

Locking Prescription Closures As A Powerful Ally in Reducing Accidental Child Poisonings

Reducing accidental childhood medication poisonings with
next generation medication packaging innovations



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SCOPE OF THIS WHITE PAPER

The intent of this white paper is to:

1. Review the increase in calls to poison control centers and emergency department visits for unintentional medication exposure.
2. Identify factors contributing to the rise of unintentional pediatric medication exposures.
3. Propose improved medication storage devices in conjunction with caregiver education to reduce instances of unintentional child poisonings.

THE PROBLEM

Powerful medications are assumed to be secure in today's child-resistant prescription packaging. However, despite the widespread use of child-resistant packaging, more than half of unintentional ingestions involve products that adhere to the Poison Prevention Packaging Act (PPPA) enacted in 1970.¹ And while on-going education stresses to parents the critical importance of keeping medications out of the reach of children, accidental medication poisonings continue to endanger and even kill children on a large scale. The issue is so significant that Healthy People 2020 has defined the reduction of Emergency Department (ED) visits resulting from accidental pediatric medication overdoses as one of the nation's ten-year goals for health promotion and disease prevention.²



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A DRAMATIC INCREASE IN POISON CONTROL CENTER CALLS AND EMERGENCY DEPARTMENT VISITS

In 2015, the 55 poison control centers in the United States received more than 440,000 phone calls involving accidental child poisonings.

In 2015 alone, the 55 poison control centers in the United States received more than 440,000 phone calls involving accidental child poisonings. That's a call from a desperate caregiver almost every minute. Some of those calls involved a child who ingested an inappropriate and dangerous medicine. Other calls involved a child who received too much of the correct medicine or the wrong medicine entirely.³

In 2014, 57,448 children under 6 years of age went to an Emergency Department because they ingested a medication while unsupervised or they received an incorrect dose of an appropriate medication.⁴ Tragically, about 16 percent of those ED visits involved severe poisonings that led to hospitalization or the death of a child.⁵

Based on data from the National Electronic Injury Surveillance System-Cooperative Adverse Event Surveillance (NEISS-CADES) project, it is estimated that every year one out of every 150 two-year-olds is treated in a US hospital ED for an accidental medication exposure.⁶ Over 90 percent of ED visits for unintentional medication exposure among children under the age of five involve children who get into medicine on their own without caregiver oversight.⁷

The increase in calls to poison control centers and hospital visits reflect a number of factors including the significant increase in the number of prescription and over-the-counter medications that are brought into the home:

- Changes in the family structure that increase the risk of easy access and vulnerability.
- Misconceptions about how child poisonings occur.
- Caretaker behaviors that are inconsistent with the awareness about poisoning possibilities.
- Reliance upon legislation written more than 50 years ago with the 1970 Poison Prevention Packaging Act that was intended to impede accidental access by children up to five years old.



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STAGGERING VOLUME OF MEDICATIONS IN AMERICAN HOMES

In 2014, retail pharmacies in the United States filled more than 4.0 billion prescriptions, which equates to more than 125 prescriptions per second.⁸ One study indicated that, in 2012, 59 percent of U.S. adults (ages 20 or older) took at least one prescription medication, and 15 percent took five or more.⁹ The prevalence of multiple prescription drug use almost doubled between 2000 and 2012.¹⁰



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Source: Trends in Prescription Drug Use Among Adults in the United States From 1999-2012. *JAMA*, Nov. 3, 2015.

Abundant over-the-counter medications also present risks to young children. One study estimates that 79 percent of the US population takes over-the-counter (OTC) medications, such as vitamins or herbal medicines, that can pose poisoning risks, if improperly consumed.¹¹

An analysis of pediatric ED visits between 2010 and 2013¹² explored the impact of both prescription and OTC medications, with the following findings:

- **Prescription medications and OTC medications both pose poisoning risks:** Approximately one-half (51.2 percent) of the ED visits were attributed to a prescription medication, and 43.4 percent were attributed to an OTC medication.
- **Most of the visits involved a single medication.** In other words, children were not accessing multiple types of medications at the same time.
- **Children were much more likely to be poisoned by solid medications (i.e., pills) than by a liquid:** Nearly three-fourths (72.5 percent) involved an oral solid medication and 15.4 percent involved an oral liquid medication.
- **Opioids are most commonly implicated in medication poisonings:** Among the prescription medications poisonings, opioids were the most commonly implicated class of solid prescription medication. This reflects the dramatic increase in the prescription of powerful opioid medications. Benzodiazepines were the second most commonly implicated class.
- **Of the ED visits for OTC poisonings, two thirds of the poisonings involved adult/family products, as opposed to pediatric products:** Twenty-five percent of those OTC poisoning ED visits involved vitamins/minerals or herbal/alternative remedies. Acetaminophen, alone, or in conjunction with another product - was involved in another twenty-five percent of the trips to the ED.

CHILDREN UNDER THE AGE OF FIVE ARE THE MOST VULNERABLE TO ACCIDENTAL POISONING

Two-thirds of emergency department visits for unsupervised medication exposure involved one or two-year-olds.

One and two-year-olds are at particular risk for accidental poisoning. Young children explore their environments by touching and tasting many things that cross their paths. The colorful pills in Grandma's pill box and the prescription medication that fell onto the floor can be quickly picked up and swallowed – often without the caregiver's awareness. Two-thirds of ED visits for unsupervised medication exposure involved one or two-year-olds¹³ This data suggests that young children are likely finding medications in unsecured locations, rather than opening a child-resistant container.¹⁴



POSSIBLE CAUSES OF ACCIDENTAL POISONING

Patients have reported that they don't comply with medication prescription instructions if they encounter obstacles associated with the packaging. If they don't have the strength or dexterity to open a cap, or if the pills spill out because the vial is too small, then patients may transfer their pills to easier-to-access containers which pose the risk of accidental poisoning.¹⁵

Data from the US Consumer Product Safety Commission's surveillance system (NEISS) indicates that seven of the ten products responsible for accidental childhood poisonings were prescription or OTC pills.

In order of frequency they were:

1. acetaminophen
2. blood pressure medications
3. antidepressants
4. ibuprofen
5. sedatives and anti-anxiety medications
6. narcotic medications
7. antihistamines

Data reveals that America's opioid epidemic is putting young children at increased risk for opioid poisoning: The Centers for Disease Control and Prevention (CDC) reports that 87 young children died of opioid intoxication in 2015, up from just 16 in 1999.¹⁶

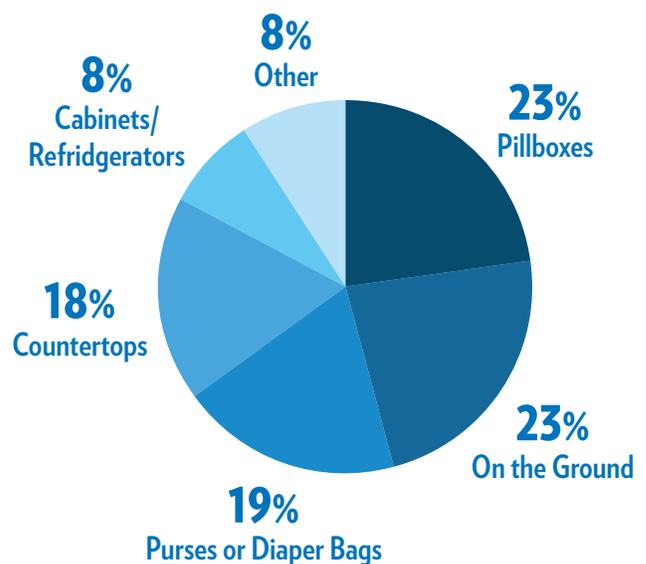


Children found easy access to these powerful medications, including opioids in:¹⁷

- Pillboxes: 23 percent
- On the ground: 23 percent
- Purses or diaper bags: 19 percent
- On countertops: 18 percent
- In cabinets or refrigerators: 8 percent

Potentially deadly medications, often within reach and unsecured, increase the possibility for accidental child access. Over 90 percent of ED visits for unintentional medication overdoses involved children, under the age of 5, who accessed the medication while their caregivers were looking the other way.¹⁸ Accidental OTC medicine poisoning incidents are most likely to occur in the bedroom or the kitchen.¹⁹

Children's Access to Medications



GREATER LONGEVITY MEANS MORE GRANDPARENTS – AND MEDICATIONS – IN THE HOME



The face of the typical American family is evolving, and it has become much more common for children to be raised by their grandparents. Tragically, many of those grandparents have assumed the role of head of household when their children died or became incarcerated because of their addiction to opioids. Households where a grandparent serves as the head of the household more than doubled between 1980 and 2014.²⁰ Grandparents may live with their children and grandchildren, even if they aren't the head of household: one study estimates that more than seven million grandparents in the U.S. live with their grown children.²¹

Modern medicine enables today's grandparents to live longer lives and play larger roles in their grandchildren's upbringing. In one study, almost one-third of the grandparents reported seeing their grandchildren at least once a week.²²

That longevity, to some degree, is a function of access to more medications than ever. Almost 40 percent of adults ages 65 and older take five or more prescription medications.²³ Young children with unsupervised access to multiple medications: it's the perfect storm of accidental poisoning, particularly when those medications are stored in an unsecured way.

VULNERABILITIES IN THE WAY GRANDPARENTS STORE MEDICATIONS

Safe Kids Worldwide 2016 study, "The Rise of Medications in the Home: Implications for Today's Children", reported that **48 percent of accidental poisonings involved a grandparent's medications**, while 38 percent involved a parent's medication, and seven percent belonged to a sibling.²⁴ These statistics reflect the fact that many seniors have memory issues, so they choose to keep their medications in a visible location where they won't be overlooked. In addition, dexterity issues can prompt Seniors to store medications in pill boxes or other easy-to-access containers.

Another 2014 study found that **28 percent of grandparents use easy-to-open or non-child resistant caps**, and 4.7 percent of those over age 64 use daily pill organizers.²⁵ In many cases, Seniors remove medications from child-resistant packaging and re-package it in containers that are easier for them - and little children - to open.



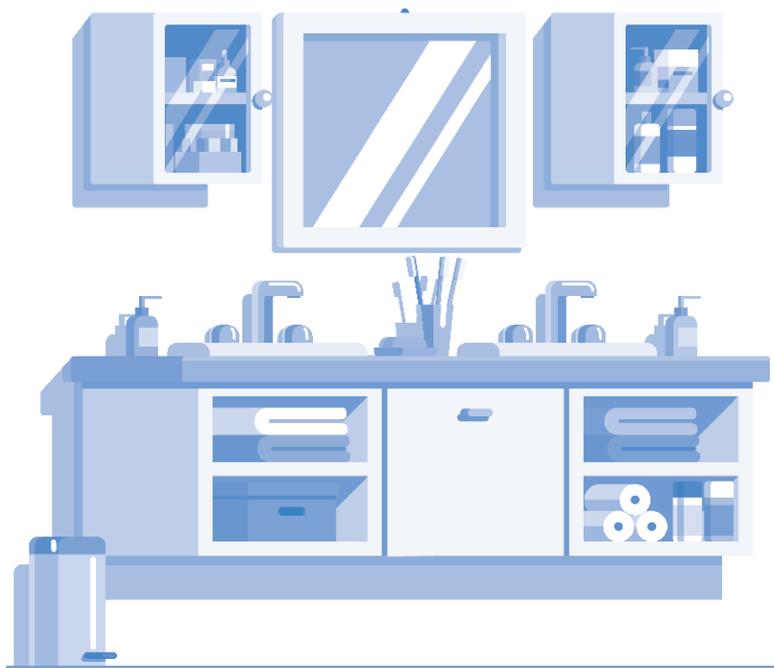
STUDY HIGHLIGHTS THE DANGER OF CARETAKER BEHAVIOR

In 2017, Safe Kids Worldwide conducted a nationwide online survey among 2,000 parents with children under age 6, in order to better understand what they know about child poisonings and what they do to prevent it in their homes.²⁶ The online survey revealed dangerous inconsistencies between what parents know about the dangers of accidental medicine poisonings and the actions they take to protect their children. Here are some key findings from the survey:

- While nine in ten parents agree it is important to store all medicine out of sight and up high after every use, nearly seven in ten report that, in reality, they often store medicine within a child's sight - on a shelf or surface at or above counter height.
- One in three parents say they or someone in their household always or often uses a daily pill organizer or baggie that children can easily get into if it's not stored out of sight and reach.
- Three in five poisonings involved medications "not in their usual place." Yet nearly five in ten parents agree that when a child is sick, it is OK to keep the medicine on the kitchen counter.
- Four in ten parents agree that it is OK to keep medicine, they or a child, takes daily on the kitchen counter or another visible location that is handy.
- The majority of parents report storing medicine in at least one location where it is unsafe - either within sight or within reach of young children.

7 in 10 parents often store medication on a shelf or surface within a child's sight.

Where Parents Report Storing Medication



52% On a shelf above counter height

45% In a cabinet or drawer above counter height

16% On a surface at counter height or above

10% In a cabinet or drawer below counter height

10% In a purse, pocketbook, or briefcase

6% On a shelf below counter height

5% On a surface below counter height

CAREGIVER DISCONNECTS AND DEADLY MISCONCEPTIONS ADD TO THE RISK

“Child-resistant means child-proof.”



Parents and grandparents often think that child-resistant packaging is child-proof packaging. In fact, the child-resistant packaging mandated by the Poison Prevention Packaging Act of 1970 merely makes it harder for a child less than five years old to access the contents of a bottle. Consequences can be deadly when parents become complacent about securing medications in an inaccessible location, and research suggests that medicine in child-resistant packaging is involved in about half of accidental pediatric medicine poisonings. Child-resistant packaging, in and of itself, was not a deterrent to accidental access; instead, the ease of access to medications was found to be the determining factor in accidental pediatric exposure.²⁷

“Kids can tell the difference between medications and candy.”



According to the Safe Kids survey,²⁸ many parents think their kids can tell the difference between prescription pills and candy. Those parents may underestimate the risk of medicine poisoning. Yet, research suggest that even older children or adults can have difficulty differentiating between some medicines and candies.²⁹

“My child understands that my pills are only for me.”



Children like to imitate their parents and may mimic their medication-taking behavior. Research suggests that imitative behavior may contribute to about 20 percent of poisonings in children under age 5 years and 30 percent of the poisonings in children ages 20 to 59 months. Instructing children to stay away from medicine and using child-resistant packaging may not be enough to discourage a young child from mimicking the ingestion of pills.³¹

“It’s out of reach, so it’s safe.”



Nearly three in five parents think if medicine is out of reach, it’s in a safe place. But children are resourceful, and in about half of OTC poisoning cases, the child climbed on a chair, toy or other device to reach the medicine.³⁰

“My child knows not to take prescription medications.”



Supervising adults may become complacent if they overestimate a child’s ability to understand potential dangers and follow safety rules. Young children are developmentally unable to understand the concept of risk. A caretaker’s presence may create a false sense of security because young children are not capable of understanding the concept of dangerous medications.³²

REDUCING THE ODDS OF CHILDHOOD POISONINGS

Although the estimated number of ED visits for accidental medicine poisonings in children under age six has continued to decline since 2010, young children are still endangered by inadequate safety packaging.³³ This encouraging downward trend may suggest that caregiver awareness and education efforts are helping to increase protective efforts and reduce risks. Still, by 2011, more children were accidentally poisoned by medications than by common household products, such as detergents.³⁴ And today, about half of child poisoning fatalities in children ages 0-14 involves a medication; that proportion is higher than in the 1980s, when less than one out of every three fatalities involved a medication.³⁵ Of particular concern is the growing rise in accidental access to the prescription opioids found in so many homes today. There is an urgent need to improve the way we secure powerful medications out of a small child's reach.



While toddlers are the most frequent victims of accidental poisoning, older children are also at risk. In particular, curious “tweens” and “teens” may outmaneuver child-resistant packaging in their quest to “experiment” with powerful medication prescribed for another family member. Their curiosity and sense of invulnerability may prove deadly as the epidemic of prescription opioid overdoses sweeps across the nation. One pill can kill - or set the stage for a lifetime of struggle with Substance Use Disorder.

We do know that child-resistant packaging – imperfect as it is – has reduced accidental poisonings significantly.³⁶ The way medications are packaged has an impact on their accessibility. **In short, well designed packaging can impede accidental and illicit access, saving lives.**

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NEXT GENERATION TECHNOLOGY ADDRESSES ROOT CAUSES OF ACCIDENTAL POISONINGS

Understanding who is at risk and how accidental poisoning takes place has inspired the next generation of accident-proof packaging. Gatekeeper Innovation's Safer Lock® is a locking cap or "locking prescription closure (LPC)" that addresses many of the vulnerabilities in the way medications are currently stored. Safer Lock is an easy-to-use medicine bottle cap that fits on standard prescription pill bottles and is designed to prevent unauthorized access to prescription medications. The cap has a four-digit combination lock that the patient can select from 10,000 possible combinations. Because access is restricted to those who know the code, the probability of accidental access is very low. Any tampering with or damage to the bottle will be evident.

The smart technology and design of the Safer Lock is designed to address several issues reported in a previous study³⁷ as obstacles to adherence, which can open the door to accidental access. Specifically, little strength is required to open the Safer Lock cap, yet the cap cannot be forced open. The Safer Lock is large enough to prevent pills from spilling out when opening but small enough to be carried in a purse, diaper bag or briefcase. Safer Lock is affordable and can be used on a wide range of prescription medication bottles. Its design is "senior friendly" for fingers constrained by mobility issues.

Safe Kids Worldwide recommends all dangerous medicines and medications will be locked up AND stored out of reach of small children.

However, the best poison-prevention device will fail if unused.

It is critical to help caretakers understand the need to take preventative steps. Grandparents need to understand how quickly a toddler can open the pretty pill box and swallow the powerful medications. Parents need to understand that poison prevention efforts must begin when the baby is born. All caretakers need to understand that OTC medications can be as deadly as prescription medications and must be locked up. Ideally, as Safe Kids Worldwide recommends, all dangerous medicines and medications will be locked up AND stored out of reach of small children. And everybody needs to understand how abuse-deterrent packaging is essential to meeting our nation's Healthy People 2020 goal of reducing the number of children who visit the ED because of accidental pediatric medication poisoning.

Pediatric medication poisonings are preventable. Adopting improved safe storage devices and behaviors, in conjunction with continuing caregiver education, will help keep our children safe from potentially dangerous medications.



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