

Physician and Parent Response to the FDA Advisory About Use of Over-the-Counter Cough and Cold Medications

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Objective.—The aim of this study was to assess the likely impact of the US Food and Drug Administration (FDA) advisory not to use over-the-counter (OTC) cough and cold products for children aged <2 years on care provided by pediatricians and parents.

Methods.—A mailed survey was completed by 105 community pediatricians (53% response rate), and 1265 parents with children aged <12 years completed a self-administered survey while waiting for an office visit.

Results.—All physicians were aware of the advisory; 75% agreed with it. Fifty-nine percent did not recommend OTC cough and cold products for children aged <2 years before the advisory, and 35% were less likely to do so afterward. Seventy-three percent of parents were aware of the advisory, 70% believed these products relieved symptoms, 68% did not believe they were dangerous, and 74% had them at home. After the advisory, 21%

of parents were more likely to request an antibiotic from the doctor. Among the parents, 225 only had children aged <2 years and 695 only had children aged 2 to 11 years; of these parental groups, 53% and 10% of parents, respectively, did not use these products before the advisory, an additional 33% and 28%, respectively, were less likely to do so afterward, and 15% and 61%, respectively, would continue use them.

Conclusions.—Pediatricians must be prepared for requests from parents for antibiotics and other remedies for symptom relief for their children with colds. As no effective alternatives are available, maybe nontreatment should be promoted.

KEY WORDS: over-the-counter medications; upper respiratory infections

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The potential for adverse effects in children from commonly used over-the-counter (OTC) cough and cold medications (including decongestants, antihistamines, and cough expectorants and suppressants) has concerned many pediatricians for years.^{1–4} In March 2007, the cumulative morbidity and mortality associated with use of these drugs prompted a group of pediatric experts to petition the US Food and Drug Administration (FDA) to advise that these medications not be used by children aged <6 years.¹ During the FDA review process, many pharmaceutical manufacturers voluntarily withdrew OTC cough and cold products that were being sold for infants and children aged <2 years.³ In January 2008, the FDA issued a nationwide Public Health Advisory “recommending that over-the-counter cough and cold medicines not be used to treat infants and children less than 2 years of age because serious and potentially life-threatening side effects can occur.”⁵ For older children, the FDA recommends that parents and caregivers “understand that

these products are just for symptom relief, and will not treat the cause of the symptoms or shorten illness duration.”⁶

Our objective was to assess the likely impact of the FDA advisory and warnings on parent and pediatrician attitudes toward and use of these products.

METHODS

We developed and implemented 2 surveys: 1 of community pediatricians and 1 of parents. As no standardized tools were available, both surveys were developed by the authors. Survey items were based on the literature and the author’s experience in primary care, and were refined after pilot testing. The reading level of the parent questionnaire was 6.4.⁶ Each survey took about 5 minutes to complete. The study was approved by Washington University Human Research Protection Office.

Physician Survey

Eligible physician subjects were community pediatricians affiliated with St. Louis Children’s Hospital. All these physicians were mailed a written invitation to participate in the survey, together with the 27-item self-administered questionnaire. As the questionnaire was anonymous, physicians indicated their participation (yes or no) by returning a postcard separate from the questionnaire. Up to 2 additional mailings were sent to those who did not return the postcard.⁷

Questions assessed the physician’s usual practice regarding recommending OTC cough and cold products,

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their knowledge of and agreement with the FDA advisory, and its likely impact on future patient care. In addition, physicians selected from a list of anticipated barriers to implementation of the advisory and provided demographic information.

Parent Survey

All pediatricians who received the physician survey were asked if they would allow an on-site research assistant (RA) to recruit subjects for the parent survey. At sites who agreed, parents who brought their child for an office visit were approached by the RA in the waiting room and invited to “complete a brief survey about OTC cough and cold medicines.” At each site, the majority of potentially eligible parents were approached during the time the RA was on site. Parents were not approached if they were immediately called to see the physician or if the RA was already busy with another parent. Unaccompanied minors or grandparents were not approached. Subjects completed the anonymous, 30-item, self-administered paper survey prior to seeing the physician. Parents were excluded from the study if they did not have at least 1 child who was aged < 12 years.

Questions assessed parents’ attitudes toward and behaviors regarding use of OTC cough and cold products, their knowledge of the FDA advisory, and its likely impact on the care they would provide for their children with an upper respiratory infection (URI). In addition, demographic data were recorded.

For both the physician and parent surveys, respondents used a 5-point categorical scale to report their agreement with attitudinal statements about characteristics of OTC cough and cold medications (“strongly disagree,” “disagree,” “neither disagree or agree” [unsure], “agree,” “strongly agree”). Respondents used a 4-point scale to indicate their likely future behaviors regarding use of these and other products for symptom relief following the advisory (“no change, do not do this;” “no change, usually do this;” “more likely to do this;” “less likely to do this”).

Statistical Analysis

For both populations, continuous variables are reported as mean (SD) or median (range), and categorical data as proportions. Responses of “agree” and “strongly agree” and “disagree” and “strongly disagree” were combined and reported as “agreed” and “disagreed,” respectively. We conducted subgroup analyses to compare responses from parents with children in different age groups (aged < 2 years, and aged 2–11 years). For clarity, parents with children in both age groups were excluded from these subgroup analyses; generally, their responses were the same as those from parents of older children. Other subgroup analyses used the whole study population to explore if race (black vs other), insurance (Medicaid vs other), parent education (college graduate vs other), and family structure (single parent vs other) were associated with an increased likelihood to request an antibiotic or symptomatic treatment following the advisory (sum of “would continue to do so” and “more likely to do so”). For these analyses, differences in the

univariable analyses were compared using the chi-square test. Logistic regression was used for the multivariable analyses. A probability of $P < .05$ (2-tailed) was used to establish statistical significance. All statistical analyses were done using Stata 9.0 (StataCorp College Station, Tex).

RESULTS

Physician Survey

Study Population

Between March 24, 2008, and May 1, 2008, physician surveys were mailed to 197 community pediatricians from 88 practices; 105 (53%) pediatricians completed the survey (Table 1). Participants were similar with respect to gender, practice type, and practice location to those who returned a postcard to indicate they would not participate.

Advice About OTC Cough and Cold Products

These pediatricians stated that they were commonly asked for and provided advice about the use of OTC cough and cold products. Of the last 10 children diagnosed with a URI, on average 6.8 parents requested advice about these products (SD = 2.7), and physicians provided advice for 7.9 parents (SD = 2.6).

Respondents selected 1 of 3 statements to best represent their usual advice to parents about the use of OTC cough and cold medicines for children aged < 2 years: “OTC cough and cold medicines may make your child more comfortable” (selected by 6%); “I don’t recommend

Table 1. Characteristics of Survey Participants*

Characteristic	No. (%)
Physician Survey (n = 105)	
Male gender	47 (45)
Age, mean (SD), y	47 (11)
Years in practice, mean (SD), y	16 (11)
Type of practice	
Solo practice	11 (11)
2-physician practice	16 (15)
Group practice	60 (57)
Multispecialty group	14 (13)
Practice location	
Urban, inner city	8 (8)
Urban, not inner city	13 (12)
Suburban	79 (75)
Rural	4 (4)
Parent Survey (n = 1265)	
Parent education	
High school or less	240 (19)
At least some college	425 (34)
College graduate	366 (29)
Postgraduate or professional degree	218 (17)
Single-parent family	217 (17)
Age groups	
Only has children aged < 2 years	225 (18)
Only has children aged 2–11 years	695 (55)
Has children from both age groups	345 (27)
Child has Medicaid insurance	235 (19)
Child is African American	228 (18)

*Values are expressed as numbers. (%) unless otherwise indicated.
SD = standard deviation.

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