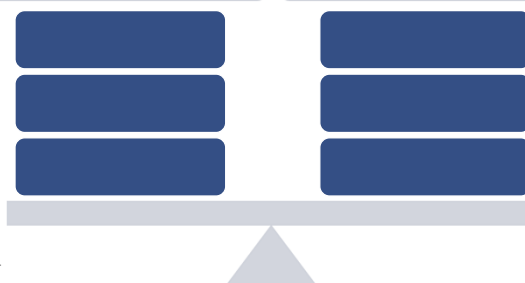
37

Gabapentin

CHEST (2016): In unexplained chronic cough, a therapeutic trial of gabapentin is recommended...as long as there is a re-assessment...at 6 months before continuing the drug (Grade 2C)

Side effect profile: Ryan et al: 31% with gabapentin vs 10% with placebo

Improvement in quality of life as measured by cough questionnaires



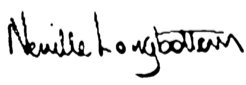
- Ryan et al. Lancet. 2012;380(9853):1583-9.
- Gibson et al. CHEST. 2016

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Gabapentin

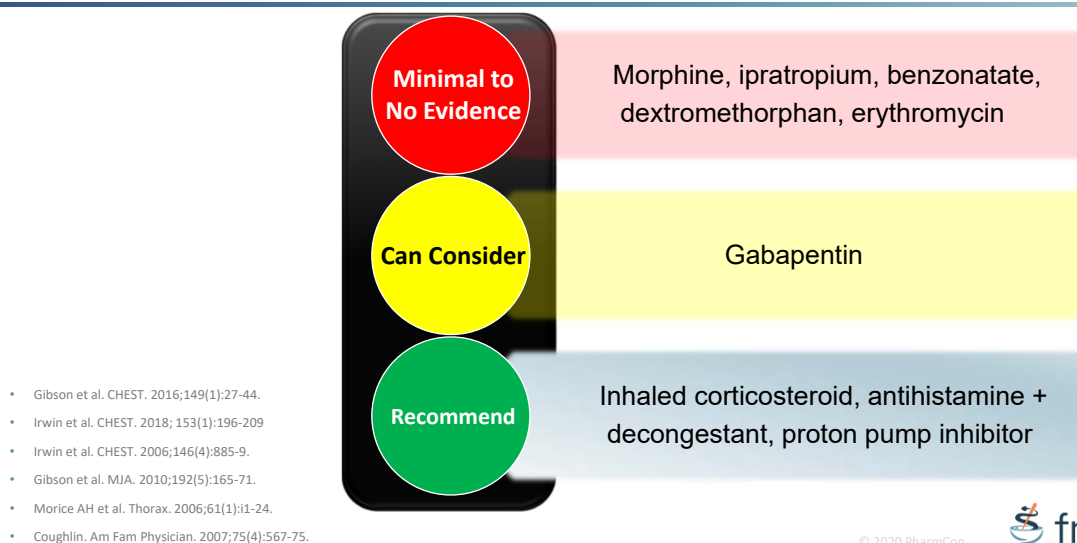
Dr. Neville Longbottom WV Family Practice Medicine 12 School of Pharmacy Drive Morgantown, WV 26508 (304) 293-5555 Fax: (304) 293-6767	
DEA Number: AL2347895	NPI: 234890567
Name: Gabrielle Smith	Date Written: 8/3/2018
DOB: 10/30/1955	
Address: 1931 Beauxbatons Circle Morgantown, WV 26501	
RX: Gabapentin 300 mg SIG: Take 1 capsule by mouth daily for cough	
Refills: 0	
#30	
	
Dispense as Written	Generic Substitution Permitted

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Treatment Summary



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ACE-Inhibitor Induced Cough

- Occurs in up to 15% of patients receiving an ACE-inhibitor
- Usually begins within 1 month of starting therapy but can be delayed for up to 1 year
- Treatment Management:
 - Discontinue medication immediately
 - Diagnosis confirmed by resolution of cough (1 week – 3 months)

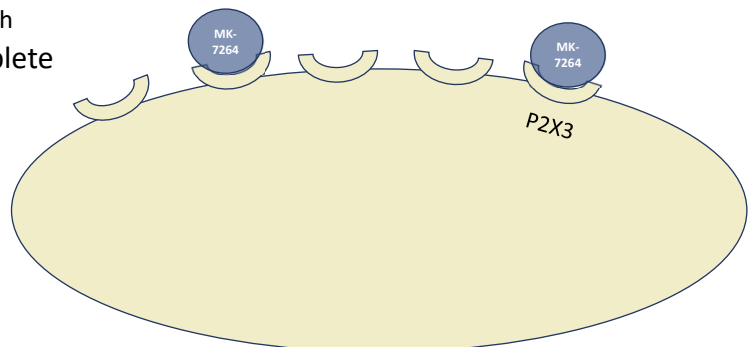
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41

Emerging Therapies: P2X3 Antagonist

- Target the cough reflex: MK-7264 (Gefapixant®)
 - P2X3 are receptors expressed by the airway afferent nerves
 - Contribute to hypersensitization of sensory neurons
 - Activation → chronic cough
 - Phase II and III trials complete
- Phase II: Change in cough frequency: -22 to -37%
- Phase III (COUGH 1 and COUGH 2): Higher doses statistically lowered cough frequency



- Smith et al. Am J Respi and Crit Care Med. 2016;193:A6524.
- Smith et al. Lancet Resp. 2020;8:775-85.
- Merck's chronic cough drug gefapixant clear phase 3 test. [Internet]. PharmaPhorum. (available: Mar 2020; accessed: Sept 2020).

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42

Emerging Therapies: Receptor Binding

NK-1 Antagonist

Orvepitant®

Blocks binding of substance P to the neurokinin 1 (NK-1) receptor

Cannabinoid CB2 Agonists

CP 55940 and JWH 133

Inhibit sensory nerve depolarizations and sensitization

- Patel HJ et al. Br J Pharmacol. 2003;140(2):261-8.
- Smith J et al. CHEST. 2020;157(1):111-8.

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43

Emerging Therapies: Channel Modulators

Transient Receptor Potential (TRP) Channels

Compounds are currently in clinical development

TRPV1 channel activated by heat and acid

Calcium-Activated Potassium Channels

NS1619

Channel activation inhibits sensory nerve function and cough induced by citric acid

- Millqvist E. Pharmaceuticals. 216;9(3):45.
- Sutovska et al. J Physiol Pharmacol. 2007;58(Suppl 5):673-83.

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44

Patient Case

A 52-year-old white female presents with a dry cough for the past 4 months. She denies any reflux, shortness of breath, or wheezing. Diet includes heavy caffeine use, chocolate, and alcohol. The patient appears to have an elevated body mass index with central adiposity. The patient has tried over-the-counter DXM, increasing water intake, and Tylenol with codeine with minimal benefit.

What options are available for this patient?

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Key Takeaways

- Chronic cough is a leading cause of outpatient healthcare utilization
- Limited options are available for patients, and diagnostic testing can be extensive
- Emerging therapies are targeting receptors and ion channel which cause hypersensitivity

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Thank You

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Activity Test

Embarrassed to Cough in Public - Understanding Chronic Cough Amid COVID-19

Activity tests must be completed online at www.freeCE.com.

A passing grade of 70 or higher and completion of an online activity evaluation are required to earn credit.

1. All the following represent potential outcomes associated with chronic cough EXCEPT:
 - a. Increased respiratory comorbidity burden
 - b. Decreased ability to complete daily activities
 - c. Increased feeling of exhaustion and fatigue
 - d. Decreased patient-reported quality of life

2. KA is a 33-year-old white male who comes to the pharmacy seeking advice for his dry, unproductive cough which has bothered him for approximately 10 weeks. He reports this occurs intermittently – going away for a few days and then coming back. On further prompting, he states his symptoms have worsened over the last 4 days. He had a cold ~2 months ago, but his symptoms resolved after two weeks and following a course of antibiotics. He denies current fever or shortness of breath. He reports some relief with guaifenesin, though not complete resolution. At this time, he asks for therapy which would provide relief. Which of the following is most consistent with the diagnosis of chronic cough?
 - a. New worsening of symptoms
 - b. Dry cough presentation
 - c. Intermittent appearance
 - d. Recent use of antibiotics

3. A 53-year-old African American male presents to the pharmacy with an ongoing cough and is seeking advice for an over-the-counter option. The patient reports being an office manager with minimal outside daily activity. He has had a cough for the past three months; it is dry without nasal or chest congestion. The cough is persistent throughout the whole day, and he endorses having pain in sternum area due to coughing constantly. Based on the patient's pharmacy records, he has filled the following medications within the last month: amlodipine (patient reports for blood pressure), omeprazole (reported for indigestion), and atorvastatin (reported for cholesterol). The patient reports trying the following therapies without relief: benzonatate, Delsym® cough, and honey cough drops. Which of the following patient-specific traits is a risk factor for the development of a chronic refractory cough?
- Age
 - Gender
 - Medication regimen
 - Medical co-morbidity
4. Novel treatment options, such as Orvepitant® and Gefapixant®, for chronic cough management directly target which process in cough development?
- Release GABA and increase brainstem relaxation
 - Delay cough center activation
 - Block hypersensitization of neurons
 - Induce dilation of chest muscles and diaphragm
5. Which of the following patients who presents with complaint of chronic cough would be the best candidate for a novel treatment option, such as Gefapixant®?
- A 56-year-old female with a chest abnormality noted on CT scan
 - A 45-year-old male diagnosed with asthma and minimal relief from inhaled corticosteroids (ICS)
 - A 72-year-old male with history of stroke and documented dysphagia
 - A 27-year-old female prescribed lisinopril within the last 2 weeks

6. Chronic refractory cough is defined as a cough that persists longer than ____ months despite guideline-recommended treatment.
- 2
 - 3
 - 4
 - 5
7. All the following tests, lab work, and procedures may be utilized to help with the diagnosis of unexplained chronic cough EXCEPT:
- Pulmonary function testing
 - Chest X-ray
 - Complete blood count
 - Bronchoscopy
8. A 57-year-old African American female presents to your family medicine center with ongoing complaints of cough. The patient reports this has occurred for ~3 months. Per the electronic health record, she has been previously prescribed benzonatate and codeine #3; her PCP previously recommended dextromethorphan. The patient reports no relief with any therapies. The cough occurs throughout the day and is non-productive. She also endorses nasal congestion. The patient has a past medical history of hypertension (currently well controlled), environmental allergies, and diabetes with neuropathy. Her current medication list includes: cetirizine 10 mg daily, metformin 1,000 mg BID, fluticasone 1 spray in each nostril daily, losartan 100 mg daily, liraglutide 1.8 mg daily, amitriptyline 25 mg daily, and cholecalciferol 1,000 units daily. She does not smoke and has no reported fever or shortness of breath. Based on the patient's presentation, medical history, and medication regimen, you recommend the following:
- Change amitriptyline to gabapentin and discontinue losartan
 - Change cetirizine to diphenhydramine and add pseudoephedrine
 - Add omeprazole and encourage dietary and lifestyle modifications
 - Increase cholecalciferol to 2,000 units daily and add vitamin B-12

9. A 35-year-old African American male presents to your clinic with complaint of a cough lasting for ~6 months. This occurs throughout the day though is worse in the morning and at night. He reports trying “everything” over the counter without success, as well as a short course of benzonatate. His past medical history is consistent with asthma, diabetes, and class II obesity. He is currently prescribed fluticasone/salmeterol 250/50 1 puff BID, albuterol 1 puff q4hours PRN (patient reports he has not needed “for months”), metformin 1,000 mg BID, losartan 100 mg daily, and empagliflozin 25 mg daily. The patient denies shortness of breath, fever, nasal or chest congestion. His only other complaint is a chest discomfort and “throat burning” in the evening before bed. Based on the patient’s presentation, medical history, and medication regimen, you recommend the following:
- Increase fluticasone/salmeterol to 500/50 1 puff BID
 - Add esomeprazole and encourage dietary modifications
 - Change albuterol to ipratropium 1 puff every 4 hours PRN
 - Add fluticasone nasal spray 1 spray in each nostril daily
10. JS is a 55-year-old white female with past medical history including diabetes and asthma. The patient presents to the pharmacy with complaint of dry, hacking cough lasting ~10 weeks. The patient reports a recent diagnosis of diabetes and was started on metformin and lisinopril ~4 months ago. The patient remembers you saying lisinopril may cause a cough. Which of the following counseling points should be discussed with the patient?
- “ACE-induced cough is unlikely as it has been >1 month since lisinopril initiation”
 - “Talk to your PCP about changing to ramipril because of a decreased cough risk”
 - “Increasing your water intake and time exercising can help with this type of cough”
 - “Even with ACE inhibitor-discontinuation, it may take 3-4 weeks for the cough to resolve”