Pediatric Over-the-Counter Medication Refresher for Pharmacists

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Goal: The goal of this article is to increase pharmacist’s awareness of barriers to appropriate pediatric OTC medication misuse, identifying methods to address these barriers, defining appropriate use of over-the-counter pharmacologic and nonpharmacologic treatment options for pediatric cough and/or cold, and identifying situations in which physician referral is appropriate.

Objectives: At the conclusion of this lesson, successful participants should be able to:
1. Identify challenges associated with over-the-counter (OTC) medication use in children.
2. Identify situations in which physician referral is appropriate for pediatric patients with cough/cold and fever symptoms.
3. Design a treatment plan, including specific counseling points for parents, for a pediatric patient with cough/cold symptoms and/or fever.

INTRODUCTION

Many over-the-counter (OTC) cough and cold product labels may contain complex instructions and misleading graphics which may guide caregivers toward administration of inappropriate products to children. Due to low literary or numeracy skills, some caregivers are at increased risk for inappropriate administration of pediatric OTC products. A recent study showed 85% of parents in the United States treat their children with OTC medications prior to seeking professional care. This makes addressing situations in which physician referral is necessary an important role of the pharmacist. Misuse of OTC products can be the direct result of incorrect indication, selection of an inappropriate product, or incorrect dosing. Although rare, an estimated 85% of pediatric fatalities caused by OTC medications involved inappropriately dosed cough and/or cold products. Factors leading to overdose of these products included administration of more than two medications containing the same ingredients, inappropriate utilization of measuring devices, use of adult products in situations where pediatric products were indicated, selection of a product which was not indicated, and involvement of more than two caregivers in the treatment or selection of the OTC product. Pharmacists can play an important role in the selection of appropriate OTC products (non-pharmacologic and pharmacologic) as well as during the provision of counseling regarding dosing, adverse effects, and administration techniques. It is essential for pharmacists to be aware of current OTC product labeling as well as recommendations in order to assist caregivers with the selection and use of OTC medications in children.

THE COMMON COLD: A BRIEF OVERVIEW

The common cold is typically a self-limited viral infection which can be caused by more than 200 viruses. The most common virus seen in children is rhinovirus. On average, most children will experience between six and eight colds per year, each lasting between ten and fourteen days per episode. Following onset, cold symptoms tend to peak around day three or four and begin to diminish on or after day seven. These symptoms may include stuffy or runny nose, frequent sneezing, accumulation of mucus in the back of the throat (often referred to as postnasal drip), sore throat, cough, and water eyes. Other symptoms such as low-grade fever, decreased appetite, and mild head or body aches can also occur. Mucus production during a cold is common and can be clear, white, yellow, or even green in color. Historically, caregivers thought the color of the mucus was an indicator of illness severity, but it has been shown that the colors merely represent the body’s production of antibodies and have no significance in determining whether antibiotic therapy is indicated. Because the majority of cold cases are viral in nature, antibiotics are often unnecessary and should generally be avoided. Communicating this to caregivers is important and can often prevent unnecessary physician visits. An important rule of thumb to remember is “green snot doesn’t mean squat.” Rest, increased fluid intake, and the use of non-pharmacologic as well as pharmacologic therapy can be used for symptomatic relief during episodes of the common cold. These methods will...
help to alleviate the cold symptoms, but **will not** shorten the length of illness.\(^6\) Although the common cold is typically a self-limiting and mild viral infection, it can sometimes lead to more serious complications including secondary bacterial infections.\(^7\) In some instances, physician referral of seriously ill infants and children is necessary, and pharmacists can play a vital role in this referral process due to their increased accessibility and contact with caregivers.

### NON-PHARMACOLOGIC THERAPY

Non-pharmacologic therapy can include a variety of approaches and should generally be considered “first-line” for symptom relief as well as immune system support during the common cold. Some recommendations include the use of humidifiers to improve the environment as well as increasing fluid intake to keep the body well hydrated. Below you will find specific instructions regarding a variety of non-pharmacologic options.

**Symptomatic Relief**\(^6,8\)

- **Humidifiers or cool mist vapors**
  - In general, cold air humidifiers are recommended when compared to warm air humidifiers due to safety concerns with regard to children. Also, regular cleaning of humidifiers and other treatment products is recommended due to the increased risk of bacterial growth and mold which may occur. If these instruments are not cleaned regularly, they may emit microorganisms into the environment and cause serious illness due to pathogen inhalation.\(^8\)
- **Bulb syringe with or without saline nasal drops**
  - This approach is considered the treatment of choice for nasal symptoms in infants. Nasal bulb syringes can be used to clear the nose every 3-4 hours.\(^6\)
- **Head elevation**
  - Elevating the head of the bed can promote better drainage of the sinus and nasal passages. A large wedge-shaped pillow that raises the upper body by 6 to 8 inches is best if the patient is experiencing significant drainage.\(^6,10\)
- **Increased water ingestion**
  - Water is considered the best expectorant for children. Proper hydration thins the mucus which can ease the child’s efforts to expel it and prevent dehydration.

**Immune System Support**\(^5\)

The common cold is caused by a viral infection and requires the body’s immune system for proper eradication. General ways to promote immune system function include:\(^5\)

- **Avoiding secondhand smoke or other air pollutants**
- **Avoiding unnecessary antibiotics**
  - Antibiotics can breed resistance, thus increasing the chance of becoming ill with antibiotic-resistant infections.
- **Breastfeeding**
  - Breast milk contains antibodies which can be passed from mother to child. These antibodies can provide protection against infection even after breastfeeding is stopped.
- **Increasing fluid intake**
  - Drinking plenty of fluids during the common cold is important. Healthcare providers should always recommend pediatric-specific fluids such as Pedialyte\(^\circledR\) because these products contain the proper amount of fluid and electrolytes and can help prevent electrolyte imbalances.
- **Eating yogurt**
  - Active cultures present in certain yogurts and probiotics contain beneficial bacteria which can aid in preventing colds.\(^5\)
  - Yogurts and probiotics containing *Lactobacillus acidophilus* with *Bifidobacterium animales* were shown to reduce both the incidence and duration of rhinorrhea, cough, and fever symptoms in children 3-5 years old.\(^11\)
  - Although sufficient efficacy evidence is lacking, the CDC considers *Lactobacillus* safe for use in children and infants but does caution regarding the use of probiotics in patients on concomitant immunosuppressive therapy.\(^12\)

**Pharmacologic Therapy**

Although not always recommended in pediatric patients, various pharmacologic agents can be used to treat the symptoms of the common cold. In general, these options include antihistamines, nasal decongestants, antitusives, expectorants, and analgesics. Other therapeutic options include complementary or alternative medicine such as chicken soup, vitamin C, zinc, Echinacea, Airborne Jr\(^\circledR\), and honey. Below are recommendations for the use of these products in pediatric patients.

**Antihistamines**

Antihistamines competitively bind, but do not activate the H\(_1\) receptor and prevent histamine from binding.\(^15\) First generation antihistamines are considered nonselective and provide mostly sedative effects. This class of antihistamines includes diphenhydramine, clemastine, and chlorpheniramine.\(^15\) Second generation antihistamines are peripherally selective and therefore provide less sedation due to an inability to cross the blood brain barrier.\(^15\) Second generation OTC antihistamines include loratadine, fexofenadine, and cetirizine.\(^15\) First generation antihistamines are often utilized during the common cold because they are associated with anticholinergic properties such as drying of mucus membranes. This association results in a reduction of nasal, lacrimal gland, and salivary hypersecretion, thus decreasing...
the amount of mucus and drainage present. When compared to first generation antihistamines, the second generation products are not considered to be as beneficial due to reduced anticholinergic properties.

A Cochrane systematic review evaluating the use of antihistamines either alone or in combination with a decongestant concluded antihistamine use as monotherapy did not provide any clinically significant effects on general recovery in the course of the common cold in either children or adults. First generation antihistamines were associated with a small decrease in sneezing and rhinorrhea, but were also associated with a significantly higher incidence of side effects such as sedation.

Many caregivers expect antihistamines to decrease nasal symptoms because they provide this effect in the setting of allergic rhinitis. The general population does not understand the pathophysiology of allergic rhinitis and the common cold differ greatly. During allergic rhinitis, large amounts of histamine are released in response to an allergen while a common cold uses bradykinin as the major cytokine mediator. Bradykinin can induce vasodilation and lead to congestion, but this mechanism is unaffected by antihistamines. Sedation of a sick child is the most likely benefit seen with the use of antihistamines although the use of these products for sedative effects alone is not currently recommended.

Although safety and efficacy data regarding antihistamine use in pediatric patients is sparse and somewhat conflicting, the general consensus is that antihistamine use as monotherapy provides no real benefit in terms of nasal symptom relief and should be avoided in pediatric patients. Combination therapy including antihistamines and decongestants has been shown to be ineffective in small children, but may provide limited benefit in older children and adults by relieving nasal symptoms such as runny nose and post-nasal drip.

**Nasal decongestants**

Topical and systemic decongestants produce vasoconstriction in the nasal mucosa, therefore reducing inflammation and swelling while improving ventilation. OTC decongestants for oral use can be found in a variety of products and include pseudoephedrine (immediate and sustained release) as well as phenylephrine. These oral options have a slower onset of action when compared to topical decongestants, but are often associated with longer decongestive effects and less local irritation. Of the oral options, pseudoephedrine is the most frequently used oral decongestant, and although considered safe, has been associated with the potential for increased blood pressure and heart rate. Additionally, use of pseudoephedrine in patients with a history of hypertension, vasospasm, and/or cardiovascular disease should be avoided due to increased risk for stroke or heart attack. Use of pseudoephedrine should also be avoided in the treatment of patients taking monoamine oxidase inhibitors such as linezolid due to the risk of severe hypertensive reactions.

At this time, insufficient data exist to support the safety and efficacy of phenylephrine as an oral decongestant in any age. However, it is suggested that phenylephrine has minimal effect on blood pressure even when taken at higher than recommended doses, making it seem like a safer alternative to pseudoephedrine. Although data is conflicting, phenylephrine is “generally recognized as safe” and may be an appropriate alternative for patients unable to tolerate the adverse effects associated with pseudoephedrine.

Topical OTC nasal decongestants are an option in patients unable to take oral medications and include phenylephrine, naphazoline, tetrahydrozoline, oxymetazoline, and xylometazoline. These topical products are extremely effective at relieving nasal congestion and produce less systemic adverse effects than oral decongestants, but may produce burning, sneezing, stinging, and dryness of the nasal mucosa.

Additionally, prolonged use (>3-5 days) can result in severe rebound congestion. Patients should be counseled to discontinue the use of topical decongestants after three days and to contact his/her doctor.

At this time, studies evaluating the safety and/or efficacy of nasal decongestants in pediatric patients have not been completed, making the use of these agents inappropriate in children due to lack of sufficient data. Some studies have shown potential benefit, including relief from nasal congestion, from oral or topical nasal decongestants in the adolescent and adult populations, making recommendations for these groups more appropriate.

**Antitussives**

Cough is one of the most common and troublesome presenting symptoms in children. This symptom is not only troublesome for the child, it can also be one of the most intolerable symptoms for caregivers because it often prevents sick children from getting enough sleep at night. The Slone Survey identified that in any given week, about 1 in 10 children in the U.S. receives some form of cough and/or cold products. With these results, it is important to address the high prevalence of medication use in children, especially given the lack of efficacy data and potential for adverse effects. Various review articles have helped to characterize the use of cough and/or cold products in children, but evidence to support the effectiveness of the agents in the pediatric population remains inconclusive.

One agent utilized in the treatment of cough is dextromethorphan. This cough suppressant is used to depress the cough center activity in the medulla and inhibits the reuptake of serotonin in the presynaptic cleft. This suppressive action can be harmful because it puts the patient at potential risk for severe respiratory depression and serotonin syndrome. These risks are especially dangerous in the pediatric population due to a lack of sufficient data, thus making the use of dextromethorphan for treatment of acute cough an
Topical antitussive options are also available for use in children to treat the symptoms commonly associated with cough and cold. These products use medicated vapors to relieve symptoms such as cough without causing the systemic side effects (i.e., drowsiness or jitters feelings) that have been associated with other cough and cold relief products. One of the most commonly used topical antitussives is Vicks VapoRub®, which includes camphor, eucalyptus oil, and menthol. Vicks VapoRub® is approved for use in children 2 years of age and older and can be applied to the neck and chest up to 3 times per day. This product is not intended for use in children less than 2 years old due to the camphor component, and should also not be applied in the nostrils or under the nose. Side effects associated with the use of Vicks VapoRub® include increased mucus production, obstruction of small airways, and rebound congestion.

Another formulation, Vicks BabyRub®, does not include camphor and is regarded as safe for children less than 2 years old when used as directed. This product is a combination of petrolatum, aloe extract, eucalyptus oil, lavender oil, and rosemary oil. Because it is marketed as “unmedicated,” very little safety and efficacy data is available regarding its use in the pediatric population.

Expectorants

Expectorants, specifically guaifenesin, are used to reduce the viscosity of respiratory tract fluid secretions and increase sputum volume. These actions are thought to improve the efficacy of the cough reflex as well as the action of the ciliary in the trachea and bronchi, making it easier for patients to expel bronchial drainage. However, like other cough and cold products, limited evidence is available to support the efficacy of guaifenesin for acute cough and upper respiratory tract infections.

Water is considered the safest and most efficacious expectorant for children with an acute cough. Little data supports the use of mucolytics or pharmacological expectorants, but it is clearly understood that ample water intake will promote thinning and loosening of the mucus and promote coughing. COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM)

All use of herbal supplementation in children under the age of 2, as well as in pregnancy and lactation, should be done with extreme caution. Many CAM therapies are associated with little clinical data regarding efficacy and safety, especially in the pediatric population. Non-pharmacologic therapy is the safest way to manage symptoms of the common cold in pediatric patients, and should be used prior to pharmacologic therapy and CAM. Vitamin C – Vitamin C is the most commonly used CAM product associated with the common cold. Vitamin C should not be used for treatment, but limited evidence suggests that prophylactic use may decrease the severity and duration of symptoms. However, excessively high doses of vitamin C should be avoided as they have been correlated with adverse effects including headaches, intestinal and urinary complications, kidney stones, and significant interactions with anticoagulants.

Oral Zinc: Oral zinc formulations have demonstrated a dose-related reduction in the duration of the common cold in adults, however studies in children did not reveal the same reduction when compared to placebo. This lack of reduction could be attributed to differences in formulation, dosing, and frequency of administration. Differences in host inflammatory responses, virus etiology and susceptibility, and even the lack of reliable third-party symptom reporting could also account for the lack of evidence. If oral zinc therapy is used in the pediatric population, it is important to use a recommended dose and to counsel patients regarding common side effects such as nausea or bad (metallic) taste.

Echinacea: This product is believed to act as a nonspecific immune stimulant and is used to stimulate white blood cell function and cell-mediated immunity. It is also reported to have broad-spectrum antimicrobial activity against bacteria, fungi, and viruses. Root preparations may be effective in lessening the severity of cold symptoms, but clinical data is inconclusive. The use of echinacea can also trigger allergic reactions and should be avoided in patients with allergies to ragweed, daisy, aster, and chrysanthemum. Also, many tinctures have high alcohol concentrations (15-90%), which should be considered when evaluating the use of echinacea in pediatric patients. Use for greater than 10 days in any population is not recommended.

Airborne Jr® – This product is marketed for children ages 4-10 as a herbal supplement designed to “boost your immune system to help your body combat germs.” The primary ingredients listed are vitamin C (835% of the daily recommended value), vitamin E, zinc, and manganese. This product has not been evaluated by the FDA and has not been proven to be clinically effective for the prevention or treatment of cough or cold. Airborne Jr® is classified as an herbal supplement, holding a similar place in therapy to vitamins with the same ingredients.

Honey: Data supporting the effectiveness of honey for the treatment of acute cough in children due to upper respiratory infections is limited. A review of two trials containing a total of 268 patients, ages 2-18, showed treatment with honey to be potentially superior to treatment with diphenhydramine but these results were consistent with “low to moderate quality evidence.”

Chicken Soup – Limited clinically significant data is available with relation to the use of chicken soup for
the common cold. Some individuals believe the hot steam from the soup may help relieve sinus pressure and inflammatory symptoms. This action is similar to the moistening of oral and nasal passage seen with other hot beverages or warm air humidifiers. Individuals also like the use of chicken soup during the common cold because it is one of the few non-pharmacologic options that is safe for the pediatric population and is not associated with adverse effects.

**PREVENTION OF THE COMMON COLD: DISINFECTION AND HAND WASHING**

In general, viruses often spread via hand-to-hand contact as well as through large-particle aerosolization. Avoiding close contact with people who have colds or other upper respiratory tract infections (URTs) can help prevent viral exposure. Infected persons are most contagious during the first three days of symptom onset and will likely no longer be contagious by about day seven of illness. Routine disinfection of commonly touched surfaces such as door knobs, sink handles, and light switches can decrease the risk of viral spreading. This disinfection should be done using an EPA-approved product such as Lysol to ensure appropriate killing of the virus. Proper hand hygiene in both children and adults may also prove beneficial in preventing illness and stopping the spread of the virus. Intermittent and frequent hand washing is recommended for all ages and should be done using antibacterial soap or hand sanitizers containing organic acids such as salicyclic acid. Recent studies have demonstrated increased efficacy at prevention of rhinovirus infection when using organic acid-based when compared to ethanol-based hand sanitizers. This difference is thought to be the product of extended residual activity against rhinovirus seen with organic acid products. These products can be found over-the-counter and are generally considered safe for use in children.

**PAIN AND FEVER RELIEF**

One of the leading causes of parental concern with regard to symptoms of illness is fever. The common belief children must maintain a “normal” temperature leads to the misuse of antipyretics on a daily basis. Many parents are not aware of the beneficial effects associated with fever including slowing of bacterial and viral growth which in turn helps the body recover more quickly from an infection. Due to this beneficial effect, the primary treatment goal for a febrile child should not be normalization of body temperature but should actually include improvement of the child’s general well-being including adequate fluid intake and prevention of more serious symptoms. Another common misconception in the pediatric population is with regard to the treatment of pain. In previous decades, pain management for infants and children was not considered a significant priority due to the assumption that these patients did not experience pain due to an “inadequately developed neuroendocrine system and nerve pathways.” However, many clinical studies have since proven the pediatric population may actually be more sensitive and potentially experience more intense pain than adults. As a result, effective practices to appropriately manage pain in children have become standard in the clinical setting, including using pain assessment as the fifth vital sign. Like adults, children can experience pain in a variety of situations including immunizations, acute illness (i.e. otitis media), chronic disease, injury, and medical procedures, thus making pain management an important part of treatment in this population.

Treatment of both fever and pain contain both non-pharmacologic and pharmacologic options. Safe and effective OTC medication options for the treatment of pain and/or fever include ibuprofen and acetaminophen. Either choice, when used in appropriate doses, may be considered first line therapy when the patient requires an analgesic or antipyretic.

**NON-PHARMACOLOGIC THERAPY**

**Fever**
- **Environmental Control**
  - Adjust room temperature to avoid extremes in heat or cold
  - Remove excess clothing and/or use lightweight clothing
- **Sponge baths with lukewarm water**
  - Do not use cold water which can induce shivering thus further increasing body temperature
  - Do not use rubbing alcohol which can be systematically absorbed and cause fume inhalation, both of which have hazardous CNS side effects (i.e. increased heart rate, headaches, dizziness, and nausea)

**Pain**
- **Hot/Cold Packs**
  - Use cold packs if pain is associated with inflammation and swelling
  - Use heating pad if patient is experiencing stiffness or chronic pain
- **Distraction**
  - Consider using an enjoyable activity or item such as TV, board games, ice cream, etc. as a distraction for children in pain
- **Massage/physical therapy**
  - Make the child more comfortable and relaxed to positively contribute to general well-being and allow the body to naturally overcome the acute situation

**PHARMACOLOGIC THERAPY**

**Acetaminophen**
The current recommendation for pharmacologic treatment of fever and pain in children is the use of acetaminophen. In the past, recommendations included the use of aspirin in these situations, but due to a confirmed association between salicylates and Reyes syndrome in children, aspirin is no longer considered a treatment option for this population. The recommended dose of acetaminophen in children is 10-15
mg/kg/day every 4-6 hours with a maximum dose of 75 mg/kg/day (or 5 doses in 24 hours).42,43 OTC acetaminophen formulations for children include a standard liquid concentration of 160mg/5mL as well as chewable tablets and Meltaways®. The generally acceptable safe and effective duration of OTC use is 5 days or less.42,43 Hepatotoxicity is a severe adverse reaction of acetaminophen use and is seen in situations of supratherapeutic dosing (greater than 15 mg/kg/dose) or in prolonged overdose situations in which appropriate single doses were given at intervals shorter than four hours.42

Ibuprofen
Ibuprofen is another option for fever and pain in the pediatric population and has been associated with a faster onset and duration of action than acetaminophen. However, data do not currently support a significant difference in safety or effectiveness between the two agents, making them both appropriate options in children.42 Dosing recommendations in children are different for the treatment of fever versus pain. For children greater than 6 months of age, the dose for treatment of fever is 7.5 mg/kg/dose given every 6 hours with a maximum dose of 30 mg/kg/day. This is slightly different than the dose for treatment of pain which is 5-10 mg/kg/dose given every 6-8 hours with a maximum dose of 4 doses in 24 hours.42,43 Dosage forms for ibuprofen in children include liquid preparations in concentrations of 40 mg/mL as well as 100 mg/5 mL.42 The variety of concentrations makes selection of the appropriate product even more important due to the risk of overdose if the wrong product is used. Ibuprofen is also available as a chewable tablet.45

One critically important point to remember in this population is the maintenance of adequate hydration while taking ibuprofen or other non-steroidal anti-inflammatory agents.42 Although only limited case reports exist, renal insufficiency has been directly correlated with the use of ibuprofen as a result of prostaglandin inhibition that ultimately disrupts renal blood flow.42 It is recommended to avoid the use of ibuprofen in children who are dehydrated, have a history of cardiovascular disease, have preexisting renal disease, or are also using other nephrotoxic agents.42

WHEN TO REFER
In general, non-pharmacologic therapy should be considered first line for treatment of cough and cold in pediatric patients. If pharmacologic therapy is used to alleviate symptoms, it is important for the caregiver to use OTC medications only for the amount of time recommended.47 If symptoms persist beyond the recommended amount of time, the caregiver should be instructed to follow-up with the primary care physician.

Here are some general situations in which physician referral is recommended:

**Cough/cold symptoms**
- Persistent cough >4 weeks
- Children <2 years old with cough
- Cough indicative of another disease state such as pertussis, croup, bronchiolitis, asthma, GERD
- Symptoms lasting >10 days

**Pain symptoms**
- Swelling or erythema at the site of pain
- No relief, no improvement, or worsening of pain despite adequate treatment

**Fever**
- Age > 6 months and temperature ≥103°F
- Age > 2 months and rectal temperature ≥100.2°F
- Age 3-6 months and temperature ≥101°F
- No fever relief or improvement despite adequate treatment
- Development of seizures or unusual drowsiness in addition to looking more “ill”
- Development of additional symptoms such as stiff neck, intractable irritability, vomiting/diarrhea, rash, headache or severe pain in throat or ear
- Fever in a immunocompromised child such as one with cancer, HIV, or history of transplant

BARRIERS TO APPROPRIATE OTC USE IN CHILDREN

Inappropriate dosing is one of the most important barriers to proper OTC use in children and plays a significant role in OTC-associated fatalities in this population.4 Inappropriate dosing instructions on these products are often confusing and result in both overdosing and underdosing situations. Because pharmacists are such an accessible healthcare provider, it is important they feel comfortable providing dosing recommendations with regard to use of these products in children.

Another barrier to appropriate OTC use in children is the selection of combination products containing the same active ingredients. Many caregivers unknowingly administer 2-3 times the daily recommended amount of medications such as acetaminophen because they are not aware of its inclusion in multiple products used in cough and cold. For this reason, single ingredient products should be recommended in order to avoid an unintentional overdose of any one ingredient.2

Selection of an inappropriate product is also a common barrier to proper OTC use in pediatric patients.2 In some instances, caregivers may select products not indicated for a child’s symptoms or even substitute adult products when pediatric formulations are indicated.2

Finally improper utilization of measuring devices also contributes to inappropriate OTC use.2 Although many caregivers are tempted to use household teaspoons and tablespoons for medication dosing, these devices are not considered appropriate because the amount of medication delivered can vary greatly. In these situations, pharmacists should offer to explain how to use the devices.
appositely or provide measuring tools which will provide the recommended dose of medication with less difficulty.\(^2\)

**PUTTING IT ALL TOGETHER**

- **Medication adherence** is an important part of medication use in children and can be negatively impacted by a variety of factors including:\(^10\)
  - Poor communication between the provider and the caregiver and/or patient
  - Lack of understanding regarding the severity of the illness
  - Lack of interest regarding taking medication (especially in adolescents)
  - Poor taste of drug formulations
  - Uncertainty or anxiety regarding potential medication related adverse effects
  - Inconvenient dosage forms and dosing schedules (i.e. administration three or more times daily)
  - Failure of the caregiver to remember to administer the drugs

- **Medication safety** is another very important part of medication use. Administration errors may result from the following scenarios:\(^16\)
  - Incorrect or inappropriate medication
  - Incorrect or inappropriate dose
  - Inappropriate medication administration technique
  - Inappropriate dosing instrument\(^2\)
  - Administration of more than two medications containing the same ingredients\(^2\)
  - Two or more caregivers contributing to the treatment and selection of the OTC product\(^2\)

To avoid life-threatening events, pharmacists can remind caregivers to keep all medications (OTC and prescription) out of the reach of children. They should also keep all medications in the original bottles or containers with the lids tightly sealed.\(^6\)

- Recognizing and understanding common flaws in the medication-use process can help providers, caregivers, and patients create strategies to prevent problems before they arise.\(^10\)

**CLINICAL PEARLS FOR PHARMACISTS**

1. Not all OTC products are approved for use in children. The FDA recommends against the use of cough and cold products, such as pseudoephedrine, phenylephrine, diphenhydramine, brompheniramine, and chlorpheniramine, in children younger than 2 years of age.\(^57\) Additionally, manufacturers of these products voluntarily changed their labels to state: “do not use in children under 4 years of age.”\(^57\) Paying close attention to product labeling, ingredients, and instructions for use allows pharmacists to provide appropriate recommendations and guidance for patients.\(^6\)

2. FDA recommends against the use of cough and cold products (decongestants, ephedrine, pseudoephedrine, or phenylephrine, and the antihistamines diphenhydramine, brompheniramine, or chlorpheniramine) in children <2 years old, but the manufacturers voluntarily changed their labels to state: “do not use in children under 4 years of age.” Although vitamin C is often used in the adult population for prophylaxis of the common cold, it should not be used as active treatment in adults or children.\(^3\)

3. Antibiotic therapy is not appropriate for treatment of the common cold in adults and children. Therapy directed toward symptom relief is a more appropriate recommendation.\(^3\)

4. Antihistamines should not be recommended for the treatment of nasal symptom relief in children.\(^3,16,19\)

5. Currently, nasal decongestants are not recommended in children due to limited safety and efficacy data. This drug class should be reserved for adolescent and adult populations.\(^16,19\)

6. Dextromethorphan is not an appropriate treatment for cough in pediatric children.\(^3\)

7. Ibuprofen is an appropriate analgesic and/or antipyretic for children greater than 6 months old.\(^6,42,43\)

8. Aspirin should NEVER be given to children due to the rare, but very serious, risk of Reyes syndrome.\(^6,42,43\)

9. Avoid cough and cold medications with multiple active ingredients. Use single ingredient products to reduce the risk of overdose.\(^48\)

10. Pharmacists are the most accessible healthcare professionals: it is critical to select the appropriate products based on the individual pediatric patient, screen each patient for potential drug-drug interactions or contraindications, and thoroughly educate caregivers about proper dosing and administration.

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**References**


2. Dart RC, Paul IM, Bond GR, et al. Pediatric Fatalities Associated With Over the Counter (Nonprescription) Cough and


