Treat Yourself: Updates in Self-Care and Nonprescription Medications—2016
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Disclosures

Dr. Angelo declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.
At the conclusion of this activity, pharmacists and pharmacy technicians should be able to:

• Educate patients and health care providers regarding the safe and effective use of OTC analgesics, proton pump inhibitors, and saline laxatives

• Discuss the appropriate treatment approach and self-care options for patients with allergy symptoms

• Describe the advantages and disadvantages of nonprescription Transcutaneous Electrical Nerve Stimulation (TENS) devices

• Identify changes made to nicotine replacement therapy labels
Self-Assessment Question 1

If a patient wants to try transcutaneous electrical nerve stimulation (TENS) for pain control, how long should the device be used each time?

a. 1 to 5 minutes
b. 5 to 10 minutes
c. 15 to 30 minutes
d. 30 to 60 minutes
Self-Assessment Question 2

If a patient wants to use an over-the-counter proton pump inhibitor to treat heartburn symptoms, what is the duration of treatment for one course of therapy?

a. 7 days  
b. 14 days  
c. 28 days  
d. 90 days
Self-Assessment Question 3

Intranasal corticosteroids can be used for both intermittent and persistent allergy symptoms.

a. True
b. False
Self-Assessment Question 4

What is one of the reasons that the FDA has recommended changes to nicotine replacement therapy (NRT) labels?

a. There are no significant safety concerns with using NRT while using another nicotine-containing product.
b. The cost of NRT products has limited use or purchasing of the products
c. The rates of tobacco use have declined significantly
d. The dependence on NRT products is higher than originally estimated
Pain Management
In July 2015, FDA strengthened warning that non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs) can cause heart attacks or strokes

- “The risk of heart attack or stroke can occur as early as the first weeks of using an NSAID. The risk may increase with longer use of the NSAID.”
- “The risk appears greater at higher doses.”
- “There is an increased risk of heart failure with NSAID use.”

Similar updates to be made to OTC labels

www.fda.gov/Drugs/DrugSafety/ucm451800.htm
Medication Guide for Nonsteroidal Anti-inflammatory Drugs (NSAIDs)

What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?

NSAIDs can cause serious side effects, including:

- Increased risk of a heart attack or stroke that can lead to death. This risk may happen early in treatment and may increase:
  - with increasing doses of NSAIDs
  - with longer use of NSAIDs

- Do not take NSAIDs right before or after a heart surgery called a “coronary artery bypass graft (CABG).”

- Avoid taking NSAIDs after a recent heart attack, unless your healthcare provider tells you to. You may have an increased risk of another heart attack if you take NSAIDs after a recent heart attack.

- Increased risk of bleeding, ulcers, and tears (perforation) of the esophagus (tube leading from the mouth to the stomach), stomach and intestines:
  - anytime during use
  - without warning symptoms
  - that may cause death

  The risk of getting an ulcer or bleeding increases with:
  - past history of stomach ulcers, or stomach or intestinal bleeding with use of NSAIDs
  - taking medicines called “corticosteroids”, “anticoagulants”, “SSRIs”, or “SNRIs”
  - increasing doses of NSAIDs
  - longer use of NSAIDs
  - smoking
  - drinking alcohol

NSAIDs should only be used:
  - exactly as prescribed
  - at the lowest dose possible for your treatment
  - for the shortest time needed

Updated May 2016

Number of cases of acetaminophen overdose in children under the age of 6 reported to poison control centers in 2010.

What is the concentration of all infant products?

- Dosing instructions for Extra Strength Tylenol®:
  - 2 caplets (1000 mg) every 6 hours
  - Do not exceed 6 caplets (3000 mg) in 24 hours

www.tylenol.com/safety-dosing/usage/dosage-for-adults
FDA Guidance for OTC Pediatric APAP Liquid Products

• Product concentration
  – Should be 160 mg per 5 mL

• Label and labeling
  – Concentration should be prominently displayed
  – If age is noted on display panel of if and image of a child is used, it should correspond to the age and units on the Drug Facts Panel
  – Use of the word “new” – only for 6 months and clearly identify what is new about the product
  – Dosing directions should only be in mL
  – Image of the dosage delivery device should be on lower half of display panel and appear empty or with lowest dose

• Drug delivery
  – Adopt safer container features, such as a flow restrictor

FDA Guidance for OTC Liquid Dosage Delivery Devices

• Dosage delivery device should be included with all liquid oral products
• Markings on the device should match the label instructions
• Device should allow for measurement of smallest and largest dose of product
• Markings on the device should be visible both before and after medication is added to device

U.S. Food and Drug Administration.
www.fda.gov/ForConsumers/ConsumerUpdates/ucm253338.htm
This recall is being initiated because some packages contain an oral dosing cup with incorrect dose markings.
Transcutaneous Electrical Nerve Stimulation (TENS) Therapy
Case (Susan)

• While holiday shopping online for her husband, Susan came across a couple products advertised to treat pain. Her husband often complains of lower back pain and she is wondering if she should purchase one of these products for him. What is your advice?
Case (Susan)

• Upon further questioning, you learn the following:
  – Husband’s Name: Bill   Age: 57
  – Medical conditions: hypertension
  – Medications: Lisinopril 10 mg qd
  – P: not sure what has caused it; it has been there for a couple years
  – Q: achy pain in lower back, gradually gets more sore as the day goes on
  – R: sometimes takes acetaminophen, doesn’t take NSAIDs due to high blood pressure; has tried Thermacare heat wraps, but doesn’t like how hot it gets
  – S: tends to be worse in the evening after a long day
  – T: pain has been there for a couple years; wife says he is a bit overweight
  – A: none
Transcutaneous Electrical Nerve Stimulation (TENS) Therapy

• Uses electrical currents to provide peripheral stimulation
• Works by decreasing the perception of pain (similar in concept to counterirritants)
• Evidence regarding efficacy is inconclusive
OTC TENS Devices

• OTC devices have been FDA approved based on safety, not efficacy
• Varying intensity levels
• Use for 15 to 30 minutes at a time
• Should feel like tapping, tingling, or pulsing sensation
• Patients are advised to consult their physicians before use
• Tolerance may develop

https://omronhealthcare.com/products/electrotherapy-tens-pain-relief-unit-pm3030/
OTC TENS Devices Warnings

• Do not use if:
  – A child
  – Pregnant
  – Using a pacemaker, defibrillator, or other implanted electronic device
  – In the bath or shower
  – While sleeping, driving, or operating machinery

• Do not place on:
  – Open wounds or rashes
  – The neck or head
  – Areas lacking normal sensation

https://omronhealthcare.com/products/electrotherapy-tens-pain-relief-unit-pm3030/
Heartburn
You see a 30-something man in the OTC aisle. When you approach him to offer assistance, he asks if you can recommend something for heartburn. Upon further questioning, you learn the following:

- Name: Steve    Age: 32
- Medical conditions: mild depression
- Medications: Lexapro (escitalopram) 10 mg qd
- P: not sure what has caused it, but seemed to begin a few weeks ago (maybe when he started his depression medication)
- Q: burns just above his stomach after eating, especially spicy foods and coffee
- R: takes Tums which helps a little, but doesn’t like the chalky taste
- S: not too bothersome, unless he eats too much; occasionally keeps him up at night
- T: began a few weeks ago; lasts a couple hours after eating; occurs several times per week
- A: sometimes burping occurs
Case (Steve)

• Is this considered frequent or infrequent heartburn?

• What self-care treatment options are available for Steve?
Self-Care of Frequent Heartburn

- Frequent heartburn occurs 2 or more days per week
- Recommend both lifestyle/dietary modifications and PPI therapy for 14 days
- If heartburn has not resolved, refer

How often can an OTC PPI regimen be repeated?
Why do *prescription* proton pump inhibitors have medication guides?
PPI’s and Antiplatelet Therapy

- Evidence regarding PPI interaction with clopidogrel is conflicting
- Clopidogrel prescribing information states, “Avoid concomitant use of omeprazole or esomeprazole”
- ACCF/AHA/SCAI 2011 and 2016 guidelines recommend PPI use in patients with a history of GI bleeding and state “some clinicians may choose to use a PPI other than omeprazole.”
- Recent meta-analysis found conflicting evidence; studies specific to omeprazole found no difference in clinical outcomes

Allergies
Case (Grace)

• A mom and her young teenage girl bring a box of Benadryl (diphenhydramine) to the counter. As your technician is ringing them up, the mom asks if this is the best product for allergies. The technician asks you for your advice.

Where do you begin?
Case (Grace)

- You learn her other daughter is attending daycamp and came home last night complaining of constant sneezing, runny nose, and itchy throat.
  - Name: Grace    Age: 12
  - Medical conditions: none
  - Medications: none
  - P: began at first day of camp
  - Q: sneezing, runny nose, and itchy throat
  - R: hasn’t tried anything yet; gets a little better when she is home in the evening
  - S: it’s annoying
  - T: symptoms present for one day
  - A: no other symptoms
Case (Grace)

• What self-care treatment options exist for Grace?
Treatment Algorithm for Allergic Rhinitis

Mild Intermittent
- Oral or intranasal H1-antihistamine
- And/or decongestant
- Or leukotriene receptor antagonist
- Or intranasal corticosteroid
- Or cromolyn sodium

Moderate-Severe Intermittent

Mild Persistent

Moderate-Severe Persistent

- Consider immunotherapy

1. Inhaled corticosteroid
2. H1-antihistamine or leukotriene modifier
3. Ipratropium for rhinorrhea
4. Decongestant or oral corticosteroid for blockage (short-term)
5. Surgery

In recent years, what has become first-line treatment for allergic rhinitis?

Triamcinolone Nasal Spray

- Switched to nonprescription status October 2013
- Not indicated for the common cold
- Includes warning about slower growth rate in children
Triamcinolone Nasal Spray Dosing

- **Adults and Children 12 Years of Age and Older:**
  - Once daily, spray two times into each nostril while snifffing gently
  - Once your allergy symptoms improve, reduce to 1 spray in each nostril per day

- **Children 6 to Under 12 Years of Age:**
  - An adult should supervise use
  - Once daily, spray 1 time into each nostril while sniffing gently
  - If allergy symptoms do not improve, increase to 2 sprays in each nostril per day. Once allergy symptoms improve, reduce to 1 spray in each nostril per day.

- **Children Under 2 Years of Age:**
  - Do not Use
Fluticasone Nasal Spray

- Switched to nonprescription status July 2014
- Not indicated for the common cold
- Includes warning about slower growth rate in children ages 4 – 11
Fluticasone Nasal Spray Dosing

• **Adults and Children 12 Years of Age and Older:**
  – Week 1: Use 2 sprays in each nostril once daily
  – Week 2 through 6 months: Use 1 or 2 sprays in each nostril once daily as needed
  – After 6 months of daily use: consult a physician

• **Children 4 to 11 Years of Age:**
  – An adult should supervise use
  – Use 1 spray in each nostril once daily
  – Limited to 2 months of use

• **Children Under 4 Years of Age:**
  – Do not Use
Budesonide Nasal Spray

- Switched to nonprescription status March 2015
- Not indicated for the common cold
- Includes warning about slower growth rate in children ages 6 – 12
**Budesonide Nasal Spray Dosing**

- **Adults and Children 12 Years of Age and Older:**
  - Use 2 sprays in each nostril once daily
  - Once allergy symptoms improve: Use 1 spray in each nostril once daily

- **Children 6 to 12 Years of Age:**
  - An adult should supervise use
  - Use 1 spray in each nostril once daily
  - If allergy symptoms do not improve, increase to 2 sprays in each nostril per day. Once allergy symptoms improve, reduce to 1 spray in each nostril per day.

- **Children Under 6 Years of Age:**
  - Do not Use

- **After 2 weeks if symptoms not improved: stop use and consult a physician**
Manufacturers’ Marketing Messages

Nasacort Allergy 24HR
• Scent-free
• Alcohol-free
• Non-drowsy
• For children 2 and older

Flonase
• The only OTC intranasal steroid for itchy, water eyes
• Outperforms loratadine 10 mg

Rhinocort
• Scent-free
• Alcohol-free
• From the makers of Zyrtec
• Lowest volume per dose

www.nasacort.com
www.flonase.com
www.rhinocort.com
Intranasal Corticosteroid Counseling Tips

Shake it whenever you take it

Shake and prime if it’s been a long time

When you spray your nose, look at your toes
Cold Symptoms
Pseudoephedrine VS Phenylephrine
Quiz!
Which of these tablets has a greater bioavailability?

a. 

b. 
And the winner is . . .

**Pseudoephedrine**
Safety and Efficacy of Phenylephrine versus Placebo

• Two recent studies evaluated phenylephrine for nasal congestion due to allergies

• Efficacy:
  – 40 mg of immediate release PE was no better than placebo
  – 30 mg of modified release PE was no better than placebo

• Safety: No alarming adverse events (headache, nausea, dry mouth)

Where Did it Go and Why is it Back?

**Drug Facts**

**Active ingredients**
- Galphimia glauca 4x
- Luffa operculata 4x
- Sabadilla 4x

**Purpose**
- Reduces duration and severity of the common cold

**Uses**
- Reduces duration of the common cold
- Reduces severity of cold symptoms:
  - dry, scratchy throat
  - runny nose
  - watery eyes
  - sneezing
  - nasal congestion

Zicam® Cold Remedy was formulated to shorten the duration of the common cold and may not be effective for flu or allergies.

**Warnings**
- For nasal use only
- Do not use if you have a sensitivity or allergy to any of the ingredients. If an allergic reaction occurs, stop use and seek medical help right away.
- Ask a doctor before use if you have:
  - ear, nose, or throat sensitivity
  - susceptibility to nosebleeds
- When using this product:
  - avoid contact with eyes. Rinse right away with water if it gets in eyes and seek medical help right away.
  - the use of individual swabs by more than one person may spread infection
  - temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge may occur
- Stop use and ask a doctor if:
  - symptoms get worse or last more than 7 days or are accompanied by fever
In Other News . . .
First OTC Retinoid Approved

- Adapalene gel 0.1% (Differin Gel 0.1%) approved for nonprescription status July 8, 2016
- For use in ages 12 and older
- Apply a thin layer to affected area once daily
- May cause skin irritation (oftentimes transient)
- Avoid use on damaged or sunburned skin
- Minimize sun exposure during use
- Do not use if pregnant or planning to become pregnant

www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm510362.htm
Sodium Phosphate Safety Warning

- Saline laxatives for constipation
- “... using more than one dose in 24 hours of over-the-counter (OTC) sodium phosphate drugs to treat constipation can cause rare but serious harm to the kidneys and heart, and even death”
- Most cases of serious harm occurred with a single dose of sodium phosphate that was larger than recommended or with more than one dose in a day
- Do not use for longer than 3 days
- Who might be at higher risk for these effects?

http://fleetlabs.com/fleet_enema_products.php
www.fda.gov/Drugs/DrugSafety/ucm380757.htm
**Nicotine Replacement Therapy Label Changes**

<table>
<thead>
<tr>
<th>Former Drug Facts Labeling</th>
<th>Revised Drug Facts Labeling</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Warnings:</strong></td>
<td>None. The &quot;Do not use&quot; statement would be deleted.</td>
</tr>
<tr>
<td>Do not use</td>
<td></td>
</tr>
<tr>
<td>• if you continue to smoke, chew tobacco, use snuff, or use [a different NRT product] or other nicotine containing products</td>
<td></td>
</tr>
<tr>
<td><strong>Directions:</strong></td>
<td></td>
</tr>
<tr>
<td>• stop smoking completely when you begin using [the NRT product]</td>
<td>• begin using [the NRT product] on your quit day</td>
</tr>
<tr>
<td>• it is important to complete treatment. Stop using [the NRT product] at the end of [a specified number of] weeks. If you still feel the need to use [the NRT product], talk to your doctor</td>
<td>• it is important to complete treatment. If you feel you need to use [the NRT product] for a longer period to keep from smoking, talk to your health care provider</td>
</tr>
</tbody>
</table>

www.fda.gov/forconsumers/consumerupdates/ucm345087.htm
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