

Medication Errors

Approximately 2 million people are injured annually in the United States following so-called ‘medication errors’. The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer...related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”

The U.S. Food and Drug Administration (FDA) currently review medication error reports that come from drug manufacturers and through MedWatch, the agency’s safety information and adverse event reporting program. The agency also receives reports about medication errors from the Institute for Safe Medication Practices (ISMP) and the U.S. Pharmacopeia.

What kinds of errors are most common?

In a study by the FDA that evaluated reports of fatal medication errors from 1993 to 1998, the most common error involving medications was related to administration of an improper dose of medicine, accounting for 41% of fatal medication errors. Giving the wrong drug and using the wrong route of administration each accounted for 16% of the errors. Almost half of the fatal medication errors occurred in people over the age of 60. Older people may be at greatest risk for medication errors because they often take multiple prescription medications.

How can you help prevent medication errors?

When your doctor gives you a prescription, ask him or her to tell you the name of the drug, the correct dosage, and what the drug is used for. Be sure you understand the directions for any medications you may be taking including the correct dosage, storage requirements, and any special

instructions. In the hospital, ask (or have a relative or friend ask) the name and purpose of each drug you are given. Be sure to tell your doctor the names of all the prescription and non-prescription drugs, dietary supplements, and herbal preparations you are taking every time he or she writes you a new prescription. This will help to prevent another type of medication problem, undesirable and potentially serious interactions among medications. Finally, never be afraid to ask questions. If the name of the drug on your prescription looks different than you expected, if the directions appear different than you thought, or if the pills or medication itself looks different, tell your doctor or pharmacist right away. Asking questions if you have any suspicions at all is a free and easy way to ensure that you do not become the victim of a medication error.

Drug Name Confusion

An 8-year-old died, it was suspected, after receiving methadone instead of methylphenidate, a drug used to treat attention deficit disorders. A 19-year-old man showed signs of potentially fatal complications after he was given clozapine instead of olanzapine, two drugs used to treat schizophrenia. And a 50-year-old woman was hospitalized after taking Flomax, used to treat the symptoms of an enlarged prostate, instead of Volmax, used to relieve bronchospasm.

In each of these cases reported to the Food and Drug Administration, the names of the dispensed drugs looked or sounded like those that were prescribed. There have been others: Serzone, an antidepressant, for Seroquel, used to treat schizophrenia, and iodine for Lodine, a non-steroidal anti-inflammatory drug.

Adverse events that can occur when drugs are dispensed as the wrong medications underscore the need for clear interpretation and better communication between the doctors who write prescriptions and the pharmacists who fill them. The FDA says that about 10 percent of all medication errors reported result from drug name confusion.

“These errors are not usually due to incompetence,” says Carol A. Holquist, R.Ph. director of the Division of Medication Errors and

Technical Support in the FDA's Office of Drug Safety. "But they are so underreported because people are afraid of the blame." Errors occur at all levels of the medication-use system, from prescribing to dispensing, Holquist says, which is why those people who receive the prescriptions must take action, too. "Everybody has a role in minimizing medication errors," she says.

The Problems

Medication errors can occur between brand names, generic names, and brand-to-generic names like Toradol and tramadol. But sometimes, medication errors involve more than just name similarities. Abbreviations, acronyms, dose designations, and other symbols used in medication prescribing also have the potential for causing problems.

For example, the abbreviation 'D/C' means both 'discharge' and 'discontinue.' The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) notes that patients' medications have been stopped prematurely when D/C--intended to mean discharge--was misinterpreted as discontinue because it was followed by a list of drugs.

Illegible handwriting; unfamiliarity with drug names; newly available products; similar packaging or labeling; and incorrect selection of a similar name from a computerized product list, all compound the problem. Although some drug names and symbols may not necessarily sound alike or look alike, they could cause confusion in prescribing errors when handwritten or communicated verbally, according to the United States Pharmacopeia (USP).

For example, Holquist says that several errors have occurred involving mix-ups with the oral diabetes drug Avandia and the anticoagulant Coumadin. Although they do not look similar when typed or printed, the names have been confused with each other when poorly written in cursive. The first 'A' in Avandia, if not fully formed, can look like a 'C,' and the final 'a' has appeared to be an 'n.'

Naming Drugs

Names are part of developing a new drug. Coming up with a catchy, snappy moniker that distinguishes one drug from another is not easy. For the most part, drug companies want a name that will boost sales, while consumers long for some indication from the name of what the drug does. The FDA, however, will not allow names that imply medical claims, suggest a use for which a drug is not approved, or promise more than they can deliver.

Naming a drug can be as complicated as creating a rhythmic cacophony of unpronounceable syllables and emphatic-sounding letters, such as C and P. Other naming strategies include letters that when strung together sound like something high-tech--think Zyprexa, Lexapro, and Xanax.

But whether it is the sound of certain letters that manufacturers like, or the vision that a name conjures up, the FDA says that selection must take into account concerns for reducing errors and for avoiding trademark infringement.

Because of today's tough trademark requirements, many drug companies are turning to a growing industry of 'naming' consultants for the task. These consultants are charged with creating a unique name that will appeal to both doctors and patients, particularly given the recent surge in direct-to-consumer advertising.

Drug Name Confusion

"Global companies want a name to be a worldwide mark," says Doug Kapp, vice president of brand strategy at RTi-DFD, a market research company in Stamford, Conn. In helping pharmaceutical companies set their products apart from others, Kapp says his company recognizes that the name must resonate with the market target and also must pass worldwide trademark requirements.

That recognition, he says, drove his company to develop "relational asemantics," a name-generation process that assists physicians in

identifying the nature of a drug. Just as the erectile dysfunction drug Viagra might suggest vitality and vigor, two of RTi-DFD's successes include Advair, linked to 'advantage air for asthma,' and Amerge, named for 'emerging from the pain of a migraine.' Kapp says that regardless of how good a name seems it must be reviewed for potential confusion with other drugs so that "any other associations would not harm the patient in the event of an error."

Every drug usually has three names: chemical, generic (non-proprietary), and brand (proprietary), and each are subject to different rules and regulations. The chemical name specifies the chemical structure of the drug. It is not preapproved by any organization, nor is it recognized in any standard manuals, such as USP publications. Therefore, chemical names are primarily used by researchers, but not in medical practice.

The FDA requires that either the established, or official, name or in the absence of an official name, the common or usual name appears on labels and labeling of a drug product. The common name, loosely referred to as the generic name, must accompany the brand name, if there is one. The established name for a drug substance is usually found in the originating country's Pharmacopeia, an official book or list of drugs and medicines and the standards established for their production, dispensation, and use.

The generic name is usually created for drug substances when a new drug is ready for marketing. It is selected by the United States Adopted Names (USAN) Council, whose expertise is recognized by the FDA, according to principles developed to ensure safety, consistency, and logic. These names are typically used by health care professionals.

Generic names are coined using an established stem, or group of letters, that represents a specific drug class. For example, the USAN stems include suffixes like -mab for monoclonal antibodies, such as infliximab, or prefixes like dopa- for dopamine receptor agonists. The arthritis medications celecoxib, valdecoxib, and rofecoxib are generic names containing the -coxib stem. Each belongs to a class of drugs known as the COX-2 inhibitors.

Names that include such stems, chemistry roots, or any other coded information are easier to remember, and give clues about what a drug is used for. These names, however, typically sound or look so much alike that they contribute to medication errors, especially if the products share common dosage forms and other similarities.

The brand name, also called trademark, can be created as soon as a generic name has been established. Only brand names of products subject to a new drug application or an abbreviated new drug application must be approved by the FDA first. This requirement distinguishes them from generic names.

According to a report in the January-February 2004 issue of the Journal of the American Pharmacists Association, there are more than 9,000 generic drug names and 33,000 trademarked brand names in use in the United States.

Fixing the Problems

To minimize confusion between drug names that look or sound alike, the FDA reviews about 400 brand names a year before they are marketed. About one-third are rejected. The last time the FDA changed a drug name after it was approved was in 2005, when the diabetes drug Amaryl was being confused with the Alzheimer's medication Reminyl, and one person died. Now the Alzheimer's medicine is called Razadyne.

Generic name confusion also has led to regulatory action, as well as to pharmacy practice recommendations. For example, the USP and the USAN changed the drug name 'amrinone' to 'inamrinone' after receiving reports of serious outcomes from medication errors involving the similar name pair 'amrinone/amiodarone.' The generic drug industry also has responded to requests from the FDA to use a mixture of uppercase and lowercase letters to highlight differences in similar generic names, such as vinBLASTine and vinCRISTine. This step also encouraged manufacturers to supplement their new drug applications with revised labels and labeling that visually differentiated their generic names with the so-called 'tall man'

letters. The NCCMERP recommendations encourage doctors to write both brand and generic names on prescriptions.

A number of other efforts are under way to reduce the incidence of medical errors stemming from similar-looking or similar-sounding names. The FDA, for example, is encouraging people to talk with their physicians to ensure that they have a complete understanding about their prescription before leaving the doctor's office, and to verify the information with the pharmacist before the medication is dispensed.

FDA health professionals also are requested to interpret both written prescriptions and verbal orders through weekly in-house studies, in an attempt to simulate the prescription-ordering process. Holquist says that these studies are a valuable tool used in every review of proposed brand names. It is important, she adds, to be able to detect any potential sound-alike, look-alike confusion with proprietary names before a new drug application is approved.

Other efforts strongly encouraged for physicians include writing prescriptions more clearly, printing in block letters rather than writing in cursive, avoiding the use of abbreviations, and indicating the reason for the drug.

According to the FDA, pharmacists can help by keeping look-alike, sound-alike products separated from one another on pharmacy shelves, by avoiding stocking multiple product sizes together, and by verifying with the doctor information that is not clear before filling a prescription.

Examples of Error-Prone Drug Information

Abbreviations	Intended Meaning	Misinterpretation	Correction
AD, AS, AU	Right ear, left ear, each ear	OD, OS, OU (right eye, left eye, each eye)	Spell out "right ear," "left ear," "each ear"
IJ	Injection	"IV" or "intrajugular"	Spell out "injection"
TIW or tiw	3 times a week	"3 times a day" or "twice in a week"	Use "3 times weekly"
Dose Designations			

Trailing zero after decimal point (1.0 mg)	1 mg	10 mg if the decimal point is not seen	Do not use trailing zeros for doses expressed in whole numbers
Abbreviations with a period following (mg. or mL.)	mg, mL	The period is unnecessary and could be mistaken as the number 1 if poorly written	Omit period and use mg, mL
Drug name and dose run together (especially problematic for drug names ending in "L" such as Tegretol300 mg)	Tegretol 300 mg	Tegretol 1300 mg	Place adequate space between the drug name, dose, and unit of measure
Symbols			
x3d	For three days	"3 doses"	Use "for three days"
/ (slash mark)	Separates two doses or indicates "per"	Number 1 (e.g., "25 units/10 units" misread as "25 units and 110" units)	Use "per" rather than a slash mark to separate doses
&	And	"2"	Use "and"

Institute for Safe Medication Practices

Here is a list of steps you can take:

- Know the name and strength of prescribed drugs before leaving the doctor's office
- Insist that the doctor include the purpose of the medication on the prescription
- Ensure that a refill is what it should be
- Tell your doctor of any medical history changes.

Source: www.fda.gov