MEDICATION ERRORS

The “Dirty Dozen”
Twelve Persistent Safety Gaffes That We Need to Resolve
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Despite the many accomplishments we’ve seen in medication safety, we can’t help but mull over persistent medication safety gaffes that continue unresolved and doggedly test our tenacity, often landing in the Institute for Safe Medication Practices (ISMP) “Worth repeating…” newsletter feature, over and over again. We would like to share these “Dirty Dozen” safety gaffes with the hope that you will join us in bringing attention to these crucial issues and the compelling need for their resolution.

1. Changing pharmaceutical business models: Negative financial impact on providers’ supply chain costs

Whether it’s the discontinuation of a low-volume but medically necessary drug leading to critical shortages or an increase in the cost of long-standing medications, such as U-500 insulin, when the demand increases, the cost of pharmaceuticals has been highly unpredictable. This has become more of an issue in the last few years, wreaking havoc on health care providers’ operational budgets. Such an offense occurred in 2014 when Genentech changed its distribution methods for three widely used cancer drugs to maximize “business efficiencies” for the company, which resulted in negative consequences for everyone downstream. Avastin (bevacizumab), Herceptin (trastuzumab), and Rituxan (ritUXimab) began to be shipped to health care providers via six authorized specialty distributors instead of the usual wholesalers. Genentech’s choice to not contract for cost relief on any of its products meant that hospitals lost prior cost savings based on wholesaler contracts and frequently incurred higher costs to manage their drug distribution process, requiring more products in stock and less just-in-time ordering. For a large cancer center, the change was estimated to add $1 million or more annually in pharmaceutical costs with little advance warning, reducing the dollars available to provide care to patients. While the Department of Health and Human Services is trying to contain the costs of health care on the provider end, there seems to be little effort to contain costs on the supply end. The budgets needed for pharmaceuticals crucial to patient care appear to be increasing at the financial whim of big pharmaceutical companies.

2. Hydrogen peroxide contact solutions: Still causing severe eye injuries years later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using 3% hydrogen peroxide cleaning and disinfecting solution for contact lenses (such as Alcon’s Clear Care). Located on store shelves near other lens disinfectants and solutions, this product differs from other commonly used solutions in that it must be used with a special lens case to neutralize the hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many consumers have used the solution inadvertently to soak their lenses in a standard lens case or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a minor label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither manufacturers nor the Food and Drug Administration (FDA) device division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps this dangerous product should be pulled from the market or available only behind the pharmacy counter?

3. Patient counseling: Still only a veiled “offer” in many states

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet studies have placed patient counseling rates at only 8% to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an “offer” to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, “Do you have any questions?” or are told to “sign here.” They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid, such as fentanyl patches, for example, and allow the patient or caregiver to walk out of the pharmacy without so much as a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for targeted high-alert medications, with less emphasis on current ineffective regulations that require an “offer” to counsel for all medications.

4. Patients impacted by dispensing errors: Callous response from pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell us that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. The patients are often asked to return the erroneous medication to the
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pharmacy (relinquishing key evidence if legal remedy is sought) and then given the correct medication. Some pharmacies also offer a $25 discount coupon or refund for the cost of the erroneous prescription, but a signature may be required to document that the patient has accepted the coupon or refund as full restitution of the mistake. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors and knowledge that there’s an action plan to reduce the risk of it happening again.

5. Manufacturers’ prefilled syringes: Misuse spanning nearly a decade

Based on surveys, observations, and error reports, ISMP is aware that many practitioners misuse prefilled syringes in a manner that renders them unsafe. First, prefilled drug cartridges are often used as single- or multiple-dose vials by removing all or part of the contents through the rubber diaphragm or the small hole at the top of the needleless system connector. However, the cartridge is not intended for puncture, and the contents do not include preservatives or antimicrobial agents; thus, the risk of contamination is high, and measurement errors are also possible. While the prefilled cartridges include a barcode, the final practitioner-prepared syringes do not and are rarely labeled. Practitioners have also misused prefilled syringes of saline flushes—when drawing a drug into the saline flush syringe to dilute the medication or when the saline is used to reconstitute a lyophilized powder and then drawn back into the saline flush syringe. This dangerous practice leads to a syringe labeled as saline but actually containing both saline and the drug. Single-dose vials of saline or sterile water for injection must be provided and used if drugs require reconstitution or dilution in a patient care area.

6. Syringe pull-back method for verifying IV admixtures: Over-reliance on a weak strategy

Many hospital intravenous admixture processes rely on the syringe pull-back method as the method the pharmacist uses to check the admixture and assess how much medication or diluent was added to the infusion container. The empty syringe is accompanied by the actual drug or diluent container displayed next to the syringe. For years, ISMP has discouraged reliance on this method, particularly for chemotherapy, complex electrolyte solutions, or compounded sterile products with other high-alert medications. The method, now prohibited by some state boards of pharmacy, is prone to errors when pulling back the plunger to the volume of product one believes was included in the admixture and when placing the syringes near the corresponding vials. Also, for the person checking the products, it may not be clear which syringe goes with which vial. Pardon our skepticism about such a long-standing practice but this method of verification is weak in comparison to manual or automated checking of the products and volumes in syringes before addition to the admixture container.

7. Compounded pain creams: High profit margin and danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, including unsafe packaging in containers without child-resistant closures. We are specifically concerned about some statements that may be unproven, such as the products’ safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. We believe regulatory or licensing oversight is necessary.

8. Disrespectful behavior: A history of tolerance in health care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and are allowed to exist while we tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey many years ago clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey a decade later demonstrated little progress. Our slow progress is not due to lack of resources or know-how but to a dysfunctional culture, central to which is an ethos that favors a sense of privilege, status, and autonomy, thus impairing teamwork and communication. Disrespect diminishes a person’s ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

9. Independent double-checks: Undervalued and misused

Manual independent double-checking of high-alert medications is a strategy that has been widely promoted to help detect potentially harmful errors before they reach patients. However, the double-checks’ value have been disputed, and their use has been a source of stress for busy prescribers, pharmacists, and nurses who are short on time. Their impact on safety has been questioned by those who rarely find mistakes during the checking process. Their inconsistent use, variability in how the task is carried out, and overuse for all high-alert medications has rendered them incapable of detecting many errors. Failed checking processes can often be traced to: auto-processing in which the person checking the work does so in a habitual manner with little real appraisal; deference to authority in which people checking the work of someone who outranks them may not ask questions; reduction of responsibility in which
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staff believe someone else will catch any mistakes; and lack of time. What is often
missing in the double-check process is a
more cognitive review of all components
of the medication, beyond verification of
the “Five Rights,” that requires purposeful
thought. In addition, independent double-
checks must be strategically placed for
just a few select high-alert medications,
and they should never serve as the only
safety net in place to prevent or detect
errors with these medications.

10. Beyond-use dating of drugs: CMS
standards lead to costly waste
To avoid the use of outdated drugs,
the Centers for Medicare and Medicaid
Services (CMS) requires pharmacists
to follow the manufacturer’s directions
regarding storage, stability, and beyond-
use dating in the official FDA-approved
prescribing information. The Joint
Commission and other accrediting orga-
nizations follow guidance from CMS on
this issue. However, this has proven
difficult and wasteful—especially in
cases of critical drug shortages—for two
primary reasons: 1) complete information
on storage, stability, compatibility, and
beyond-use dating is often not provided
in the official prescribing information, and
2) newer, evidence-based information on
these matters can sometimes be found
in peer-reviewed scientific journals and
compendia fully endorsed by national
pharmacy organizations. If information on
storage, stability, and beyond-use dating
is not available in the manufacturer’s
directions, CMS and accrediting agen-
cies defer to recommendations available
in nationally recognized sources. ISMP
and the American Society of Health- Sys-
tem Pharmacists have brought the issue
to CMS, but the government agency is
confronted with a dilemma if the official,
FDA-approved manufacturer’s directions
differ from newer, evidence-based recom-
mandations in national compendia.

11. Vaccine errors: Repetitive errors
reported in the last decade
How often do mix-ups involving
diphtheria and tetanus toxoids and
acellular pertussis (DTaP) vaccine and
tetanus toxoid, reduced diphtheria toxoid,
and acellular pertussis (Tdap) vaccine
need to occur before regulatory action
is taken to prevent confusion? Whatever
the number, we can say that we have
probably met that threshold. Yet vaccine
errors like this continue to occur at an
alarming rate (based on those reported to
ISMP alone). Vaccine mix-ups occur often
due to age-dependent formulations of
the same vaccine, similar vaccine abbre-
viations, similar vaccine containers and
labels, and storage near each other. Con-
fusion between the diluent and vaccine
has led to administration of the diluent
alone or use of the wrong diluent (which
happened in Syria in 2014, causing the
death of 15 children). With an unfortunate
rise in parents choosing not to vaccinate
their children or themselves, we cannot
continue to make errors when vaccinating
those who choose to be immunized—the
impact on both individual and community
immunity may be far-reaching.

12. Wrong patient errors:
Not opening the bag
at the point of sale
Community pharmacies are vulner-
able to dispensing correctly filled pre-
scriptions to the wrong patient (or family
member, friend, or caregiver) at the point
of sale, a risk that is well substantiated
in the literature. This error is not influ-
enced by the attributes of a specific medici-
ation; thus, dispensing any prescription
medication to the wrong patient at the
point of sale carries a similar level of
risk. Based on an ISMP study, the error
happens frequently at an estimated rate
of 1.22 per 1,000 prescriptions. Among
approximately 56,000 community phar-
macies in the U.S., this error rate sug-
gests that 332,755 prescriptions will be
dispensed to the wrong patient each
month, or about six every month per
pharmacy. One of the most effective ways
to prevent this error is to open the bag of
filled prescriptions at the point of sale to
verify that the drugs are for the correct
patient. With this simple step, the risk of
error is reduced by 56%, according to the
ISMP study. Yet few pharmacies follow
this practice.

The reports described in this column were
received through the ISMP Medication
Errors Reporting Program (MERP). Errors,
close calls, or hazardous condi-
tions may be reported on the ISMP website
(www.ismp.org) or communicated directly
to ISMP by calling 1-800-FAILSAFE or
via email at ismpinfo@ismp.org.