Using information from external errors to signal a “clear and present danger”

Chances are you’ve scanned the headlines and read many of the stories about medication errors published in the ISMP Medication Safety Alert! Community/Ambulatory Care Edition, particularly the tragic errors. Just a few examples of the tragic errors we’ve published include:

- The death of a 2-year-old boy who placed a used fentanyl patch in his mouth after he ran over it with his toy truck in his great grandmother’s room at a long-term care facility
- A 6-year-old boy who died after he was given chloral hydrate before a procedure
- A 60-year-old woman who died after accidentally taking the equivalent of 3 cycles of oral lomustine therapy at one time (450 mg), believing the pharmacy had dispensed just a single dose (150 mg)
- A 66-year-old woman who died from a methotrexate overdose after an oral medication error

Table 1. Steps for learning from external errors

<table>
<thead>
<tr>
<th><strong>Leadership commitment</strong></th>
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<tr>
<td>Leaders must convey that external errors offer necessary learning and should be regularly reviewed by the organization.</td>
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<td>Leaders must convey that the organization is vulnerable to errors, including the same types of errors that have happened elsewhere. They should convey a mindset of “How could this happen here?” rather than “Could this happen here?”</td>
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<td>Leaders must convey that they consider an external error to be a “clear and present danger” in their organization and the important steps that have been or will be taken to prevent a similar occurrence.</td>
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<th><strong>Infrastructure for learning</strong></th>
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<td>Identify reliable sources of information about external errors and risks (e.g., ISMP, US Food and Drug Administration, peer-reviewed journals).</td>
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<td>Assign a specific professional(s) to routinely search the reliable sources and literature for published errors and adverse event experiences and to understand how and why the errors and events happened.</td>
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<tr>
<td>Establish a systematic way to review information about external errors and assess the organization’s vulnerability to similar errors.</td>
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<td>Establish a systematic way to obtain outside knowledge from the literature or experts when reviewing internal errors to obtain an outside point of view.</td>
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<td>Listen to updated follow-up reports about high-profile events, particularly studies concerning why the errors occurred, and learn how the affected organizations are handling these events, if possible.</td>
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<td>Establish group (pharmacy/practice site level, district level, corporate level) responsibility for reviewing the published external errors or events, with standing items on meeting and committee agendas.</td>
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<th><strong>Taking action</strong></th>
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<td>Determine a workable action plan to address vulnerabilities and assign staff to ensure the action occurs.</td>
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<td>Use error stories as persuasive tools to drive improvements.</td>
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<tr>
<td>Reassess vulnerabilities after the action plan has been implemented.</td>
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New International Fellowship at ISMP

A 2-year International Fellowship program, funded by a grant from Baxter International, will begin this year to educate a healthcare professional seeking a long-term career in medication and patient safety at an international level. While relocation to the Horsham, Pennsylvania (near Philadelphia) area is required, the Fellow will have an opportunity to travel to safety-oriented international functions and visit practice locations outside the US to learn about drug distribution systems in other countries. There will also be at least one rotation at a medication safety center outside the US.

Throughout the Fellowship, the individual will work closely with ISMP staff and members of the International Medication Safety Network (www.intmedsafe.net) to enhance international communications about worldwide medication safety issues, share error-prevention strategies, and promote error reporting. Since countries around the world share many of the same drugs, errors that happen in one country can also happen in other countries. Thus, the Fellow will be sharing safety information with international professional organizations, medication safety centers, government-run safety agencies, pharmacovigilance centers, and regulatory agencies.

One long-term goal of the Fellowship program is to promote international cooperation and the development of industry-wide guidance to improve the safety of drug labeling, packaging, and naming. The Fellow’s efforts to communicate medication safety issues will also help demonstrate the need for global expansion of safer technologies (e.g., barcoding, sterile compounding technology) and products (e.g., pre-filled syringes, premixed solutions) to replace error-prone manual systems (e.g., preparing parenteral products without quality controls).

Applications will be accepted starting April 3, 2017. Keep an eye on our website for more information about this unique opportunity.
Biases that make it difficult to learn from others’ mistakes

There are several attribution biases that lead to normalization of errors and thwart our learning from mistakes, particularly the mistakes of others. Attribution biases refer to the way we evaluate or try to find reasons for our own behavior and others’ behavior. Unfortunately, these attributions do not always mirror reality.

First, we tend to attribute good outcomes to skill and bad outcomes to bad luck—a bias called self-serving attribution. We have a relatively fragile sense of self-esteem and a tendency to protect our professional self-image (and the image of our workplace) by believing the same errors we read about could not happen to us or in our own organization. It was just terrible luck that led to the bad outcome in another organization, soon to be forgotten by all except the few who were most intimately involved in the event.

Next, we tend to quickly attribute the behavior of others to their personal disposition and personality, while overlooking the significant influence of external situational factors. This is called fundamental attribution bias. However, we tend to explain our own behavior in light of external situations, often undervaluing any personal explanations. This is known as the actor-observer bias. When we overestimate the role of personal factors and overlook the impact of external conditions or situations in others’ behavior, it becomes difficult to learn from their mistakes because we chalk them up to being caused by internal, personal flaws that don’t exist in us. This tendency to ascribe culpability to individual flaws increases as the outcome becomes more severe—a bias called defensive attribution—making it especially hard to learn from fatal events.

Finally, we tend to be too optimistic and overconfident in our abilities and systems, particularly when assessing our vulnerability to potentially serious or fatal events. We thirst for agreement with our expectations that the tragic errors we read about could not happen in our workplace, seeking confirmation about our expectations of safety while avoiding any evidence of serious risk. We may even go through the motions of looking at our abilities and systems to determine if similar errors might continue on page 3—External errors—continued from page 1

You’ve also likely read about recurring harmful errors that continue despite repeated descriptions of these events in our newsletters, often found in our Worth Repeating feature. For example, we have written multiple times about wrong patient errors and daily rather than weekly administration of methotrexate for non-oncologic indications.

As you’ve read about these tragic medication errors, you’ve probably felt surprised, saddened, anxious, unsettled, and perhaps even a little angry or frustrated, as we often feel at ISMP when these errors continue to harm patients. These initial feelings cause you to feel leery about errors, even if you can’t put your finger on the exact cause of your uneasiness. Unfortunately, we tend to gloss over these initial feelings and treat many errors as inconsequential in our own lives and work. Thus, the tragic medication errors you hear about may be compelling, but are perhaps felt to be irrelevant to your practice—a sad story, but not something that could happen to you or at your practice site. People tend to “normalize” the errors that have led to tragic events, and subsequently, they have difficulty learning from them.

You’ve also likely read about the tragic medication errors you hear about may be compelling, but are perhaps felt to be irrelevant to your practice—a sad story, but not something that could happen to you or in your workplace. To avoid this risk, do not return medications into manufacturer stock bottles. At a minimum, keep the medications in the pharmacy prescription vial and obscure any patient- and physician-identifying information on the pharmacy label. For bulk packages (e.g., topical products), remove all patient-specific labels. However, best practice calls for the pharmacy computer system to be able to generate a return-to-stock (RTS) label that includes the drug name and strength as well as a barcode that can be scanned during production and/or verification when used to fill a subsequent prescription. Consider enhancing the RTS calling for a pharmacist to verify a prescription for rifampin 150 mg capsules. When she opened the prescription vial to visually inspect the capsules, she noticed capsules with very slight differences in appearance. On closer inspection, some capsules had different capsule markings than others. The prescription had been filled with rifampin 150 mg and rifampin 300 mg capsules. It appears that a previous prescription for rifampin 300 mg capsules had been returned to stock and added back into a bottle of rifampin 150 mg.

While the capsules and manufacturer stock bottles look similar (Figure 1), likely contributing to the error, risk is introduced when medications are placed back into a manufacturer’s stock bottle when returning a prescription to stock. To avoid this risk, do not return medications into manufacturer stock bottles. At a minimum, keep the medications in the pharmacy prescription vial and obscure any patient- and physician-identifying information on the pharmacy label. For bulk packages (e.g., topical products), remove all patient-specific labels. However, best practice calls for the pharmacy computer system to be able to generate a return-to-stock (RTS) label that includes the drug name and strength as well as a barcode that can be scanned during production and/or verification when used to fill a subsequent prescription. Consider enhancing the RTS calling for a pharmacist to verify a prescription for rifampin 150 mg capsules. When she opened the prescription vial to visually inspect the capsules, she noticed capsules with very slight differences in appearance. On closer inspection, some capsules had different capsule markings than others. The prescription had been filled with rifampin 150 mg and rifampin 300 mg capsules. It appears that a previous prescription for rifampin 300 mg capsules had been returned to stock and added back into a bottle of rifampin 150 mg.

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Figure 1. Look-alike bottles of rifampin 150 mg and rifampin 300 mg capsules.

SAFETY briefs

Barcode your return to stock process.

A pharmacist was verifying a prescription for rifampin 150 mg capsules. When she opened the prescription vial to visually inspect the capsules, she noticed capsules with very slight differences in appearance. On closer inspection, some capsules had different capsule markings than others. The prescription had been filled with rifampin 150 mg and rifampin 300 mg capsules. It appears that a previous prescription for rifampin 300 mg capsules had been returned to stock and added back into a bottle of rifampin 150 mg.

Abort the return to stock process. While the capsules and manufacturer stock bottles look similar (Figure 1), likely contributing to the error, risk is introduced when medications are placed back into a manufacturer’s stock bottle when returning a prescription to stock. To avoid this risk, do not return medications into manufacturer stock bottles. At a minimum, keep the medications in the pharmacy prescription vial and obscure any patient- and physician-identifying information on the pharmacy label. For bulk packages (e.g., topical products), remove all patient-specific labels. However, best practice calls for the pharmacy computer system to be able to generate a return-to-stock (RTS) label that includes the drug name and strength as well as a barcode that can be scanned during production and/or verification when used to fill a subsequent prescription. Consider enhancing the RTS calling for a pharmacist to verify a prescription for rifampin 150 mg capsules. When she opened the prescription vial to visually inspect the capsules, she noticed capsules with very slight differences in appearance. On closer inspection, some capsules had different capsule markings than others. The prescription had been filled with rifampin 150 mg and rifampin 300 mg capsules. It appears that a previous prescription for rifampin 300 mg capsules had been returned to stock and added back into a bottle of rifampin 150 mg.

Figure 1. Look-alike bottles of rifampin 150 mg and rifampin 300 mg capsules.
happen in our organizations, but in the end, we tend to overlook any evidence that may suggest trouble (much like confirmation bias in which we see what we expect to see on a medication label, failing to see any disconfirming evidence). We subconsciously reach the conclusions we want to draw when it comes to assessing whether our patients are safe.2

**Seeking outside knowledge**

Experience has shown that a medication error reported in one organization is also likely to occur in another, given enough time. Much knowledge can be gained when organizations look outside themselves to learn from the experiences of others. Unfortunately, recommendations for improvement, often made by those investigating a devastating error, go unheeded by others who feel they don’t apply to their organization. Still others have committees that are working on tough issues and doing their best, but they may only have an internal focus. Real knowledge about medication error prevention will not come from a person or committee with only an internal focus. A system cannot understand itself, regardless of the number and quality of investigations and root cause analyses conducted on internal errors. Quality guru Dr. W. Edwards Deming summarized this phenomenon by noting that organizations with an internal focus “may learn a lot about ice, yet know very little about water.”4

This concept is applicable to learning from your internal errors, too. Seeking outside knowledge from the literature or experts in the field when reviewing your own errors can open your eyes to vulnerabilities that are hard to see within the processes you have built or work in every day. Even including staff from a different location when reviewing errors can be an eye-opening experience. Knowledge from the outside is necessary and provides us with a lens to examine what we are doing, suggestions for what we might do differently, and a roadmap for improvement.5

External resources also provide us with a wealth of information that can be used to make the safest decisions when providing patient care. When we stand at a fork in the road and are unsure where each one leads, it would be foolish to choose whichever “seems” best without looking at information easily within our reach from others who have already traveled each road.

**Overcoming biases to allow learning**

To best promote patient safety, it is crucial to seek out information about external errors, to hold on to your initial feelings of surprise and uncertainty when you read about these errors, and to resist the temptation to gloss over what happened or attribute the problem to an individual different than you.1 It is in the brief interval between the initial unease when reading about an external error and the normalization of error—convincing yourself that it couldn’t happen to you—that significant learning can occur. For that reason, ISMP highly recommends sharing stories of external errors with staff, such as those published in the ISMP Medication Safety Alert! and summarized three times a year in the ISMP Ambulatory Care Action Agenda (www.ismp.org/sc?id=2884).

The ISMP Ambulatory Care Action Agenda was initiated 11 years ago for the purpose of encouraging organizations to use information about safety problems and errors that have happened in other organizations to prevent similar problems or errors in their practice sites. The Agenda is prepared for a pharmacy, office, or committee to stimulate discussion and action to reduce the risk of medication errors. Each item in the Agenda includes a brief description of the medication safety problem, a few recent 

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**SAFETY briefs cont’d from page 2**

label by adding a description of the product. Apply the RTS label to all vials or bottles of products that are returned to stock. Develop an organizational policy for recording the expiration date on the RTS label attached to products returned to stock. Periodically review and observe the RTS process to ensure adherence.

**Are patients who are allergic to antibiotics at risk for reactions to vaccine ingredients?** Several vaccines contain small amounts of antibiotics such as neomycin, streptomycin, polymyxin B, and gentamicin. They are added to help prevent contamination of the vaccine during manufacturing. For example, the influenza vaccine FLUARIX contain small amounts of gentamicin. Still, the antibiotics most likely to cause severe allergic reactions (e.g., penicillin, cephalosporins, and sulfa drugs) are not contained in vaccines. Also, only minute quantities of the antibiotics remain in the final vaccination products.

According to a referenced website (www.ismp.org/sc?id=1657) maintained by The Children’s Hospital of Philadelphia (CHOP), these small quantities have never been clearly found to cause severe allergic reactions. CHOP says that the possibility of severe allergic reactions caused by the trace quantities remains, at best, theoretical. The website lists the vaccines that contain antibiotics along with the quantities. Of course, not all vaccines have antibiotics, so if a concern exists, you may be able to avoid them by using an alternate brand. For example, some influenza vaccines contain no antibiotics. Another issue is that package inserts often mention contraindications to “vaccine components,” but an alert may not appear to the practitioner when an influenza vaccine that contains an antibiotic is selected from a computer listing.

We asked a major drug information vendor about this, and the company said that an allergy alert will occur only in a patient...
> External errors—continued from page 3
ommendations to reduce the risk of errors, and the issue number to locate additional information. The Agenda is also available in a Microsoft Word format that allows organizational documentation of an assessment, actions required, and assignments for each agenda item. The latest Ambulatory Care Action Agenda was published in the January 2017 newsletter and it will continue to be published three times a year, in the January, May, and September issues.

Additional steps organizations should take to establish a system for ongoing risk identification and learning from external errors can be found in Table 1 (on page 1).

**Table 1**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Patient Safety</strong></td>
<td>Focus on protecting patients from harm</td>
</tr>
<tr>
<td><strong>Process Improvement</strong></td>
<td>Implementing changes to improve care</td>
</tr>
<tr>
<td><strong>Leadership Engagement</strong></td>
<td>Involving leaders in the process</td>
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**Conclusion**

The only way to make significant safety improvements is to challenge the status quo, inspire and encourage all staff to track down “bad news” about errors and risk—both internal and external—and to learn from the “bad news” so that targeted improvements can be made. We need to shatter the assumption that systems are safe until proven dangerous by a tragic event. No news is not good news when it comes to patient safety. Each organization and practice site needs to accurately assess how susceptible its systems are to the same errors that have happened in other organizations and acknowledge that the absence of similar errors is not evidence of safety. Personal experience is a powerful teacher, but the price is too high if we only learn from firsthand experiences. Learning from the mistakes of others is imperative.

**References**


> SAFETY briefs cont’d from page 3

with a documented aminoglycoside allergy who is prescribed an influenza vaccine with an NDC that is associated with an ingredient set that contains trace amounts of an aminoglycoside. Regardless of an alert, though, the risk of an allergic reaction is probably minimal.

**Poison prevention—it’s about protecting your own kids, too!** It’s amazing what kids can get into and how easy we can make it! A recent survey of 2,000 parents showed a gap between what we know we should do to protect our kids and what we are actually doing. For example, while 9 out of 10 parents agree it is important to store all medications up high and out of the reach of children after every use (www.upandaway.org), nearly 7 out of 10 say they often store medications within a child’s sight, on a shelf or surface at or above counter height. So, it seems that parents may be choosing convenience over caution or slipping into unsafe choices.

A new report from Safe Kids Worldwide, *Safe Medicine Storage: A Look at the Disconnect Between Parent Knowledge and Behavior*, covers this topic and provides additional information that is worth considering and putting into action for parents and grandparents. Who can forget the “Granny Syndrome” (www.ismp.org/sc?id=2881), a documented safety issue in which children have accessed their grandparent’s medicines that have been left on a table or countertop, on low shelves, or in their grandmother’s purse. You can access the Safe Kids Worldwide survey results and additional information at www.ismp.org/sc?id=2882. Also, be sure to join efforts by the Centers for Disease Control and Prevention (CDC) Medication Safety Program and the PROTECT Initiative (www.ismp.org/sc?id=2883) to help protect children from unintentional overdoses and spread the word about the importance of keeping all medicines up and out of the sight and reach of children.