Emergency Hospitalizations for Unsupervised Prescription Medication Ingestions by Young Children

WHAT’S KNOWN ON THIS SUBJECT: Despite child-resistant packaging requirements for most medications and safe storage education for all medicines, tens of thousands of young children are brought to emergency departments and thousands are hospitalized annually after ingesting prescription medications. Targeted prevention efforts may be needed.

WHAT THIS STUDY ADDS: Twelve medications were implicated in nearly half of hospitalizations for prescription medication ingestions. Buprenorphine and clonidine were most commonly implicated and had the highest hospitalization rates when accounting for outpatient use. Prevention efforts should focus on most commonly implicated medications.

BACKGROUND: Emergency department visits and subsequent hospitalizations of young children after unsupervised ingestions of prescription medications are increasing despite widespread use of child-resistant packaging and caregiver education efforts. Data on the medications implicated in ingestions are limited but could help identify prevention priorities and intervention strategies.

METHODS: We used nationally representative adverse drug event data from the National Electronic Injury Surveillance System—Cooperative Adverse Drug Event Surveillance project and national retail pharmacy prescription data from IMS Health to estimate the frequency and rates of emergency hospitalizations for unsupervised prescription medication ingestions by young children (2007–2011).

RESULTS: On the basis of 1513 surveillance cases, 9490 estimated emergency hospitalizations (65% confidence interval: 6420–12 560) occurred annually in the United States for unsupervised prescription medication ingestions among children aged <6 years from 2007 through 2011; 75.4% involved 1- or 2-year-old children. Opioids (17.6%) and benzodiazepines (10.1%) were the most commonly implicated medication classes. The most commonly implicated active ingredients were buprenorphine (7.7%) and clonidine (7.4%). The top 12 active ingredients, alone or in combination with others, were implicated in nearly half (45.0%) of hospitalizations. Accounting for the number of unique patients who received dispensed prescriptions, the hospitalization rate for unsupervised ingestion of buprenorphine products was significantly higher than rates for all other commonly implicated medications and 97-fold higher than the rate for oxycodone products (200.1 vs 2.1 hospitalizations per 100 000 unique patients).

CONCLUSIONS: Focusing unsupervised ingestion prevention efforts on medications with the highest hospitalization rates may efficiently achieve large public health impact. *Pediatrics* 2014;134:e1009–e1018

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**KEY WORDS**
poisoning, unintentional overdose, pediatric hospitalization, buprenorphine, opioids, sulfonylureas, prescription drugs, drug packaging

**ABBREVIATIONS**
CI—confidence interval
OR—child-resistant
ED—emergency department
NEISS-CADES—National Electronic Injury Surveillance System—Cooperative Adverse Drug Event Surveillance
PPPA—Poison Prevention Packaging Act

Maribeth C. Lovegrove conceptualized and designed the study, conducted the analyses, contributed to interpretation of data, drafted the initial manuscript, and reviewed and revised the manuscript; Justin Mathew participated in the study concept and design, contributed to acquisition, analysis, and interpretation of data; and reviewed and revised the manuscript; Drs Hamp and Wysowski participated in the study concept and design, contributed to the interpretation of data, and reviewed and revised the manuscript; and Drs Governale participated in the study concept and design, contributed to the acquisition and interpretation of data, and reviewed and revised the manuscript; Drs Hampp and Wysowski participated in the study concept and design, contributed to the interpretation of data, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted.

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 or the Food and Drug Administration.

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(Continued on last page)
In the decades since the 1970 Poison Prevention Packaging Act (PPPA) was enacted, child-resistant (CR) packaging and education on safe medication storage have saved thousands of children’s lives.1,2 Despite these interventions, unsupervised medication ingestions (young children accessing medications without adult permission or oversight) remain an important cause of preventable pediatric harm, leading to >60 000 emergency department (ED) visits by children aged <6 years and ~500 000 calls to poison centers annually in the United States.3–5 Serious unsupervised ingestions have been increasing and most hospitalizations for unsupervised ingestions involve prescription medications.6

In the United States, nearly all prescription medications are dispensed in bottles with CR caps that patients or caregivers must correctly resecure after each and every use. Even when correctly secured, CR packaging is not intended to be impervious, but rather to delay young children from opening the container and obtaining a toxic amount.7 Circumstances leading to unsupervised ingestions are multifactorial, but leaving medications in locations accessible to young children, even temporarily, as well as failing to fully resecure CR caps are known contributors.8–11 Enhancing safety packaging with elements beyond those currently required by the PPPA holds promise for reducing the incidence and severity of pediatric medication ingestions but may add marginal cost and inconvenience for adults.3,6,8,12,15 Data on the specific medications involved in serious unsupervised ingestions by young children may help prioritize products for enhanced safety packaging. We used nationally representative surveillance data to characterize emergency hospitalizations for unsupervised prescription medication ingestions by children aged <6 years and to identify the prescription medications with the highest frequencies and rates of hospitalization.

METHODS

Data Sources

National estimates of ED visits and subsequent hospitalizations for unsupervised medication ingestions were based on data from the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance (NEISS-CADES) project. NEISS-CADES is an ED-based public health active surveillance system based on a nationally representative sample of hospitals in the United States and its territories with a minimum of 6 beds and a 24-hour ED and has been described in detail.14,15 Briefly, trained coders at 63 participating hospitals review the clinical diagnoses and supporting information in all ED visit medical records to identify adverse drug events, including unsupervised medication ingestions, diagnosed by treating clinicians. Coders report up to 2 medications implicated in each adverse event, verbatim diagnoses, and narrative descriptions of the event, including precipitating circumstances, clinical manifestations, treatments administered in the ED, and discharge disposition.

National estimates of dispensed prescriptions from outpatient retail pharmacies were obtained from the IMS Health, Vector One: National database, and national estimates of unique patients receiving dispensed prescriptions were obtained from IMS Health, Vector One: Total Patient Tracker.16,17 The Vector One database integrates retail pharmacy prescription activity from a sample of chain, independent, food store, and mass merchandiser pharmacies. Each year, Vector One receives >1.9 billion prescription claims, representing >158 million unique patients and nearly half of all US retail prescription activity.

Outcome Measures

The primary outcome measure was hospitalization after an ED visit for unsupervised ingestion of an oral prescription medication by a child aged <6 years. Secondary outcomes included rates of emergency hospitalizations for unsupervised prescription medication ingestions per 100 000 dispensed outpatient prescriptions and per 100 000 unique patients receiving dispensed prescriptions.

Definitions

A surveillance case of an unsupervised ingestion was defined as hospitalization after an ED visit by a child aged <6 years for accessing prescription medication without adult permission or oversight from January 1, 2007, through December 31, 2011, as documented by the treating clinician. Hospitalizations included inpatient admissions, transfers to another hospital, and observation admissions (time-limited assessment, treatment, and reassessment, typically lasting <24 to 48 hours). For this analysis, prescription medications included oral medications available only by prescription. Because detailed information about dosage strength and brand name was not consistently documented, cases involving medications commonly available in both prescription and over-the-counter formulations were not included (eg, single-ingredient ibuprofen). When only a medication class was documented, only cases involving classes comprising solely prescription medications were included (eg, opioid analgesics were included, unspecified nonsteroidal anti-inflammatory drugs were excluded). Outpatient use of commonly implicated oral medications during the study period was estimated by using 2 measures, numbers of dispensed outpatient prescriptions and numbers of unique patients receiving dispensed prescriptions, regardless of indication or intended recipient.

Statistical Analysis

Each NEISS-CADES case was assigned a sample weight on the basis of the inverse probability of selection, adjusted for nonresponse and poststratified to
adjust for the number of annual hospital ED visits.\textsuperscript{18} National estimates of ED visits, subsequent hospitalizations, and corresponding 95% confidence intervals (CIs) were calculated by using the SURVEYMEANS procedure in SAS, version 9.2 (SAS Institute, Cary, NC), to account for the sample weights and complex sample designs. Annual national estimates were calculated by dividing the NEISS-CADES estimates for the 5-year period from 2007 through 2011 by 5. Estimates based on <20 cases, total estimates <1200 over the 5-year study period, and estimates with a coefficient of variation >50% may be statistically unreliable and are noted. IMS Health projects national estimates of dispensed outpatient prescriptions and unique patients from the Vector One sample by using proprietary analytical methods.

To calculate hospitalization rates for unsupervised ingestions, we divided the estimated number of emergency hospitalizations by both estimates of medication use (number of dispensed outpatient prescriptions and number of unique patients receiving dispensed prescriptions). Accompanying 95% CIs for rate estimates were calculated incorporating variance estimates for both numerator and denominator components.\textsuperscript{19} Because these components were calculated from separate surveillance systems, they were treated as independent (ie, having zero covariance).

RESULTS

On the basis of 3638 surveillance cases, we estimated 34 503 ED visits (95% CI: 27 296–41 709) for unsupervised ingestion of oral prescription medications annually from 2007 through 2011 among children aged <6 years. An estimated 27.5% of these ED visits (9490 visits; 95% CI: 6420–12 560) resulted in hospitalization; 5887 hospitalizations (95% CI: 4152–7622) involved inpatient admission or transfer to another hospital, and the remaining hospitalizations were observation admissions. Three-quarters of hospitalizations for unsupervised prescription medication ingestions involved 1- or 2-year-old children (75.4%; 95% CI: 72.1%–78.7%) and one-fifth involved ingestion of \( \geq 2 \) medications (21.9%; 95% CI: 18.3%–25.5%) (Table 1).

Twelve medication classes, alone or in combination with others, were implicated in 79.1% (95% CI: 73.4%–84.9%) of hospitalizations for unsupervised prescription medication ingestions (Table 2). Opioid analgesics were implicated in a significantly higher proportion of hospitalizations (17.6%; 95% CI: 13.9%–21.2%) than any other medication class. Other commonly implicated classes included benzodiazepines (10.1%), sulfonylureas (8.2%), \( \beta \)-blockers (8.0%), centrally acting antiadrenergics (8.0%), and calcium channel blockers (7.8%). These 6 classes were implicated in 57.4% (95% CI: 51.8%–63.1%) of hospitalizations. More than half of ED visits for unsupervised ingestion of sulfonylureas (77.8%), calcium channel blockers (57.4%), and centrally acting antiadrenergics (53.5%) resulted in hospitalization.

Twelve active ingredients, alone or in combination with others, were implicated in 45.0% (95% CI: 39.5%–50.5%) of hospitalizations for unsupervised prescription medication ingestions (Table 3). Buprenorphine and clonidine were most commonly implicated, accounting for 7.7% and 7.4% of hospitalizations, respectively. Nearly all hospitalizations for buprenorphine ingestions (97.2%; 95% CI: 93.5%–100.0%) involved a combination buprenorphine/naloxone product. The proportion of ED visits resulting in hospitalization for buprenorphine (62.4%) and clonidine (58.2%) was high and exceeded only by that for sulfonylureas.

Accounting for estimated numbers of dispensed outpatient prescriptions, the hospitalization rate for unsupervised ingestion of buprenorphine products (13.6 hospitalizations per 100 000 outpatient prescriptions) was significantly higher than the rate for all other commonly implicated medications except for clonidine (6.0 hospitalizations per 100 000 outpatient prescriptions) (Fig 1A). Accounting for numbers of dispensed prescriptions, the hospitalization rate for buprenorphine products was 27 times higher than the rate for oxycodone products (0.5 hospitalizations per 100 000 outpatient prescriptions) and 67 times higher than the rate for hydrocodone products (0.2 hospitalizations per 100 000 outpatient prescriptions).

Similarly, accounting for estimated numbers of unique patients who received dispensed prescriptions, the hospitalization rate for unsupervised ingestion of buprenorphine products (200.1 hospitalizations per 100 000 unique patients) was significantly higher than the rate for all other commonly implicated medications (Fig 1B). The hospitalization rate for clonidine (47.4 hospitalizations per 100 000 unique patients) was significantly higher than the rate for all other medications except for the 2 sulfonylureas. Accounting for numbers of unique patients, the hospitalization rate for buprenorphine products was 97 times higher than the rate for oxycodone products (2.1 hospitalizations per 100 000 unique patients) and 238 times higher than the rate for hydrocodone products (0.8 hospitalizations per 100 000 unique patients). The national estimate of hospitalizations for hydrocodone product ingestions used to calculate hospitalization rates had a coefficient of variation of 30.8%, a value on the border of statistical reliability.

DISCUSSION

Prescription medication ingestions by children aged <6 years lead to >9000 estimated US hospitalizations annually; 75% involve 1- or 2-year-old children. Although thousands of unique prescription

<table>
<thead>
<tr>
<th>Patient and Case Characteristics</th>
<th>Surveillance Cases</th>
<th>Annual National Estimate of Hospitalizations</th>
<th>Proportion of ED Visits Resulting in Hospitalization, %</th>
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<tr>
<td></td>
<td>Number</td>
<td>Number Percentage (95% CI)</td>
<td></td>
</tr>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1 year</td>
<td>103</td>
<td>641</td>
<td>6.8 (4.9–8.6)</td>
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<tr>
<td>1 year</td>
<td>526</td>
<td>3296</td>
<td>34.4 (30.0–38.9)</td>
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<td>2 years</td>
<td>582</td>
<td>3887</td>
<td>41.0 (35.6–46.3)</td>
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<td>3 years</td>
<td>186</td>
<td>1053</td>
<td>11.1 (8.7–13.5)</td>
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<tr>
<td>4 years</td>
<td>80</td>
<td>442</td>
<td>4.7 (2.9–6.4)</td>
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<tr>
<td>5 years</td>
<td>36</td>
<td>—</td>
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<tr>
<td>Gender</td>
<td></td>
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<tr>
<td>Female</td>
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<td>4555</td>
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<tr>
<td>Male</td>
<td>804</td>
<td>4935</td>
<td>52.0 (48.0–56.0)</td>
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<td>Number of implicated medications</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1136</td>
<td>7412</td>
<td>78.1 (74.5–81.7)</td>
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<td>&gt;=2a</td>
<td>377</td>
<td>2078</td>
<td>21.9 (18.3–25.5)</td>
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<tr>
<td>Total</td>
<td>1513</td>
<td>9490</td>
<td>100.0 (95.8–100.0)</td>
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</table>

Surveillance cases and estimates were based on data from the NEISS-CADES project, 2007–2011. Hospitalizations included inpatient admissions, transfers to another hospital, and observation admissions (time-limited assessment, treatment, and reassessment, typically lasting <24 to 48 h). The proportion of ED visits resulting in hospitalization is the ratio of hospitalizations to total ED visits for unsupervised ingestions of medications for each patient or case characteristic. Estimates that do not meet the criteria for statistical reliability are not shown.

a Includes cases in which >1 oral prescription medications were implicated and cases in which both an oral prescription medication and an over-the-counter or a nonoral medication were implicated.

medications are currently marketed in the United States, 12 active ingredients were implicated in 45% of estimated hospitalizations, with the top 2 ingredients (buprenorphine and clonidine) implicated in 15% of hospitalizations. Accounting for the estimated number of unique patients receiving dispensed prescriptions, buprenorphine had the highest rate of unsupervised ingestion hospitalizations compared with all other commonly implicated active ingredients and clonidine had the second highest hospitalization rate. A targeted prevention approach that focuses on medications with the highest rates of unsupervised ingestion hospitalization, relative to outpatient use, has the potential to efficiently achieve large public health impact.

Efforts to prevent unsupervised prescription medication ingestions have often been part of broader poisoning prevention initiatives. CR packaging and test protocols mandated by the PPRA apply equally to all specified products (including household cleaners, pesticides, and medications) on the basis of the premise that they all have potential for significant toxicity if accessed by young children.20 Although a handful of prescription medications with low potential for toxicity are excluded from CR packaging requirements, other prescription medications that are potentially highly toxic to young children in small amounts, such as those identified on “one pill can kill” lists,21,22 have no additional requirements. Similarly, a wide range of potential poisons is typically included in educational programs on safe storage practices.23,24 Although existing efforts have been credited with preventing thousands of pediatric deaths from medication ingestions over several decades,1,2 the finding of >9000 estimated hospitalizations annually resulting from prescription medication ingestions indicates that pediatric ingestions remain a serious, but preventable, public health concern.


<table>
<thead>
<tr>
<th>Medication Class</th>
<th>Annual National Estimate of Hospitalizations</th>
<th>Proportion of ED Visits Resulting in Hospitalization, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percentage (95% CI)</td>
</tr>
<tr>
<td>Opioid analgesics</td>
<td>1666</td>
<td>17.6 (13.9–21.2)</td>
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<tr>
<td>Benzodiazepines</td>
<td>960</td>
<td>10.1 (8.0–12.3)</td>
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<tr>
<td>Sulfonylureas</td>
<td>774a</td>
<td>8.2 (4.4–11.9)</td>
</tr>
<tr>
<td>β-Blockers</td>
<td>760</td>
<td>8.0 (5.8–10.2)</td>
</tr>
<tr>
<td>Centrally acting antidiureticsb</td>
<td>759</td>
<td>8.0 (5.5–10.5)</td>
</tr>
<tr>
<td>Calcium channel blockersc</td>
<td>739</td>
<td>7.8 (4.4–11.2)</td>
</tr>
<tr>
<td>Atypical antipsychotics</td>
<td>629</td>
<td>6.6 (4.8–8.4)</td>
</tr>
<tr>
<td>SSRIsp</td>
<td>457</td>
<td>4.8 (2.6–7.0)</td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td>438</td>
<td>4.6 (3.2–6.1)</td>
</tr>
<tr>
<td>ACE inhibitorsd</td>
<td>388</td>
<td>4.1 (2.8–5.3)</td>
</tr>
<tr>
<td>Skeletal muscle relaxants</td>
<td>294</td>
<td>3.1 (1.3–4.2)</td>
</tr>
<tr>
<td>Amphetamine-related stimulants</td>
<td>292d</td>
<td>3.1 (1.5–4.7)</td>
</tr>
</tbody>
</table>

Estimates were based on data from the NEISS-CADES project, 2007–2011. ACE, angiotensin-converting enzyme; SSRI, selective serotonin reuptake inhibitor.

a Coefficient of variation >30%.
b Includes clonidine, guanfacine, and methyldopa.
c Includes those implicated in combination products.
d Three surveillance cases involving hospitalizations for unsupervised ingestion of calcium channel blocker/ACE inhibitor combination products are included in national estimates for both medication classes.
Interventions to reduce unsupervised ingestions by young children should focus on the medications that most commonly lead to harm. In this study, opioids, benzodiazepines, sulfonylureas, and 3 classes of antiadrenergic agents (β-blockers, calcium channel blockers, and centrally acting antiadrenergics) were implicated in nearly 60% of hospitalizations. Previous studies also identified these classes as significant contributors to pediatric medication ingestions.6,13,25–28 Recently, there has been growing concern for harm from pediatric buprenorphine ingestions,6,29,30 and we previously noted a marked increase in estimated buprenorphine ingestion ED visits over several years.31 What has not been previously reported is that just 12 active ingredients, alone or in combination with other medications, were implicated in nearly half of all hospitalizations for unsupervised ingestions of prescription medications, and 2 ingredients, buprenorphine and clonidine, were implicated in 15% of hospitalizations. The finding that buprenorphine and clonidine were the leading contributors to unsupervised ingestion hospitalizations likely reflects the interplay of pharmacologic properties, clinical presentation, medication dose forms, availability, and other factors. Emergency hospitalization rates among pharmacologically similar medications (eg, buprenorphine versus other opioids) varied greatly. Recent studies showed an association between increased use of specific prescription medications, including opioids, and increases in child exposures.25,26,28 However, in this study, estimated numbers of both prescriptions and unique patients were highest for oxycodone- and hydrocodone-containing analgesics, whereas estimated rates of unsupervised ingestion hospitalizations were significantly higher for buprenorphine products and clonidine. After adjusting for medication utilization during the study period, 1 child was hospitalized for an unsupervised ingestion per 500 unique patients receiving buprenorphine, compared with 1 child hospitalized per 48 500 unique patients receiving oxycodone and 1 child hospitalized per 119 000 unique patients receiving hydrocodone. Passive safety features can augment existing CR packaging by addressing a key limitation: reliance on patients or caregivers to properly cap and safely store medications immediately after every use. For example, adding flow restrictors to the neck of liquid medication bottles has been shown to be efficacious in delaying preschool-aged children from accessing bottle contents and limiting the amount accessed even when safety caps are not reapplied.32 Flow restrictors are currently used in conjunction with CR caps to provide a secondary layer of protection on infants’ and children’s acetaminophen.33 The prescription medications most commonly implicated in unsupervised ingestion hospitalizations, however, are largely available in solid dosage forms (ie, tablets, capsules, or films). Unit-dose packaging, in which each individual dose has CR protection, is another passive approach to limiting unsupervised ingestions of solid medications6,8,12 and may provide benefits in addition to enhanced child safety.34 Unlike multidose bottles, which rely on users to keep medications in original bottles and fully resecure caps after every use, there is no need to resecure safety barriers of unit-dose packaging, which remain in place for unused doses. Additionally, if a child opens a CR cap or finds a bottle that was left open, all contents are readily accessible; however, with unit-dose packaging, each unit must be opened individually. Unit-dose packaging has begun to be implemented for buprenorphine products. A study of calls to poison centers (from October 2009 through March 2012) found that rates of child exposure to buprenorphine/naloxone tablets packaged in multidose bottles were significantly higher than rates of child exposure to buprenorphine/naloxone film packaged in unit-dose pouches,8 although exposure rates may have been affected by differences in formulation as well as differences in packaging. In 2013, all branded buprenorphine/naloxone products transitioned to unit-dose packaging, but generic buprenorphine/naloxone tablets packaged in multidose bottles became available. In 2014, the US Food and Drug Administration approved amended applications allowing
2 manufacturers to transition generic buprenorphine/naloxone products to unit-dose packaging. \(^{37}\) Although complicated by the staggered implementation of unit-dose packaging, continued monitoring and further investigations should assess the impact of unit-dose packaging designs on pediatric ingestions. Study findings should be interpreted in the context of the limitations of public health surveillance data, which likely underestimate the burden of unsupervised medication ingestions. First, the ED is the most appropriate setting to identify hospitalizations for unsupervised medication ingestions; however, NEISS-CADES does not include hospitalizations for children who were directly admitted for treatment or transferred from another hospital without undergoing ED evaluation. Although some hospitalizations may reflect provider precaution rather than symptom severity, hospitalization is itself a serious and costly event. Additionally, NEISS-CADES does not include adverse events resulting in death.
before or during ED evaluation. Second, hospitalizations for unsupervised ingestion of nonoral prescription medications (eg, fentanyl patches) were not included. Third, because narrative details about adverse events are collected in an emergency setting from distressed caregivers, when timely diagnosis and treatment are the priority, detailed information about medication formulation, dosage strength, or brand name, and precipitating circumstances may not be completely documented. We did not differentiate extended-release or long-acting formulations from immediate-release or short-acting formulations (eg, extended-release oxycodone versus immediate-release oxycodone). This information could guide targeted educational efforts, such as the educational components of Risk Evaluation and Mitigation Strategies (REMS) currently required for specified medications, including oral buprenorphine products.38 Similarly, information on indication and intended recipient of ingested medications was not consistently documented but could be useful for targeting interventions to specific audiences. Fourth, for ingestions involving >1 medication (22%), we did not attempt to prioritize the contribution of individual medications to hospitalization. Fifth, the IMS Health sample is limited to outpatient retail pharmacy settings. Medications obtained from other settings (eg, mail order/specialty pharmacies) were not included; however, buprenorphine and the other commonly implicated medications are primarily distributed in the outpatient retail pharmacy setting. Lastly, IMS estimates do not account for medication diversion, medication safeguarding practices, psychosocial or behavioral characteristics, or the presence of young children in medication recipients’ households, which may differ by medication. However, these factors do not nullify the multifold higher hospitalization rates for buprenorphine and clonidine ingestions and do not negate the need to address these harms to young children.

CONCLUSIONS
To efficiently achieve large public health impact, strategies to reduce harm from unsupervised pediatric ingestions of prescription medications, such as implementation of enhanced child safety packaging and patient/caregiver education, should target specific medications with the highest frequencies and highest rates of emergency hospitalizations.

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