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The Last Mile: Taking the Final Steps in Preventing Pediatric Pharmaceutical Poisonings

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The dramatic reduction in pediatric deaths from unintentional poisonings in the last half of the 20th century is a model of the successful application of injury prevention theory and practice. The increases in hospitalizations and emergency department (ED) visits and persistence of deaths caused by unintentional pediatric pharmaceutical poisonings in the first decade of this century described by Bond et al in this issue of *The Journal* remind us that this effort is not yet complete.[1] Hopefully the findings in this study can help catalyze targeted efforts to reverse the rise in injuries from pediatric pharmaceutical poisonings and push the number of pediatric deaths closer to zero.

Educational initiatives, engineering modifications, and enforcement actions (the three E's of injury prevention) all contributed to a decrease in pediatric poisonings in the 20th century. Educational initiatives for parents, caregivers, and children became a cornerstone of poisoning prevention activities when the third week of March was designated as National Poison Prevention Week in 1961.[2] An engineering approach to pharmaceutical poisoning prevention was introduced in the 1950s when Dr. Jay Arena convinced manufacturers to place "safety closures" on bottles of flavored children's aspirin to prevent self-ingestion by young children.[3] Unfortunately, the number of pediatric salicylate poisoning deaths continued to increase. The most popular early cap design depended on friction to keep the cap in place, and although many young children could not open these caps with their hands, they could open them using their teeth. With adoption of other types of closures, such as those which required pressure and rotation, deaths began to decline.[4] After studies in the late 1960s demonstrated that child resistant closures (CRCs) on bottles of adult prescription medicines reduced unintentional poisonings among children, the Poison Prevention and Packaging Act (PPPA) was passed in 1970.[5] The U.S. Consumer Product Safety Commission now enforces the use of CRCs on potentially toxic products, including many over-the-counter (OTC) and nearly all prescription medications.[6,7]

Poisoning prevention interventions of the last century also addressed each of the three phases of the injury process (pre-event, event, post-event). Education to encourage safe use and storage practices seeks to alter conditions of the pre-event phase. Voluntary restrictions

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on the amount of medication sold in a single container limits the dose exposure in the event a child accesses the contents of a container. Access to poison centers, now through a national toll-free number (1–800-222–1222), provides expert assistance for triage and management after an ingestion.

Poisoning morbidity and mortality did decrease significantly in the 1970s. In particular, the use of CRCs on medications has been credited with preventing more than a thousand pediatric deaths and many more injuries from non-fatal poisonings.[6,8] The most dramatic reductions have been in poisonings from non-pharmaceutical products, however, and the problem of accidental pharmaceutical poisonings has persisted.[9] Studies from the 1950s found that approximately two-thirds of accidental poisoning deaths among children < 5 years in the United States involved substances other than medicines.[10,11] In the 2000s, pharmaceutical products are now the predominant cause of pediatric poisonings, accounting for 60% of accidental deaths and sending 1 of every 150 two-year-olds to an ED.[12,13]

The study by Bond et al in this issue of *The Journal* provides additional details on the rising tide of unintentional pharmaceutical poisonings among young children.[1] Using the National Poison Data System of the American Association of Poison Control Centers, Bond and colleagues analyzed calls to poison centers for unintentional exposures of a single pharmaceutical product by a child < 6 years old for which evaluation in a healthcare facility (most commonly an ED) was sought. From 2001 to 2008, Bond et al found a 43% increase in the number of moderate or serious injuries, a 36% increase in number of admissions, and a 28% increase in ED visits. Of 453,559 visits identified over the 8-year study period, 95% were for self-ingestions (55% involving prescription medications; 40% involving OTC products) and only 5% involved therapeutic errors. Bond's findings that the overwhelming majority of these ED visits (as well as injuries and admissions) are due to child self-ingestions is consistent with other studies and should lead us to conclude that preventing these self-ingestions is an important pediatric patient safety issue with significant morbidity and mortality.[14]

What can be done to reduce morbidity and mortality from child self-ingestions in 2011 in addition to what has been tried in previous decades? Limitations of CRCs were evident to their earliest proponents. In 1970, Col. Robert Scherz who led one of the early studies of CRCs at Madigan General Hospital and McChord Air Force Base noted that "[t]he chief weakness of CRCs in current use is the accessibility of the entire contents of the vial to the child once it is opened. The theoretical ideal of an inexpensive practical CRC that dispenses small quantities of medicine is yet to be developed, tested, and distributed commercially".[15] Forty years later, a public-private collaboration to address pediatric pharmaceutical poisonings, the PROTECT Initiative, has inspired the commercial development of packaging that seeks to approach Col. Scherz's "theoretical ideal" for liquid medicines.[16]

This next generation safety packaging is designed to provide a second, passive mechanism to limit the amount of liquid medication that could be accessed by a child when the child-resistant cap is compromised or improperly replaced. One example of this new packaging requires insertion of a needleless syringe into a valve that covers the bottle opening. Another design requires applying pressure to the bottle to extrude the liquid medication through a

one-way valve. Such “pediatric exposure-limiting packaging” will soon be distributed commercially on selected liquid OTC products, including all single-ingredient infants’ acetaminophen products and Children’s Tylenol® products.[17–18] As was the case for the early CRCs, the testing and refinement of these innovative safety packaging designs for liquid medications will be needed to confirm effectiveness and assess for unintended consequences.

Of course, pediatric pharmaceutical poisonings involve products other than OTC children’s liquid preparations. Are there innovative interventions to address child self-ingestions of pills? Again, early poisoning preventionists recognized this challenge. In 1981 Dr. Paul Palmisano suggested a “double barrier” approach of packaging pills in blister packs and dispensing these blister packs within a traditional child-resistant container.[19] Dr. Palmisano acknowledged that additional cost and patient inconvenience may be barriers to this approach so he suggested targeting only a few compounds with high clinical toxicity and widespread availability. High toxicity medications that can be fatal to toddlers in small doses have been identified,[20] but an even better approach than identifying which of these are highly available is to directly examine national data on frequency and severity of actual harms to children to identify priority targets for intervention. Based on their analysis of ED visits, admissions, injuries, and deaths, Bond et al suggest directing attention to opioids, cardiovascular agents, and sedative-hypnotics. These are broad and widely used categories of medicines, so a more focused approach could examine the intersection of high toxicity medications and pediatric poisoning deaths to identify the specific opioid, cardiovascular, or sedative-hypnotic preparations which might maximize the impact of “double barrier” approaches and minimize cost and inconvenience to adult pill-takers.

Bond et al provide much useful information for targeting prevention activities but a number of questions remain. First, while self-ingestions led to the greatest number of ED visits and hospitalizations, the contribution of therapeutic errors in pediatric deaths is not clearly detailed. Labeling and education targeting these errors may also be needed to fully address mortality.[21,22] Second, identification of the specific formulations of medications (e.g., pill vs. liquid; pediatric vs. adult) that were responsible for the greatest proportion of ED visits, hospitalizations, and deaths could help identify target areas for intervention. Third, additional details on the circumstances of ingestions could further guide intervention priorities. Although limited, data from previous studies have shown that a fair number of unsupervised ingestions involved a child accessing medicine from a bottle that had been left open or improperly closed or from a container, such as a bag or pillbox, to which the medication had been transferred.[23,24] Lastly, as acknowledged by the authors, the findings in this study are based on a passive surveillance system and such systems can be susceptible to reporting biases, incomplete data, and under-reporting, but all these limitations would result in underestimates of the actual health burden.

Tremendous progress was made in poisoning prevention in the second half of the 20th century, particularly in reducing pediatric mortality. Now the baton has been passed to another generation. A new Healthy People 2020 objective aims to reduce morbidity by decreasing the number of ED visits for medication overdoses in children <5 years by at least 10% by the end of this decade.[25] It will take creativity, collaboration, and commitment, but

working together physicians, pharmacists, packaging professionals, pharmaceutical companies, poison preventionists, and parents can convert pediatric pharmaceutical poisonings from a re-emerging risk to a historical footnote.

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