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Acetaminophen and Expired Medication Storage in Homes with Young Children

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Abstract

Research Article

Objective: To describe the storage of acetaminophen and expired medications in homes with young children.

Methods: This pilot study used direct observation of medication storage practices of 24 families with children aged 2-6 years. An observer conducted home interviews documenting specific information about where and how each medication was stored and if the medication contained acetaminophen or was expired. Safe storage was defined as medications stored above 5 feet or if stored below 5 feet, medications must be locked.

Results: Acetaminophen was found in 23 homes and all homes had at least one expired medication. Of the 799 medications, 99 (12%) contained acetaminophen and 219 (27%) were expired. Approximately 30% of acetaminophen and 15% of expired medications were stored unsafely. Acetaminophen was more likely to be stored unsafely compared to non-acetaminophen products [odds ratio=1.65, 95% confidence interval (CI): 1.07, 2.55], whereas the odds of unsafe storage for expired medications were 0.36 (95% CI: 0.21, 0.64) compared to non-expired medications. Acetaminophen-containing and expired medications were more likely to be stored in the bathroom.

Conclusions: The high proportion of unsafely stored acetaminophen-containing medications and high number of expired medications in the home are of concern for families with young children. It is unclear if parents are aware of the toxicity of acetaminophen or the risk of harm from expired medications being in the home where young children are present. These results can be used to develop an intervention program aimed at improving the safe storage of medications in homes with young children.

Keywords: Acetaminophen; Expired medications; Safe storage; Youth

Introduction

Unintentional poisoning is a major public health concern in the U.S., especially among children less than 6 years [1-3]. In 2009, the nonfatal unintentional poisoning rate for youth under the age of 6 was 185 per 100,000 [4]. Since the majority of poisonings occur in the home [1,2], the unsafe storage of medication creates an unnecessary poisoning risk [5].

Medications containing acetaminophen are of particular concern as acetaminophen, the most commonly used analgesic, is hazardous when taken above therapeutic levels [6]. In the U.S., it is the most frequent cause of acute liver failure [7], with possible outcomes including hepatotoxicity, liver transplant, and death [7,8]. In 2009 there were 153,443 single medication human exposures involving acetaminophen reported to U.S. Poison Control Centers, with 47,131 (31%) of those in children under 6 years [2]. Due to overdose concerns, in January 2011 the U.S. Food and Drug Administration requested prescription drug manufacturers limit the dosage of acetaminophen and issue a boxed warning indicating the risk of liver injury [9].

Additionally, there is some debate about the safety of expired medication. Expired medications primarily lose their potency, but they may cause harm due to a breakdown of the chemicals [10]. The extent of the deterioration in expired medications is unknown without laboratory testing [11]. Environmental conditions can impact the chemical and physical properties of medications and shorten the shelf-life [10,12,13]. The American Academy of Pediatrics (AAP) recommends that all unused medications and medications that are no

longer needed should be properly disposed [14]. Several developed countries consider expired drugs to be hazardous, prohibiting their export for donation [12] due to their unknown safety.

In order to reduce the number of unintentional poisonings of youth in the home, it is essential to prevent children from accessing medications [15]. Several studies have described storage practices of all medications, but to our knowledge, none have specifically detailed the storage of acetaminophen-containing medications or expired medications in homes with young children. In addition, most studies of medication storage rely on self-report, which might be underestimating the true extent of unsafe medication storage practices. Having an accurate description of medication storage practices can prompt targeted interventions in homes with young children in an effort to reduce the risk of unintentional poisoning. The purpose of this study was to describe medication storage patterns and the presence of acetaminophen and expired medications in the home using direct observation.

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Characteristic	Acetaminophen (n=99)	Non-Acetaminophen (n=691)	Unadjusted Odds Ratio (95% Cl) ^ь	Adjusted Odds Ratio (95% Cl) ^{b,c}
Unsafe storage ^d				
No	66 (67)	530 (77)	reference	reference
Yes	30 (30)	143 (21)	1.68 (1.09, 2.60)*	1.65 (1.07, 2.55)*
Missing	3 (3)	18 (2)		
Type of medication				
Over-the-counter	82 (83)	416 (60)	reference	reference
Prescription	16 (16)	271 (39)	0.30 (0.14, 0.63)*	0.26 (0.12, 0.59)*
Missing	1 (1)	4 (1)		
Storage location of medication				
Bathroom	45 (46)	220 (32)	1.96 (1.24, 3.10)*	1.58 (1.02, 2.44)*
Bedroom	3 (3)	21 (3)	1.37 (0.39, 4.82)	0.98 (0.29, 3.31)
Kitchen	41 (41)	393 (57)	reference	reference
Other location	10 (10)	57 (8)	1.68 (0.82, 3.45)	1.67 (0.82, 3.39)

^aData on acetaminophen content was missing for 99 medications.

^bLogistic regression analyses compare acetaminophen to non-acetaminophen medications and account for clustering within individual households.

Adjusted odds ratios include all listed variables as independent variables.

^dUnsafe storage defined as medications stored below 5 feet that are not locked.

*Significant result (α=0.05)

Table 1: Acetaminophen storage in 24 homes^a.

Methods

We conducted a pilot study involving home observations of 24 families with children aged 2-6 years using a convenience sample from Nationwide Children's Hospital (NCH) where we documented storage information of every medication in the home. During the home observation, we recorded specific medication storage details, including the specific room, exact location in that room (i.e. in a drawer, cabinet, etc.), height of location, and whether the medication was stored in a locked container. We also documented whether the medication was prescription or over-the-counter (OTC). We then grouped each medication into specific categories depending upon the medication type/function: antibiotic, asthma and respiratory, behavioral, cold and allergy, pain, stomach and digestive, vitamin, or other (which included multipurpose medications).

The AAP recommends that medications should be stored out of the reach and sight of children and locked [14]. For the purposes of this study, safe storage was defined as medications stored above 5 feet or if stored below 5 feet, medications must be locked. Five feet was used as the cutoff for safe storage because it is consistent with other studies that have used "adult eye level" or 1.5 meters (approximately 4 feet 9 inches) [15-17]. Childproof packages and caps were not evaluated due to the variability in package type and strength or dexterity required to open a package or bottle. Additionally, the AAP indicates that medications should be locked if they are stored within reach of children as this is a better deterrent for children compared to childproof packaging. Descriptive statistics were calculated regarding the storage of acetaminophen-containing medications and expired medications at the household and individual medication levels. A home was considered to have the medication present if at least one medication of interest was found in the home. Univariate and multivariable logistic regression was conducted, accounting for the clustering of medications by home, to determine differences between acetaminophen and nonacetaminophen medications as well as expired and non-expired medications. Significance was determined at P<0.05. All analyses were conducted using SAS 9.2 (Cary, NC). This study was approved by the Internal Review Board of NCH.

Results

There were a total of 55 children in the 24 homes. Most homes had

J Clinic Toxicol ISSN: 2161-0495 JCT, an open access journal two adults (92%) and at least two children (96%). From the 24 homes, we documented 799 medications, 174 (22%) of which were stored unsafely and only 55 (7%) were locked. The majority of medications were stored in the kitchen (441/799=55%) or bathroom (266/799=33%). A total of 90 (52%) unsafely stored medications were found in the bathroom.

Of the 799 medications, 99 (12%) contained acetaminophen. At the household level, acetaminophen was found in 23 (96%) homes for an average of 4.3 acetaminophen-containing medications per home. Ten homes (43%) had prescription medications containing acetaminophen. As seen in Table 1, more medicines with acetaminophen were stored unsafely compared to medicines without acetaminophen [odds ratio (OR)=1.65; 95% confidence interval (CI): (1.07, 2.55)]. Acetaminophen-containing medicines were more likely to be stored in bathrooms [OR=1.58; 95% CI: (1.02, 2.44)], whereas medicines not containing acetaminophen were more likely to be stored in kitchens. Acetaminophen medications were also less likely to be prescription instead of OTC [OR=0.26; 95% CI: (0.12, 0.59)].

There were 219 (27%) expired medications with all homes having at least one expired medication for an average of 9.1 expired medications per home. One home had 31 expired medications in their home (72% of all medications in this home). As shown in Table 2, a protective effect is seen with the safe storage of expired medications where the odds of expired medications being stored unsafely were 0.36 [95% CI: (0.21, 0.64)] times the odds of non-expired medications being stored unsafely. More expired medications were stored in the bathroom or in another location, such as the basement, hallway, or dining room [OR=2.35; 95% CI: (1.57, 3.51) and OR=2.22; 95% CI: (1.22, 4.04) respectively], while non-expired medications were stored in the kitchen.

Discussion

Our home-based observational study showed a high percentage (30%) of acetaminophen products being stored unsafely, which increases the risk of unintentional poisoning since they are accessible to children. The study by Smolinske and Kaufman [18] only found that 3.4% of acetaminophen medications were stored unsafely and their low height cutoff was at 4 feet whereas our definition of safe storage required medications to be stored at least 5 feet high. This difference in the percentage of acetaminophen medications being stored unsafely might also be due to the problems associated with using self-report

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Characteristic	Expired (n=219)	Not Expired (n=541)	Unadjusted Odds Ratio (95% CI) ^b	Adjusted Odds Ratio (95% CI) ^{b,c}
Unsafe storage ^d				
No	184 (84)	397 (73)	reference	reference
Yes	33 (15)	127 (23)	0.56 (0.35, 0.89)*	0.36 (0.21, 0.64)*
Missing	2 (1)	17 (4)		
Medication category				
Antibiotics	6 (3)	14 (3)	1.07 (0.39, 2.93)	1.45 (0.52, 4.04)
Asthma and respiratory	9 (4)	27 (5)	0.83 (0.35, 1.98)	0.98 (0.33, 2.95)
Behavioral	7 (3)	19 (4)	0.92 (0.36, 2.38)	1.34 (0.50, 3.56)
Cold and allergy	43 (20)	103 (19)	1.04 (0.62, 1.77)	0.94 (0.52, 1.72)
Pain	41 (19)	124 (23)	0.83 (0.48, 1.42)	0.74 (0.40, 1.36)
Stomach and digestive	29 (13)	52 (10)	1.39 (0.78, 2.49)	1.26 (0.67, 2.40)
Vitamins	15 (7)	72 (13)	0.52 (0.24, 1.12)	0.41 (0.17, 1.01)
Other	66 (30)	124 (23)	reference	reference
Missing	3 (1)	6 (1)		
Type of medication				
Over-the-counter	145 (66)	340 (63)	reference	reference
Prescription	74 (34)	199 (37)	0.87 (0.62, 1.22)	0.72 (0.44, 1.19)
Missing	0 (0)	2 (0)		
Storage location of medication				
Bathroom	88 (40)	161 (30)	1.75 (1.25, 2.45)*	2.35 (1.57, 3.51)*
Bedroom	5 (2)	18 (3)	0.89 (0.29, 2.67)	1.36 (0.47, 3.95)
Kitchen	102 (47)	326 (60)	reference	reference
Other location	24 (11)	36 (7)	2.13 (1.26, 3.61)*	2.22 (1.22, 4.04)*

^aExpiration dates were missing on 99 medications.

^bLogistic regression analyses compare acetaminophen to non-acetaminophen medications and account for clustering within individual households.

Adjusted odds ratios include all listed variables as independent variables.

^dUnsafe storage defined as medications stored below 5 feet that are not locked.

*Significant result (α=0.05)

Table 2: Expired medication Storage in 24 homes^a.

instead of direct observation.

We also found that 27% of all medications were expired, an average of nine expired medications per home, and that all homes had at least one expired medication. Expired medications were however likely to be stored safely. Our findings are in agreement with past research that has shown that 22-35% of all medications in the home are expired [19,20] but one study only found an average of two expired medications per home [20]. The high number of expired medications we found per home is concerning because this might increase the risk of unintentional poisoning among children. Another study found that only 19.6% (40/204) of elderly patients had expired medication in every home, but their sample size was larger than ours.

We also found only 7% of medications were stored in a locked container, which is much lower than what previous research has shown. One study showed that self-report of locked medications was 71%, whereas investigator observations indicated that only 17% of medications were in locked cabinets, indicating a strong difference between self-reported storage practices and direct observation [21]. These findings are cause for concern because parents might not be aware of the toxicity of acetaminophen or the danger of having expired medications in their home, especially when medications are not locked.

The biggest limitation to this study is the small sample size and that it was a convenience sample, which limit generalizability. However, the use of home observations rather than relying on the self-report of medication storage minimized misclassification of the number and types of medications in the home, storage practices, and reduced reporter bias. Unfortunately we did not document certain demographic characteristics of the sample or all individuals in each home preventing us from providing a better description of the sample. Additionally, this study did not inquire why the parents stored the medications in their homes that way, did not ask about their knowledge of safe medication storage practices, and did not ask about their knowledge of the medicines in their home.

Future research should involve testing of the safety and stability of medications (expired and not expired) under conditions seen commonly in the household, such as open containers and exposure to humidity, increased temperature, and light. With 45% of acetaminophen medications and 40% of expired medications in this study being stored in the bathroom, the true safety of these medications is unknown. Expiration dates only apply if the medications are stored in the conditions specified on the medication container [12] and storage in the bathroom subjects them to heat and humidity, which can increase the decomposition of the drug and reduce the shelf-life [10,12,13]. Some small studies have shown the instability of specific medications under non-recommended environmental conditions [22,23], which is often the case in households. The Department of Defense and American Medical Association are interested in investigating extending the shelf-lives of various medications in case of an emergency through the Shelf-Life Extension Program (SLEP) [11,24,25]. The study by Lyon et al. [11] tested 122 different drug products (3,005 lots) and showed that many medicines can be used past the expiration date, but there is high variability with this extension and routine testing would be required to determine the safety of these medicines past their original expiration date. The stability of the medicines in the Lyon et al study was dependent on the type of medication but also on the lot being tested [11]. It is important to note that consideration for extending the use of medications past their expiration date requires the medications be in their original sealed containers and in controlled environmental

conditions [11], which is often not the case in households. Our study showed that every household had at least one expired medication in each home and the safety of expired medications and medication stored in non-recommended conditions is unknown. It is important that parents are aware of the potential risk of improper storage of medication and the presence of expired medication in the home.

Future research should also be conducted to determine parental knowledge about safe storage and toxicity of various medications. It is essential for adults to be aware of the hazards associated with acetaminophen-containing and expired medications and how to prevent injury. Understanding and minimizing these risks is essential for the safety of those in their home, but can also protect others visiting their home [26]. Future research should also focus on programs that educate parents about safe storage of medications and prompt removal of expired medication. Proper storage of acetaminophen and prompt removal of expired medications will reduce the risk of harm to youth by limiting their accessibility.

Conclusions

This pilot study shows that medications are often stored within the reach of children and not in a locked container, which places children at increased risk for unintentional poisoning. The majority of medications were also stored in the bathroom, an environment that encourages faster deterioration and a potential cause for harm. Unintentional medication poisoning in children under the age of 6 is a public health concern that needs to be addressed through the education of parents. Parents need to be aware of what is in their medicine cabinets and how to properly store these medications to reduce the risk of injury to children.

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