Over-the-Counter (OTC) Cough & Cold Update

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Objectives
- To discuss self-care assessment and patient counseling
- To summarize recommendations and exclusions for providing self-care of OTC Cough & Cold (C & C) products to:
  - Pregnant and/or breastfeeding mothers
  - Patients with chronic disease(s)
  - Elderly Patients
  - Pediatric Patients
- To identify potential OTC drugs of abuse

Statistics
- 52% of Americans had taken OTC Cough/Cold/Flu/Sore Throat medication in the last 6 months
- $3,600,000 was spent on OTC C & C products in 2006
- Persons > 65 years purchase 40% of all OTC’s, yet represent only 12% of the population

Self-Care
Independent act of preventing, diagnosing, and treating one’s own illness without seeking professional advice

Quick Patient Assessment

QuEST/SCHOLAR-MAC

Establish if patient can self-treat

- No severe symptoms
- No symptoms that persist or return repeatedly without an identifiable cause
- No self-treating to avoid medical care

Suggest self-care strategies

- Over-the-counter Medications
- General care measures
  - Alternatives to OTC products
  - Life-style changes
- Refer if patient is not a self-care candidate

Talk to the patient

- About medication action
- About administration
- About adverse effects and how to manage them
- About what to expect from treatment
- About reading an OTC label
- About appropriate follow-up

Drug Facts

- Teach your patients how to read an OTC label
  - Active Ingredients/Purposes
    - Make sure the Active ingredients aren't the same as those in another medicine already being used.
    - If the med contains more than one Active ingredient, read the purposes of each to make sure all ingredients are needed for the problem(s) or symptom(s).
  - Uses
    - Find medicine that treats only the problem(s) or symptom(s) to be treated.
  - Warnings
    - Is there any reason this medicine shouldn't be used?
    - Is there any reason to talk to a doctor or pharmacist before using this medicine?
  - Directions
    - Find the correct dose on the package.
    - Make sure liquid medicine comes with a measuring tool (such as dosing or measuring cup). If not, ask for one at the pharmacy. Spoons made for eating and cooking may give the wrong dose and should not be used.

Special Populations to consider when recommending Cough & Cold Products

- Pregnant and/or breastfeeding mothers
- Patients with chronic disease(s)
- Elderly Patients
- Pediatric Patients

Key points for the technician and pharmacist to discuss with the patient.

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143551.htm
Meet Kathy...

Kathy is 32 years-old and expecting her first child. She has been suffering with nasal congestion, sore throat, headache, low-grade fever, sneezing and coughing; all of which are keeping her up at night. She asks you, her pharmacist, what she could take.

- Symptoms: Nasal congestion, sore throat, headache, low-grade fever, sneezing and coughing
- Characteristics: Symptoms have been the same for 4 days
- History: Humidifier in her bedroom
- Onset: Last week
- Location: Nose, Throat, Head and Chest
- Aggravating Factors: Being outdoors
- Remitting Factors: Peppermints
- Medications: PNV, Folic Acid, Nifedipine, Meclizine PRN
- Allergies: NKDA
- Coexisting Conditions: Pregnancy – 23 weeks; Pregnancy-induced hypertension; h/o seasonal allergies

Pregnant Patients

- Non-drug treatment is first-line
  - Hydration, saline nasal spray, humidifier, saline gargles
  - Vicks Breath Right nasal strips
  - Aromatic products (Sudacare Shower Soothers, Theraflu Vapor Patch, Vicks VapoRub)
- Avoid drug therapy in the 1st Trimester
  - Choose older agents in the class of drugs
- Avoid long-acting, extended-release, combination and/or alcohol containing products

Drug Therapy during Pregnancy & Lactation

- Congestion and Rhinorrhea
  - Oxytazoline – Preferred in pregnancy
  - Pseudoephedrine – Preferred in lactating mothers; should be avoided in 1st Trimester pregnancy.
- Pharyngitis & Cough
  - Dextromethorphan – Appears safe for use (Category C)
  - Guaifenesin – Avoid in 1st Trimester
  - Local anesthetic sprays or lozenges – use with caution, studies have not been conducted on pregnant or lactating mothers
Drug Therapy during Pregnancy & Lactation

- Allergic Rhinitis
  - Intranasal Cromolyn
  - Chlorpheniramine – 1st Line antihistamine
  - Cetirizine and Loratadine – acceptable alternative EXCEPT in the 1st Trimester
    - 1st Generation Antihistamines are CI in lactating women
- Aches/Pains/Fever
  - Acetaminophen

Talk to Kathy...

- Encourage non-drug therapy
- Avoid decongestants use with High Blood Pressure
- Explain pregnancy categories
- Discourage long-acting, extra-strength, or combination products
- Seek medical care if her cold gets worse

Elderly ± Chronic Disease

Meet Wilbert...

Wilbert is a 70 year-old man with Diabetes, Hypertension, dyslipidemia and BPH. He is complaining of being stopped up, sneezing fits, and a runny nose. He states that he “won’t go to the doctor for a stickin’ cold no matter what!” He trust you, his pharmacist more than he trust “those docs up the bayou!” What can you do for Mr. Wilbert?

Treat or Refer: Questions to Ask

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Congestion, Sneezing, and Rhinorrhea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristics</td>
<td>Persistent most of the week (Today is Friday)</td>
</tr>
<tr>
<td>History</td>
<td>TYLENOL Cold: Severe Head Congestion at night</td>
</tr>
<tr>
<td>Onset</td>
<td>About a week ago, getting worse</td>
</tr>
<tr>
<td>Location</td>
<td>Head and nose</td>
</tr>
<tr>
<td>Aggravating Factors</td>
<td>None</td>
</tr>
<tr>
<td>Remitting Factors</td>
<td>Feels the best in the morning</td>
</tr>
<tr>
<td>Medications</td>
<td>Micardis, Lasix, Lipitor, Metformin, Flomax, Vitarin</td>
</tr>
<tr>
<td>Allergies</td>
<td>NKDA</td>
</tr>
<tr>
<td>Coexisting Conditions</td>
<td>Diabetes, HTN, Dyslipidemia, BPH, H/o gout and Cataract</td>
</tr>
</tbody>
</table>

Self Care Exclusions- Cold

- Fever > 101.5°F
- Chest Pain
- Shortness of Breath
- Worsening of symptoms during self-care
- COPD, CHF, asthma
- AIDS or Chronic Immunosuppressant therapy
- Infants < 9 months of age
- Frail patients of advanced age

Elderly Patients with or without Chronic Diseases

- Refer for medical care if patient has a chronic uncontrolled condition
- Drug-drug interactions with concomitant drug therapy
- Decreased kidney and/or liver perfusion
- Avoid extra-strength and long-acting preparations
- Take lowest recommended OTC dose for the shortest time. Avoid combination products
- Avoid anticholinergics!
- Make sure the patient can READ the label!

Diseases/ Symptoms Associated with Cough

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>Wheezing or chest tightness; coughing primarily at night and in response to irritants such as dust, smoke, or pollen</td>
</tr>
<tr>
<td>CHF</td>
<td>Fatigue, edema, breathlessness</td>
</tr>
<tr>
<td>COPD</td>
<td>Productive cough most days of the month</td>
</tr>
<tr>
<td>GERD</td>
<td>Heartburn, worsening of symptoms when supine, improves with H2’s or PPI</td>
</tr>
<tr>
<td>Lower Respiratory Tract Infection (RTI)</td>
<td>Temp &gt; 101.5°F; thick, purulent, discolored phlegm, night sweats</td>
</tr>
<tr>
<td>Upper Airway Cough Syndrome</td>
<td>Mucus drainage from nose, frequent throat clearing</td>
</tr>
<tr>
<td>Viral Upper RTI</td>
<td>Sneezing, sore throat, rhinorrhea, low grade temperature</td>
</tr>
</tbody>
</table>

Drug Therapy for Elderly

Decongestants

<table>
<thead>
<tr>
<th>Exacerbate Diseases</th>
<th>Drug-Drug Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>MAOIs, Methyldopa</td>
</tr>
<tr>
<td>Hypertension</td>
<td>TCAs</td>
</tr>
<tr>
<td>Prostatic hypertrophy</td>
<td>Antacids/alkalinizers</td>
</tr>
<tr>
<td>Hyperthyroidism</td>
<td></td>
</tr>
<tr>
<td>Coronary and Ischemic heart disease</td>
<td></td>
</tr>
<tr>
<td>Elevated intraocular pressure</td>
<td></td>
</tr>
</tbody>
</table>

Antihistamines

<table>
<thead>
<tr>
<th>Exacerbate Diseases</th>
<th>Drug-Drug Interactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primarily 1st Generations</td>
<td>Prostatic hypertrophy</td>
</tr>
<tr>
<td></td>
<td>Narrow angle glaucoma</td>
</tr>
<tr>
<td></td>
<td>Acute asthma exacerbation</td>
</tr>
<tr>
<td></td>
<td>Stenosing peptic ulcer</td>
</tr>
<tr>
<td></td>
<td>Kidney / Liver dysfunction</td>
</tr>
<tr>
<td>CNS Depressants</td>
<td>MAOIs</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>Ketoconazole</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>Cimetidine</td>
</tr>
<tr>
<td>Theophylline</td>
<td>Theophylline</td>
</tr>
<tr>
<td>Kidney / Liver dysfunction</td>
<td>Doses &gt; 400 mg</td>
</tr>
</tbody>
</table>

Drug Therapy for Elderly

- Allergic Rhinitis and Rhinorrhea
  - Intranasal Cromolyn
  - Loratadine
  - Order of Sedation: Diphenhydramine → Doxylamine → Brompheniramine → Chlorpheniramine
- Aches/Pains/Fever
  - Acetaminophen
  - Use Aspirin or NSAIDS with caution

Coricidin HBP Products

- Cough & Cold
  - Chlorpheniramine 4 mg, Dextromethorphan (DXM) 30 mg
- Max Strength Flu
  - APAP 500 mg, Chlorpheniramine 2 mg, DXM 15 mg
- Cold & Flu
  - APAP 325 mg, Chlorpheniramine 2 mg
- Chest Congestion & Cough
  - DMX 10 mg, Guaifenesin 200 mg
- Nighttime Multi-Symptom Cold
  - APAP 500 mg, DXM 15 mg, Doxylamine 6.25 mg
Talk to Wilbert...
- Encourage non drug therapy
  - Increase fluid intake, adequate rest, humidification, nasal irrigation
- Avoid decongestants if possible with High BP
  - Monitor BP while on any OTC medications
- Recommend Loratadine for his sneezing and runny nose
- Explain how medicines work, how often to take them, and their adverse effects
- Encourage Wilbert to see the doctor for follow-up if his cold gets worse in a couple of days

Meet Harley...
Harley is a 5-year-old active little girl. She hasn’t been able to play outside because she is suffering with a sore throat, runny nose, and dry cough. She is also complaining of feeling achy all over. Her mom states she had fever the night before, but has now subsided. She has been giving her some OTC medications, but is wondering if another medicine would be better.

Self Care Exclusions- Cough & Cold

<table>
<thead>
<tr>
<th>Cold</th>
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</thead>
<tbody>
<tr>
<td>Fever &gt; 101.5°F</td>
</tr>
<tr>
<td>Chest Pain</td>
</tr>
<tr>
<td>Shortness of Breath</td>
</tr>
<tr>
<td>Worsening of symptoms during self-care</td>
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<tr>
<td>COPD, CHF, asthma</td>
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<tr>
<td>AIDS or Chronic Immunosuppressant therapy</td>
</tr>
<tr>
<td>Infants &lt; 9 months of age</td>
</tr>
<tr>
<td>Frail patients of advanced age</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cough</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever &gt; 101.5°F</td>
</tr>
<tr>
<td>Thick yellow or green phlegm</td>
</tr>
<tr>
<td>Unintended weight loss</td>
</tr>
<tr>
<td>Drenching nighttime sweats</td>
</tr>
<tr>
<td>Hemoptysis</td>
</tr>
<tr>
<td>COPD, CHF, asthma, chronic bronchitis</td>
</tr>
<tr>
<td>Foreign object aspiration</td>
</tr>
<tr>
<td>Cough &gt; 7 days</td>
</tr>
<tr>
<td>Worsening of symptoms during self-care</td>
</tr>
</tbody>
</table>

Pediatrics

Treat or Refer: Questions to Ask

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Sore throat, runny nose, dry cough, ± fever</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristics</td>
<td>Symptoms of a cold for 2 days with intermittent fever, clear nasal drainage</td>
</tr>
<tr>
<td>History</td>
<td>Children's Benadryl &amp; Motrin PRN. Vick's VapoRub at night</td>
</tr>
<tr>
<td>Onset</td>
<td>2 days after her birthday party</td>
</tr>
<tr>
<td>Location</td>
<td>Throat, Nose, Body Temperature</td>
</tr>
<tr>
<td>Aggravating Factors</td>
<td>Being outdoors and getting hot</td>
</tr>
<tr>
<td>Remitting Factors</td>
<td>OTC Medicines and ice cream for her throat</td>
</tr>
<tr>
<td>Medications</td>
<td>None</td>
</tr>
<tr>
<td>Allergies</td>
<td>NKDA</td>
</tr>
<tr>
<td>Coexisting Conditions</td>
<td>None; Patient weighs 33 lb (15 kg)</td>
</tr>
</tbody>
</table>

Pediatric Patients

- **Kids are not just small adults!**
  - Dosage guidelines are not always available for OTC’s and often contain no specific label recommendations for children
  - **FDA: January 2008**
    - OTC cold medications should not be given to children < 2 years of age; considering < 6 years of age
  - **CHPA: October 2008**
    - Mfg voluntarily updated OTC C&C labeling to state “Do not use in children under 4 years of age.” Also, added the warning label “Do not use antihistamines for sedation”
Efficacy Concerns in Children

- Limited information to support efficacy of C & C products in pediatrics
- Dextromethorphan and diphenhydramine
  - Studied in ages 2 – 18 years; neither drug significantly improved cough or sleep quality compared to placebo
  - Not good evidence for or against the effectiveness of OTC cough remedies
  - Single-ingredient antihistamines are not effective in improving nasal symptoms in children with the common cold

Safety Concerns in Children

- When used appropriately, the ingredients in OTC C & C preparations are safe in most children
- Misuse can lead to serious adverse effects
  - Use of multiple combination products with the same drugs
  - Giving the wrong formulation (Ex. APAP Infant drops vs. APAP Children’s Suspension)
  - Dosing inaccuracies - kitchen spoons used to measure
  - Nonadherence to dosing recommendations - calculation of a dose based on product dosing for older children. "Kids are not just small adults"

Pediatric Response to drug therapy

- Response to drug therapy is not as predictable as adults
  - Absorption
    - pH – caution in pH dependent passive diffusion
    - Rate of absorption – inefficient muscular contraction, reduced skeletal muscle blood flow
  - Distribution
    - ↑ Vd, ↓ Fat and ↓ Protein binding
  - Metabolism
    - Slower in infants compared with older children and adults
  - Excretion
    - ↓ Clearance – longer half-life of medications

Drug Therapy for Pediatrics

- Rhinorhea & Congestion
  - Phenylephrine
    - 2.5 mg Q 4 H (Max: 15 mg/day)
  - Pseudoephedrine
    - 15 mg Q 4-6 H (Max: 60 mg/day)
- Pharyngitis & Cough
  - Dextromethorphan
    - 2.5 – 5 mg Q 4 H or 7.5 Q 6 - 8 H (Max: 30 mg/day)
  - Guaifenesin
    - 50-100 mg Q 4 H (Max: 600 mg/day)

Drug Therapy for Pediatrics Ages 2-6 Years

- Aches/Pains/Fever
  - Temperature Measurement:
    - Children < 6 months: Rectal only preferred
    - Children 6 months – 5 years: Rectal preferred
  - Acetaminophen (FDA Approved for age > 2 years)
    - 15 mg/kg/dose for fever; never exceed 5 doses in 24 hours
  - Ibuprofen (FDA Approved for age > 6 months)
    - 10 mg/kg/dose for fever (Max dose: 40 mg/kg/day)
  - Allergies (Children 2-6 years of age)
    - Never use antihistamines to make a child sleepy!
    - Cetirizine – 2.5 – 5 mg Q24 hours
    - Loratadine – 5 mg Q 24 hours

Talk to Harley’s Parents...

- Encourage non-drug therapy
  - Fever: Sponge baths with tepid water, hydrate (1 oz per hour)
  - Dry Cough/sore throat: hydration
  - Runny nose: nasal suctioning, keep child upright
- Avoid combination medicines! Stop the Benadryl and the Vicks VapoRub
- Explain Pediatric dosing and the importance of asking the physician or pharmacist for the correct dose
- Seek medical care if the child:
  - < 3 months old, fever for > 24 hours if < 2 years of age, ear pain or severe sore throat, symptoms do not improve within 10-14 days


2FDA briefing information. Joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee. October 18-19,2007


4Handbook of Nonprescription Drugs, 16th Edition
### Vicks VapoRub Safety

- Combination of menthol, camphor, and eucalyptus oil
- Menthol
  - Responsible for the “feeling” of congestion relief
  - Leads to increased airflow resistance which is increased within 1 minute and last for ≥ 3 hours
- Camphor
  - Increases mucus secretion and decreases ciliary beat frequency
- Vicks VapoRub leads to mucus obstruction of small airways and increased nasal resistance

2Abanses JC, Arima S. Vicks VapoRub induces mucus secretion..Chest 2009;135:143-48

### OTC Drug of Abuse - DXM

- Dextromethorphan Street Names
  - “Triple C” or “C-C-C” – derived from Coricidin Cough & Cold
  - “Tussin” – derived from Robitussin
  - “Robo Tripping” or “DXM Tripping”
  - “Skittles” or “Red Devils”
- Symptoms of Dextromethorphan Abuse
  - “Plateaus” Mild distortions of color and sound → visual hallucinations
  - “Out-of-body” dissociative sensations
  - Loss of motor control
  - Impaired judgment and mental performance, loss of coordination, slurred speech, nausea, dizziness, disassociation, hallucinations, tachycardia, hypertension, agitation, ataxia, and psychosis

### OTC Drugs of Abuse – Related to Methamphetamine

- Iodine Tincture
  - Used along with hydrogen peroxide to produce high quality methamphetamine
- What to watch for
  - Purchase of > 120 mL of Iodine Tincture
  - Hydrogen peroxide
  - Red phosphorous (striking pads of matches)
  - Others – acetone (polish remover), rubbing alcohol, camp stove fuel, drain cleaner, rock salt, and road flares
- Note: Keep iodine tincture behind the counter!

2US DEA Changes in regulation of iodine crystal’s

### Recommended Sources

- FDA. Public Health Advisory for Nonprescription Cough and Cold Medicines & Resources for patients/professionals http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessional.s/default.htm
- Consumer Healthcare Products Association http://www.chpa-info.org/

### Consumer Education

Be Safe, Be Healthy!!
Choose OTC medicines wisely

Available at http://www.chpa-info.org