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J Pediatr. Author manuscript; available in PMC 2024 March 13.

Published in final edited form as:

J Pediatr. 2020 April ; 219: 188–195.e6. doi:10.1016/j.jpeds.2019.12.027.

Circumstances Involved in Unsupervised Solid Dose Medication Exposures Among Young Children

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Abstract

Background: Despite widespread adoption of child-resistant packaging (CRP), emergency department visits and calls to poison centers for unsupervised medication exposures by young children remain common. We sought to identify types of containers from which young children accessed solid dose medications (SDMs) and the intended recipients to advance prevention.

Methods: From February-September 2017, five U.S. poison centers enrolled individuals calling about unsupervised SDM exposures by children ≤5 years. Study participants answered contextually directed questions about exposure circumstances.

Results: Sixty-two percent of eligible callers participated. Among 4,496 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 CRP, and 29.9% involved ≥1 OTC product that does not require CRP. Over half (51.5%) of exposures 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 [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 [3.26-4.87]).

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Conflict of Interest Disclosures: The authors have no conflicts of interest relevant to this article to disclose.

Financial Disclosures: The authors have no financial relationships relevant to this article to disclose.

Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Conclusions: New efforts to reduce pediatric SDM exposures should also address exposures in which adults, rather than children, remove medications from CRP. Packaging/storage innovations designed to encourage adults to keep products within CRP and specific educational messages could be targeted based on common exposure circumstances, medication classes, and medication intended recipients.

Keywords

drug packaging; medication safety; medication ingestion; pediatric poisoning; poison prevention; unit-dose packaging

Child-resistant packaging (CRP) 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 CRP for most medications in the United States.[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 (ED) visits and 540,000 calls to U.S. poison control centers (PCCs) in 2010.[4-7] Solid dose medications (SDMs) account for 70% of ED visits due to unsupervised medication exposures in young children;[5] however, data characterizing the circumstances surrounding these exposures are limited,[8, 9] hindering advancement of poisoning prevention efforts. 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 five PCCs serving over 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 five PCCs use 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).

Prior to 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 (e.g., 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 up to six contextually directed questions about the exposure circumstances. If the caller was unable to participate during

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the initial contact (e.g., due to 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 up to six 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; online). 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 (e.g., ibuprofen) or only available OTC (e.g., herbal/homeopathic products) were categorized as 'available OTC'. OTC products were further categorized by whether or not they require CRP under the PPPA.[2, 11] Data recorded as free-text were reviewed to assist categorization.

Chi-square tests were used to analyze difference in proportions between groups. Two-sided *P* values <.05 were considered statistically significant. Multiple logistic regression analyses were used to model the proportion of calls where the container type was not original versus original, and the proportion of calls involving prescription medication versus OTC medication. Child age, gender, 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. Adjusted odds ratios and 95% confidence intervals are reported. All data were de-identified and analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC). The study protocol was approved by the Institutional Review Board of each participating site.

Results

Sample Characteristics

During the 8-month study period, of 7,252 eligible calls involving an unsupervised SDM exposure by a child aged ≤5 years, 4,496 (62.0%) callers agreed to participate (Table 1; online). A higher proportion of non-participant calls originated from a healthcare setting compared with participant calls (25.9% vs. 12.7%) (*P*<.0001).

Patient Characteristics

Among the 4,496 participants, 71.6% of calls involved children aged ≤2 years, 47.6% involved girls, and 92.8% involved access to a single medication (Table 2). Exposures were nearly equally divided among calls involving prescription-only products (33.8%), OTC products that require CRP (32.8%), and at least one OTC product that does not require CRP (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 [2.93-4.87]) and had a documented minor, moderate, or major clinical

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effect (15.1% vs. 4.1%; aOR=3.36 [2.48-4.57]) (Table3; online). Major clinical effects were documented in 8 cases involving short-acting opioids and tramadol (4), clonidine (2), clonazepam (1), and methadone (1) (Table 4; online).

Exposure Circumstances

Overall, in 33.2% of calls for SDM exposures, a child accessed medication that had been removed from the original container or packaging (i.e., 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 CRP (Table 5). Over half (51.5%) of exposures involving prescription medications involved children accessing medications that had previously been removed from original packaging, compared with one-fifth (20.8%) of exposures involving OTC products (aOR=3.39 [2.87-4.00] (Table 6; online).

Overall, in 70.5% of calls for SDM 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 2). Eighty-one percent (81.1%) of prescription medication exposures involved medications intended for adults, compared with 64.8% of OTC product exposures (aOR=1.69 [1.34-2.14]) (Table 7; online). Grandparents' medications were involved in nearly four times as many prescription medication exposures as OTC product exposures (30.7% vs. 7.8%; aOR=3.99 [3.26-4.87]) (Table 8; online).

Exposures involving grandparents' medications more commonly involved medications that had been transferred to alternate containers prior to access by children compared with exposures involving parents' medications (24.2% vs. 8.5%; aOR=2.63 [2.02-3.42]) (Table 9; online). 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 SDM 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 prior to access by young children, the new medication placement differed by drug class. Prescription medication exposures which most commonly involved medications accessed from alternate containers (e.g., travel pill boxes, weekly pill minders) included anticonvulsants (41.1%), hypoglycemic agents (33.8%), and cardiovascular/antithrombotic agents (30.8%) (Figure 1). The prescription medication exposures which most commonly involved medications that were not in any container (i.e., loose pills) included ADHD medications (49.3%), opioids (42.6%), and muscle relaxants (36.7%).

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On the other hand, for all OTC product classes except analgesics (34.8%), less than one-third of SDM exposures involved medications that previously had been removed from original packaging. For all OTC classes, fewer than 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 over half of exposures involving hypoglycemic agents (62.6%) and cardiovascular/antithrombotic agents (56.2%). Another child (e.g., a sibling) was reported to be the intended recipient for nearly half (47.0%) of exposures involving ADHD medications.

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

Reasons Medications Removed from Original Packaging

The reasons medications were removed from original packaging prior to access by young children differed by intended recipient (eTable 10; online). 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, 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, 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".

Discussion

Overall, 61% of calls for SDM 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 CRP, 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 of prescription medications are just as often the result of adults removing medications from original containers as the result of improper use or failure of CRP. In 52% of calls for prescription SDM

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exposures, an adult had removed the medication from the original container prior to a child accessing the prescription medication. While the PPPA requires CRP for nearly all prescription medications in the United States,[2, 11] CRP cannot protect a pill that an adult has intentionally removed from the original packaging. 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 CR-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 over one-third of exposures involving anticonvulsants and hypoglycemic agents and in over 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 (e.g., 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 CRP due 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 CRP, 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 pre-sorted packets (e.g., 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 (i.e., loose pills) in over 40% of pediatric exposures involving opioid analgesics and ADHD medications. These medications may be less likely to be kept in pill minders, since 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, since the child safety barrier

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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 CRP retained until the moment the pill is used by an adult or older child.

Implementation of unit-dose packaging has been associated with reductions in PCC calls and ED visits for unsupervised exposures of buprenorphine products and thyroxine.[15-19] Some 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 U.S. Food and Drug Administration (FDA) to require certain packaging for opioids and other drugs with 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 to 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 half (48%) of the calls for OTC product exposures involved products that do not require CRP, it is notable that nearly as many children accessed OTC products that require CRP from original containers (71%) as children accessed OTC products that do not require CRP (79%). While many OTC products are not required to have CRP, some are nonetheless voluntarily packaged in CRP. In addition, CRP is designed to delay rather than to completely prevent child access, and since 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 (e.g., 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 (e.g., hypoglycemic agents and cardiovascular/antithrombotic agents), and other children (e.g., a sibling) were the most common intended recipients for ADHD medication exposures. While 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 (e.g., 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. 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.

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Additionally, there may be non-response 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, inflating the proportion of exposures involving medications which were in 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 CRP, 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.

Conclusion

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

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgements

We thank Alfred Aleguas, PharmD, Daniel Brooks, MD, Keith Boesen, PharmD, Stephanie Hon, PharmD, Wendy Stephan, MPH, and all staff members at participating poison centers for their assistance with data collection. We also thank Andrew I. Geller, MD, from the Centers for Disease Control and Prevention, and Ruth Moro, MD, MPH, from Northrup Grumman (contractor to Centers for Disease Control and Prevention), for thoughtful review of the manuscript.

Funding/Support:

This work was supported by Centers for Disease Control and Prevention award number 2016-N-17812 to Emory University.

Abbreviations and Acronyms:

ADHD	attention-deficit/hyperactivity disorder
CRP	child-resistant packaging

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ED	emergency department
FDA	U.S. Food and Drug Administration
OTC	over-the-counter
PCC	poison control center
PPPA	Poison Prevention Packaging Act
SDM	solid dose medication
SPI	specialist in poison information

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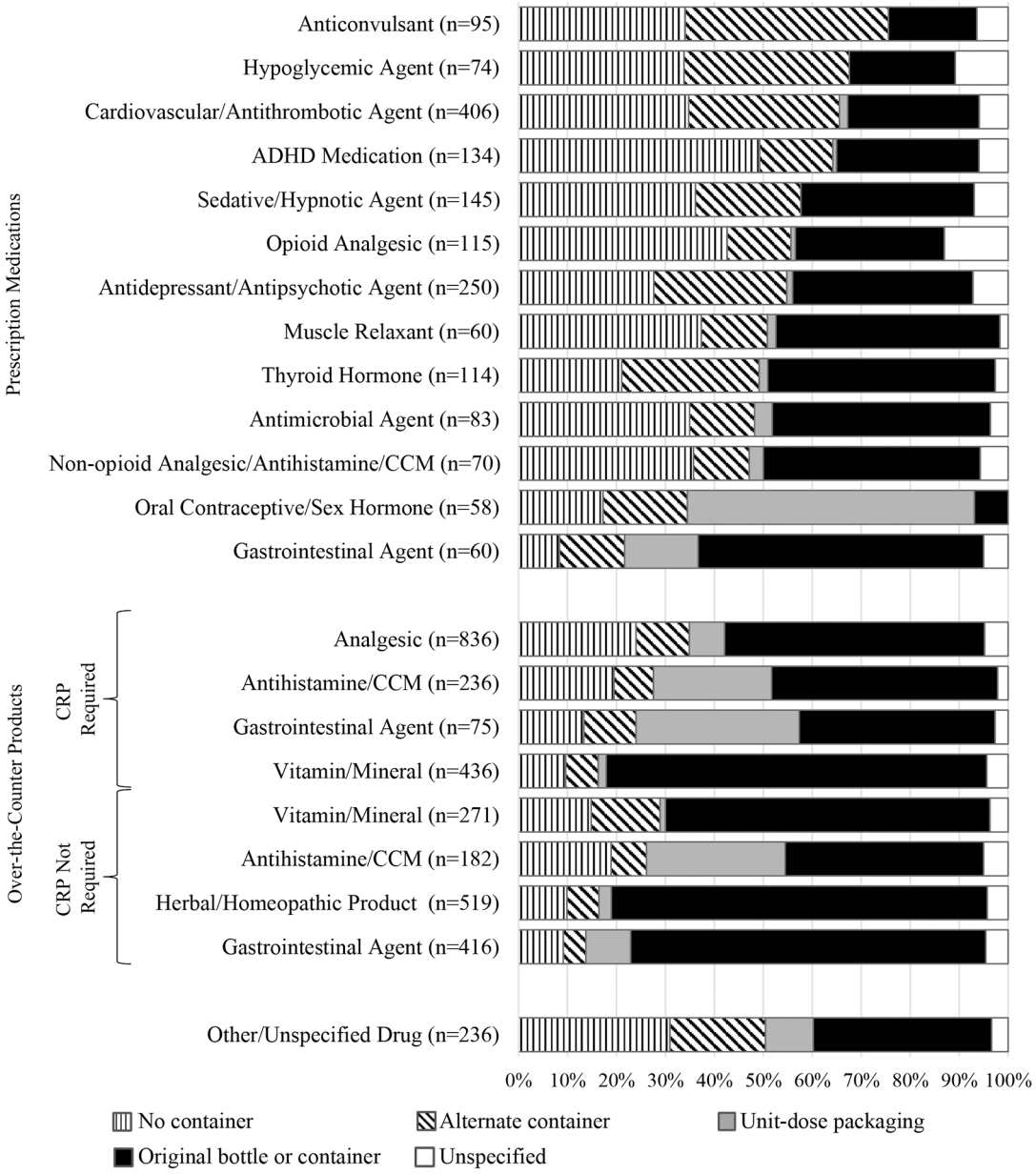

Figure 2. Type of Container from which Medications Were Accessed, by Drug Class, Children Aged ≤5 Years, February 2017 - September 2017

ADHD= attention-deficit/hyperactivity disorder; CCM=cough and cold medicine; CRP=child-resistant packaging.

Data collected from February-September 2017. Six cases involving medications accessed from ≥1 different type of container are not shown.

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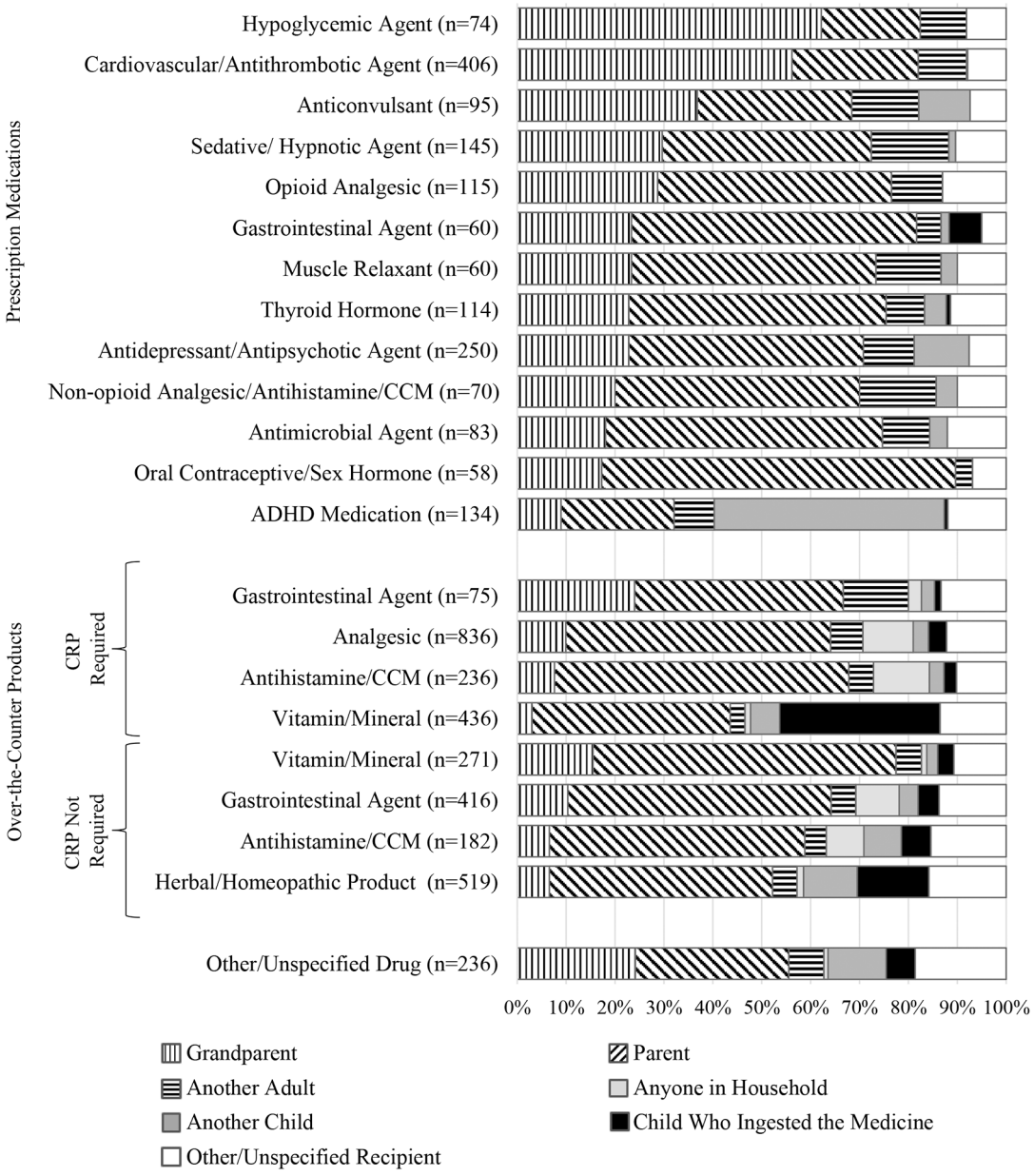

Figure 3. Intended Recipient of Medications Accessed by Children Aged ≤5 Years, by Drug Class

ADHD= attention-deficit/hyperactivity disorder; CCM=cough and cold medicine; CRP=child-resistant packaging.

Data collected from February-September 2017.

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Table 2.

Poison Center Calls for Solid Dose Medication Exposures Among Children Aged ≤5 Years, by Patient and Case Characteristics[a]

Patient and Case Characteristics	Prescription Only[b]		Available OTC Only, CRP Required for All		Available OTC Only, CRP not Required for All[c]	
	n	%	n	%	n	%
Patient Age (Years)						
<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 Years	0	0.0	0	0.0	1	0.1
Gender						
Female	739	48.6	679	46.1	653	48.5
Male	778	51.2	786	53.4	686	51.0
Unspecified Gender	3	0.2	8	0.5	7	0.5
No. Implicated Substances						
1	1,374	90.4	1,454	98.7	1,297	96.4
2	90	5.9	16	1.1	38	2.8
3 or more	56	3.7	3	0.2	11	0.8
Exposure Site						
Own Residence	1,399	92.0	1,401	95.1	1,287	95.6
Other Residence	98	6.5	48	3.3	42	3.1
Other Exposure Site	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	1,068	70.3	1,283	87.1	1,226	91.1
Healthcare Setting[d]	349	23.0	113	7.7	62	4.6
Other Residence	47	3.1	23	1.6	20	1.5
Other Call Site	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	1,045	70.9	924	68.7

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Patient and Case Characteristics	Prescription Only[b]		Available OTC Only, CRP Required for All		Available OTC Only, CRP not Required for All[c]	
	n	%	n	%	n	%
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	**1,520**	**100.0**	**1,473**	**100.0**	**1,346**	**100.0**

OTC=over-the-counter; CRP=child-resistant packaging

[a] Data collected from February-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.

[b] Most implicated prescription medications require CRP.

[c] Includes 33 cases in which both OTC products that do and that do not require CRP were implicated.

[d] Includes calls from hospitals, emergency departments, outpatient clinics, emergency medical services, and police response.

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Table 5.

Poison Center Calls for Solid Dose Medication Exposures Among Children Aged ≤5 Years, by Exposure Circumstances[a]

Exposure Circumstances	Prescription Only[b]		Available OTC Only, CRP Required for All		Available OTC Only, CRP not Required for All[c]	
	n	%	n	%	n	%
Type of Container						
Original Packaging	644	42.4	1,045	71.0	1,070	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[d]	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	1,232	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	**1,520**	**100**	**1,473**	**100**	**1,346**	**100**

OTC=over-the-counter; CRP=child-resistant packaging

[a]Data collected from February-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.

[b]Most implicated prescription medications require CRP.

[c]Includes 33 cases in which both OTC products that do and that do not require CRP were implicated.

[d]Includes pill minders/organizers, pill boxes, containers intended for other medications, sandwich-type plastic bags, food containers, and other container types.