Circumstances Involved in Unsupervised Solid Dose Medication Exposures among Young Children

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Objective To identify types of containers from which young children accessed solid dose medications (SDMs) during unsupervised medication exposures and the intended recipients of the medications to advance prevention.

Study design From February to September 2017, 5 US poison centers enrolled individuals calling about unsupervised solid dose medication exposures by children ≤5 years. Study participants answered contextually directed questions about exposure circumstances.

Results Sixty-two percent of eligible callers participated. Among 4496 participants, 71.6% of SDM exposures involved children aged ≤2 years; 33.8% involved only prescription medications, 32.8% involved only over-the-counter (OTC) products that require child-resistant packaging, and 29.9% involved ≥1 OTC product that does not require child-resistant packaging. More than one-half of exposures (51.5%) involving prescription medications involved children accessing medications that had previously been removed from original packaging, compared with 20.8% of exposures involving OTC products (aOR, 3.39; 95% CI, 2.87-4.00). Attention deficit hyperactivity disorder medications (49.3%) and opioids (42.6%) were often not in any container when accessed; anticonvulsants (41.1%), hypoglycemic agents (33.8%), and cardiovascular/antithrombotic agents (30.8%) were often transferred to alternate containers. Grandparents' medications were involved in 30.7% of prescription medication exposures, but only 7.8% of OTC product exposures (aOR, 3.99; 95% CI, 3.26-4.87).

Conclusions Efforts to reduce pediatric SDM exposures should also address exposures in which adults, rather than children, remove medications from child-resistant packaging. Packaging/storage innovations designed to encourage adults to keep products within child-resistant packaging and specific educational messages could be targeted based on common exposure circumstances, medication classes, and medication intended recipients. *(J Pediatr 2020; ■:1-8)*.

Child-resistant packaging is a notable public health success. Mortality from unintentional medication poisonings in young children fell significantly after the 1970s Poison Prevention Packaging Act (PPPA) mandated the use of child-resistant packaging for most medications in the US.[1,2] However, in the 2000s, as the prevalence of medication use increased,[3] unsupervised medication exposures in young children also increased, with approximately 75 000 emergency department visits and 540 000 calls to US poison control centers (PCCs) in 2010.[4-7] Solid dose medications (SDMs) account for 70% of emergency department visits for unsupervised medication exposures in young children; however, data characterizing the circumstances surrounding these exposures are limited, hindering advancement of poisoning prevention efforts.[5,8,9] We sought to identify the types of containers from which young children accessed SDMs and the intended recipients of those SDMs.

Methods

This prospective cross-sectional study involved 5 PCCs serving >40 million people in Arizona, Florida, and Georgia. At all PCCs, specialists in poison information (SPIs) respond to telephone inquiries regarding potential poisonings 24 hours a day, 365 days a year. These 5 PCCs use the same electronic case management system, ToxSentry, which allows rule-based, real-time identification of

ADHD	Attention deficit hyperactivity disorder
OTC	Over-the-counter
PCC	Poison control center
PPPA	Poison Prevention Packaging Act
SDM	Solid dose medication
SPI	Specialists in poison information

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eligible callers and standardized data collection (ToxSentry, Florida/Georgia Poison Center Software Consortium, 2019).

Before data collection, a lead investigator from each PCC participated in an in-person study protocol training session. Lead investigators subsequently trained all SPIs at their PCC on protocol use. Data collection began after SPIs had gained familiarity with the data collection protocol.

From February 1 through September 30, 2017, all callers reporting unsupervised exposures of SDMs by children aged ≤5 years were asked to participate. Unsupervised exposures included incidents in which young children accessed medication without caregiver knowledge, direction, or oversight. SDMs included prescription or over-the-counter (OTC) medications, dietary supplements, or homeopathic products available in solid forms (eg, pills, tablets, capsules, film strips) intended for oral human use. Powders or crushed pills intended to be mixed with food or liquid, gums, and lozenges were excluded. Eligible callers were fluent English speakers or Spanish speakers (when an SPI fluent in Spanish was available), and provided oral consent. Participants answered ≤6 contextually directed questions about the exposure circumstances. If the caller was unable to participate during the initial contact (eg, owing to a need for immediate medical intervention), SPIs made 3 subsequent attempts to contact the caller for study enrollment.

Standard PCC data collection included patient age and sex, names and dosage forms of ≤6 substances involved in the exposure, exposure site, call site, and medical outcome. Additional data collected for this study included the type of container and the intended recipient of the medications implicated in the exposure, and, when relevant, reasons the medications were not in the fully closed original container when accessed, using context-based branching logic (**Figure 1**; available at www.jpeds.com). When multiple SDMs were involved, SPIs clarified whether the circumstances surrounding all exposures were the same. A free-text field was used to record additional details reported.

Implicated medications were categorized by prescription status[10] and drug class based on primary indication. For this analysis, medications available by prescription only were categorized as prescription medications. Medications available by prescription or OTC (eg, ibuprofen) or only available OTC (eg, herbal/homeopathic products) were categorized as available OTC. OTC products were further categorized by whether or not they require child-resistant packaging under the PPPA.[2,11] Data recorded as free-text were reviewed to assist categorization.

We used χ^2 to analyze difference in proportions between groups. Two-sided P values of <.05 were considered statistically significant. Multiple logistic regression analyses were used to model the proportion of calls where the container type was not original vs original, and the proportion of calls involving prescription medication vs OTC medication. Child age, child sex, intended recipient, call site, and medical outcome were also included as adjustment factors in the models. Cases with other/unspecified or missing values were removed for modeling. The aORs and 95% CIs are reported. All data were de-identified and analyses were conducted using SAS version 9.4 (SAS Institute, Cary, North Carolina). The study protocol was approved by the institutional review board of each participating site.

Results

During the 8-month study period, of 7252 eligible calls involving an unsupervised solid dose medication exposure by a child aged ≤5 years, 4496 callers (62.0%) agreed to participate (**Table I**; available at www.jpeds.com). A higher proportion of nonparticipant calls originated from a healthcare setting compared with participant calls (25.9% vs 12.7%) ($P < .0001$).

Among the 4496 participants, 71.6% of calls involved children aged ≤2 years, 47.6% involved girls, and 92.8% involved access to a single medication (**Table II**). Exposures were nearly equally divided among calls involving prescription-only products (33.8%), OTC products that require child-resistant packaging (32.8%), and ≥1 OTC product that does not require child-resistant packaging (29.9%). Compared with calls for OTC product exposures, a higher proportion of calls for prescription medication exposures originated from a healthcare or emergency setting (23.0% vs 6.2%; aOR, 3.78; 95% CI, 2.93-4.87) and had a documented minor, moderate, or major clinical effect (15.1% vs 4.1%; aOR, 3.36; 95% CI, 2.48-4.57) (**Table III**; available at www.jpeds.com). Major clinical effects were documented in 8 cases involving short-acting opioids and tramadol (n = 4), clonidine (n = 2), clonazepam (n = 1), and methadone (n = 1) (**Table IV**; available at www.jpeds.com).

Exposure Circumstances

Overall, in 33.2% of calls for solid dose medication exposures, a child accessed medication that had been removed from the original container or packaging (ie, at the time of exposure the medicine was not in any container or had been transferred to an alternate container). However, the exposure circumstances varied by medication prescription status and requirement for child-resistant packaging (**Table V**). More than one-half of exposures (51.5%) involving prescription medications involved children accessing medications that had previously been removed from original packaging, compared with one-fifth of exposures (20.8%) involving OTC products (aOR, 3.39; 95% CI, 2.87-4.00) (**Table VI**; available at www.jpeds.com).

Overall, in 70.5% of calls for solid dose medication exposures, a child accessed medication intended for use by an adult, most commonly a parent (47.4%); however, the intended recipient also varied by medication prescription status (**Table II**). Among prescription medication exposures, 81.1% involved medications intended for adults, compared with 64.8% among OTC product exposures (aOR, 1.69; 95% CI, 1.34-2.14) (**Table VII**; available at www.jpeds.com). Grandparents' medications were involved in nearly

Table II. Poison center calls for solid dose medication exposures among children aged ≤5 years, by patient and case characteristics*

Patient and case characteristics	Prescription Only† n (%)	Available OTC only, child-resistant packaging required for all n (%)	Available OTC only, child-resistant packaging not required for all‡ n (%)
Patient age (y)			
<1	63 (4.1)	80 (5.4)	34 (2.5)
1	469 (30.9)	397 (27.0)	276 (20.5)
2	632 (41.6)	586 (39.8)	557 (41.4)
3	234 (15.4)	228 (15.5)	308 (22.9)
4	81 (5.3)	126 (8.6)	114 (8.5)
5	41 (2.7)	56 (3.8)	56 (4.2)
Unspecified, ≤5	0 (0.0)	0 (0.0)	1 (0.1)
Patient sex			
Female	739 (48.6)	679 (46.1)	653 (48.5)
Male	778 (51.2)	786 (53.4)	686 (51.0)
Unspecified sex	3 (0.2)	8 (0.5)	7 (0.5)
No. of implicated substances			
1	1374 (90.4)	1454 (98.7)	1297 (96.4)
2	90 (5.9)	16 (1.1)	38 (2.8)
≥3	56 (3.7)	3 (0.2)	11 (0.8)
Exposure site			
Own residence	1399 (92.0)	1401 (95.1)	1287 (95.6)
Other residence	98 (6.5)	48 (3.3)	42 (3.1)
Other	15 (1.0)	20 (1.4)	13 (1.0)
Unspecified exposure site	8 (0.5)	4 (0.3)	4 (0.3)
Call site			
Own residence	1068 (70.3)	1283 (87.1)	1226 (91.1)
Healthcare setting§	349 (23.0)	113 (7.7)	62 (4.6)
Other residence	47 (3.1)	23 (1.6)	20 (1.5)
Other	48 (3.2)	48 (3.3)	36 (2.7)
Unspecified call site	8 (0.5)	6 (0.4)	2 (0.2)
Medical outcome			
No effect	543 (35.7)	384 (26.1)	349 (25.9)
Minor effect	166 (10.9)	43 (2.9)	70 (5.2)
Moderate effect	55 (3.6)	0 (0.0)	3 (0.2)
Major effect	8 (0.5)	0 (0.0)	0 (0.0)
Not followed	742 (48.8)	1045 (70.9)	924 (68.7)
Judged as nontoxic	78 (5.1)	170 (11.5)	141 (10.5)
Minimal effects possible	589 (38.8)	842 (57.2)	775 (57.6)
Judged as potentially toxic	75 (4.9)	33 (2.2)	8 (0.6)
Unspecified outcome	6 (0.4)	1 (0.1)	0 (0.0)
Total	1520 (100.0)	1473 (100.0)	1346 (100.0)

*Data collected from February to September 2017. Excludes 157 cases in which the prescription status could not be determined or in which both a medication that is available by prescription only and a medication that is available OTC were implicated. Categorizations based on standardized definitions of the National Poison Data System of the American Association of Poison Control Centers.
†Most implicated prescription medications require child-resistant packaging.
‡Includes 33 cases in which both OTC products that do and that do not require child-resistant packaging were implicated.
§Includes calls from hospitals, emergency departments, outpatient clinics, emergency medical services, and police response.

four times as many prescription medication exposures as OTC product exposures (30.7% vs 7.8%; aOR, 3.99; 95% CI, 3.26-4.87) (**Table VIII**; available at www.jpeds.com).

Exposures involving grandparents' medications more commonly involved medications that had been transferred to alternate containers before access by children compared with exposures involving parents' medications (24.2% vs 8.5%; aOR, 2.63; 95% CI, 2.02-3.42) (**Table IX**; available at www.jpeds.com). In the 489 instances where medications had been reported transferred to alternate containers, pill minders (66.3%) and sandwich-type plastic bags (20.3%) were the most common container types.

Type of Container by Drug Class

The types of containers implicated in these pediatric solid dose medication exposures varied by drug class. For anticonvulsants (74.7%), hypoglycemic agents (67.6%), cardiovascular/antithrombotic agents (65.5%), and attention deficit hyperactivity disorder (ADHD) medications (64.2%) approximately two-thirds of exposures involved medications that had previously been removed from the original container or packaging (**Figure 2**). For prescription gastrointestinal agents (21.7%) and contraceptive/sex hormones (34.5%), fewer exposures involved medications accessed outside of original containers.

When prescription medications were removed from original packaging by another person before access by young children, the new medication placement differed by drug class. Prescription medication exposures which most commonly involved medications accessed from alternate containers (eg, travel pill boxes, weekly pill minders)

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Table V. Poison center calls for solid dose medication exposures among children aged ≤5 years, by exposure circumstances*

Exposure circumstances	Prescription only† n (%)	Available OTC only, child-resistant packaging required for all n (%)	Available OTC only, child-resistant packaging not required for all‡ n (%)
Type of container			
Original packaging	644 (42.4)	1045 (71.0)	1070 (79.5)
Original bottle or container	574 (37.8)	902 (61.2)	953 (70.8)
Unit-dose packaging	70 (4.6)	143 (9.7)	117 (8.7)
Removed from original packaging	783 (51.5)	371 (25.2)	215 (16.0)
No container	518 (34.1)	279 (18.9)	154 (11.4)
Alternate container§	265 (17.4)	92 (6.3)	61 (4.5)
Different container types	2 (0.1)	0 (0.0)	4 (0.3)
Unspecified container type	91 (6.0)	57 (3.9)	57 (4.2)
Intended recipient			
Adults	1232 (81.1)	940 (63.8)	887 (65.9)
Parent	616 (40.5)	756 (51.3)	707 (52.5)
Grandparent	466 (30.7)	108 (7.3)	111 (8.3)
Another adult	150 (9.9)	76 (5.2)	69 (5.1)
Children	148 (9.7)	237 (16.1)	204 (15.2)
Child who ingested the medicine	18 (1.2)	179 (12.2)	114 (8.5)
Another child	130 (8.6)	58 (3.9)	90 (6.7)
Anyone in household	0 (0.0)	119 (8.1)	62 (4.6)
Other/unspecified recipient	140 (9.2)	177 (12.0)	193 (14.3)
Total	1520 (100.0)	1473 (100.0)	1346 (100.0)

*Data collected from February to September 2017. Excludes 157 cases in which the prescription status could not be determined or in which both a medication that is available by prescription only and a medication that is available OTC were implicated.
†Most implicated prescription medications require child-resistant packaging.
‡Includes 33 cases in which both OTC products that do and that do not require child-resistant packaging were implicated.
§Includes pill minders/organizers, pill boxes, containers intended for other medications, sandwich-type plastic bags, food containers, and other container types.

included anticonvulsants (41.1%), hypoglycemic agents (33.8%), and cardiovascular/antithrombotic agents (30.8%) (Figure 1). The prescription medication exposures that most commonly involved medications that were not in any container (ie, loose pills) included ADHD medications (49.3%), opioids (42.6%), and muscle relaxants (36.7%).

In contrast, for all OTC product classes except analgesics (34.8%), fewer than one-third of solid dose medication exposures involved medications that previously had been removed from original packaging. For all OTC classes, <15% of exposures involved medications transferred to alternate containers.

Intended Recipient by Drug Class

For most prescription drug classes, parents were most commonly reported to be the intended recipients of medications (Figure 3). However, grandparents were reported to be the intended recipients in more than one-half of exposures involving hypoglycemic agents (62.6%) and cardiovascular/antithrombotic agents (56.2%). Another child (eg, a sibling) was reported to be the intended recipient for nearly one-half of exposures (47.0%) involving ADHD medications.

For OTC product exposures, parents were reported to be the intended recipients in ≥40% of exposures across classes (range, 40.6%-61.2%). A child was reported to be the intended recipient in more than one-quarter of exposures involving OTC vitamins/minerals that require child-resistant packaging (38.8%) or OTC herbal/homeopathic products (25.6%).

Reasons Medications Removed from Original Packaging

The reasons medications were removed from original packaging before access by young children differed by intended recipient (Table X; available at www.jpeds.com). When parents' medications had been transferred to alternate containers, the most commonly reported reasons were to remember to take it (36.5%) and to make it easier to travel with the medicine (34.3%). When grandparents' medications were transferred to alternate containers, one-half of the time (56.3%) the reason reported was to remember to take it, which was 5-fold more commonly reported than to make it easier to travel (10.8%).

When parents' medications were not in any container at the time of exposure, the most commonly reported reasons were that the medicine had been dropped or accidentally left out (38.0%) and that someone was getting ready to take it (34.3%). When grandparents' medications were not in any container, one-half of the time (50.2%) the reason reported was that it had been dropped or accidentally left out, followed by the reason that someone was getting ready to take it (28.0%). Notably, when medications intended for a child were not in any container, nearly two-thirds of the time (65.1%) the reason reported was that someone was getting ready to take it.

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Discussion

Overall, 61% of calls for solid dose medication exposures among young children involved medications accessed from the original container or packaging; however, the circumstances in which children most commonly accessed medications differed significantly by prescription status, drug class, requirement for child-resistant packaging, and intended recipient of the medication, suggesting that prevention efforts should be targeted to specific exposure scenarios.

The findings of this study suggest that pediatric exposures to prescription medications are just as often the result of adults removing medications from original containers as the result of improper use or failure of child-resistant packaging. In 52% of calls for prescription solid dose medication exposures, an adult had removed the medication from the original container before a child accessed the prescription medication. Although the PPPA requires child-resistant packaging for nearly all prescription medications in the US, child-resistant packaging cannot protect a pill that an adult has intentionally removed from the original packaging.[2,11] Thus, to prevent many, if not most, prescription medication exposures, a new paradigm may be required that focuses on encouraging adults to keep medications within some type of child-resistant container until the moment that they take each pill or tablet.

The optimal approach for encouraging adults to keep medication within containers that are child-resistant will likely vary by drug class. In this study, adults transferred pills to alternate containers in more than one-third of exposures involving anticonvulsants and hypoglycemic agents and in more than one-fourth of exposures involving cardiovascular/antithrombotic agents, antidepressant/antipsychotic agents, and thyroid hormones. Notably, these medications are used to treat chronic conditions and are typically taken one or more times daily. The most common reported reasons SDMs were transferred to alternate containers were to help remember to take medications and to make it easier to travel with the medications (eg, to carry them in a purse when going out). Calendarized compliance packaging has been used for decades to encourage adherence to oral contraceptives, including when traveling/commuting, but oral contraceptives do not require child-resistant packaging owing to low toxicity.[11] Using child-resistant calendarized compliance packs, which are also senior friendly, for chronic medications of high pediatric toxicity could help encourage adults to keep pills within the child-resistant packaging, while also facilitating adherence and portability.

However, many adults, particularly older adults, must remember to take multiple medications, and neither multiple bottles nor multiple calendarized compliance packages of single medications may be the optimal approach for child safety or regimen compliance. These patients often comingle multiple pills in the wells of weekly pill minders, which are rarely child-resistant to PPPA standards, and have been associated with an increased risk of unsupervised pediatric exposures.[12] Some pharmacy retailers now re-package multiple medications together into presorted packets (eg, morning medications) to facilitate medication compliance, but this packaging is also not child-resistant to PPPA standards.[13] Developing child-resistant pill minders could be one approach to limit pediatric medication exposures; however, unless such child-resistant pill minders automatically reclose, they would still require adults to remember to immediately reengage child-resistant features after every use. Another approach could be to design perforated child-resistant blister packaging, so that individual doses could be separated and placed inside weekly pill minders with wells large enough to accommodate them.

In this study, adults left pills outside of containers altogether (ie, loose pills) in >40% of pediatric exposures involving opioid analgesics and ADHD medications. These medications may be less likely to be kept in pill minders, because opioid analgesics are often prescribed to be taken as needed for pain control, and ADHD medications are commonly taken by children, whose medications are likely managed by an adult caregiver. The most commonly reported reasons SDMs were not in any container when accessed were that pills had been accidentally dropped or were left out for someone to take. Child-resistant unit-dose packaging also has the potential to prevent these exposures, because the child safety barrier remains around each dose until the medication is taken.[14] Unit-dose packaging can also prevent spills of multiple pills that may occur with bottles, and make it easier to account for dropped pills. Finally, instead of leaving a loose pill on a table or counter to take with a meal, an individual blister with perforations between doses could be broken off with the child-resistant packaging retained until the moment the pill is used by an adult or older child.

Implementation of unit-dose packaging has been associated with decreases in PCC calls and emergency department visits for unsupervised exposures of buprenorphine products and thyroxine.[15-19] Some investigators have suggested that unit-dose packaging be implemented more broadly, for medications that can be very harmful to young children in small amounts, such as opioid analgesics.[19] The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act now authorizes the US Food and Drug Administration to require certain packaging for opioids and other drugs with a high risk for abuse.[20,21] Once implemented, it will be important to continue to monitor pediatric exposures, as well as assess potential implementation challenges such as costs and environmental impacts.

In contrast with calls for exposures to prescription medications, young children most frequently (70%-80%) accessed OTC products from the original container and rarely (<7%) accessed OTC products from alternate containers. Although nearly one-half of the calls (48%) for OTC product exposures involved products that do not require child-resistant packaging, it is notable that nearly as many children accessed OTC products that require child-resistant packaging from original containers (71%) as children accessed

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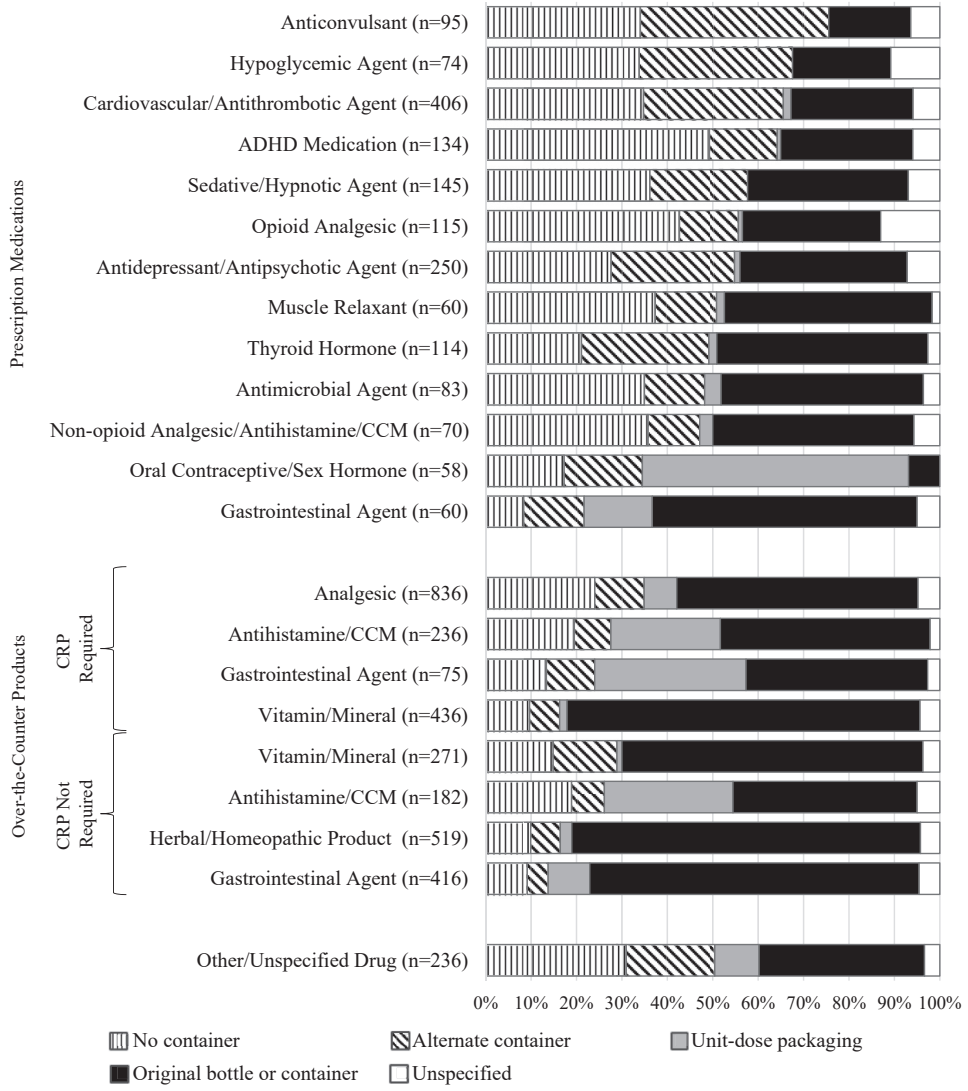

Figure 2. Type of container from which medications were accessed, by drug class, children aged ≤5 years. *CRP*, child-resistant packaging; *CCM*, cough and cold medicine. Data collected from February to September 2017. Six cases involving medications accessed from more than 1 different type of container are not shown.

OTC products that do not require child-resistant packaging (79%). Although many OTC products are not required to have child-resistant packaging, some are nonetheless voluntarily packaged in child-resistant packaging. In addition, child-resistant packaging is designed to delay rather than to completely prevent child access, and because many OTC products are used multiple times a day for symptom relief, adults may be more likely to leave the container in an easily accessible location (eg, bedside table, kitchen counter).

Prevention messages can be targeted based on the intended recipient of accessed medications and drug class. Parents were the most commonly reported intended recipient for pediatric exposures overall; however, grandparents were the most common intended recipient for exposures involving some chronic medications (eg, hypoglycemic agents and cardiovascular/antithrombotic agents), and other children (eg, a sibling) were the most common intended recipients for ADHD medication exposures. Although most educational campaigns have focused on parents of young children, these study findings suggest that it is important to also target messages to grandparents, especially considering the toxicity of medications more commonly intended for grandparents (eg, beta-blockers, sulfonylureas).[22] This study also identified common exposure scenarios that could be addressed in educational messages such as grandparents transferring medications to non-child-resistant alternate containers or parents leaving medications out for older children.

Potential limitations of this study include generalizability and several types of reporting bias. First, only exposures resulting in calls to participating poison centers were included.

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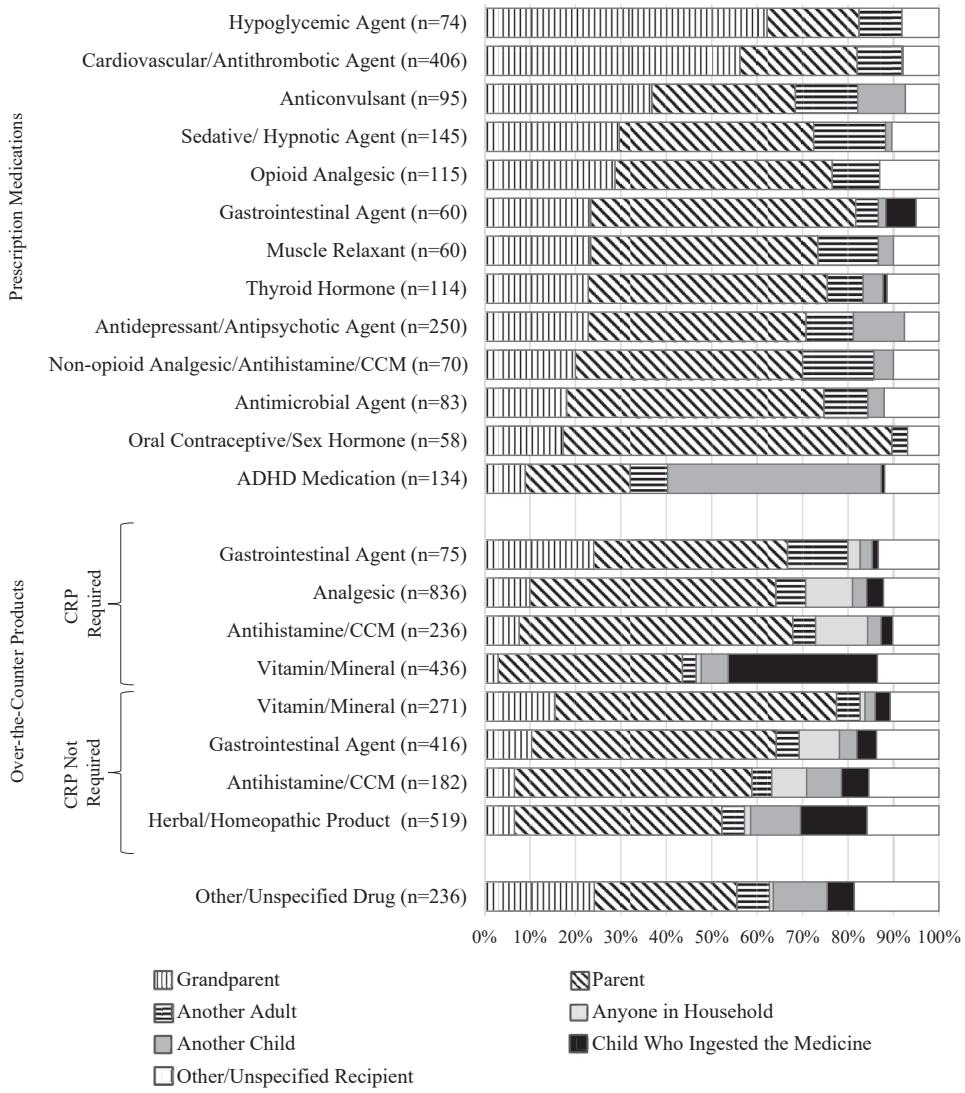

Figure 3. Intended recipient of medications accessed by children aged ≤5 years, by drug class. Data collected from February to September 2017.

Parents may not call if they suspect less toxic or lower dose exposures, if they are not aware of how to contact poison centers, or if they immediately seek healthcare treatment. Additionally, there may be nonresponse bias, as callers from healthcare settings were less likely to participate in the study. Calls for serious exposures may be more likely to originate from healthcare settings, and thus these exposures may be under-represented. Second, data were self-reported by caregivers, introducing the potential for social desirability bias. Caregivers may have been more likely to report that medications were accessed from original containers when they actually had not been, artificially inflating the proportion of exposures involving medications that were in the original packaging. Third, in some cases, the container type, intended recipient, or reasons for removing medications from original packaging were not specified. Thus, the actual proportion of medications removed from the original container may be higher than reported. Nonetheless, if responses were subject to these biases, the result would be underestimation of how often medications were removed from child-resistant packaging, and would only bolster the importance of addressing these exposure circumstances. Although case and patient characteristics of eligible and enrolled calls were similar to nationally reported PCC data,[23] the states represented have a higher proportion of older adults and Hispanic residents than the national average.

Recent progress in reducing pediatric medication exposures coincided with innovations in packaging designed to limit access by children (eg, unit-dose packaging for solid buprenorphine products) and education targeted to parents.[24] Further reductions in pediatric exposures will require efforts to prevent solid dose medication exposures in which adults, rather than children, remove medications from child-resistant packaging. One approach is targeted implementation of packaging innovations designed to limit adult circumvention of child-resistant packaging. Educational

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messages to keep medications up and away and out of sight of young children should target grandparents, as well as parents of young children, and include messages on improving safety if adults use alternate containers. ■

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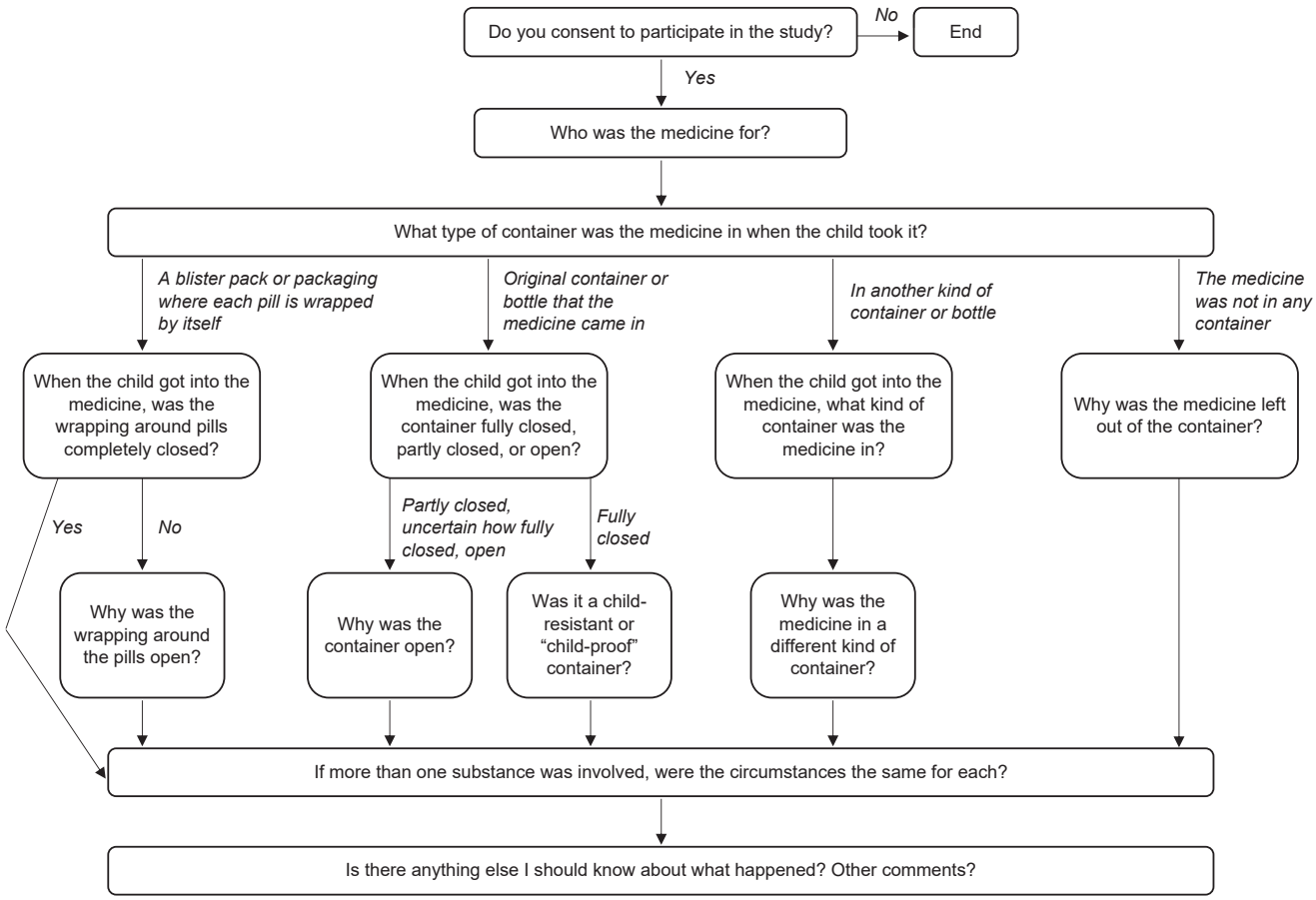

Figure 1. Question flow diagram. Participants were fluent English speakers or Spanish speakers (when a specialist in poison information fluent in Spanish was available) who called one of 5 PCCs from February to September 2017. These 5 PCCs all used the same electronic case management system, ToxSentry, which allows rule-based, real-time identification of eligible callers and standardized data collection (ToxSentry, Florida/Georgia Poison Center Software Consortium, 2019).

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Table I. Poison center calls for solid dose medication exposures among children aged ≤5 years, by study participation*

Patient and case characteristics	Participants n (%)	Nonparticipants n (%)
Patient age (y)		
<1	186 (4.1)	122 (4.4)
1	1192 (26.5)	706 (25.6)
2	1839 (40.9)	1052 (38.2)
3	799 (17.8)	531 (19.3)
4	323 (7.2)	209 (7.6)
5	156 (3.5)	125 (4.5)
Unspecified, ≤5	1 (0.0)	11 (0.4)
Patient sex		
Female	2140 (47.6)	1336 (48.5)
Male	2338 (52.0)	1402 (50.9)
Unspecified sex	18 (0.4)	18 (0.7)
No. of implicated substances		
1	4172 (92.8)	2556 (92.7)
2	196 (4.4)	127 (4.6)
≥3	128 (2.9)	73 (2.6)
Exposure site		
Own residence	4220 (93.9)	2622 (95.1)
Other residence	200 (4.5)	91 (3.3)
Other	57 (1.3)	18 (0.7)
Unspecified exposure site	19 (0.4)	25 (0.9)
Call site		
Own residence	3660 (81.4)	1871 (67.9)
Healthcare setting†	573 (12.7)	713 (25.9)
Other residence	97 (2.2)	33 (1.2)
Other call site	149 (3.3)	119 (4.3)
Unspecified call site	17 (0.4)	20 (0.7)
Medical outcome		
No effect	1363 (30.3)	814 (29.5)
Minor effect	290 (6.5)	184 (6.7)
Moderate effect	58 (1.3)	64 (2.3)
Major effect	8 (0.2)	4 (0.2)
Not followed	2769 (61.6)	1684 (61.1)
Judged as nontoxic	395 (8.8)	220 (8.0)
Minimal effects possible	2240 (49.8)	1282 (46.5)
Judged as potentially toxic	134 (3.0)	182 (6.6)
Unspecified outcome	8 (0.2)	6 (0.2)
Total	4496 (100.0)	2756 (100.0)

*Data collected from February to September 2017. Categorizations based on standardized definitions of the National Poison Data System of the American Association of Poison Control Centers.
†Includes calls from hospitals, emergency departments, outpatient clinics, emergency medical services, and police response.

Table III. aORs for pediatric exposures involving prescription (vs OTC) medications among children aged ≤5 years

	aOR (95% CI)	*P* value
Patient age (y)		
<1	0.76 (0.41-1.4)	.3745
1	1.02 (0.62-1.68)	.9308
2	0.99 (0.61-1.62)	.9798
3	1.00 (0.6-1.66)	.9893
4	0.88 (0.5-1.56)	.6624
5	ref	ref
Patient sex		
Female	0.92 (0.78-1.08)	.3013
Male	ref	ref
Type of container		
Removed from original packaging	3.36 (2.85-3.97)	<.0001
In original packaging	ref	ref
Intended recipient		
Grandparent	17.92 (10.57-30.38)	<.0001
Parent	4.67 (2.82-7.73)	<.0001
Another adult	8.28 (4.73-14.49)	<.0001
Another child	7.87 (4.49-13.79)	<.0001
Anyone in household	*	*
Child who ingested the medicine	ref	ref
Medical outcome		
Documented clinical effect	3.36 (2.48-4.57)	<.0001
No effect or not followed	ref	ref
Call site		
Healthcare setting	3.78 (2.93-4.87)	<.0001
Non-healthcare setting	ref	ref

Data collected from February to September 2017. There were 3632 cases included. Cases with other/unspecified values or missing values and cases in which prescription status could not be determined or in which both a medication that is available by prescription only and a medication that is available OTC were implicated were excluded.
*All calls involved only OTC medications.

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Table IV. Poison center calls for solid dose medication exposures among children aged ≤5 years, major effects reported*

Case no.	Patient age (y)	Patient sex	Implicated medication(s)	Type of container from which medications were accessed	Intended recipient
1	1	Female	Clonazepam	No container	Other recipient
2	1	Female	Clonidine	No container	Unspecified recipient
3	<1	Female	Methadone	Unspecified container	Parent
4	1	Female	Morphine	Alternate container	Other recipient
5	1	Male	Oxycodone	No container	Unspecified recipient
6	1	Female	Tramadol	Unspecified container	Grandparent
7	3	Female	Acetaminophen/oxycodone; Acetaminophen/hydrocodone	No container	Grandparent
8	1	Male	Clonidine; quetiapine; divalproex; methylphenidate	Alternate container	Another Adult

*Data collected from February to September 2017.

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Table VI. aORs for pediatric exposures involving medications that were removed from original packaging (vs in original packaging) among children aged ≤5 years

Characteristics	aOR (95% CI)	*P* value
Patient age (y)		
<1	2.8 (1.56-5.05)	.0006
1	1.69 (1.03-2.77)	.0385
2	1.14 (0.7-1.86)	.6088
3	1.15 (0.69-1.92)	.5877
4	1.2 (0.68-2.11)	.537
5	ref	ref
Patient sex		
Female	1.16 (1-1.35)	.0498
Male	ref	ref
Prescription status		
Prescription only	3.39 (2.87-4.00)	<.0001
Available OTC only	ref	ref
Intended recipient		
Grandparent	10.25 (5.85-17.95)	<.0001
Parent	5.08 (2.96-8.71)	<.0001
Another adult	10.15 (5.64-18.26)	<.0001
Another child	8.79 (4.87-15.84)	<.0001
Anyone in household	2.85 (1.43-5.67)	.003
Child who ingested the medicine	ref	ref
Medical outcome		
Documented clinical effect	0.82 (0.62-1.08)	.1613
No effect or not followed	ref	ref
Call site		
Healthcare setting	0.78 (0.62-0.99)	.0423
Non-healthcare setting	ref	ref

Date collected from February to September 2017. There were 3632 cases included. Cases with other/unspecified values or missing values and cases in which prescription status could not be determined or in which both a medication that is available by prescription only and a medication that is available OTC were implicated were excluded.

Table VII. aORs for pediatric exposures involving prescription (vs OTC) medications among children aged ≤5 years, with intended recipient categorized as adult vs child

Characteristics	aOR (95% CI)	*P* value
Patient age (y)		
<1	0.93 (0.52-1.68)	.8137
1	1.33 (0.82-2.14)	.2481
2	1.31 (0.82-2.09)	.2636
3	1.15 (0.7-1.88)	.5758
4	0.98 (0.57-1.7)	.9455
5	ref	ref
Patient sex		
Female	0.96 (0.82-1.11)	.5599
Male	ref	ref
Type of container		
Removed from original packaging	4.25 (3.63-4.98)	<.0001
In original packaging	ref	ref
Intended recipient		
Adult	1.69 (1.34-2.14)	<.0001
Child	ref	ref
Medical outcome		
Documented clinical effect	3.64 (2.72-4.88)	<.0001
No effect or not followed	ref	ref
Call site		
Healthcare setting	3.98 (3.12-5.07)	<.0001
Non-healthcare setting	ref	ref

Data collected from February to September 2017. There were 3459 cases included. Cases with other/unspecified values or missing values, cases in which prescription status could not be determined or in which both a medication that is available by prescription only and a medication that is available OTC were implicated, and cases involving medication intended for anyone in the household were excluded.

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Table VIII. aORs for pediatric exposures involving prescription (vs OTC) medications among children aged ≤5 years, with intended recipient categorized as grandparent vs other recipient

Characteristics	aOR (95% CI)	*P* value
Patient age (y)		
<1	0.89 (0.49-1.6)	.686
1	1.17 (0.73-1.88)	.5098
2	1.14 (0.72-1.82)	.5679
3	1.06 (0.65-1.72)	.8242
4	0.87 (0.51-1.5)	.6195
5	ref	ref
Patient sex		
Female	0.94 (0.8-1.1)	.4176
Male	ref	ref
Type of container		
Removed from original packaging	4.01 (3.41-4.71)	<.0001
In original packaging	ref	ref
Intended recipient		
Grandparent	3.99 (3.26-4.87)	<.0001
Other recipient	ref	ref
Medical outcome		
Documented clinical effect	3.59 (2.68-4.81)	<.0001
No effect or not followed	ref	ref
Call site		
Healthcare setting	3.57 (2.8-4.54)	<.0001
Non-healthcare setting	ref	ref

Data collected from February to September 2017. There were 3632 cases included. Cases with other/unspecified values or missing values and cases in which prescription status could not be determined or in which both a medication that is available by prescription only and a medication that is available OTC were implicated were excluded.

Table IX. aORs for pediatric exposures involving medications that were transferred to alternate containers (vs not transferred to alternate containers) among children aged ≤5 years

Characteristics	aOR (95% CI)	*P* value
Patient age (y)		
<1	0.39 (0.13-1.14)	.0854
1	0.79 (0.37-1.72)	.5549
2	1.24 (0.58-2.64)	.5743
3	1.27 (0.58-2.77)	.5549
4	1.01 (0.42-2.43)	.9781
5	ref	ref
Patient sex		
Female	1.19 (0.95-1.49)	.1241
Male	ref	ref
Prescription status		
Prescription only	2.7 (2.1-3.47)	<.0001
Available OTC only	ref	ref
Intended recipient		
Grandparent	2.63 (2.02-3.42)	<.0001
Parent	ref	ref
Another adult	1.76 (1.2-2.58)	.004
Another child	0.91 (0.56-1.48)	.6995
Anyone in household	0.32 (0.1-1.02)	.0536
Child who ingested the medicine	0.36 (0.17-0.8)	.0112
Medical outcome		
Documented clinical effect	0.84 (0.57-1.25)	.3901
No effect or not followed	ref	ref
Call site		
Healthcare setting	1.13 (0.82-1.55)	.4498
Non-healthcare setting	ref	ref

Data collected from February to September 2017. There were 3632 cases included. Cases with other/unspecified values or missing values and cases in which prescription status could not be determined or in which both a medication that is available by prescription only and a medication that is available OTC were implicated were excluded.

Table X. Reasons why medications had been removed from original packaging before solid dose medication exposures among children aged ≤5 years, by intended recipient*

Reasons medications removed from original container/packaging	Intended recipient				
	Parent	Grandparent	Another adult	Child†	Other/unspecified recipient
	n (%)	n (%)	n (%)	n (%)	n (%)
Transferred to alternate container					
To remember to take it	66 (36.5)	99 (56.3)	18 (36.7)	6 (18.8)	16 (31.4)
To make it easier to travel with it	62 (34.3)	19 (10.8)	8 (16.3)	15 (46.9)	16 (31.4)
Another reason	12 (6.6)	8 (4.6)	4 (8.2)	3 (9.4)	2 (3.9)
Unspecified reason	41 (22.7)	50 (28.4)	19 (38.8)	8 (25.0)	17 (33.3)
Total transferred	181 (100.0)	176 (100.0)	49 (100.0)	32 (100.0)	51 (100.0)
Not in any container					
Accidentally dropped or left out	166 (38.0)	106 (50.2)	53 (50.0)	21 (20.4)	80 (53.7)
Someone was getting ready to take it	150 (34.3)	59 (28.0)	25 (23.6)	67 (65.1)	36 (24.2)
Another reason	73 (16.7)	21 (10.0)	17 (16.0)	13 (12.6)	8 (5.4)
Unspecified reason	48 (11.0)	25 (11.9)	11 (10.4)	2 (1.9)	25 (16.8)
Total not in any container	437 (100.0)	211 (100.0)	106 (100.0)	103 (100)	149 (100.0)

*Data collected from February to September 2017.
†Includes medications intended for the child who ingested the medicine and those intended for another child.

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