Pharmacological Therapies for Cough, Cold and Fever Symptoms

Notes to Accompany
The Program

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An internationally recognized presenter, Dr. Fitzgerald has provided thousands of programs for numerous professional organizations, universities, national and state healthcare associations on a wide variety of topics including clinical pharmacology, assessment, laboratory diagnosis, healthcare and nurse practitioner practice. For more than 20 years she has provided graduate-level pharmacology courses for nurse practitioner students at a number of universities, including Simmons College (Boston, MA), Husson College (Bangor, ME), University of Massachusetts Worcester, Pennsylvania State University, La Salle University (Philadelphia, PA), and Samford University (Birmingham, AL). In addition, she is a family nurse practitioner at the Greater Lawrence Family Health Center, Lawrence, MA, and adjunct faculty for the Greater Lawrence Family Health Center Family Practice Residency Program. She holds a Doctor of Nursing Practice from Case Western Reserve University, Cleveland, OH, where she received the Alumni Association Award for Clinical Excellence.

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The goal of this educational program is:
To provide quality continuing education to advanced practice nurses to enhance their knowledge of pharmacological therapies for cough, cold and fever symptoms.

Objectives:
1. Describe the most common and bothersome symptoms in upper respiratory tract illnesses.
2. Identify the ingredients in common multisymptom cough and cold remedies.
3. Understand the mechanism of action of and caution in the use of common over-the-counter cough, cold and fever remedies.
4. Describe the current recommendations for the treatment of fever in children.
Pharmacological Therapies for Cough, Cold and Fever Symptoms

Objectives
• Upon completion of this program, the participant will be able to:
  - Describe the most common and bothersome symptoms in upper respiratory tract illnesses.
  - Identify the ingredients in common multisymptom cough and cold remedies.

Objectives (continued)
• Upon completion of this program, the participant will be able to:
  - Understand the mechanism of action and caution in the use of common over-the-counter cough, cold and fever remedies.
  - Describe the current recommendations for the treatment of fever in children.

URI
• How many
  - 1 billion colds/year in US
  - 5% of population at any time
• How contracted
  - Droplet
  - Hand contact with contaminated surface then transferred to mouth, nose, eye

How many colds per year?
• Preschool age child
  - 4-8/year
• School age child
  - 2-4/year
• Adult
  - 1-4/year
• Elder
  - 1/year

Sources: Prescriber’s Letter 2003; 10(12):191251

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Natural History and Frequency of Respiratory Tract Infection in Adults

- **Self-reported colds**
  - Confirmed by RT-PCR or culture
- **Median duration of colds in adults**
  - 9.5 to 11 days
- **Colds interfered with daily activities**
  - 7 days
- **Disturbed their sleep**
  - 4 nights


- **First finding**
  - Sore throat= 39%
  - Stuffy nose= 17%
- **Most bothersome symptom**
  - Runny nose= 36%
  - Stuffy nose= 20%
- **Most persistent symptom**
  - Runny and stuffy nose

What causes URI?

- >200 different viruses
  - Rhinovirus
  - Corona virus
  - Parainfluenzae
  - Influenza
  - Adenovirus 1,2,3,5,6
  - 3 and 7 also cause conjunctivitis

You see a patient with URI...

- ...who mentions he caught “this darn cold from my brother who visited 2 weeks ago and sneezed on me.”
- What is the typical URI incubation period?

Incubation Period for Viral URI

- **Rhinoviruses**
  - 1-5 days
- **Influenza virus and parainfluenza**
  - 1-4 days
- **Respiratory syncytial virus (RSV)**
  - 7 days

Incubation Period for Less Common Pathogens Causing URI

- **Pertussis**
  - 7-10 days, as long as 21 days
- **Diphtheria**
  - 1-10 days
- **Epstein-Barr virus (EBV)**
  - 4-6 weeks

True or false?

- The viral dose needed to cause a URI is tens of thousands of organisms.

Can URI be prevented?

Echinacea

- Proposed mechanism of action
  - Antiviral and antibacterial in vitro, possible immune system booster, increases lymphocytes and granulocytes in circulation and at site of infection
  - Reduction of symptom severity and duration
    - Range from about 10% to 30%

  - J Clin Pharm Ther 2004 Feb;29(1);75-83.

Echinacea Caution

- Potentially toxic with long term (>3 month) use
  - German Commission E recommends a 1 week holiday q 3 mo if taken chronically
- Not be used in chronic health conditions such as lupus, MS, RA, others
- Caution in those with ragweed, asters, chrysanthemums, chamomile allergies

Echinacea Use

- Start short term use in earliest stages of viral URI symptoms.
- Choose a reliable provider of the product.
- Follow the labeled use.
  - Typical dose- Extract or whole plant 250-500 mg/d
- Avoid chronic use.

Per UpToDate

- “Although echinacea may have some immune stimulating effects, the evidence to date does not support its efficacy in treating or preventing the common cold…”
Zinc: Mechanism of Action

- Zinc ions bind to rhinovirus
  - Prevents virus from binding to somatic cells through intercellular adhesion molecules (ICAM)
  - "Docking point" for HRV on the surface of nasal epithelial cells
  - End product is reduced rhinovirus replication.

The Cleveland Clinic Study

- 50 participants
  - Took zinc gluconate 13.3 mg lozenges q 2 h while awake as long as they had cold symptoms
- 50 participants
  - Received placebo with same instructions

The Cleveland Clinic Study (continued)

- Time to complete resolution of symptoms was significantly shorter in the zinc group than in the placebo group (4.4 days vs. 7.6 days)

Vitamin C

- Possibly helpful to immune function
  - T-lymphocyte activity, phagocyte function, leukocyte mobility, and increase in antibody and interferon production
  - Limited study to support that 1 g/d reduces duration of cold symptoms by about ½ d.

Look at the Label

- Use zinc gluconate
  - Releases substantially more free zinc than released by zinc complexes with citrate, mannitol/sorbitol, tartrate, acetate or citric forms

What about treating cold symptoms?


» www.prescribersletter.com, Rumor vs. Truth, 2.11.05. accessed 10.23.11.
Pathogenesis of Cold Symptoms

- Cholinergic stimulation
  - Increased mucous secretion
  - Increased serum in nasal secretions
- Inflammatory mediators
  - Histamine and others
  - Increased vascular permeability
  - Edema
  - Nasal stuffiness

Pathogenesis of Cold Symptoms (continued)

- Tissue damage in pharynx
  - “Tickle in throat”
- Bronchial constriction
  - Circadian rhythm influence
  - Cough attempting to cleanse and open airways

With this in mind...

- At what point in this equation do OTC cough and cold medications work?
- Will this alter the natural history of the disease?
- What symptom(s) do patients report as being most problematic?

OTC Cold and Allergy Medications

- “Dries runny nose”
  - 1st gen antihistamine
- “Relieves nasal stuffiness”
  - Decongestant
- “Calms cough”
  - Dextromethorphan
- “Relieves body aches”
  - Most likely acetaminophen, occasionally ibuprofen

And a Few Added Ingredients

- “Helps you to sleep”
  - 1st gen antihistamine, alcohol
- “Loosens mucous”
  - Guaifenesin

Antihistamine Mechanism of Action

- Inactivates action of formed inflammatory mediators by blocking H1 receptor sites
  - Oral antihistamine
  - Antihistamine nasal spray, eye drops
    - Astelin nasal spray, others
Rescue Therapy by Inactivating Formed Inflammatory Mediators

• Oral antihistamines
  – 1st generation, more lipophilic
    • Chlorpheniramine {Chlor-Trimeton®}, diphenhydramine {Benadryl®}, brompheniramine {Bromfed®/Dimetapp®}, hydroxyzine {Vistaril®/Atarax®}, tripolidine {in Actifed with pseudoephedrine®}
  – 2d generation, more hydrophilic
    • Loratadine {Claritin®}, desloratadine {Clarinex®}, cetirizine {Zyrtec®}, fexofenadine {Allegra®}, levocetirizine {Xyzal®}

American College of Chest Physicians: Evidence-Based Clinical Practice Guidelines: Diagnosis and Management of Cough


ACCP Recommendations

• Individuals with acute cough associated with the common cold can be treated with a 1st-generation antihistamine/decongestant preparation such as brompheniramine and sustained-release pseudoephedrine (trade name-Bromfed®).
  – The newer generation of non-sedating antihistamines such as loratadine plays no role in treating cough in this setting.

1st Generation Antihistamine Adverse Effects (Anticholinergic Effect)

• Dry mouth, skin
• Blurred vision
• Urinary retention
  – Usually w/ BPH
• Sedation
• Agitation
• Tachycardia
• Hyperpnea
• Mydriasis
• Flushing
• psychosis
• Seizure
• Coma
• Hyperthermia

Or...

• Dry as a bone (dry mouth)
• Red as a beet (flushing)
• Mad as a hatter (confusion)
• Hot as a hare (hyperthermia)
• Can’t see (vision changes)
• Can’t pee (urinary retention)
• Can’t spit (dry mouth)
• Can’t (something that rhymes with spit) (constipation)

Anticholinergic Activity and Acute Urinary Retention

• Benign prostatic hyperplasia
  – Present in ~80% of men at age 80 with ~50% with symptoms
  – Increase in prostate size by about 2-4 fold
• What happens?
  – Medication-induced weakened urinary bladder detrusor muscle contractility
Phenylephrine (Sudafed PE®) vs Pseudoephedrine (Sudafed®)

- Phenylephrine
  - Alpha-adrenergic agonist
  - PK
  - T ½ = 2.5 hours
  - Adult dose= 10 mg

- Pseudoephedrine
  - Alpha-, beta-adrenergic activity, indirect effect of release of norepinephrine
  - PK
  - T ½ = 9-16 h
  - Adult dose= 60 mg

Efficacy
- Pseudoephedrine 60 mg vs. phenylpropanolamine 40 mg showed equal efficacy
- Phenylephrine 10 mg no more effective than placebo


Phenylephrine as a Pseudoephedrine Substitute

Intranasal Decongestants

- Examples
  - Phenylephrine (Neo-Synephrine®, Dristan®)
  - Oxymetazoline (Afrin®, Dristan 12-hour®, Allerest 12-hour®)

- Mechanism of action
  - Localized vasoconstriction

- Impact on BP
  - Negligible with recommended use

True or false?

- The majority of people who use decongestant nasal sprays for the duration of a typical viral URI develop rebound congestion.


ACCP Recommendations

- Post infectious cough should be considered in the person who complains of cough that has been present for 3-8 weeks following symptoms of an acute respiratory infection.
ACCP Recommendations (continued)

• The use of inhaled ipratropium bromide (Atrovent®) can be helpful in attenuating the post infectious cough.

• In patients with post infectious cough, when the cough adversely affects the patient’s quality of life and when cough persists despite use of inhaled ipratropium, consider the use of inhaled corticosteroids with the recognition that this product will take about 1 week of use prior to providing significant symptom relief.

• For severe paroxysms of post infectious cough, consider prescribing 30 to 40 mg of prednisone per day for a short, finite period of time when other common causes of cough including rhinosinusitis, asthma, or gastroesophageal reflux disease have been ruled out.

• Central acting antitussive agents such as codeine and dextromethorphan should be considered when other measures fail. In children and adults with cough following an acute respiratory tract infection, if cough has persisted for more than 8 weeks, another diagnosis other than post infectious cough should be considered.

Dextromethorphan

• Mechanism of action
  – D-isomer of codeine analog levorphanol
  – Agonist of receptor sites involved with cough control
  – Possibly central and peripheral action

• Likely marginally effective at recommended doses
  – 60-120 mg/d total in the adult

• Examples of OTC doses
  – Robitussin DM® = 15 mg/5 ml
  – Delsym® = 30 mg/5 ml

Potential Drug Interactions with Dextromethorphan

- Should not be taken with:
  - Monoamine oxidase inhibitors (MAOIs), serotonin reuptake inhibitors (SSRIs, SSNRIs, TCAs) due to cumulative serotonergic effects
  - Opiates, opioids, alcohol due to cumulative CNS suppression

When Therapeutic Dextromethorphan Dose Exceeded

- Dissociative psychedelic drug
  - Effects that are similar to those of ketamine and phencyclidine (PCP)
- Anticipated adverse effects
  - Visual field distortion, dissociation, bodily perception distortion, excitement, loss of time comprehension

Codeine vs. DM in Cough Suppressing Efficacy

- DM 30 mg (10 ml)= Codeine 15 mg
  - Codeine dose needed for superior cough suppression= 30 mg
- Tylenol® with codeine
  - #1= 7.5 mg
  - #2= 15 mg
  - #3= 30 mg
  - #4= 60 mg

Truth or fiction?

- “Robitussin DM® and codeine do nothing but make me and everyone in my family really nervous. I can take Tussionex® or Vicodin® or Percocet® without any problem.”

Tussionex®

- Sustained release opioid-containing medication with first-generation antihistamine (chlorpheniramine) for cough control
  - Dose--one tsp BID= 10 mg hydrocodone= 5 ml
  - 5 mg hydrocodone= 30 mg codeine

CYP2D6 Population-Based Variations

- Slow acting enzyme form
  - 5- 10% of European ancestry population
- Absent
  - Up to 10% of European ancestry population
- Likely inherited two copies of a gene or genes that encoded either an enzyme with decreased CYP2D6 activity or 1-2 with no activity
CYP 2D6 Absent or Slow Acting Form?

- Codeine makes me nervous but morphine is OK.
- Robitussin DM® keeps me up all night.

CYP2D6 Population-Based Variations

- Ultrametabolizers
  - Relatively infrequent among northern Europeans
  - Select east African populations, as much as 29%
  - Likely with multiple copies of the CYP2D6 gene

CYP 2D6 Ultra Metabolizer

- Codeine really snows me at first then does not help with the pain unless I take it every 2 hours.
- Robitussin DM® does nothing to help my cough.

Guaifenesin

- Mechanism of action
  - Likely act as irritant to gastric vagal receptors, recruits efferent parasympathetic reflexes that cause glandular exocytosis of a less viscous mucus mixture
  - Potentially thins tenacious, congealed mucopurulent material from obstructed small airways

Guaifenesin (continued)

- Mechanism of action (cont.)
  - Possible mechanisms include a central antitussive effect, or a peripheral effect by increased sputum volume, serving as barrier and shielding cough receptors within respiratory epithelium from tussive stimulus

Guaifenesin Efficacy: Limited Study

- Conclusion
  - Guaifenesin inhibits cough reflex sensitivity in subjects with URI, whose cough receptors are transiently hypersensitive, but not in healthy volunteers.
Guaifenesin

- Adult dose
  - Not to exceed 2.4 g per day
- Child age 6-12 years
  - 600 mg q 12 hr, not to exceed 1.2 g/day
- Pediatric, 2-6 years
  - 300 mg q 12 hr, not to exceed 600 mg/day

Tessalon Perles

- Mechanism of action
  - Anesthetizes respiratory passage, lung, and pleural stretch receptors, reducing cough reflex (antitussive)
  - Variable reports of efficacy

FDA Advisory

Cough and Cold Medication Use in Children Age <2 years

- Clinicians should use caution when prescribing cough and cold medications to children aged <2 years. Moreover, clinicians should always ask caregivers about their use of over-the-counter combination medications to avoid overdose in children from multiple medications that contain the same ingredient.


Honey vs. Dextromethorphan vs. Nothing for Cough: Which won?


Paul et al. Conclusions

- In a comparison of honey, DM, and no treatment, parents rated honey most favorably for symptomatic relief of their child's nocturnal cough and sleep difficulty due to upper respiratory tract infection. Honey may be a preferable treatment for the cough and sleep difficulty associated with childhood upper respiratory tract infection.

The Buckwheat Honey Dose: Given ½ h Prior to Bedtime

- For children age <1 y
  - Do not use due to botulism risk
- 2-5 years
  - ½ tsp
- 6-11 years
  - 1 tsp
- 12-18 years
  - 2 tsp

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Proposed Mechanisms of Action: Honey

- Sweet taste induces endogenous opioids
- Increased salivary production
- Antioxidant properties

Concerning the use of antipyretics in the febrile young child, which of the following is true?

...Use of Antipyretics in the Febrile Young Child... (continued)

a) A child with a serious bacterial infection will not have fever reduction with an antipyretic.

b) The degree of temperature reduction in response to antipyretic therapy is not predictive of presence or absence of bacteremia.

c) In comparison with ibuprofen, acetaminophen is more effective in reducing higher fevers.

d) Ibuprofen should not be used if the child is also taking a macrolide.

What do parents and caregivers think about fever?

Is “Fever Phobia,” a term coined about 30 years ago, still alive and well?

Fever
A Complex Physiologic Reaction

- Exogenous pyrogens
  - Microorganisms and their products including endotoxins, drugs, incompatible blood products
Fever
A Complex Physiologic Reaction (continued)

- Triggers endogenous pyrogens
  - Polypeptides produced by host cells such as monocytes, macrophages; interleukin 1A, interleukin 1B, interferon A, interferon B, TNF

Fever
A Complex Physiologic Reaction (continued)

- Endogenous pyrogens
  - Increase prostaglandin synthesis
  - Prostaglandins activate thermo-regulatory neurons, alter hypothalamic set point
  - Vasomotor center reactions increase heat conservation, heat production

Physiologic Effects of Fever

- Increase in body temperature has benefits
  - WBC activity enhanced with higher body temperature
    - Lowers viral replication rate
    - Toxic to encapsulated bacteria, in particular S. pneumoniae

American Academy of Pediatrics Clinical Report Fever and Antipyretic Use
Available at http://pediatrics.aappublications.org/cgi/reprint/peds.2010-3852v1, accessed 10.23.11.

Fever and Antipyretic Use

- “Fever is not the primary illness but is a physiologic mechanism that has beneficial effects in fighting infection. There is no evidence that fever itself worsens the course of an illness or that it causes long-term neurologic complications.”

Fever and Antipyretic Use (continued)

- “Thus, the primary goal of treating the febrile child should be to improve the child's overall comfort rather than focus on the normalization of body temperature.”
Fever Treatment Options

• Acetaminophen
  - Thought to be less effective when compared to ibuprofen, likely same
  Select NSAIDs
  - Rapid onset such as ibuprofen
  - Likely superior analgesic control, longer duration of action, mixed evidence on superior fever reducing effect

Acetaminophen as an Antipyretic

• Mechanism of action
  - Reduces fever by acting directly on hypothalamic heat-regulating centers, which increases dissipation of body heat via vasodilation and sweating

Why the concern about acetaminophen toxicity?

• Potentially hepatotoxic
  - ~ 5-10% of drug oxidized by CYP450-dependent pathways to metabolite, N-acetyl-p-benzoquinone imine (NAPQI)
  NAPQI detoxified by glutathione and eliminated in the urine or bile

Why the concern about acetaminophen toxicity? (continued)

• NAPQI that is not detoxified
  - Can bind to hepatocytes and produce cellular necrosis
  Typically not a problem
  - Little NAPQI produced and adequate supply of glutathione

Acetaminophen toxicity in children: True or false?

• Pediatric patients younger than 5 years appear to fare better than adults after APAP poisoning, perhaps owing to a greater capacity to conjugate acetaminophen, enhanced detoxification of NAPQI, or greater glutathione stores.

Risk Factors for Acetaminophen Toxicity

• Concomitant medication use
  - Ethanol
    • Glutathione depletion
  - Via drug metabolism enzyme depletion
    • Carbamazepine, phenobarbital, rifampin
Risk Factors for Acetaminophen Toxicity (continued)

- Prolonged fasting
  - Increased metabolism to NAPQI
- Excessive acetaminophen use
  - Glutathione depletion

Acetaminophen Dosing in Children

- 10-15 mg/kg PO/PR q4-6h
  - Dosing interval on PO form= 4 h, rectal= 6 h (rectal use not recommended routinely per AAP)
- Not to exceed 5 doses/d
  - Major risk with excessive dosing= Liver toxicity

How much could be toxic?

- 120-150 mg/kg in a single dose
- A 10 kg (22 lb) toddler= 1200 mg dose
  - ~ 7.5 tsp (36.97 ml) cold medicine or liquid acetaminophen
  - ~ 13 droppers of infant drops
  - ~ 7-8 jr. melting tablets

...Or perhaps a scenario where this child receives 1140 mg in 4 h

- A 10 kg toddler is given
  - 1 tsp of acetaminophen liquid (160 mg)
  - 1 tsp cold medicine with acetaminophen (160 mg)
  - These meds are repeated by family member who did not realize 1st doses was given (360 mg)

...Or perhaps a scenario where this child receives 1140 mg in 4 h (cont.)

- 4 h later, 1 ES tablet (500 mg) dissolved when family runs out of liquid medicine

Ibuprofen

- Mechanism of action
  - Inhibits prostaglandin formation, a substance critical to the febrile-producing cascade
- Pediatric dosing
  - Analgesic/fever= 5-10 mg/kg/d, dosed every 6-8 h
Using both? Alternating Ibuprofen with Acetaminophen

- No scientific evidence that combination is safe or achieves faster antipyresis than either agent alone
- Increased adverse effects risk, esp. with hepatotoxicity from accidentally “double dosing” acetaminophen


When Fever is Worrisome

- In pregnancy
  - Potentially teratogenic in 1st trimester, increased metabolic demands throughout pregnancy
- In CV, lung disease, CNS disease
  - Increased metabolic demand issues

Febrile Seizure Defined

- An event in infancy or childhood usually occurring between three months and five years of age, associated with fever, but without evidence of intracranial infection or defined cause.


Fever in Younger Children: True or false?

- Antipyretics use does not appear to prevent recurrence of febrile seizures.

End of Presentation!

Thank you for your time and attention.

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