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Misunderstanding and Potential Unintended Misuse of Acetaminophen among Adolescents and Young Adults

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Abstract

Purpose—Acetaminophen is highly accessible yet potentially dangerous when used incorrectly. In attempts to address concerns about acetaminophen, The U.S. Food and Drug Administration (FDA) has identified gaps in evidence about unintentional misuse among adolescents. Therefore, our objectives were to assess: adolescents': 1) health literacy; 2) knowledge about acetaminophen; 3) recent use of over-the-counter (OTC) medicines; 4) and use of medication dosing instructions to understand the medicine and how to use it ('acetaminophen skills').

Methods—*Subjects and Setting:* We conducted a cross-sectional survey of adolescents and young adults (ages 16–23 years) recruited from education settings and health care sites in Monroe County, New York, from 11/08–9/09. *Measures:* Using structured in-person interviews, we assessed acetaminophen knowledge and recent use of over-the-counter (OTC) medicines. We assessed participants' ability to identify acetaminophen in OTC products and answer questions

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about instructions for acetaminophen use through role-plays of everyday health scenarios. We measured health literacy with the Rapid Estimate of Adult Literacy in Medicine (REALM) for participants >18, and the REALM-Teen for those <18.

Results—Confusion about acetaminophen and its use was common. Limited health literacy was an independent risk factor for poor knowledge, misunderstanding, and potential unsafe use of acetaminophen-containing medicines, however, most participants at all health literacy levels erred dangerously in ‘unsafe’ understanding of acetaminophen use from label instructions.

Conclusions—Individuals with limited health literacy may face disproportionate risk of unsafe use of acetaminophen due to confusion and misunderstanding of label information. Better labeling, public health programs, and educational efforts could facilitate safer use of acetaminophen.

Keywords

Health literacy; patient safety; adolescent medicine use; adolescents; young adults; acetaminophen knowledge; acetaminophen safety; OTC or over the counter medicines; safe use of medicines; acetaminophen risk; FDA Safe Use Initiative

Introduction

Medication errors in ambulatory care have received increasing attention as patients assume a greater role in self-administering their medicines. According to the 2006 Institute of Medicine (IOM) report, *Preventing Medication Error*, approximately one third of the annual 1.5 million preventable adverse drug events occur in outpatient settings, at a conservative cost to the healthcare system of \$1 billion annually.(1) Health literacy investigations have found that misunderstanding of dosing instructions on prescription drug labels is common. This misunderstanding has been cited as a leading root cause of known outpatient medication errors and adverse events.(2–6)

Far less is known about the prevalence and root causes of patient misunderstanding of non-prescription, or ‘over-the-counter’ (OTC) medication label instructions, yet the frequency of OTC medicine use may eclipse that of prescription medicines. According to the National Council on Patient Information and Education, 59% of Americans reported having taken an OTC drug in the last six months, which is slightly more than those reporting use of a prescription medicine (54%).(7) However, unlike prescription medications, no guidance or intervention from a physician or pharmacist is provided for OTC medications unless the patient requests assistance. The potential for error and adverse events could therefore be far greater than with prescription drugs.

Use of OTC medicines is similarly common among adolescents; with 78% of adolescents in one study reporting use of OTC medicines within the past month.(8) Self-administration of OTC medicines among adolescents can begin by ages 11–12 years, increasing markedly with each grade-level from grades seven to nine.(9) Adolescents’ self-administration of OTC medicines *for pain* is common, with half to ¾ of junior high students (7th thru 9th grades) in a Canadian study reporting that they used OTC medication for pain relief without first

checking with an adult.(9) Furthermore, checking with an adult does not ensure safety; misinterpretation of OTC labels is also common among parents.(10)

Evidence suggests that the use of certain OTC drugs is causing significant harm. Studies have shown that consumers may misuse acetaminophen, a common ingredient in OTC analgesics as well as prescription products. Acetaminophen overdose has surpassed viral hepatitis as the leading cause of acute liver failure in the United States,(11–13) and may cause more deaths by overdose each year than any other pharmaceutical product.(14) Moreover, one half to two-thirds of overdoses that have led to acute liver failure are unintentional, suggesting the root cause may be poor understanding of medication labeling or failure to recognize the consequences of exceeding the recommended maximum daily dosage.(11–13) To address the growing concern of acetaminophen misuse, in June 2009 the U.S. Food and Drug Administration (FDA) convened a panel to discuss the maximum dose recommendations of acetaminophen found in non-prescription medications. The panel identified notable gaps in evidence about consumer understanding and use of OTC acetaminophen products in general, and about unintentional misuse among adolescents specifically.

Misunderstanding of acetaminophen toxicity may also be more common among adolescents than among adults. One study of over 1,000 British and American teens found that teens may markedly overestimate the size of a lethal dose of acetaminophen,(15) while others have found that teens may not comprehend that it is possible to ingest a lethal amount of acetaminophen.(16–18) Motivated by the potential risks of acetaminophen and evidence that adolescents may commonly self-administer pain medicines without parental oversight, we examined understanding of acetaminophen among a sample of adolescents and young adults. Individuals in this age range can access OTC medicines without adult supervision, yet may still be developing their health skills, including early perceptions and understanding of how to safely use non-prescription products.

Patients and Methods

Participants and Procedure

We recruited 266 youth (16–23 yrs) for in-person interviews from 4 education and 2 health care sites in Monroe County, NY from November 2008 to September 2009. Education sites included an urban public high school, a vocational training center, graduate –equivalency (GED) programs, and a community college. Health care sites included a teen clinic and a hospital-based ambulatory clinic. Collectively, these sites are representative of 16–23 year-olds from urban, suburban, and rural areas and a range of socioeconomic levels.

Across the performance sites, we used a combination of consecutive subject recruitment and promotional study flyer postings. Consistent with privacy policies, potential participants were identified by others (i.e.: health care staff or teachers) and referred to the on-site interviewer during a rotating schedule of clinic sessions or classroom sessions. We used a rotating rather than a fixed schedule to vary days of the week and times of day and better distribute recruitment across a representative range of clinic and/or classroom sessions. We also posted English-language flyers in common areas (i.e.: waiting room, student gathering

areas), inviting youth to self-identify to the on-site interviewer to participate in a study about how adolescents and young adults understand health information and what they find confusing. We used quota sampling strategies, based on local demographic data, to distribute our sample across age and gender categories and setting, with preset quotas by age, gender, and site (health care versus education). The interviewers completed eligibility screening (for age and ability to speak English) and obtained verbal informed consent. We conducted this minimal-risk study with a waiver of documentation of consent and a waiver of Health Insurance Portability and Accountability Act (HIPAA) authorization, thus no parental consent was required and study participation was completely anonymous (neither individual identifiers nor personal health information were collected, however, because some of our recruitment took place in health care settings, a HIPAA authorization was required). This approach was essential to preserve the confidentiality of medical visits made by participants who were recruited at health care sites. Participants received a free movie ticket upon completion of the interview. The study was approved by the Institutional Review Board of the University of Rochester and appropriate review boards at each participating site.

Measures

Interviews took between 30 and 45 minutes, beginning with health literacy assessment. Participants were given as much time as they needed to complete the interview at a comfortable pace. We used structured in-person interviews to measure demographic characteristics and to assess recent use of OTC medicines and acetaminophen knowledge. We provided participants with seven OTC package props and asked them to: 1) identify the active ingredient in Tylenol™; 2) demonstrate understanding of Tylenol™ dosing instructions; and 3) distinguish acetaminophen containing products from non-containing products. We measured health literacy using the Rapid Estimate of Adult Literacy in Medicine (REALM) for participants > 18 and the REALM-Teen for those < 18. The REALM is the most commonly used test of patient literacy in medical settings.(19) Health literacy is categorized as “limited” or “adequate”.(20) We asked respondents to self-define their race and ethnicity per the following: “Which one of the following best describes your race?” (Black, White, Asian/Pacific Islander, or Other) and “Are you Hispanic or Latino?”

Recent use of OTC medicines—Before asking about any specific medicines, we asked about participants' use of OTC medicines within the past month (Within the past month, have you taken any over-the-counter medicines?; What medicine(s) did you take?; How long ago did you last use an over-the-counter medicine?). From this list, we measured acetaminophen use by comparing the self-reported list of OTC medicines used in the last month to the list of active ingredients found on the products' manufacturers' websites. If detail was insufficient to distinguish between an acetaminophen-containing and non-containing version of the same medicine, we considered the medicine to be acetaminophen-free.

Acetaminophen knowledge and understanding of labeling information—We assessed respondents' familiarity with acetaminophen, ability to recognize acetaminophen-containing products, and understanding of label information on a package of Tylenol™. We first asked whether respondents had ever heard of acetaminophen. We then handed the

participant a set of five OTC medicine packages, including TylenolTM and assessed whether they could identify the active ingredient based on the package label information (some products contained acetaminophen; others did not). We assessed participants' understanding of TylenolTM dosing instructions using a previously-validated set of questions about the label information, including: 1) How many pills are in one dose?; 2) How many doses of TylenolTM could be taken during the course of one day?; and 3) If you took the highest dose of TylenolTM you should take in one day, starting at 8 AM, what time would you take each dose and how many pills would you take each time? (the interviewer used prompts to walk the participant through the sequence from 'first' to 'next' and so on). Responses were categorized as 'correct' if they matched the instructions provided on the package (i.e. two pills per dose, four doses per day, four, five or six hours between doses and eight pills in 24 hours), 'over' if the sum of responses was larger, and 'under' if the sum of responses was smaller. We created categories to represent 'don't know' (if the respondent said 'don't know' or did not give an answer) and 'inappropriate' to categorize responses that did not answer the question (for example, a response of "500 mg" to a question about number of pills would be coded 'inappropriate'). Following the TylenolTM-specific questions, we presented packages for seven common OTC medicines (TylenolTM, BayerTM, MotrinTM, SudafedTM PE Sinus Headache, DayQuilTM, SudafedTM Nasal Decongestant (pseudoephedrine HCl), and SudafedTM PE Cold/Cough) and asked participants: 1) whether any of them contained acetaminophen; and 2) (if yes) which ones [contained acetaminophen].

We created additional variables for use in multivariate analyses. We created the dichotomous variable "safe" (or unsafe) by combining the: a) number of pills in one dose, b) number of doses in one day and c) interval between hypothetical doses, to represent performance on dosing tasks as a whole. We coded this variable as 'unsafe' if at least one of the measures was incorrect and placed the participant at risk of overdosing. Examples of 'unsafe' responses include: >2 pills per dose, >4 doses per day, intervals shorter than 4 hours between doses, or 'don't know' or 'inappropriate' responses to any of the three prompts. In contrast, we coded responses as 'safe' if the participant indicated that they would take: 2 pills per dose, 4 doses per day, at intervals of 4 hours between doses. We also created the dichotomous variable "over" (or under) to represent potential overdose. From the four levels of maximum daily dose, we combined: 1) 'don't know' with 'over'; and 2) 'under' with 'correct' to distinguish maximum daily doses that could exceed safe limits within 24 hours from those that were within or below safe limits.

Analyses

We used Chi-square tests to bivariate associations between: 1) health literacy level (limited, adequate) and the sociodemographic and OTC use variables (Table 1); and between health literacy and the measures of acetaminophen knowledge and dosing skills (Table 2).

We generated multivariate models to assess the associations of health literacy, sociodemographic characteristics and prior OTC use with 1) failure to identify acetaminophen as the active ingredient in TylenolTM, 2) unsafely completing dosing tasks and 3) exceeding the maximum dose in 24 hours. We did not use logistic regression because each of these outcome variables had a high percentage of responses in one category (either

most ‘yes’ or most ‘no’), and estimated odds ratios from logistic regression could overestimate the associations. Instead, we used generalized linear models with a Poisson distribution and log link function with robust variance estimates to estimate prevalence ratios with 95% confidence intervals.(21, 22) We used STATA SE Version 10.1 for all analyses. (23)

Results

We interviewed 266 respondents. Over half were female (56.4%). Slightly less than half identified themselves as non-Hispanic white (47.4%) and just over a third (36.1%) had private health insurance. The mean (SD) age of respondents was 18.6 (2.0) years, two-thirds had not completed high school, and 36% had limited health literacy (Table 1). Overall, 74% of respondents had used OTC medicines within the past month. Sixty-four percent of all respondents had never heard of acetaminophen, yet 33% of those (21% of all respondents) had unknowingly used one or more acetaminophen-containing products within the past month. In contrast, 13% of all respondents had heard of acetaminophen and used it within the past month (Table 2).

Also shown in Table 2, most participants could identify acetaminophen as the active ingredient in Tylenol (86%), however, there were significant differences by health literacy level, with poorer outcomes among those whose health literacy was limited. We found significant differences by health literacy for all measures -- the dosing tasks individually as well as the summary variable that evaluated performance across all knowledge tasks. Nearly 94% of those with limited health literacy and 79% of those with adequate health literacy unsafely completed at least one of the acetaminophen knowledge measures, for a total of nearly 85% of participants ‘unsafe’ overall ($p=.002$). We also found differences in the ability to correctly distinguish acetaminophen-containing products from products that did not contain acetaminophen, with 65% of those with adequate health literacy and 37% of respondents with limited health literacy correctly distinguishing all acetaminophen-containing products ($p<0.001$). One-third of respondents overall correctly distinguished some products but not all, with no difference by health literacy level, and one-third of respondents with inadequate health literacy failed to correctly identify any of the products that contained acetaminophen (Table 2).

In multivariate analyses, limited health literacy (Adjusted Relative Risk (ARR) 7.37, 95% CI 3.02–18.0), having public health insurance (ARR 2.50, 95%CI 1.16–5.40) and not using an OTC in the last month (ARR 1.83, 95%CI 1.10–3.05) were significant independent predictors for *incorrectly* identifying the active ingredient in Tylenol™. Limited health literacy (ARR 1.13, 95%CI 1.00–1.28) was also an independent predictor for unsafely completing the dosing tasks; along with non-Hispanic black race (ARR 1.16, 95%CI 1.01–1.34) and other race (ARR 1.31, 95%CI 1.11–1.54). Female gender (ARR 1.87, 95%CI 1.15–3.06) was a predictor of exceeding the maximum dose of medicine in 24 hours, while being uninsured (ARR 0.33, 95%CI 0.11–0.98) was found to protect against exceeding the maximum dose (Table 3).

Discussion

Misunderstanding of many aspects of acetaminophen use was common in our sample of adolescents and young adults, and limited health literacy was an independent risk factor for poor knowledge, misunderstanding, and potential unsafe use of OTC medicines that contain acetaminophen. Given the established dangers of acetaminophen overdose,^{8–10} the wide range of acetaminophen-containing products available over-the-counter, and the increase in autonomy of adolescents and young adults in caring for their own health including self-administration of medicines, our findings suggest that this may be a major public health concern.

Specific elements of label instructions may be particularly confusing for adolescents and young adults, namely, the ‘active ingredient’ and the ‘dosing instructions’. With regard to the active ingredient, more than one-fifth of our respondents reported recent use of OTC products that *contain* acetaminophen, yet said they had never heard of acetaminophen itself. However, when we handed them a package and asked them to identify the active ingredient, most of our respondents *could* identify it as acetaminophen. There are several ways to interpret these findings. Individuals may: 1) misread or misunderstand label information; 2) read and understand label information yet later misremember the details; or 3) be unaccustomed to reading or unable to read label information at all. Second, with regard to dosing, most participants in our study were *unable* to correctly identify the number of doses to take in one day. The overwhelming majority of respondents (85% overall), erred dangerously, in ‘unsafe’ understanding of acetaminophen use. Although error was prevalent at both levels of health literacy, those with limited health literacy were still significantly more likely to report ‘unsafe’ error compared with those whose health literacy was adequate. Both of these findings point toward label instructions as a potential root cause of confusion about safe use of acetaminophen.

Both public insurance and black race were independent predictors of misunderstanding. It is possible that both of these covariates address socioeconomic status (SES), which may explain less familiarity and less use of OTC products. As in other health literacy studies as well as national surveys of general literacy, SES and minority race/ethnicity are both strongly linked to poorer reading and numeracy skills. In contrast, another socioeconomic indicator, lack of health insurance, was protective against exceeding the maximum dose of acetaminophen in 24 hours. It is possible that those with limited means may be accustomed to using less medicine, to conserve OTC medicines by taking fewer pills per dose or waiting longer intervals between doses.

Our study has notable limitations. We excluded non-English speakers due to the complexities of distinguishing HL from limited English proficiency (LEP). We examined comprehension of label instructions via experimental ‘role-play’ scenarios rather than actual use, and real world behavior could differ from our results. On one hand, the experimental tasks could have had limited salience for participants in relation to their current health or concerns, whereas real world behavior could be safer when health concerns are immediate. On the other hand, participants could have been more careful under experimental conditions, raising concerns about whether real-world behavior could pose even greater risk than that

observed here. This study did not assess where teens obtain medicines or whether parents were aware of their child's medicine use. Although we selected our recruitment sites and sample quotas to reflect census and local demographic characteristics, the results of our study in one community may have limited generalizability to all adolescents. However, the demographic characteristics of our sample are representative of the sample frame,(24) and the frequency of reported OTC use in our sample of young people is consistent with prior studies in similar age groups.(8, 9) Ours is the first study, to our best knowledge, to examine questions of OTC medicine use and understanding of label instructions for acetaminophen among adolescents and young adults *in association with health literacy*.

In summary, there are serious safety concerns associated with OTC products, and individuals with limited health literacy may face disproportionate risk of unsafe use due to confusion and misunderstanding of label information. However, this risk is not limited to those whose health literacy is limited -- those with adequate health literacy also face considerable risk. To improve safety for all users of OTC medicines, there is a need for better labeling and public health information about the importance of information on medicine labels, and for complementary educational efforts to teach how to decode label information to better recognize active ingredients and understand dosing instructions. Existing evidence that certain formats for communicating medicine information can improve comprehension(25) should inform such efforts.

Clinicians and parents must work together to provide developmentally-appropriate opportunities throughout adolescence – within clinical encounters and beyond --for learning, modeling and rehearsal, and acquisition of autonomous skills for safe use of acetaminophen.

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Abbreviations

ARR	Adjusted Relative Risk
FDA	Food and Drug Administration
GED	Graduate-equivalency degree
HIPAA	Health Insurance Portability and Accountability Act
IOM	Institute of Medicine
OTC	Over-the-Counter
REALM	Rapid Estimate of [Adult/Adolescent] Literacy in Medicine
SD	Standard Deviation

U.S United States

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Table 1

Demographic Characteristics by Literacy Level:

Characteristic	All Participants (n=266)	Literacy Level		* p value
		Limited (n=96)	Adequate (n=170)	
Age, Mean years (SD)	18.6 (2.0)	18.4 (1.9)	18.8 (2.0)	0.17
16–17	33.1	36.5	31.2	0.65
18–19	38.4	35.4	40.0	
20–23	28.6	28.1	28.8	
Gender				0.19
Male	43.6	49.0	40.6	
Female	56.4	51.0	59.4	
Race/Ethnicity				<0.001
Non-Hispanic White	47.4	27.1	58.8	
Non-Hispanic Black	32.3	51.0	21.8	
Hispanic	13.2	13.5	12.9	
Other	7.1	8.3	6.5	
Education				<0.001
< High School	59.4	79.2	48.2	
High School Grad/GED	13.5	9.4	15.9	
Some College	27.1	11.5	35.9	
Health Insurance				0.02
Private	36.1	28.1	40.6	
Public	32.3	43.8	25.9	
Uninsured	14.7	14.6	14.7	
Don't Know	16.9	13.5	18.8	
Used OTC in Last Month				0.005
Yes	73.7	63.5	79.4	
No	26.3	36.5	20.6	

* Fisher's exact used for expected cell counts less than 5

Table 2

Measures of Acetaminophen Understanding by Literacy Level:

Acetaminophen Knowledge Measure	All Participants (n=266)	Literacy Level		p value*
		Limited (n=96)	Adequate (n=170)	
Active Ingredient				<0.001
Correct (Acetaminophen)	86.1	67.7	96.5	
Incorrect	13.9	32.3	3.5	
Number of Pills in 1 Dose				<0.001
Correct	65.0	49.0	74.1	
Under	6.8	7.3	6.5	
Over	13.2	16.7	11.2	
Don't Know	7.9	15.6	3.5	
Inappropriate	7.1	11.5	4.7	
Number of Doses in 1 Day				<0.001
Correct	21.4	16.7	24.1	
Under	8.7	14.6	5.3	
Over	62.8	55.2	67.1	
Don't Know	3.4	8.3	0.6	
Inappropriate	3.8	5.2	2.9	
Minimum Recorded Time Between Doses				0.004
Correct	75.2	63.5	81.8	
Under	8.7	11.5	7.1	
Over	2.3	2.1	2.4	
Don't Know	13.9	22.9	8.8	
Maximum Daily Dose				<0.001
Correct	53.0	39.6	60.6	
Under	23.3	32.3	18.2	
Over	9.8	5.2	12.4	
Don't Know	13.9	22.9	8.8	0.002
All Measures Correct or Safe Error				
Yes	15.8	6.3	20.6	
No	84.6	93.8	79.4	
Familiarity with & Use of Acetaminophen in Past Month				<0.001
Heard of & used acetaminophen	12.8	4.2	17.7	
Heard of & not used acetaminophen	24.1	12.5	30.6	
NOT heard of & not used acetaminophen	42.1	56.3	34.1	
NOT heard of & used acetaminophen	21.1	27.1	17.7	
Ability to Correctly ID Acetaminophen Products				<0.001
All Correctly Identified	54.9	36.5	65.3	
Some Correctly Identified	33.8	34.4	33.5	
None Correctly Identified	11.3	29.2	1.2	

* Fisher's Exact used for expected cell counts less than 5

Table 3

Factors in *Unsafe* Completion of Acetaminophen Dosing Measures

Variable	Incorrectly identifying active ingredient			Unsafely completing dosing tasks			Exceeding maximum dose in 24hrs		
	Adj. Relative Risk	95% CI		Adj. Relative Risk	95% CI		Adj. Relative Risk	95% CI	
Literacy									
Adequate	Ref	---		Ref	---		Ref	---	
Limited	7.37	3.02 – 8.00		1.13	1.00 – 1.28		1.46	0.89 – 2.40	
Age									
20–23 years	Ref	---		Ref	---		Ref	---	
18–19 years	0.92	0.51 – 1.67		1.05	0.90 – 1.23		0.67	0.34 – 1.33	
16–17 years	0.85	0.43 – 1.67		1.08	0.92 – 1.27		0.66	0.34 – 1.27	
Gender									
Male	Ref	---		Ref	---		Ref	---	
Female	1.15	0.64 – 2.07		1.05	0.92 – 1.19		1.87	1.15 – 3.06	
Race									
NH-White	Ref	---		Ref	---		Ref	---	
NH-Black	1.57	0.81 – 3.05		1.16	1.01 – 1.34		0.94	0.56 – 1.58	
Hispanic	1.40	0.56 – 3.53		1.09	0.90 – 1.32		0.88	0.44 – 1.78	
Other	0.34	0.04 – 2.63		1.31	1.11 – 1.54		0.17	0.03 – 1.03	
Education									
Some College	Ref	---		Ref	---		Ref	---	
High School Grad or GED	0.44	0.11 – 1.78		1.04	0.83 – 1.31		1.32	0.59 – 2.96	
< High School	0.62	0.33 – 1.14		1.04	0.88 – 1.23		1.15	0.56 – 2.34	
Health Insurance									
Private	Ref	---		Ref	---		Ref	---	
Public	2.50	1.16 – 5.40		0.97	0.83 – 1.12		0.85	0.49 – 1.48	
No Insurance	0.72	0.20 – 2.57		1.04	0.87 – 1.26		0.33	0.11 – 0.98	
Don't Know	1.82	0.60 – 5.51		1.16	0.99 – 1.35		1.59	0.93 – 2.71	
Used OTC in Last Month									
Yes	Ref	---		Ref	---		Ref	---	
No	1.83	1.10 – 3.05		1.11	0.99 – 1.25		1.16	0.72 – 1.87	