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ISMP

Nurse AdviseERR®

Educating the Healthcare Community About Safe Medication Practices

ISMP Canada identifies themes associated with fatal medication events in the home

Medication safety in the home is an important public health issue. Almost half of all Americans have taken at least one prescription medication in the last month,[1] and more than three-quarters have taken an over-the-counter (OTC) medication.[2] Almost two-thirds of Americans take at least one medication daily to treat a chronic health problem.[3] Most of these medications are taken in the consumer's home, group home, or other residential or community setting. In these settings, the risk of medication errors is ever present as consumers with variable health literacy[4] and unlicensed healthcare personnel undertake the complex processes associated with safe medication management.

To learn more about medication errors that happen in the home, our sister organization, the Institute for Safe Medication Practices (ISMP) Canada, collaborated with several provincial Offices of the Chief Coroner and Chief Medical Examiner in Canada[5] to conduct an analysis of medication events associated with deaths in the community setting.[6] The goal of the analysis was to better understand the challenges faced by unlicensed healthcare personnel and consumers when managing medications in the home, and to identify opportunities to prevent similar tragic events in the future. This novel analysis uncovered clear themes and contributing factors that led to the fatal events. We believe these findings are noteworthy and valuable to US healthcare professionals, as there is good reason to believe that the same issues are causing fatal medication errors in US homes.

Investigations of 122 fatal medication events spanning over 6 years (2007-2012) were reviewed by an interdisciplinary team at ISMP Canada. Of these, 45 events occurred in a consumer's home, group home, or other residential setting. In all of the 45 cases, the medications were administered by the consumer, family members, or unlicensed healthcare personnel. The overarching theme linking the 45 events was knowledge deficits leading to various patient safety risks. These fell into three key areas: knowledge deficits related to misperceptions about medications, knowledge deficits related to signs and symptoms of toxicity, and knowledge deficits about specific medications. ISMP Canada published a detailed account of its analysis,[6] which is summarized with permission below.

I Knowledge deficits related to misperceptions about medications

The largest category of knowledge deficits involved misperceptions about the medications, including a failure to appreciate the general risks associated with prescription and OTC drug therapy. Most of the deaths involved an intentional therapeutic overdose, therapeutic sharing, or unsafe storage of medications.

Intentional therapeutic overdose: "If one is good, two will be better." A number of events involved a prescription or OTC medication that was taken or given at a higher dose than prescribed or recommended on the package. Either extra doses were taken, dosing instructions were disregarded, or "as needed" doses were

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check it out

Be sure to cover these topics when educating patients about the medications they take at home:

- The increased risk of side effects and serious toxicity if the dose of the medication is increased or the drug is taken more frequently (or treatment failure if taken less frequently) than prescribed or indicated
- The importance of following medication instructions on the label (for both prescription and OTC medications)
- The importance of seeking out assistance from a licensed healthcare provider if the directions for taking a medicine are unclear or say "take as needed"
- The potential side effects of medications, how to differentiate potentially dangerous effects (i.e., excessive sleeping, gurgling noises) from more benign ones, and the actions needed to mitigate harm
- The signs and symptoms of toxicity necessitating intervention by licensed healthcare providers
- The importance of not sharing medications with anyone or taking medications from others
- Specific safeguards for the most frequent medications involved in these fatal events, particularly high-alert medications such as opioids (e.g., how to evaluate the level of sedation and signs of toxicity, safe storage)
- The need to immediately communicate to a healthcare provider any changing or worsening symptoms related to the medications and conditions being treated, or unusual or sudden behavioral changes
- The importance of reporting all medication errors to a healthcare provider
- A plan to assess symptoms and medication effects (e.g., pain control when taking opioids) at regular intervals appropriate to the clinical situation

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used routinely. In the analyzed events, it appears that most consumers or unlicensed healthcare personnel lack awareness that a higher dose would increase the risk of side effects and serious toxicity, particularly with OTC medications. The following is an example of a fatal error in this category.

An elderly woman with peripheral vascular disease died because of complications from overuse of an OTC Chinese herbal medicine containing methyl salicylate. The medicine was intended to be applied once or twice daily on the legs to provide relief from arthritic pain. The woman was frequently seen applying the medicine at least 3 or 4 times daily and would hide the medicine from the rest of the family after being reminded to use it less often. Overuse of the herbal medicine led to multiple medical problems, which contributed to her eventual death.

Therapeutic sharing: "What works for me will work for you." In a few instances, well-meaning people shared their prescription medications with others. However, they were unaware that a medication's effect is highly dependent upon the individual's medical conditions, tolerance to the medication, drug interactions, and the pharmacologic properties of the drug itself. Many drugs require individual assessment, dosing, and monitoring, and cannot be safely shared from one person to another. Some consumers felt their symptoms were not being appropriately addressed by their healthcare provider, which may have led them to consider recommendations from a friend. An example in this category follows.

*A man with chronic alcoholism and chronic pain from a work injury was found dead at home. A fenta**NYL** 100 mcg/hour patch was found on his body, although the drug had never been prescribed for him. The man told his wife that the patch had been provided by a friend. His death was attributed to alcohol and fenta**NYL** toxicity in an apparent opioid-naïve person.*

Unsafe storage: "Does it really matter where I keep my medications?" In this category, death occurred when medications were accessed and taken by others for whom the medication was not intended, particularly children. Pre-pouring medications and unsafe storage of drugs contributed to the events. Opioids caused most of the deaths in this category.

A young child died after ingesting some of her father's liquid methadone dose. The child's father had taken part of the dose and mixed the remainder with orange juice in a cup that was accessible to the child. The child was later observed drinking what appeared to be juice. The following morning, the child could not be awakened and subsequently died in the hospital.

II Knowledge deficits related to signs and symptoms of toxicity

Opportunities to mitigate harm or prevent death may exist even after the occurrence of a medication event. Unfortunately, in many of the events analyzed, caregivers or family members did not know or recognize warning signs of toxicity, which hindered timely recognition of distress and resulted in missed opportunities to rescue the consumer. Analysis revealed that the majority of deaths falling under this category involved: unconsciousness mistaken for sleep, a sudden change in behavior, or a reluctance or hesitancy to seek help.

Unconsciousness mistaken for sleep. In numerous events, family members or caregivers thought the person was sleeping when, in fact, he or she was unconscious. If unconsciousness is detected in a timely manner, there may be an opportunity to

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SAFETY wires

Does ClariSpray look familiar? **CLARISPRAY** is fluticasone propionate, a corticosteroid nasal spray that is generically equivalent to **FLONASE ALLERGY RELIEF**. In the upper right hand corner of the ClariSpray package label (**Figure 1**, left), Bayer, the distributor of the product, notes that it is "from the Makers of Claritin." **CLARITIN** is loratadine, an antihistamine. With this product association, the similar package colors and graphics, and similar names that begin with "CLARI-," it's possible that some may think that ClariSpray is a spray form of loratadine. No cases of confusion have been reported yet. Consumers and healthcare providers need to be aware of the differences between these products.

Figure 1. ClariSpray (L) is labeled "from the Makers of Claritin," but it doesn't contain loratadine (R).

It's Exelan, not Exelon. It's rare for the name of a drug company to be so close to the name of a drug that it leads to a medication error. But that's exactly what happened in the following case, and it almost led to harm for an elderly patient who nearly got the wrong medication.

After a patient was admitted to the hospital, a family member brought in a prescription bottle that contained meloxicam, a non-steroidal anti-inflammatory agent that the patient had been taking at home. See **Figure 1** (on page 3) for a photo of the prescription container label. To develop an active medication list for the patient's physician to reconcile, a nurse inadvertently copied down the manufacturer name, Exelan, thinking it was a brand name for meloxicam. The doctor then ordered **EXELON**, a brand name for rivastigmine tartrate, along with the meloxicam strength and frequency–"Exelon 7.5 mg one tablet daily." Rivastigmine tartrate is an anticholinesterase inhibitor indicated for patients with mild to

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intervene and rescue the person from harm. Many caregivers or family members recalled hearing the person snore or make gurgling or groaning noises but did not know that unusual and irregular snoring is often a sign of dangerous stupor. In the events analyzed, family members or caregivers had not tried to awaken the person until it was too late, assuming that "sleep is good," as in the following example.

*A resident of a halfway house died from accidental oxy**CODONE** toxicity. He had been taking morphine and gabapentin prescribed by his family physician but was later referred to a pain specialist who suggested a long-acting oxy**CODONE** product. The written recommendation from the specialist was misinterpreted by the family physician, who prescribed a very high dose of oxy**CODONE**. After confirmation of the dose with the pharmacy and family physician, the medication was given to the resident for 3 days. On the day of death, the "sleeping" (but really unconscious) resident was not "awakened" for his scheduled dose of medication. Staff returned 2 hours later and found the resident was not breathing.*

Sudden change in behavior. Analysis identified cases in which there was a notable change in the consumer's behavior, which might have represented an opportunity for timely intervention. Behavior changes can be caused by drug toxicity. There are many medications used to treat a variety of conditions that can cause irregular behavior if given too frequently or at a higher dose than required. In the analyzed cases, the seriousness of the changed behavior prior to death was not recognized. An example follows.

A man with a history of mental illness was found dead at home. He had been taking multiple medications, including an opioid. A family member noted that, 2 days before his death, the man had been very groggy and did not seem like himself. The patient's death was associated with opioid toxicity.

Reluctance or hesitancy to seek help. In a number of the cases reviewed, the consumers' condition or pain had worsened, and they may have made changes in their medication regimen without seeking advice from a healthcare professional. In some instances, the consumer had told friends or family members of new or worsening symptoms lasting anywhere from 3 days to 3 weeks before death but had never reported these concerns to a healthcare provider. The following event illustrates a reluctance to seek help, even when an error was known to have occurred.

*A man lived in a communal house for people with various mental health issues. The owner of the house was responsible for distributing medications to the tenants at mealtimes. On the day of the event, the owner was ill and asked a family member to oversee the medication routine. Instead of receiving his usual medications, the man was given someone else's medications, including amitriptyline, **QUE**tiapine, loxapine, and **OLANZ**apine. When the family member realized the error, he immediately notified the owner of the house, who thought the medications the man had received were not significant enough to warrant medical attention. The man went to bed that evening and was found dead in his room the following morning.*

III Knowledge deficits related to specific medications

The most frequent medication classes identified during analysis of the fatal events included:

- opioids (20 cases)
- psychotherapeutic drugs (17 cases)

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moderate dementia of the Alzheimer's type or mild to moderate dementia associated with Parkinson's disease. Although Exelon isn't available in a tablet, it is available as a patch and capsule. When used orally, the starting dose is just 1.5 mg twice a day with subsequent dose titration after tolerating that dose for 2-4 weeks. Then additional dose titration takes place again after 2-4 weeks, until a maximum dose of 12 mg daily is tolerated. Among the capsule strengths available are 1.5 mg, 3 mg, 4.5 mg, and 6 mg, so a 7.5 mg oral dose could be ordered and dispensed as two capsules (6 mg and 1.5 mg, or 3 mg and 4.5 mg). Fortunately, a pharmacist noticed the unusual Exelon dose and recognized the error when he received the order.

Figure 1. The drug company name, Exelan, was mistaken as the name of a medication, which was then confused with Exelon.

Perhaps the pharmacy label would have been a bit less error-prone if the manufacturer's name was listed far away from the drug name—a recommendation we made to the mail order pharmacy that displayed the manufacturer's name above the directions for use. This type of error also demonstrates the importance of including the drug indication with prescription communications. We have also notified Novartis, Exelan, and the US Food and Drug Administration (FDA). Exelon, a Novartis product, initially received FDA-approval in 2000. Exelan, the company, was incorporated in 2010. Neither ISMP nor FDA have any similar reports of mix-ups between Exelan and Exelon in our databases.

Vecuronium and vancomycin vial mix-ups. An anesthesiologist reported a hazardous situation with look-alike vials of Mylan's vecuronium 20 mg injection and vancomycin 1 g injection. The medications are stored in pharmacies and are both used in the operating room. Although their

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Newsletter also partially supported by an educational grant from NEOMED®

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- insulins (5 cases)
- OTC medicines (5 cases)
- cardiovascular drugs (4 cases)
- anticoagulants (3 cases)
- anticonvulsants (2 cases)

Several of these drug classes are also considered high-alert medications (e.g., opioids, insulin, anticoagulants). While the knowledge deficits associated with these medications are not generalizable to all events within the drug class, an illustrative example with insulin follows.

An older man died after an inadvertent insulin overdose. He and his family were recent immigrants, and there was a language barrier. Day-to-day care was provided by his adult children, who prepared meals and administered medications, including insulin. They believed that additional insulin was needed to treat low blood glucose and continued to give insulin when blood glucose readings were low.

Conclusion

ISMP Canada has highlighted important underlying knowledge deficits that contributed to preventable medication-related deaths in the home setting. The themes and contributing factors identified in this analysis illustrate the need to educate consumers about the medications they take at home. See the **check *it* out!** column on page 1 (right column), for specific educational topics to help consumers, families, and caregivers prevent errors in the home.

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4) Coleman EA, Smith JD, Raha D, Min S. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med.* 2005;165(16):1842-7.
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Special Announcements

ISMP webinar. You don't want to miss our next webinar, ***Implementation of Best Practices for Safer Insulin Pen Use: Stories from the Frontline***, to be held on **March 28**. The webinar will explore challenges associated with the safe use of insulin pens from the pharmacy with the support of integrated electronic prescribing and bar-coding systems. To register, visit: www.ismp.org/sc?id=349.

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cap colors are different (vecuronium has a tan cap while vancomycin's cap is yellow), these vials are nearly identical in appearance once the caps are removed (**Figure 1**) if one does not see the paralyzing agent warning on the ferrule of the vecuronium vial. The similar vials were also mentioned in a review of neuromuscular blocker safety that appeared in our August 2016 nursing newsletter. A mix-up between these drugs could prove fatal since vecuronium is a paralyzing agent.

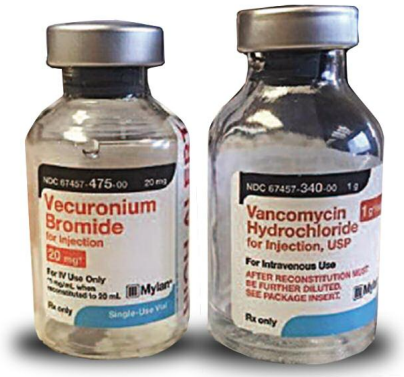

Figure 1. Mylan vecuronium and vancomycin vials look nearly identical once the caps are removed.

These two products from Mylan should not be present together in any facility. Instead, purchase one or the other from a different manufacturer. We've notified both the US Food and Drug Administration (FDA) and the manufacturer, Mylan, about the problem.

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Safe Medication Management Fellowships

ISMP is now accepting applications for three unique **2017-2018 Fellowship** programs

One ISMP Safe Medication Management Fellowship

Location and Term: This 12-month Fellowship, sponsored by **Baxter International Inc.**, commences summer 2017 at the Horsham, Pennsylvania (near Philadelphia) office of ISMP. Relocation to the Horsham/Philadelphia area is required.

Description: The Fellowship **offers a nurse, pharmacist, or physician with at least 1 year of postgraduate clinical experience** an unparalleled opportunity to learn from and work with some of the nation's experts in medication safety. This Fellowship is open to US citizens only. Now in its 25th year, the Fellowship allows the candidate to work collaboratively with practitioners in various healthcare settings to assess and develop interdisciplinary medication error-prevention strategies.

Sponsored by: Baxter

Two FDA/ISMP Safe Medication Management Fellowships

Location and Term: These 12-month Fellowships commence August/September 2017. The Fellows will spend 6 months at the Horsham, Pennsylvania (near Philadelphia) office of ISMP and 6 months at the Silver Spring, Maryland (near Washington, DC) office of the US Food and Drug Administration (FDA). Relocation to the Horsham/Philadelphia and Silver Spring/Washington, DC, area is required.

Description: The Fellowships, **open to healthcare professionals with at least 1 year of postgraduate clinical experience**, are a joint effort between ISMP and FDA's Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, and Division of Medication Error Prevention and Analysis. These Fellowships are open to US citizens only. The Fellowships allows candidates to benefit from ISMP's years of experience devoted to medication error prevention. At FDA, valuable regulatory experience is gained by working with the division focused on medication error prevention.

A competitive stipend, paid vacation, and health benefits are provided with all Fellowship programs.

How to Apply

Information and applications can be found at: www.ismp.org/profdevelopment/.
Applications can also be requested by calling 215-947-7797.

The application deadline for all Fellowship Programs is March 31, 2017.