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Adverse Events From Cough and Cold Medications in Children

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What's Known on This Subject

Recent attention has focused on potential harmful effects of children's cough and cold medications. FDA is currently weighing recommendations from its advisory committee to decide whether these medications should continue to be marketed to children less than 6 years.

What This Study Adds

This study adds nationally representative morbidity data about age-specific adverse events from cough and cold medications in children and puts it in the context of all other medications and makes targeted safety recommendations.

ABSTRACT

BACKGROUND. Adverse drug events in children from cough and cold medications have been identified as a public health issue with clinical and policy implications. Nationally representative morbidity data could be useful for targeting age-appropriate safety interventions.

OBJECTIVE. To describe emergency department visits for adverse drug events from cough and cold medications in children.

METHODS. Emergency department visits for adverse drug events attributed to cough and cold medications among children aged <12 years were identified from a nationally representative stratified probability sample of 63 US emergency departments from January 1, 2004, through December 31, 2005.

RESULTS. Annually, an estimated 7091 patients aged <12 years were treated in emergency departments for adverse drug events from cough and cold medications, accounting for 5.7% of emergency department visits for all medications in this age group. Most visits were for children aged 2 to 5 years (64%). Unsupervised ingestions accounted for 66% of estimated emergency department visits, which was significantly higher than unsupervised ingestions of other medications (47%), and most of these ingestions involved children aged 2 to 5 years (77%). Most children did not require admission or extended observation (93%).

CONCLUSIONS. Timely national surveillance data can help target education, enforcement, and engineering strategies for reducing adverse events from cough and cold medications among children. Engineering innovations could be particularly helpful in addressing unsupervised ingestions, which is the most frequent cause of adverse events. These innovations could be applicable to other children's medications.

OVER-THE-COUNTER (OTC) AND prescription cough and cold medications are frequently used to treat upper respiratory symptoms among children.^{1,2} In 2006, pseudoephedrine (a decongestant) and dextromethorphan (an antitussive) ranked among the top medications taken by children aged <12 years in the United States, and upper respiratory infections were the most commonly reported reason for medication use in children.² Although these medications have been used for decades, debate continues over their safety in children.^{3,4}

Recently, attention has focused on the potential harmful effects of these medications.⁴ Because of reports of unintentional overdoses of cough and cold medications and links between these medications and infant deaths,^{5,6} a number of national pediatric experts petitioned the US Food and Drug Administration (FDA) to advise that these medications not be used in children aged <6 years.⁶ The FDA's Nonprescription Drugs Committee and Pediatric Advisory Committee have since unanimously recommended that these agents not be used in children aged <2 years and by majority vote that they not be used in children aged <6 years based on lack of evidence of effectiveness and increased risk of harm.^{4,7} The Consumer Healthcare Products Association, which represents manufacturers of OTC medications, has issued a

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the funding agency. Dr Shehab had full access to the data and is responsible for the analysis.

Key Words

adverse events, drug safety, poisoning, medication errors, drug packaging, nasal decongestants, expectorants, antitussives, non-prescription drugs

Abbreviations

OTC—over-the-counter
 FDA—Food and Drug Administration
 ED—emergency department
 ADE—adverse drug event
 NEISS-CADES—National Electronic Injury Surveillance System—Cooperative Adverse Drug Event Surveillance
 CI—confidence interval

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voluntary market recall of OTC cough and cold medications labeled for use in infants but has also issued a position statement that cautioned against the recommendation to make cough and cold medications unavailable to children aged 2 to 6 years.⁸ The FDA has not yet ruled on these issues.

Despite this widespread attention, the role of these medications in adverse events among children has not been described in the context of other medications. Questions remain regarding the relative contribution of adverse effects from recommended use, unsupervised ingestions, and inadvertent overdoses, as well as the relative burden of adverse events according to age. We used nationally representative public health surveillance data to describe emergency department (ED) visits for adverse drug events (ADEs) attributable to cough and cold medications ingested by children and discuss the implications of our findings for safety interventions.

METHODS

National estimates of ED visits for ADEs attributed to cough and cold medications are based on data from the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance (NEISS-CADES) project, a nationally stratified probability sample of 63 hospitals in the United States and its territories with a minimum of 6 beds and a 24-hour ED; NEISS-CADES has been described in detail.^{9,10} All hospitals treat pediatric patients, and 5 exclusively treat children. Trained coders at each hospital review clinical records of ED visits to identify physician-diagnosed ADEs, report up to 2 medications implicated, and record narrative descriptions of the incident.

An ADE was defined as an incident ED visit by a patient aged <12 years from January 1, 2004, through December 31, 2005, for a condition that the treating physician explicitly attributed to the use of cough and cold medication. Cough and cold medications were defined as oral prescription or OTC products that contained decongestants, expectorants, or decongestant, antihistamine, antitussive, and/or expectorant combinations. ED visits were excluded if they were attributed to drug abuse or harmful intent or if the ADE occurred during the ED visit.

Each NEISS-CADES visit was assigned a sample weight based on the inverse probability of selection and was adjusted for nonresponse and population changes. National estimates of ED visits and corresponding 95% confidence intervals (CIs) were calculated by using the “surveymeans” procedure in SAS 9.1 (SAS Institute, Inc, Cary, NC) to account for weighting and complex sample design. Frequency estimates and CIs were divided by 2 to obtain annual estimates. National estimates based on <20 cases or with a coefficient of variation of >30% were considered statistically unstable. Therefore, some age-stratified analyses were based on the number of cases rather than national estimates.

RESULTS

National Estimates

Annually, an estimated 7091 children aged <12 years visit EDs for ADEs from cough and cold medications, accounting for 5.7% of ED visits from all medications in this age group (Table 1). Most ED visits (64%) attributed to cough and cold medications involved children aged 2 to 5 years. Boys accounted for slightly more ED visits (55%) than girls.

Unsupervised ingestions of cough and cold medications caused two thirds of the estimated ED visits, a significantly higher proportion than for other medications (66% vs 47%, respectively) (Table 1). Unsupervised ingestions were most common among children aged 2 to 5 years and caused an estimated 3495 ED visits, 77% (95% CI: 69%–85%) of the ED visits in this age group and 49% (95% CI: 40%–59%) of the ED visits among all children.

Supervised administrations of cough and cold medications caused one third of the estimated ED visits (Table 1). ED visits in which a caregiver administered medication appropriately but an undesired reaction (eg, allergic reaction) occurred were less commonly caused by cough and cold medications than other medications (26% vs 51%, respectively). A significantly higher proportion of ED visits that resulted from cough and cold medications involved medication errors (eg, administering an excessive dose) compared with ED visits from all other medications combined (8% vs 1%, respectively).

No ADE-related symptoms were documented at ED evaluation in 63% (95% CI: 55%–72%) of the estimated visits attributed to cough and cold medications. Of those who were symptomatic, 19% (95% CI: 11%–27%) had allergic symptoms (eg, rash, urticaria), and 13% (95% CI: 7%–18%) had neurologic symptoms (eg, somnolence, unsteady gait).

Almost all of the children (93%) were treated and released from the ED (Table 1), but nearly one fourth (23% [95% CI: 15%–30%]) underwent gastric decontamination. In 93% (95% CI: 89%–97%) of the ED visits, attributed to these medications were the only agents implicated in the ADE.

Case-Based Analysis

Among ED cases that involved children aged <2 years, an equal number were from unsupervised and supervised ingestions (Table 2). Of unsupervised ingestions in this age group, almost all (30 of 33 cases) involved children aged ≥12 months. Children aged <2 years accounted for half (12 of 24 cases) of all cold and cough medication errors that led to ED cases. Of these visits attributable to medication errors, almost half (5 of 12 cases) involved excessive dosing by caregivers (Table 3).

Among ED visits that involved children aged 2 to 5 years, most (155 of 199 cases) involved unsupervised ingestions (Table 2); among children aged 6 to 11 years, most visits (20 of 36 cases) were from supervised administrations without a documented medication error.

Of cases that required admission or extended observation, most (25 of 31 cases) were from unsupervised

TABLE 1 Number of Cases and Annual Estimates of ADEs Among Children Aged <12 Years Treated in EDs According to Case Characteristics: United States, 2004–2005

Case Characteristics	ED Visits Attributed to Cough and Cold Medications				ED Visits Attributed to Other Medications			
	Cases, <i>n</i>	National Estimate			Cases, <i>n</i> ^a	National Estimate		
		<i>n</i>	%	95% CI		<i>n</i>	%	95% CI
Age, y								
<2	66	1609	22.7	15.2–30.2	2026	46 977	40.4	37.2–43.5
2–5	199	4541	64.0	56.0–72.0	2160	50 082	43.0	40.0–46.1
6–11	36	942	13.3	6.8–19.8	827	19 308	16.6	14.8–18.4
Gender								
Female	145	3215	45.3	38.1–52.5	2313	53 396	45.9	43.6–48.1
Male	156	3877	54.7	47.5–61.9	2699	62 930	54.1	51.8–56.4
Type of ingestion ^b								
Unsupervised ingestion	200	4674	65.9	55.8–76.1	2351	55 202	47.4	40.6–54.2
Supervised administration without documented medication error	77	1836	25.9	17.2–34.6	2589	59 855	51.4	44.7–58.2
Supervised administration with documented error	24	582	8.2	4.1–12.3	73	1311	1.1	0.7–1.5
Disposition								
Admitted, observed, or transferred	31	491 ^c	6.9 ^c	2.1–11.7	687	12 304	10.6	7.2–13.9
Treated and released or left against medical advice	270	6601	93.1	88.3–97.9	4325	104 058	89.4	86.1–92.8
Total	301	7091	NA	NA	5013	116 366	NA	NA

Case counts and estimates are from the 2004–2005 NEISS-CADES project, Centers for Disease Control and Prevention. “Cough and cold medications” refers to oral prescription or OTC drug products that contain decongestant, antihistamine, antitussive, and/or expectorant combinations, as well as single-ingredient decongestants and expectorants. “All other medications” refers to all prescription or OTC medications including vitamins, vaccines, and herbal/dietary supplements that are not cough and cold medications. NA, not applicable.

^a Gender and disposition were unknown for 1 case.

^b “Unsupervised ingestions” refers to cases in which children accessed the medications without adult permission or oversight; “supervised administration” refers to cases in which the medication was administered by a caregiver; and “medication errors” refers to errors made during the prescribing, dispensing, or administration of the medication. Medication errors that involved cough and cold medications are described further in Table 3.

^c Estimates with a coefficient of variation of >30%.

ingestions, and most (21 of 31 cases) involved children aged 2 to 5 years.

DISCUSSION

Between 2004 and 2005, two thirds of the estimated ED visits for ADEs attributable to cough and cold medications resulted from children accessing these medications without adult supervision, a significantly higher proportion than for ADEs attributable to all other medications combined. As expected, children aged 2 to 5 years accounted for the most unsupervised ingestions. One fourth of the estimated ED visits were a result of adverse

effects unrelated to medication error. Medication errors were more common among cough and cold medications than other medications, and most errors occurred in children aged <2 years, for whom OTC cough and cold medication labels did not specify dosages but, instead, directed caregivers to consult a pediatrician.

Important advances have been made in protecting

TABLE 3 Number of Cases of ADEs That Involved Medication Errors and Cough and Cold Medications Among Children Aged <12 Years According to Type of Error and Patient Age: United States, 2004–2005

Type of Error	No. of Cases		
	Age <2 y	Ages 2–5 y	Ages 6–11 y
Excess dose administered	5	2	2
Wrong medication administered	2	2	0
Confused units of measure	0	4	0
>1 medication with same active ingredient administered	2	0	0
Wrong formulation administered	2	0	0
Other errors ^a	1	0	2
Total	12	8	4

Case counts are from NEISS-CADES 2004–2005, Centers for Disease Control and Prevention. “Cough and cold medications” refers to oral prescription or OTC drug products that contain decongestant, antihistamine, antitussive, and/or expectorant combinations, as well as single-ingredient decongestants and expectorants.

^a “Other errors” include intentional administration of a sibling’s medication (1 case), wrong route of medication administration (1 case), and administration of an expired medication (1 case).

TABLE 2 Number of Cases of ADEs From Cough and Cold Medications Treated in EDs Among Children Aged <12 Years According to Exposure Type and Patient Age: United States, 2004–2005

Patient Age, y	Unsupervised Ingestion		Supervised Administration			
	Cases, <i>n</i>	%	No Medication Error Documented		Medication Error Documented	
			Cases, <i>n</i>	%	Cases, <i>n</i>	%
<2	33	50.0	21	31.8	12	18.2
2–5	155	77.9	36	18.1	8	4.0
6–11	12	33.3	20	55.6	4	11.0

Case counts are from NEISS-CADES 2004–2005, Centers for Disease Control and Prevention. “Cough and cold medications” refers to oral prescription or OTC drug products that contain decongestant, antihistamine, antitussive, and/or expectorant combinations, as well as single-ingredient decongestants and expectorants.

children from medication injuries by using a combination of education, engineering, and enforcement strategies. Educating caregivers to keep all medications locked away from children, to refrain from telling children that medication is candy, and to avoid taking their own medications in front of children has been a cornerstone of prevention efforts.¹¹ The engineering innovation of child-resistant packaging has resulted in an estimated 45% reduction in mortality in children from medication ingestions.¹² The FDA's enforcement activities have helped to ensure the safety of cough and cold medications (eg, restricting access to phenylpropanolamine and codeine).^{4,13} The timely national surveillance data we report here can help target age-specific education, engineering, and enforcement measures to prevent injury from cough and cold medications.

Infants and toddlers (aged <2 years) accounted for most medication errors that resulted in ADEs. The voluntary recall of cough and cold products that have been marketed for this age group should reduce adverse events. However, to discourage caregivers from substituting products that are not labeled for infant use, reeducation efforts for clinicians and caregivers on appropriate, nonpharmacologic therapies to treat cough and cold symptoms are needed.

Preschool-aged children (2–5 years) accounted for most ADEs. Nearly 80% of these cases were from unsupervised ingestions, and only 18% were from supervised ingestions without a medication error. Removing OTC cough and cold products that are marketed for this age group could reduce the number of adverse events. However, if these medications are removed from the market, caregivers may be tempted to substitute products that are labeled for use by older children and adults, as even after the recall of products for children aged <2 years, 64% of parents responding to a national survey still considered these medications very safe or somewhat safe and 20% plan to continue to use OTC cough and cold medication for their children <2 years.¹⁴ Thus, if products marketed to young children are made unavailable, some children will likely continue to find and ingest these products.

Another approach is to introduce engineering innovations designed to minimize unsupervised ingestions of cough and cold medications for children. One packaging innovation is incorporating adaptors onto bottles of liquid medication such that medication can only be accessed with a needle-less syringe, which prevents unsupervised preschool-aged children from drinking directly from the bottle. Clearly labeling this syringe could help reduce dosing errors. Expanded use of child-resistant unit-dose packaging, which is not routinely used for cough and cold medications, could also reduce dosing errors and unsupervised ingestions. Additional innovations could target formulation modifications. For example, removing coloring from cough and cold medications might reduce unsupervised ingestions, because the colors can make the medications appear similar to flavored drinks or candy.

Among older children (6–11 years), ED visits that result from cough and cold medications are less com-

mon. Most ADEs were from supervised ingestions without medication errors. Expanding educational efforts on appropriate indications for these medications could be the most effective prevention strategy for this age group.

Adverse-event surveillance has several limitations that likely result in underestimating the burden of ADEs attributable to cough and cold medications ingested by children. This system does not identify ADEs that result in calls to poison control centers, visits to outpatient offices, or deaths. However, the ED is probably the best single setting to use when trying to identify severe ADEs, because it is the most likely location to which children with serious symptoms will be brought for treatment. The system relies on the assessment and documentation of ED physicians. Thus, it is more likely to identify well-recognized adverse events (eg, unintentional ingestions) and less likely to identify newly recognized effects or effects that are difficult to attribute to medications. Also, ADEs are not classified on the basis of the individual active ingredients of the ingested cough and cold medication. Therefore, inferences cannot be made about the contribution of a specific ingredient to the ADEs.

Policy decisions should not be based solely on morbidity data but also should include considerations of mortality, quality of life, and an overall assessment of risks and benefits, which are beyond the scope of NEISS-CADES data. A number of national pediatric experts have cited lack of evidence demonstrating the efficacy of cough and cold medication in children, and some have called for the removal of these products pending additional pediatric studies.¹⁵ Manufacturers have stated that they will continue to market these products for children but would work with FDA to design efficacy studies.⁸ As long as these products continue to be marketed for use in children, additional safety interventions should address the primary cause of injuries from these products: unsupervised ingestions which are a particular safety concern in 2- to 5-year olds. Although cough and cold medications represent a small proportion of all ED visits for ADEs among pediatric patients, focus on these medications highlights how targeted strategies, particularly packaging innovations, could reduce pediatric ADEs from other medications.

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PRE-CHEWED BABY FOOD SAID TO TRANSMIT HIV

“Boston—Researchers have identified another way that babies can be infected with HIV—through food pre-chewed by an infected parent or caretaker. Although thousands of babies have been infected in the United States over the last 15 years, pre-chewed food has been documented as the cause of just three cases, federal epidemiologists said here Wednesday. But such transmission may not be so rare, Dr Kenneth L. Dominguez's team from the Centers for Disease Control and Prevention said at the 15th Conference on Retroviruses and Opportunistic Infections. Pre-chewing food apparently occurs among many groups in this country and elsewhere. So transmission of HIV, the AIDS virus, to infants may be an unrecognized problem in developing countries where dental care is lacking, commercially prepared baby foods and blenders are not available and parents and caretakers may need to soften foods, Dr Dominguez said in an interview. Researchers will try to determine whether other dangerous microbes like hepatitis B virus and *Helicobacter pylori* might be transmitted through pre-chewed food.”

Altman LK. *New York Times*. February 7, 2008

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