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*Pediatrics* 2008;122:e318-e322

DOI: 10.1542/peds.2007-3813

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# Unexpected Infant Deaths Associated With Use of Cough and Cold Medications

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The authors have indicated they have no financial relationships relevant to this article to disclose.

## What's Known on This Subject

OTC CCMs are commonly given to infants despite lack of evidence of their efficacy. The CDC has recommended that these medications not be administered to infants because of safety concerns; however, no study has examined the use of these drugs in infants who died unexpectedly.

## What This Study Adds

This study supports the recommendation that such medications not be given to infants and that these medications may play a role in unexpected infant deaths. Postmortem toxicology studies and interviews of caregivers should be conducted to determine whether OTC CCMs were given to the infant before death.

## ABSTRACT

**OBJECTIVE.** The objective of this study was to determine whether caregivers had given infants who died unexpectedly over-the-counter cough and cold medications before the infant deaths to identify sociodemographic risk factors for their use.

**METHODS.** The Arizona Child Fatality Review Program reviews the circumstances surrounding every child death that occurs in the state each year. By statute, the multidisciplinary review teams have access to all medical charts, autopsy reports, law enforcement reports, and other records for their review and use these data to determine the cause of death and its preventability. The data on all infants who died unexpectedly in 2006 and had an autopsy and postmortem toxicologic studies were reviewed for this analysis.

**RESULTS.** Ten unexpected infant deaths that were associated with cold-medication use were identified. The infants ranged in age from 17 days to 10 months. Postmortem toxicology testing found evidence of recent administration of pseudoephedrine, antihistamine, dextromethorphan, and/or other cold-medication ingredients in these infants. The families who used these medications were poor and publicly insured, and 50% of them had limited English proficiency. Only 4 of these infants had received medical care for their current illness before their death. The over-the-counter cough and cold medication had been prescribed by a clinician for only 1 of these infants.

**CONCLUSIONS.** Review of these infants' deaths raises concern about the role of the over-the-counter cough and cold medications in these deaths. These findings support the recommendation that such medications not be given to infants. In addition, these findings suggest that warnings on these medications "to consult a clinician" before use are not being followed by parents. Educational campaigns to decrease the use of over-the-counter cough and cold medications in infants need to be increased. *Pediatrics* 2008;122:e318–e322

[www.pediatrics.org/cgi/doi/10.1542/peds.2007-3813](http://www.pediatrics.org/cgi/doi/10.1542/peds.2007-3813)

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### Key Words

over-the-counter medications, cough and cold preparations, unexpected infant death, pseudoephedrine, antihistamine, dextromethorphan

### Abbreviations

OTC—over-the-counter  
CCM—cough and cold medication  
FDA—Food and Drug Administration  
ACFRP—Arizona Child Fatality Review Program  
CFR—child fatality review

Accepted for publication Apr 4, 2008

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**O**VER-THE-COUNTER (OTC) COUGH and cold medications (CCMs), which may include antihistamines, decongestants, antitussives, and expectorants, are frequently purchased by parents for their children who have colds, coughs, and upper respiratory conditions. The US Food and Drug Administration (FDA) recently issued a warning that OTC CCMs should not be given to children who are younger than 2 years, and the FDA's Nonprescription Drugs and Pediatric Advisory Committee has recommended that these products not be given to children who are younger than 6 years. These OTC CCMs continue to be used despite the lack of evidence of their efficacy in children.<sup>1,2</sup> Because of the ubiquitous use of OTC CCMs and the lack of information on their use in young infants who have died unexpectedly, we examined the data from the Arizona Child Fatality Review Program (ACFRP) to determine whether unexpected infant deaths are associated with the use of OTC CCMs.

In Arizona, every child death is reviewed by a multidisciplinary team to determine whether the death is preventable.<sup>3</sup> The child fatality review (CFR) teams have access to a wide variety of data that can provide information on the circumstances surrounding each child's death that is provided by first responders, law enforcement, medical examiners, and clinicians. This detailed information may provide greater information on the use of OTC CCMs than is traditionally available from review of medical charts or autopsy reports alone.

## METHODS

The ACFRP reviews the circumstances surrounding every child death that occurs in Arizona annually and prepares an annual report summarizing the findings of this review.<sup>3</sup> The review process begins when a copy of the child's death certificate is sent to a local CFR team that has the authority to request the deceased child's autopsy report, hospital charts, child protective services records, law enforcement reports, and any other relevant documents that may provide insight in the child's death. For children who were younger than 1 year, their birth certificate is also sent to the local CFR team for the review. After reviewing all the documents, the local team completes a standardized child death review case report created by the National Maternal and Child Health Center for Child Death Review that includes extensive information regarding the circumstances surrounding the death. It takes ~1 year from the time of death to complete the review of all deaths, so the annual report is issued in November of the year after a child's death. For this study, the child death review case reports of all previously healthy infants who died unexpectedly in 2006 and had evidence of receiving an OTC CCM were analyzed. An infant was considered to have been administered an OTC CCM when toxicologic studies from the blood, gastric contents, bile, or urine revealed the presence of antihistamines, mucolytics, dextromethorphan, or other ingredients that commonly are included in OTC CCMs. Evidence of antipyretic administration alone was not considered sufficient proof of OTC CCM use, although antipyretics are frequently included in OTC CCMs. Toxicologic testing was done by the Maricopa County Medical Examiner's toxicology laboratory. Preliminary screening of specimens was by enzyme-linked immunoassay, and positive results were confirmed by gas chromatograph-mass spectrometry. Screening included testing for drugs of abuse, including cocaine, fentanyl, opiates, methamphetamine, benzodiazepines, and barbiturates. Qualitative results were followed up with quantitative testing when the pathologist believed that the drug may have been a contributing factor in the infant's death.

## RESULTS

In 2006, there were 90 unexpected infant deaths in Arizona. The causes of death for these infants as determined by the CFR teams are shown in Table 1. The most common cause was sudden infant death syndrome, followed by suffocation and other injuries. The remainder of the deaths were determined to be attributable to natural causes, most often a respiratory tract infection.

TABLE 1 Unexpected Infant Deaths in Arizona, 2006 (N = 90)

Cause of Death	n (%)
Sudden infant death syndrome	28 (31)
Suffocation	23 (25)
Other injury	19 (21)
Respiratory infection	11 (12)
Other infection	3 (3)
Other medical condition	3 (3)
Unknown	3 (3)

The 42 unexpected infant deaths that were determined to be attributable to suffocation or other injury (except poisoning) were excluded from additional analysis. Of the remaining 48 deaths, autopsy and toxicologic information was available for 21 infants. Although the ACFRP recommends that an autopsy and toxicologic studies be done for all unexpected infant deaths, local medical examiners in each of Arizona's 15 counties may choose not to do these studies. This is especially common in rural counties with limited financial resources.

There was evidence of the recent administration of an OTC CCM in 10 of the 21 deaths. Eight of these 10 infants died at home; 1 died in licensed foster care, and another died at a licensed child care center. None of the infants had a history of any chronic illness, although 2 had been exposed to methamphetamine during fetal life. The average gestational age of these infants was 38 weeks. All of the infants were reported to have cough and cold symptoms at the time of their death, but only 4 of the infants had been seen by a clinician for their illness. Only 1 of these infants had been prescribed OTC CCMs. One infant had been prescribed an antibiotic, prednisone, and albuterol; another had been prescribed albuterol; and no medications had been prescribed for the fourth infant who had received medical care. Three of these infants had received care in emergency facilities, and only 1 infant had received care from a primary care provider. There is no evidence in the written records reviewed that any of the families received counseling by their clinician regarding the use of OTC CCMs. The characteristics of these 10 infants are shown in Table 2. Postmortem toxicology revealed evidence of the administration of pseudoephedrine ( $n = 3$ ), antihistamine ( $n = 6$ ), dextromethorphan ( $n = 5$ ), and other cold-medication ingredients ( $n = 4$ ) to these infants. In 5 cases, there was evidence of administration of multiple OTC CCM ingredients to the infant. Medical examiners recorded that the manner of death was natural in 8 of these deaths and undetermined in 2 deaths (cases 3 and 8). In only 1 of these deaths (case 8) did the medical examiner report that the OTC CCMs caused the death. This infant who was reported to have died of poisoning had been given large doses of OTC CCMs that contained dextromethorphan, antihistamines, and atropine for the treatment of an upper respiratory infection. Postmortem analysis of this infant's cardiac blood revealed a dextromethorphan concentration of 0.22 mg/L and a dextromethorphan concentration of 0.10 mg/L in gastric contents.

In the other 9 deaths, the cause of death was listed by the medical examiner as attributed to a respiratory illness ( $n = 6$ ), undetermined ( $n = 1$ ), or sudden infant death syndrome ( $n = 2$ ) without mention of the positive toxicologic results as a significant factor. The CFR teams disagreed with the cause of death noted by the medical examiner in 4 of these deaths. Although medical examiners participate in local CFR teams, because the review is not done until ~6 to 9 months after the death, the CFR teams do not advise the medical examiner on their postmortem examination or the cause and manner of death that they report. Eight of the 10 infants were from minority groups, including 2 children whose parents had recently immigrated to the United States from Africa, 5

**TABLE 2** Characteristics of the Infants

Case	Age	Gender	Race/Ethnicity	Toxicology	Cause of Death	Social Risk Factors	Limited English?	Insurance Status	Consulted Clinician About OTC Medication?
1	17 d	M	Black	Pseudoephedrine 2.14 mg/L (blood), dextromethorphan (blood), brompheniramine (blood)	Pneumonia	Poverty, parents recent immigrants from Africa	Yes	Public	No
2	6 mo	F	White Hispanic	Chlorpheniramine (blood)	Pneumonia	Poverty, unkempt home, 4 children <5 y old, no care since birth, no immunizations	Yes	Public	No
3	10 mo	M	American Indian	Dextromethorphan (blood, bile)	Undetermined	Abandoned at birth, substance-exposed newborn	No	Public	No
4	4 mo	F	White Hispanic	Pseudoephedrine 0.65 mg/L (blood), dextromethorphan (blood), carbinoxamine (blood), atropine (blood)	SIDS	Poverty, no health insurance	Yes	None	Yes
5	2 mo	M	White Hispanic	Ambroxol (blood, gastric), atropine (blood)	SIDS	Poverty, teen parents, immigrant	No	Public	No
6	6 mo	F	Black	Promethazine (urine)	Pneumonitis	Poverty, mother recent immigrant from Africa	Yes	Public	No
7	3 mo	F	White	Pseudoephedrine >2.0 mg/L (blood), dextromethorphan (blood), carbinoxamine (blood), pseudoephedrine (gastric)	Viral pneumonia	Poverty, teen mother, 15 y old, living with grandmother	No	Public	Yes
8	3 mo	F	White	Dextromethorphan 0.22 mg/L (blood), 0.10 mg/L (gastric); diphenhydramine (0.07 mg/L) gastric, also in blood; atropine (blood)	Dextromethorphan poisoning	Poverty, babysitter who was a substance user	No	Public	No
9	6 mo	M	White Hispanic	Chlorpheniramine (blood)	Viral pneumonia	Poverty, methamphetamine use during pregnancy	Yes	Public	Yes
10	5 mo	F	White Hispanic	Ambroxol (blood)	Viral respiratory infection	Poverty	No	Public	No

SIDS indicates sudden infant death syndrome.

Hispanic children, and 1 American Indian. According to the child death case report form and other records, the parents of 5 of these infants had very limited English proficiency. Three of these 5 families were Spanish-speaking only, and 2 spoke only an African dialect.

The child death case report form and other records also revealed that in 9 of the 10 cases, multiple social risk factors were present, including teen parenthood ( $n = 2$ ), substance use ( $n = 3$ ), and poverty ( $n = 10$ ). Nine of the infants were on public insurance programs, and 1 was uninsured at the time of the infant's death. Six of the 10 infants had not been seen by a clinician for their current illness.

## DISCUSSION

OTC CCMs were responsible for >1500 emergency department visits in 2004 and 2005 for children who were younger than 2 years, and poison control centers have reported >750 000 calls of concern related to these medications in the past 7 years. A total of 123 deaths of children younger than 6 years have been reported to the FDA.<sup>2</sup> In January 2007, the Centers for Disease Control

and Prevention reported on the deaths of 3 infants for which OTC CCMs were determined to be the underlying cause.<sup>1</sup> In March 2007, Wingert et al<sup>4</sup> reported on the possible role of OTC CCM in the deaths of 13 infants and 2 toddlers during a 6-year period in which the OTC CCM was listed as either the direct cause of death or a contributory factor. In 2005, Marinetti et al<sup>5</sup> reported on a series of 10 infant deaths in which OTC CCMs were identified by postmortem toxicologic analysis. In the majority of these deaths, the OTC CCM was determined to be the cause of death or a contributing factor. In 2003, Boland et al<sup>6</sup> reported on the death of an infant who had been given an OTC CCM in an infant bottle. One of the infants in our series (case 9) had been given an OTC CCM in an infant bottle.

More than 800 OTC CCMs of varying composition are available in the United States.<sup>7</sup> Common ingredients include antihistamines, decongestants, cough suppressants, expectorants, and/or analgesics. The potential toxicity of an OTC CCM will vary with its composition, the dosage administered, and the age and health status of the infant. None of the infants described in this study had any under-

lying chronic disease; however, all of them had had symptoms of an upper respiratory illness before their death. Three of the infants in this report had been given OTC CCMs that contained pseudoephedrine. All of the infants reported by Wingert et al and the Centers for Disease Control and Prevention had ingested pseudoephedrine.<sup>1,4</sup> Gunn et al<sup>8</sup> reported on the death of a 9-month-old infant who had ingested a pseudoephedrine-containing OTC CCM. Pseudoephedrine is a sympathomimetic agent that can cause hypertension, cardiac dysrhythmias, and seizures. Because therapeutic and toxicologic data on post-mortem concentrations of this drug are limited,<sup>4</sup> it is difficult to determine by toxicologic studies alone whether pseudoephedrine alone or in combination with other drugs was responsible for the deaths of these 3 infants. In the series reported by Wingert et al, the mean level of pseudoephedrine was 3.34 mg/L but ranged from 0.10 to 17.0 mg/L in postmortem cardiac blood. Pseudoephedrine levels ranged from 0.65 to >2 mg/L in the 3 infants in our series.

Six of the 10 infants had been given OTC CCMs that contained antihistamines, including brompheniramine, chlorpheniramine, and carbinoxamine. Antihistamines have similar adverse effects as pseudoephedrine, which could be additive when used with pseudoephedrine.<sup>9</sup> The previously reported adverse effects of antihistamines include central nervous system depression, dysrhythmias including torsades de pointes, seizures, and death.<sup>8,10</sup> One additional infant had been given promethazine, which is a phenothiazine type of antihistamine that is often combined with a cough suppressant. In 2006, the FDA published a health care alert warning that this medication should not be given to children who are younger than 2 years because of the potential for fatal respiratory depression with its use. They noted that 22 children who ranged in age from 1.5 months to 2 years had experienced respiratory depression after the administration of promethazine; 7 of these children died.<sup>11</sup>

Dextromethorphan, an antitussive, is another common ingredient in OTC CCMs that can cause respiratory depression.<sup>12</sup> Two deaths of adults who had dextromethorphan concentrations of 3 to 9  $\mu\text{g/L}$  were previously reported.<sup>13</sup> These levels are far less than the post-mortem blood level of the infant described in this study and support the conclusion that this death was attributable to dextromethorphan intoxication.

Although we cannot definitively prove that OTC CCMs were the cause of these unexpected infant deaths or a contributing factor, none of these infants should have been receiving these medications. The lack of any autopsy findings to explain these deaths raises concerns about the possible role that these medications might have played in their deaths by causing respiratory depression, apnea, and/or cardiac dysrhythmia. Nine of the 10 infants whom we described were younger than 7 months. The relative immaturity of hepatic enzyme systems that metabolize drugs in young children may especially enhance the risk for adverse effects of OTC CCMs in these young infants.<sup>12</sup>

Unfortunately, parents generally consider OTC CCMs to be safe and efficacious; however, 6 randomized, placebo-controlled studies of children showed that these medica-

tions are not better than placebo.<sup>2</sup> Although drug manufacturers claim that all cases of serious injury or death associated with the use of OTC CCMs in children are attributable to overdose, the appropriate dosage of these medications alone or in combination is unknown. Serious adverse effects of OTC CCMs may be the result of accidental or intentional overdose or the result of drug–drug or drug–host interactions in children who have been given the recommended dosage. Because these medications are often given to infants who have respiratory illnesses, the adverse effects of these medications may be increased as a result of the infant’s underlying illness (eg, mild hypoxemia, airway obstruction). There have been previous reports of intentional overdosing of infants with OTC CCMs that resulted in apnea or death.<sup>5,10,14</sup> Parents have admitted giving these medications to induce sleep and sometimes have added it to the infant’s bottle.<sup>6,10,14,15</sup> One of the infants in our series had been given an OTC CCM in an infant bottle.

The parents of 5 of the 10 infants in our study had limited English proficiency that could have resulted in dosing errors and limited access to health information. In addition, 2 of the parents were young teen mothers, who also might be expected to have limited knowledge of appropriate treatment for a child with mild respiratory illness; however, we cannot rule out that some of these infants may have been purposely given more than the recommended dosage to sedate a fussy infant. Allotey et al<sup>15</sup> surveyed parents regarding their use of OTC medications and found that they are often used as “social medication” to reduce undesired behaviors (eg, fussiness, irritability) in a child who is ill. In some cases, parents may also use these medications to mask the infant’s symptoms so that they may continue to attend child care despite their illness. When the desired symptomatic outcome is not achieved, parents may increase the dosage, use >1 pediatric OTC CCM simultaneously, or substitute more potent adult OTC CCMs that parents perceive as stronger.<sup>8</sup>

In 6 of these 10 cases, the parents had not sought medical care for their infant’s illness. In the remaining 4 cases, the parents had sought medical care, but it is unclear whether they had been advised by their clinicians regarding the appropriate use of OTC CCMs to treat their infant’s symptoms. Indeed, in only 1 case was there evidence from an interview with the infant’s mother by law enforcement personnel that the OTC CCM that she had given to her infant was prescribed by a clinician. When OTC CCMs initially were reviewed by an expert advisory panel of the FDA in 1976, the panel recommended against marketing these medications for children who are younger than 2 years because of the “negligible or nonexistent” data on pediatric use; however, the FDA permitted the manufacturers to market these drugs for children below these ages if labeling instructed parents to consult a doctor before use.<sup>2</sup> In October 2007, several drug companies voluntarily recalled OTC CCMs that targeted children who are younger than 2 years.<sup>16</sup> This study shows that although OTC CCMs include explicit instructions and warnings regarding dosage and physician consultation, caregivers may not heed these warnings. Because some manufacturers have reformulated their OTC CCMs that are marketed for toddlers as concen-

trated drops, this may encourage parents to use these formulations in infants. Today, many families do not have access to a medical home and thus are unlikely to be able to seek physician consultation when their child develops cough and cold symptoms. Thus, labels that advise contacting a physician before use are not an effective way to prevent inappropriate use of these medications, especially among poor families with limited access to health care. Furthermore, use of these medications may actually lead to delays in seeking medical care because parents perceive that these medications are safe and effective. It is unknown whether any of the 4 families in our series who sought medical care were advised verbally of the dangers that are associated with the use of these medications.

This study demonstrates the value of using Child Fatality Review Program data to assess the association of OTC CCM use and unexpected infant death but has several limitations. By statute, the ACFRP is not allowed to contact families directly as part of their review and must rely on the records of interviews of families that have been completed by law enforcement, first responders, and child protective services workers for information. Because there was little publicity regarding the risks of OTC CCMs in 2006, interviews of families in 2006 may not have included questioning regarding the use of OTC CCMs. In addition, because autopsy and/or toxicologic data were available for only 21 of the 48 unexpected deaths, the number of unexpected infant deaths that are associated with these drugs may be higher than we have reported. Finally, in many cases, only qualitative toxicologic results were available to the CFR teams, which limits our ability to determine whether the OTC CCMs were the cause of death.

## CONCLUSIONS

Ten unexpected infant deaths that were associated with use of OTC CCMs were identified in a 1-year period through review of ACFRP data. Although only 1 of these deaths was attributed by the local medical examiner to OTC CCMs, the lack of clear evidence of another cause in the other deaths raises concern about the role of OTC CCMs in these deaths because the adverse effects of these medications may result in death from respiratory depression and/or dysrhythmia. These findings support the recommendation that such medications not be given to infants because they may present a serious health hazard and there is no evidence to support the efficacy and safe dosages of these medications in infants; however, because these medications continue to be available for use in older children, clinicians also should take time to advise parents on the dangers of using these medications for young infants and the appropriate, safe treatments for coughs and colds.

The role of OTC CCMs in unexpected infant deaths requires additional study, including routine postmortem toxicologic studies and interviews of caregivers regarding the use of OTC CCMs in all unexpected deaths and any other deaths for which the cause cannot be determined.

Whenever these drugs are identified in postmortem specimens, quantitative results should be reported. Also, first responders should routinely ask caregivers about the use of OTC CCMs and collect OTC CCM bottles or containers as part of their scene investigation. This information should be recorded on unexpected infant death checklists that are completed by first responders. Finally, the National Child Fatality Reporting Form should be modified to include questions regarding the "therapeutic" use of these medications, which would assist us in determining the use of these medications and their role in infant deaths.

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DOI: 10.1542/peds.2007-3813

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