Safe management of cough-cold in children

INTRODUCTION
For years the message to patients (and parents of patients) has been that if they have a common cold it is caused by a virus, and antibiotics won’t be of any help, so the best they can do is to use one of several OTC products available to manage symptoms. And data show that OTC cough-cold products have indeed become popular among consumers. How? Several recent findings have raised questions and concerns regarding the safety of OTC cough-cold products use in infants and young children.1-3

Physiological differences between infants, young children and older children or adults are among the fundamental issues that are part of this concern. While pharmacists have the background and education to understand and appreciate the significance of these differences, most members of the general public do not. Retail pharmacists are in a position to play a critical role in helping members of the public (and parents of young children in particular) understand the significance of recent warnings and assist parents in selecting safe options for management of cough-cold symptoms in their children.

COUGH-COLD PRODUCT USE
Over-the-counter cough-cold products frequently are administered to young children. In 2006, upper respiratory infections were the most commonly reported reason for medication use in children.1 In these children, pseudoephedrine and dextromethorphan ranked among the top medications given to children under age 12.1

In the Slone study, cough-cold product use was evaluated in more than 4,000 children. More than 10 percent of children had received a cough-cold product in the previous week. The most commonly used medications included decongestants, first-generation antihistamines and antibiotics. More than 60 percent of the products used were multiple-ingredient products. When asked why the child had received medication, 35 percent of answers were not related to cough, cold or allergy symptoms.

As noted previously, an increasing number of concerns have been raised regarding the risk associated with using these products in infants and young children. In 2004, the Toxic Exposure Surveillance System documented nearly 90,000 calls associated with cough-cold product use in U.S. children. They also reported three accidental deaths related to cough-cold products.

The Center for Disease Control and Prevention linked cough-cold products to more than 1,500 emergency department visits and three deaths among children younger than 2 years of age in 2005.2 All three children involved were 6 months old or younger. Postmortem blood levels were extremely high for pseudoephedrine. One of the infants had received a prescription and an over-the-counter cough-cold combination medication at the same time, both containing pseudoephedrine. The other infants received either a prescription or an over-the-counter pseudoephedrine product.

A recent study also identified more than 7,000 annual emergency department visits attributable to cough-cold product use in children less than 12 years old.3 This accounts for nearly 6 percent of all emergency department visits due to any medication in this age group. The majority of these visits involved children between 2 and 5 years old. Unsupervised ingestion of cough-cold medications caused one-third of the emergency department visits, higher than with other medications. More than 75 percent of emergency department visits for children ages 2 to 5 years old involved unsupervised ingestion. For supervised administration of cough-cold products, 26 percent of emergency department visits were due to undesired effects despite proper administration, while 8 percent were due to medication errors. Children under the age of 2 years old accounted for most medication errors resulting in adverse events. Nearly one-quarter of all emergency department visits resulted in gastric decontamination.

The Food and Drug Administration recently enforced measures to control marketing of carboxinoxamine, an antihistamine, following 21 deaths since 1983 in children under 2 years of age.4 A direct causal relationship was not established between these deaths and carboxinoxamine because many of the involved products were combination products containing multiple ingredients. As a result, the FDA realized that young children may be at increased susceptibility for adverse events related to cough-cold products. Because carboxinoxamine was approved under a DESI review, the FDA was concerned that it was not adequately studied in this population. As a result, manufacturers no longer were allowed to market unapproved carboxinoxamine-containing products.
to children under 2 years of age. Only carbinoxamine-containing products that have undergone a full FDA review can remain on the market.

Based on its determination that no well-controlled scientific studies were available to support the safety and efficacy of codeine and dextromethorphan for the treatment of cough in children, the American Academy of Pediatrics developed a policy statement advising that parents and patients should be educated about the lack of antitussive effects and risks associated with these agents.

This document also articulated the AAP’s concern that dosage guidelines for these products are extrapolated from adult data or clinical experience rather than studies involving children. In addition, the academy felt that suppression of cough may be hazardous and contraindicated in many pulmonary airway diseases. They recommend the use of fluids and humidity to reduce cough.

The American College of Chest Physicians developed similar clinical guidelines in 2006. The college advises healthcare providers to refrain from recommending cough suppressants and other over-the-counter cough medications for young children due to the increased risk of morbidity and mortality.

In March 2007, the FDA received a citizen’s petition that raised concerns regarding the safety and efficacy of OTC cough-cold products in children less than 6 years old. Among other things, this petition requested revised labeling for OTC antitussive, expectorant, nasal decongestant, and combination cough-cold products to state that these products should not be used in children under 6 years of age for cough and cold.

The petition also asked that manufacturers not be allowed to use pictures of children under age 6.

Given the various concerns, including those raised in the petition, the FDA undertook a review of cough-cold medicines intended for pediatric use. As part of this review, the FDA convened a joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee for the purpose of discussing the safety and efficacy of OTC cough-cold products marketed for pediatric use.

Attention was given to the use of OTC cough-cold products in children less than 2 years, 2 to 5 years of age, and 6 to 11 years of age. Also considered was the extent of use of the products in children under 2 years of age; the potential for misuse, unintentional overdose and excessive dosing, as well as the ability of parents or caregivers to correctly dose and administer cough-cold products to their children.

Among the committee members there was strong consensus regarding the need for more data regarding efficacy of the products in children. A majority of the members also voted to recommend that the products not be used in children under 6 years of age while the rule-making that would be necessary for revised OTC monographs proceeded.

With regard to products intended for children ages 6 to 12, a majority recommended the continued availability of these products during the rule-making process.

In January, the FDA issued a Public Health Advisory (PHA) in which it recommended that OTC cough-cold products not be used in infants and children under 2 years of age. The FDA also indicated that the review of safety of these products in children ages 2 though 11 was not yet complete and provided the following precautions:

- Carefully follow the directions on the Drug Facts label.
- Choose products with safety caps.
- Use appropriate measuring spoons.
- Avoid concurrent use of multiple OTC cough-cold products.
- Do not use OTC cough-cold products to sedate.

Parents cannot be expected to understand the significant differences in an infant’s or young child’s physiology. Especially if the child has been cranky or had a sleepless night, the primary thought on a parent’s mind is likely to find something—anything—that will provide relief.

Subsequent to the release of the FDA’s PHA, most manufacturers voluntarily withdrew their cough-cold products for children under 2 years of age.

More recently, on Aug. 20, the FDA announced that it has scheduled a special public meeting for Oct. 2 to gather information including scientific, regulatory and product-use issues. As part of this announcement, the FDA noted its support for the voluntary action taken by many pharmaceutical manufacturers to withdraw cough-cold products intended for use in children under 2 years of age. Also noted was information from the FDA’s Adverse Event Reporting database, that although many adverse events were due to overdoses and allergic reactions, children under 4 years of age who received the labeled dose were more likely to experience non-allergic adverse events than were older children.

Babies and Children Are Not Small Adults

Few drugs, prescription or OTC, have been tested in infants or children. According to the National Institutes of Health’s Pediatric Pharmacology Research Units Network, only five of the 80 drugs most frequently used in newborns and infants are labeled for pediatric use. Historically, determination of dosage of medications for infants and young children has been based on calculations of weight and prior experience. However, calculations on weight alone can be problematic, as the physiology of infants and young children is known to be very different from that of older children and adults.

Kidney and liver function may be very different in an infant or young child compared with an adult, affecting the rate at which a drug may be metabolized. And infants and young children have neurological systems that still are developing and which may be sensitive to sedating effects.

Parents cannot be expected to understand the significant differences in an infant’s or young child’s physiology. Especially if the child has been cranky or had a sleepless night, the primary thought on a parent’s mind is likely to find something—anything—that will provide relief.

In March 2007, the FDA received a citizen’s petition that raised concerns regarding the safety and efficacy of OTC cough-cold products in children less than 6 years old. Among other things, this petition requested revised labeling for OTC antitussive, expectorant, nasal decongestant, and combination cough-cold products to state that these products should not be used in children under 6 years of age for cough and cold. The petition also asked that manufacturers not be allowed to use pictures of children under age 6.

Given the various concerns, including those raised in the petition, the FDA undertook a review of cough-cold medicines intended for pediatric use. As part of this review, the FDA convened a joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee for the purpose of discussing the safety and efficacy of OTC cough-cold products marketed for pediatric use.

Attention was given to the use of OTC cough-cold products in children less than 2 years, 2 to 5 years of age, and 6 to 11 years of age. Also considered was the extent of use of the products in children under 2 years of age; the potential for misuse, unintentional overdose and excessive dosing, as well as the ability of parents or caregivers to correctly dose and administer cough-cold products to their children.

Among the committee members there was strong consensus regarding the need for more data regarding efficacy of the products in children. A majority of the members also voted to recommend that the products not be used in children under 6 years of age while the rule-making that would be necessary for revised OTC monographs proceeded.

With regard to products intended for children ages 6 to 12, a majority recommended the continued availability of these products during the rule-making process.

In January, the FDA issued a Public Health Advisory (PHA) in which it recommended that OTC cough-cold products not be used in infants and children under 2 years of age. The FDA also indicated that the review of safety of these products in children ages 2 though 11 was not yet complete and provided the following precautions:

- Carefully follow the directions on the Drug Facts label.
- Choose products with safety caps.
- Use appropriate measuring spoons.
- Avoid concurrent use of multiple OTC cough-cold products.
- Do not use OTC cough-cold products to sedate.

Parents cannot be expected to understand the significant differences in an infant’s or young child’s physiology. Especially if the child has been cranky or had a sleepless night, the primary thought on a parent’s mind is likely to find something—anything—that will provide relief.

Subsequent to the release of the FDA’s PHA, most manufacturers voluntarily withdrew their cough-cold products for children under 2 years of age.

More recently, on Aug. 20, the FDA announced that it has scheduled a special public meeting for Oct. 2 to gather information including scientific, regulatory and product-use issues. As part of this announcement, the FDA noted its support for the voluntary action taken by many pharmaceutical manufacturers to withdraw cough-cold products intended for use in children under 2 years of age. Also noted was information from the FDA’s Adverse Event Reporting database that although many adverse events were due to overdoses and allergic reactions, children under 4 years of age who received the labeled dose were more likely to experience non-allergic adverse events than were older children.

Babies and Children Are Not Small Adults

Few drugs, prescription or OTC, have been tested in infants or children. According to the National Institutes of Health’s Pediatric Pharmacology Research Units Network, only five of the 80 drugs most frequently used in newborns and infants are labeled for pediatric use. Historically, determination of dosage of medications for infants and young children has been based on calculations of weight and prior experience. However, calculations on weight alone can be problematic, as the physiology of infants and young children is known to be very different from that of older children and adults.

Kidney and liver function may be very different in an infant or young child compared with an adult, affecting the rate at which a drug may be metabolized. And infants and young children have neurological systems that still are developing and which may be sensitive to sedating effects.

Parents cannot be expected to understand the significant differences in an infant’s or young child’s physiology. Especially if the child has been cranky or had a sleepless night, the primary thought on a parent’s mind is likely to find something—anything—that will provide relief.

Mrs. Arnold is at the pharmacy counter picking up a refill of birth control pills. She is holding her 18-month-old daughter, Sarah, who is fussy and has a runny nose. Mrs. Arnold has placed a number of children’s cough-cold remedies on the counter and as she rings them up she remarks, “I can’t believe you can’t find any infant cough-cold stuff anymore. It’s such a hassle trying to figure out how much to give Sarah, much less measure it correctly. I heard they may even do away with the stuff for kids over 2, so I’m stocking up now just in case. Sarah’s in day care and there are just too many colds going around to be without this stuff.”

Case Discussion

Mrs. Arnold is aware that products no longer are available for children under 2 years old and that there is discussion about the need to restrict products for older children as well. However, she clearly does not understand why these products have been removed or may be further restricted. This is an important opportunity for the pharmacist to discuss the safety issues that have been raised and to encourage Mrs. Arnold to follow the FDA’s recommendations.
active role in helping parents understand that the reason OTC cough-cold products for infants no longer are available is related to concern for safety and that these concerns are based on documented cases of adverse effects to infants and very young children.

ADVICE FOR PARENTS
The only cure available for the common cold is time. All available treatments are aimed at symptom management. As important as it is that parents pay attention to the various precautions on OTC cough-cold products in order to avoid risk for their child, from the parents’ point of view, they still have a sick kid on their hands and need to know what to do to help their child feel better. It is important that pharmacists not only explain why OTC cough-cold products should not be used in infants and very young children, but also provide parents with some recommendations for options that are safe.

The Mayo Clinic is among those organizations that provide quality healthcare information in a consumer-friendly style and format. Among these materials are two articles regarding colds and cold remedies, one of which addresses cold remedies in general and one that has recommendations for managing babies with colds. These articles can be found at www.mayoclinic.com/print/cold-remedies/I000036/METHOD=print and www.mayoclinic.com/print/commoncold/PR00038/METHOD=print, respectively.

Among the key points in these materials is the importance of hydration. This is particularly true for babies, whose nasal passages are small and thus easily clogged. For babies, recommendations include offering plenty of fluids, use of saline drops to thin mucus, suctioning the baby’s nose and moisturizing the air though the use of a humidifier. Recommendations regarding cold remedies in general (which may apply to older children) include many of the same recommendations: drinking plenty of fluids, gargling with salt water, using saline nasal sprays and using a humidifier.

Pharmacists can make a number of recommendations to such patients. These include the need for appropriate rest and nutrition, staying hydrated and using a humidifier or vaporizer, as well as approaches to fever reduction.

ALTERNATIVES FOR PARENTS WHO ARE CONCERNED ABOUT COUGH-COLD PRODUCTS
Parents should understand that viral infections, such as the common cold, are not cured by antibiotics. Antibiotics only work on bacteria infections. Parents do not like their children to be sick, so they want a quick cure. Antibiotics are not the quick cure that parents are seeking when the infection is viral. Instead the parent should look to ease the child’s discomfort and assist the recuperation process while the infection runs its course.

Parents should make sure the child remains well-rested. Taking naps, getting to bed early and refraining from strenuous activities will allow the body to recuperate faster.

Although the child may not have much appetite, particularly during the first days of the cold, nutritious foods should be encouraged as much as they will tolerate them. Feeding the child junk food simply because it is what the parent can convince him to eat, will not provide the child with the vitamins and minerals the body needs during recuperation.

The parent especially should make sure that the child remains adequately hydrated, because children are more easily dehydrated than adults. For bottle- or breast-fed children, clearing the nose of secretion before feeding is important, so the child can breathe while sucking. To facilitate the drainage of secretions, the parent may elevate a child’s head with a pillow or raise the head of the bed. Pillows should not be used for infants due to the risk of suffocation.

DECONGESTION
Saline nasal sprays or drops can be used to alleviate irritation of the mucosal membranes and to loosen encrusted mucus. Saline also acts as a decongestant. Since saline has minimal side effects, it is safe for use in small children. The recommend dosage for saline drops is one to two drops into each nostril 15 to 20 minutes before feeding and bedtime, with a repeated dose 10 minutes later.

To administer saline nose drops, the child should blow his nose first, if he is old enough to do so. The parent should make sure that the dropper tip is not chipped or cracked. The child should avoid touching the dropper tip against the nose or anything else in order to keep it clean. The child’s head should be tilted back as far as possible or the child can lie down on his back on a flat surface. If the child is lying down, it is preferable to have his head hang over the edge, but small children will resist being in this position. After instilling the drops into the nose, the child should bend his head forward toward his knees and move his head from side to side, if the child is old enough to understand how to do this. The child should remain in this position for a few minutes.

The parent should clean the dropper tip with warm water before storing to prevent contamination.

For older children, saline nasal spray may be preferred to nasal drops. Before administering nasal spray, the child should gently blow his nose to clear it of mucus. The bottle should be shaken before use. The child should attempt to avoid touching the inside of the nostril with the tip to avoid contamination. The tip should be aimed slightly towards the outer edge of the nostril, rather than straight up or toward the septum. The child should tilt his head forward slightly and breathe out slowly. Using a finger on the other hand to close the other nostril, the child should squeeze/pump the bottle as he begins to breathe in slowly through the nose. The child should try not to sneeze or blow his nose immediately after using the spray.

Saline works especially well in small children in conjunction with suctioning using a soft rubber bulb. To suction, the parent should squeeze the bulb before placing it in the child’s nose, gently sticking the tip into the nostril, closing off the other nostril and slowly releasing the bulb to allow the mucus to be suctioned into the bulb. This process should be...
TABLE 1

Respiratory conditions with symptoms similar to the common cold

<table>
<thead>
<tr>
<th>Respiratory condition</th>
<th>Common symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic rhinitis</td>
<td>Congestion, clear nasal drainage, itchy eyes/throat, water eyes, history of allergies</td>
</tr>
<tr>
<td>Asthma</td>
<td>Nonproductive cough, dyspnea, wheezing, fatigue, chest tightness</td>
</tr>
<tr>
<td>Bacterial throat infection (Strep throat)</td>
<td>Sore throat, fever</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>Productive cough, persistent fever, dyspnea, discolored or foul-smelling sputum, chills, chest tightness</td>
</tr>
<tr>
<td>Croup</td>
<td>Initially presents with fever, rhinitis and pharyngitis, then progresses to “barking” cough, dyspnea, change of temperature or humidity can relieve cough</td>
</tr>
<tr>
<td>Epiglottitis</td>
<td>Severe throat pain, dysphagia, stridor, hoarseness, drooling</td>
</tr>
<tr>
<td>Infectious mononucleosis</td>
<td>Fatigue, severe throat pain, enlarged lymph nodes, persistent fever</td>
</tr>
<tr>
<td>Influenza</td>
<td>Nonproductive cough, arthralgia, myalgia, fever, sore throat</td>
</tr>
<tr>
<td>Otitis media</td>
<td>Ear pain, draining, fullness and popping, dizziness</td>
</tr>
<tr>
<td>Pertussis</td>
<td>Prodromal typical URI symptoms followed by severe paroxysmal cough, whoop in children (not adults and adolescents), gagging, vomiting</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>Productive cough (longer than 7 days); persistent fever, dyspnea, discolored or foul-smelling sputum, chills, pleuritic chest pain, chest tightness</td>
</tr>
<tr>
<td>Sinus infection</td>
<td>Fever, sinus tenderness, facial pain (particularly with postural changes), ear pressure, malaise, persistent upper respiratory symptoms (longer than 7 days), upper-respiratory symptoms that do not respond to decongestants</td>
</tr>
<tr>
<td>Streptococcal pharyngitis</td>
<td>Sore throat (rapid onset), exudative tonsillitis, tender anterior cervical adenopathy, lack of rhinorrhea or hoarseness, lack of cough positive history of fever</td>
</tr>
</tbody>
</table>

For a non-drug approach to reduction of fever, parents can give the child a sponge bath. The parent should be advised to use lukewarm water, not cold. The evaporation of the water will create a cooling sensation on the skin and draw the heat to the surface.

For a non-drug approach to reduction of fever, parents should be reminded that acetaminophen use is restricted to children 2 years and older, while the use of ibuprofen is restricted to children 6 months and older. Aspirin should never be used in a child under age 18 with a fever due to the risk of Reye’s syndrome.

HUMIDIFIERS AND VAPORIZERS

Humidifiers can be utilized to increase the amount of moisture in inspired air. The increase in humidity can clear secretions, soothe airways and reduce cough. Moist air also can assist in minimizing the feeling of having a dry, scratchy throat. Cold viruses’ tendency to thrive in dry air is one reason colds are more common in winter.

Different types of humidifiers and vaporizers are available: cool-mist impeller, steam (vaporizer), warm-mist, evaporative and ultrasonic. Cool-mist (impeller) humidifiers work by creating water vapor. The vapor is created by a rapidly rotating disk within the water that splashes it into the air. Cold mist inhalants because there is no heat produced. The use of cool-mist humidifiers cannot be used with medicated inhalants because there is no heat produced. The use of cool-mist humidifiers to prevent dispersion of minerals and organisms found in tap water. Because the water is not heated (as it is in the steam vaporizers), humidifier vaporizers should be cleaned daily with soap and hot water to prevent bacteria production. Using antimicrobial

petroleum jelly underneath the nose to relieve raw skin.

FEVER REDUCERS AND PAIN RELIEVERS

The use of acetaminophen and ibuprofen in children has not been restricted, but some parents may prefer to avoid all pharmacologic options. Parents who use acetaminophen or ibuprofen should be repeated until the nose is clear. The bulb should be washed out with warm water between suctionings. Keeping the bowl of warm water nearby will provide the parent with easy access without having to move the child or leave him unattended.

Repeated wiping of the nose can irritate the skin underneath. The parent can apply a thin layer of
Guidelines for referral

- Infant or child who is having rapid or difficult breathing
- Infant or child who has a bark-like cough, stridor or hoarseness
- Infant younger than three months who has a rectal temp >100.4°F or <97.5°F
- Child who has an oral temp >102°F
- Infant or child who has a fever longer than two days
- Infant or child who cannot be comforted
- Infant or child who is unusually quiet
- Infant or child who has a cold longer than seven days
- Infant who is not feeding
- Infant who has fever without diarrhea or normal
- Infant or child who has had vomiting for more than 12 hours
- Infant or child who has had diarrhea for longer than two days
- Infant or child who has constant ear pain, often present as pulling at ear
- Infant or child who has a chronic cough
- Infant or child who has experienced a seizure
- Child who has severe abdominal pain or cramping
- Infant or child who develops a skin rash

The increasing concern about the use of cough-cold products in young children has left many parents wondering what options are available for relieving their child’s symptoms. The pharmacist plays a critical role in educating parents on nonpharmacologic options that are available for management of symptoms.

Cleaning cartridges also can help protect the humidifier against bacteria. Evaporative humidifiers utilize a wick system to draw water from the reservoir. A fan blowing over the wick lets the air absorb the moisture. As the humidity level in the room increases, the humidifier’s water vapor output decreases because the air cannot evaporate from the filter, thus allowing the machine to self-regulate. Due to the use of non-heat- ed water, many of these machines offer wicks treated with an antimicrobial agent or antimicrobial water additives or UV technology to inhibit bacterial growth.

Ultrasonic humidifiers release vapor by creating ultrasonic vibrations in the water. A metal diaphragm within the machine vibrates at an ultrasonic frequency to create the water droplets. These machines often make little to no noise, compared with cool-mist machines which often are noisy. Similar to cool-mist machines, ultrasonic humidifiers allow for the growth of bacteria, which is dispersed into the room if not cleaned regularly. High-end ultrasonic units may have antibacterial features. Many machines also feature a demineralization cartridge to filter minerals out of the water, eliminating the need for distilled water.

Steam vaporizers and warm-mist humidifiers work by boiling water and releasing the steam into the air. The steam allows for the use of medicated inhalants. Because the water is boiled, these vaporizers do not release organisms into the air. Steam vaporizers usually are the least-expensive humidifiers.

For parents who want to use medicated inhalants with the vaporizer, camphor- or menthol-containing products are available to add to the machine to temporarily relieve cough associated with a cold. The mechanism of action of these agents remains debated. Some researchers suggest that vapors do not affect nasal airflow resistance, rather they produce a cold sensation in the nose which produces a feeling of improved breathing. The solution is added directly to cold water for use in a steam vaporizer.

For children 2 years and older, a tablespoon of the solution is added to each quart of water or 1 teaspoon of solution is added to each pint of water. This may be repeated up to three times a day. These products should not be confused with topical rubs. Topical rubs containing camphor and menthol also are available and are labeled for use in children two years and older. In addition, pediatric topical formulations that do not contain camphor or menthol are available. These formulations contain such ingredients as eucalyptus, lavender and rosemary, and are labeled for use in babies three months and older.

A wide variety of humidifiers with various features are available. The pharmacist can help parents select a product that best fits their needs. Available characteristics include:

- The size of the holding tank and how long the humidifier can run without needing to be refilled
- One or more settings to control the degree of moisture
- Adjustable humidity control to set the desired humidity level
- Night light (as these products often are used at night, this makes it easier to locate in a dark room)
- Filters and other features, such as ultraviolet light to eliminate bacteria
- Automatic shut-off
- Sound level
- Ease of cleaning

Whichever machine the parent uses, general safety issues should be addressed. The humidifier always should be placed on a firm, flat, level surface. It should be at least five inches away from walls and heat sources. The humidifier should be placed in an area that is out of the reach of children. The humidifier always should be unplugged and emptied when not in operation.

To reduce the risk of bacterial growth with any type of humidifier, the pharmacist should counsel the parent to clean the humidifier routinely. Most humidifiers require daily cleaning, along with weekly disinfection and routine filter replacement. The pharmacist also should advise the parent that increased humidity can be soothing for people who have asthma flare-ups due to dry indoor air; however, increased humidity can also cause increases in mold and dust mites, which may aggravate asthma and some allergies. A humidity level of 40 percent to 60 percent is recommended as providing enough humidity to minimize the survival of airborne-transmitted infectious bacteria and viruses while at the same time staying below levels of humidity that are optimal for dust mites and fungal populations.

**COMMON CHILDHOOD ILLNESSES**

Typical cough-cold symptoms are somewhat nonspecific and may be confused with symptoms of other common childhood illnesses. The potential for these illnesses (Table 1) should be considered if a child’s illness does not resolve in 10 to 14 days.

**SEEKING FURTHER CARE**

Due to their small size, children are at risk of severe complications. Parents should be counseled that most children do not have any complications from the common cold, but they also should be educated on signs and symptoms that indicate it is necessary to seek medical attention (Table 2).

**CONCLUSION**

Cough-cold medications have not been demonstrated to be effective in small children, and carry the risk of potentially serious adverse effects. The FDA has recommended that these medications not be used in children less than 2 years old. Further restrictions for the use of these products in children ages 2 to 11 may follow in the near future. The increasing concern about the use of cough-cold products in young children has left many parents wondering what options are available for relieving their child’s symptoms. The pharmacist plays a critical role in educating parents on nonpharmacologic options that are available for management of symptoms. Hydration and humidi fication are among the easily available options.

---

TABLE 2

<table>
<thead>
<tr>
<th>Guidelines for referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infants or children who are suffering from cough, fever, or cold symptoms</td>
</tr>
<tr>
<td>Infants or children who have been diagnosed with a respiratory infection</td>
</tr>
<tr>
<td>Infants or children who are experiencing difficulty breathing</td>
</tr>
<tr>
<td>Infants or children who are suspected to have a foreign body in the airway</td>
</tr>
<tr>
<td>Infants or children who are experiencing symptoms that are not responding to OTC treatments</td>
</tr>
</tbody>
</table>

For a complete list of references, visit www.cedrugstorenews.com.
Successful completion of “Safe management of cough-cold in children” (lesson 401-000-08-012-H01) is worth two contact hours of credit. Mail completed answer sheet to DrSN/Pharmacy Practice, P.O. Box 31180, Tampa, FL 33631-3180. For faster service, fax to (813) 626-7203. For fastest service, visit our Web site at www.cedrugstorenews.com.

1. A recent study found that ______ percent of children had received a cough-cold product in the previous week.
   a. 5
   b. 10
   c. 20
   d. 50

2. A study of emergency room visits of children less than 12 years old found that ______ percent of visits due to any medication were due to use of cough-cold products.
   a. less than 1
   b. 3
   c. 6
   d. 9

3. The American Academy of Pediatrics developed a policy statement discouraging the use of ______ in children.
   a. Decongestants
   b. Antihistamines
   c. Antitussives
   d. Analgesics

4. In January 2008, the FDA issued a Public Health Advisory recommending:
   a. Cough-cold products not be used in children under the age of 6 months
   b. Cough-cold products not be used in children under the age of 2 years
   c. Cough-cold products not be used in children under the age of 12
   d. Cough-cold products not be used in children under the age of 18 years

5. Which of the following issues did the FDA Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee consider?
   a. Potential for misuse
   b. Potential for unintentional overdose
   c. Ability of parents to correctly administer cough-cold medicines to their children
   d. All of the above

6. Following the FDA’s PHA, most manufacturers of cough-cold products:
   a. Voluntarily withdrew their products intended for children under the age of 2
   b. Listed the FDA’s recommendation on cough-cold products for all children
   c. Reformulated products with smaller doses
   d. None of the above

7. When measuring cough-cold medicines, the parent should use a household spoon.
   a. True
   b. False

8. Using a cough and cold medication to “make the child sleep” is a good practice.
   a. True
   b. False

9. In the notice for a special public meeting on Oct. 2, 2008, to gather information on scientific, regulatory, and product uses of cough-cold products, the FDA noted that information from its Adverse Event Reporting database indicated that children below what age are more likely to experience nonallergic adverse events than older children?
   a. 2 years of age
   b. 3 years of age
   c. 4 years of age
   d. 5 years of age

10. The Mayo Clinic recommends which of the following to maintain hydration?
    a. Drink plenty of fluids
    b. Use saline drops to thin mucus
    c. Moisten the air through the use of a humidifier
    d. All of the above

11. Which of the following would be acceptable to reduce a fever?
    a. Acetaminophen for an 18-month-old child
    b. Ibuprofen for an 18-month-old child
    c. Aspirin for a 6-year-old child
    d. Ibuprofen for a 3-month-old child

12. Honey should not be given to children:
    a. Under the age of 6 years
    b. Under the age of 2 years
    c. Under the age of 1 year
    d. Honey can be given but only in moderation to avoid excess sugar consumption.

13. Cold viruses thrive in dry air.
    a. True
    b. False

14. A child with which of the following requires medical care?
    a. Rectal temp >100.4 F if less than 3 months old
    b. Fever lasting longer than two days
    c. Is not feeding
    d. All of the above

15. Rather than using OTC cough-cold products, children less than 2 years old should receive an antibiotic for the common cold.
    a. True
    b. False

16. Babies’ nasal passages are easily clogged due to their small size.
    a. True
    b. False

17. To prevent dispersion of minerals, ______ should be used in humidifiers.
    a. Distilled water
    b. Tap water
    c. Medicated inhalant
    d. Soap

18. Steam vaporizers and warm-mist humidifiers:
    a. Allow for the use of medicated inhalants
    b. Work by boiling water and thus do not release bacteria
    c. Are among the least-expensive humidifiers
    d. All of the above

19. When using a medicated inhalant, a ______ of solution is added to each quart of water.
    a. Teaspoon
    b. Tablespoon
    c. Cup
    d. Dropperful

20. The recommended level for indoor humidity is:
    a. 20 percent to 30 percent
    b. 30 percent to 50 percent
    c. 40 percent to 60 percent
    d. 50 percent to 70 percent