



CLINICAL COMMUNICATOR

Recognizing and Reducing Adverse Drug Events

Drug therapy is a miracle of modern science. Drug therapy not only saves lives, but also improves the quality of life for many people. However, sometimes drug therapy has undesirable consequences that can range in severity from those that are insignificant to those that are fatal. While it is widely recognized that medication errors sometimes result in a drug-related injury, many other adverse drug events are essentially a consequence of the drug's actions on the human body.

Definitions of adverse drug events (ADE) and adverse drug reactions (ADR) vary in the medical literature. The World Health Organization (WHO) lists the following definition:

Adverse drug reactions (ADRs) are harmful, unintended reactions to medicines that occur at doses normally used for treatment

In addition to the above definition, there are other terms that are useful:

Side Effect: Dose-related and predictable reaction to a drug

Drug Allergy: A non-dose related, unpredictable effect of a drug

The cost of ADRs and ADEs to individuals and to the healthcare system is significant. The Agency for Healthcare Research and Quality (AHRQ) estimates that in the U.S. over 770,000 people are injured or die each year in hospitals from adverse drug events. Annual expenses to treat patients who suffer ADEs during hospitalization are estimated at between \$1.56 and \$5.6 billion. A patient who experiences an ADE has a longer hospital stay (up to 8-12 days longer) and their hospital costs are \$16,000 – \$24,000 higher. These figures do not include ADEs that cause hospital admissions, any related malpractice and litigation costs, or the costs of injuries to patients.

Experts at the WHO estimate that 60% of ADRs are preventable, such as those caused by:

- Wrong diagnosis of the patient's condition
- Prescribing the wrong drug or the wrong dose of the right drug
- An undetected medical, genetic, or allergic condition that might cause a patient reaction
- Self-medication with prescription medicines
- Not following the instructions for taking the medication
- Reactions with other drugs (including folk remedies) and certain foods
- Use of a sub-standard medication whose composition or ingredients do not meet standards of content or purity
- Use of counterfeit medication with no active ingredient or the wrong ingredients

All drugs have side effects, many of which are discovered during the clinical trials required by the Food and Drug Administration (FDA). However, these trials are conducted in small patient populations and additional problems are often discovered once the drug is used in more people. In studies funded by the AHRQ, it was found that some classes of drugs were more likely to be involved in significant ADRs or ADEs, including antibiotics, pain medications, electrolyte concentrates, cardiovascular drugs, sedatives, antineoplastic drugs, and blood-thinning drugs.

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SPECIAL POINTS OF INTEREST

Circumstances that may increase the risk of drug-related problems include older age, severity of illness, intensity of treatment and polypharmacy

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There is no simple formula for predicting which patient may suffer an ADE or an ADR from a specific drug. Some factors that could have a higher association with drug-related problems include older age, severity of illness, intensity of treatment and polypharmacy (prescribing multiple medications to treat multiple medical conditions). It is especially important to watch for and report adverse effects from drugs that are new to the market.

Recognizing and Managing Drug-Related Problems

It can be very difficult to distinguish between an adverse drug effect, a new medical problem, or the worsening of an existing condition. The first step to identifying an ADE/ADR is to remember that a drug could be the cause of a problem. The use of various electronic systems may increase the ability of an institution to recognize medication errors and ADEs. Whether or not a facility has these capabilities, the staff can be trained to recognize and report clinical signs that could help to identify and minimize the consequences of a drug-related problem. Early reporting can reduce the severity of a drug reaction and the associated increases in hospital stay and costs. The following could be evidence of a possible drug reaction and should be reported to the physician:

- Rash
- Change in respiratory rate, heart rate, hearing, or mental state
- Seizure
- Anaphylaxis
- Diarrhea
- Fever
- Lab tests
- Altered blood levels of other medications
- Exacerbation of an existing condition or development of a new medical problem

When a drug-related problem is suspected, the clinician should investigate whether the drug is known to cause such a reaction, rule out other explanations, and establish a temporal link between the onset of the reaction and drug administration. Another important element to investigate is the possibility of a medication error. Questions that healthcare providers can ask to help prevent drug-related problems from medication errors include:

- Is this dose appropriate for the patient's age or weight?
- Is this drug normally used for this medical condition?
- Does this dose look different than the last time I prepared or administered it?
- Is the amount of drug I am preparing or administering much larger than usual?
- Asking for a review or double-check when using an unfamiliar infusion pump

Reporting Drug-Related Problems – Fight “Bystander Apathy”

There have been many studies of why medication errors and ADRs/ADEs are not reported. Often a situation is not reported because it is assumed that someone else has already reported it. This response is part of the phenomenon of “bystander apathy”. When people work in groups, each individual tends to assume that someone else will report or deal with a problem. The result is that *no one reports the problem*.

In other cases, especially if an error is involved, an employee may be afraid of punishment or ridicule if they speak up. Research has shown that punishment is a deterrent to reporting an error. Healthcare workers can find it difficult to acknowledge that they personally made a mistake or failed to recognize an error that ultimately harmed a patient.

The culture of an institution, and even the attitude in a particular department or work unit, can help employees to recognize and report drug-related problems (and other safety concerns). Work groups can be encouraged to support the individual members when they report problems. The team members can agree together that they will not assume someone else has reported a problem, and that they will not criticize each other for reporting problems. The Institute for Safe Medication Practices also suggests the following:

1. Ask – is something wrong? Am I too busy to notice a problem?
2. Ask – is my help needed? Ask your colleagues if you are not sure.
3. Ask – is it my responsibility to do something? Promote the idea that it is everyone's responsibility to report a problem.

Every healthcare provider can help to increase the awareness and reporting of adverse drug effects, adverse drug reactions, and medication errors. Encourage your work group to communicate these events, and lead by example.

Reference: ISMP Medication Safety Alert, November 20, 2008; other references are available upon request.