Preventing Medication Overdoses in Young Children: An Opportunity for Harm Elimination
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Preventing Medication Overdoses in Young Children: An Opportunity for Harm Elimination

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ABBREVIATIONS
CRP—child-resistant packaging
ED—emergency department
OTC—over-the-counter
PROTECT—Preventing Overdoses and Treatment Exposures Task Force
FDA—Food and Drug Administration

Medication overdoses in young children are an increasingly common public health problem, but it is a preventable problem that can be addressed by combining strategies. The introduction of child-resistant packaging (CRP), product reformulations, heightened parental awareness, and poison control professionals and systems have made deaths from pediatric poisonings uncommon. However, the morbidity rate from medication overdoses, measured by emergency department (ED) visits and from calls to poison control centers, has been rising.

Medications have surpassed household products (eg, cleaning agents) as the predominant cause of pediatric poisonings. More than 70,000 children are brought to EDs for unintentional medication overdoses annually; the peak incidence is in 2-year-olds (Fig 1). Between 2005 and 2009, ED visits for medication overdoses among children younger than 5 years rose 20%. In 2009, 1 of every 151 2-year-olds was assessed in an ED for a medication overdose. Among children younger than 5 years, 95% of these ED visits for medication overdoses were a result of unsupervised (accidental) ingestions. Fewer than 5% of ED visits were a result of errors made by a caregiver; such visits primarily involve incorrect dosing. Recognizing the significance of this problem, a new Healthy People 2020 objective calls for reversal of these morbidity trends and a reduction in ED visits by 10% by 2020.

PUBLIC-PRIVATE COLLABORATION
Collaboration across the public and private sectors is a promising strategy for addressing pediatric medication overdoses. In 2008, the Centers for Disease Control and Prevention convened a meeting of public and private stakeholders involved in over-the-counter (OTC) medication and pediatric safety to identify and prioritize key strategies for addressing unintentional medication overdoses based on projected impact and feasibility. From this meeting, an innovative public-private initiative, Preventing Overdoses and Treatment Exposures Task Force (PROTECT), emerged. This ongoing initiative was predicated on voluntary collaboration by stakeholders who share a commitment to reducing unintentional medication overdoses in children.
properly, the safeguard becomes ineffective. To address this limitation, PROTECT promotes the development and implementation of a new generation of safety packaging that incorporates passive mechanisms of protection in addition to that required under the PPPA. These innovations are intended to limit the amount of medication that could be ingested by a child even if a child-resistant cap has not been rescued properly. Several PROTECT partners plan to introduce such passive flow-restrictor technology on a number of marketed pediatric liquid products this year. In addition, the marketplace has already seen the introduction of a number of unit-dose packages that eliminate the need for a bulk bottle-and-cap system.

However, even enhanced safety packaging will not be 100% “child-proof,” so PROTECT is launching a public education campaign named “Up and Away” to promote safe use and storage of medications among the current generation of child caregivers. PROTECT stakeholders, including the American Association of Poison Control Centers, have extensive experience in providing public education about medication safety. The new campaign emphasizes key lapses, such as the need to return medicines to a safe storage location immediately after every use, and updates messages to take advantage of current technology (eg, to have caregivers program the national poison center number (800-222-1222) into their cell phones.)

FIGURE 1
Rate of ED visits for unintentional medication overdoses in young children: United States, 2006–2009. Population rate estimates were based on the National Electronic Injury Surveillance System–Cooperative Adverse Drug Event Surveillance project, CDC, and midyear US Census estimates. Bars represent the 95% confidence intervals. We excluded 1.0% of the cases in which the type of error was unspecified.

STANDARDS FOR PRODUCT LABELS AND DOSING DEVICES TO FOSTER SAFE USE

In late 2009, the US Food and Drug Administration (FDA) issued draft guidance for industry that specified recommendations for firms that manufacture, market, or distribute OTC liquid medications packaged with dosage-delivery devices. The guidance is aimed at improving the clarity of the markings on dosing devices and the consistency between product labeling and dosing devices. In addition, the Consumer Healthcare Products Association reviewed issues identified in a 118-product survey completed by PROTECT participants and adopted voluntary guidelines that contain many of the same recommendations made by the FDA. Before the release of these recommendations, Yin et al assessed consistency in labels and dosing devices of OTC liquid medications but did not attempt to assess the inconsistencies that were identified on the basis of their potential to cause significant harm. Now that standards have been recommended, PROTECT participants will assess products’ compliance with these standards in the fall of 2011 and highlight any serious inconsistencies that persist.

The FDA also monitors for such inconsistencies and acts to remove from the marketplace OTC liquid drug products that are packaged with misleading dosage-delivery devices that may pose serious safety concerns. For example, the FDA identified and monitored the recall of a potentially unsafe nasal decongestant product with directions for use that read, “take 2 teaspoonfuls (tsp) every 4–6 hours.” The dosage-delivery device packaged with the product did not display a “2 tsp” marking but did display a marking for 2 tablespoonfuls as “2 TBS,” potentially leading to a dangerous threefold increase in the administered dose. Such inconsistencies may also be identified by clinicians or caregivers and can be reported to the FDA by submitting a MedWatch report at www.fda.gov/Safety/MedWatch/HowToReport/default.htm.

FUTURE EFFORTS

Packaging innovations, public education, and dosing standardization for OTC liquid products are only the first steps toward solving the problem of pediatric medication overdoses. As shown by Lung and Olson in their study of pediatric sulfonylurea poisoning.
ings (in this issue of Pediatrics), overdoses from prescription products and tablet medications will need to be addressed, and further engagement by clinicians is needed. The FDA’s Safe Use initiative (www.fda.gov/Drugs/DrugSafety/ucm187806.htm) is a new program intended to develop targeted solutions for reducing unnecessary injuries from avoidable medication misuse, errors, and other problems by facilitating public and private collaborations. Administrators of this program plan to help broaden current prevention activities and help to complete the task of reducing morbidity from pediatric overdoses this decade.

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REFERENCES

8. Yin HS, Kochanowski BA, Mrazik TJ, et al. Improving consistency in dose-related volumetric measures on nonprescription pediatric liquid medication labels and measuring devices. Presented at: Pediatric Academic Societies’ annual meeting; May 1-4, 2010; Vancouver, British Columbia, Canada
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