Strategies to Reduce Medication Errors

2.0 Contact Hours

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Strategies to Reduce Medication Errors

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The contents of this course are taken from the U.S. Food and Drug Administration. Learning objectives and post test have been prepared by Dr. Ratnakar P. Kini

Objectives:

Upon completion of this course, the learner will be able to:

1. Discuss the magnitude of medication errors and how they occur
2. Discuss the different agencies which track medication errors
3. Discuss the regulatory approach followed by FDA to minimize medication errors
4. Explain the role of consumers in minimizing medication errors
5. Discuss the Patient Safety proposals
6. Discuss the Hospital strategies in preventing medication errors
7. Relate a few examples of medication errors

Introduction

When Jacquelyn Ley shattered her elbow on the soccer field two years ago, her parents set out to find her the best care in Minneapolis. "We drove past five other hospitals to get to the one we wanted," says Carol Ley, M.D., an occupational health physician. Her husband, an orthopedic surgeon, made sure Jacquelyn got the right surgeon. After a successful three-hour surgery to repair the broken bones, Jacquelyn, who was 9 at the time, received the pain medicine morphine through a pump and was hooked up to a heart monitor, breathing monitor, and blood oxygen monitor. Her recovery was going so well that doctors decided to turn off the morphine pump and to forgo regular checks of her vital signs.

Carol Ley slept in her daughter's hospital room that night. When she woke up in the middle of the night and checked on her, Jacquelyn was barely breathing. "I called her name, but she wouldn't respond," she says. "I shook her and called for help." The morphine pump hadn't been shut down, but had accidentally been turned up high. The narcotic flooded Jacquelyn's body. She survived the overdose, but it was a close call. "If three more hours had gone by, I don't think Jacquelyn would have survived," Ley says. "Fortunately, I woke up."

Ley was pleased with the way the hospital handled the error. "They came right out and said the morphine pump was incorrectly programmed, they told me the steps they were going to take to make sure Jacquelyn was OK, and they also told me what they were

going to do to make sure this kind of mistake won't happen again. And that's very important to me." The hospital began using pumps that are easier to use and revamped nurse's training. Ley believes there were many contributors to the error, including the fact that it was Labor Day weekend and there were staff shortages. "It goes to show that this can happen to anyone, anywhere," says Ley, who now chairs the board of the National Patient Safety Foundation.

Multiple Factors

Since 1992, the Food and Drug Administration has received about 20,000 reports of medication errors. These are voluntary reports, so the number of medication errors that actually occur is thought to be much higher. There is no "typical" medication error, and health professionals, patients, and their families are all involved. Some examples:

A physician ordered a 260-milligram preparation of Taxol for a patient, but the pharmacist prepared 260 milligrams of Taxotere instead. Both are chemotherapy drugs used for different types of cancer and with different recommended doses. The patient died several days later, though the death couldn't be linked to the error because the patient was already severely ill.

An elderly patient with rheumatoid arthritis died after receiving an overdose of methotrexate--a 10-milligram daily dose of the drug rather than the intended 10-milligram weekly dose. Some dosing mix-ups have occurred because daily dosing of methotrexate is typically used to treat people with cancer, while low weekly doses of the drug have been prescribed for other conditions, such as arthritis, asthma, and inflammatory bowel disease.

One patient died because 20 units of insulin was abbreviated as "20 U," but the "U" was mistaken for a "zero." As a result, a dose of 200 units of insulin was accidentally injected.

A man died after his wife mistakenly applied six transdermal patches to his skin at one time. The multiple patches delivered an overdose of the narcotic pain medicine fentanyl through his skin.

A patient developed a fatal hemorrhage when given another patient's prescription for the blood thinner warfarin.

These and other medication errors reported to the FDA may stem from poor communication, misinterpreted handwriting, drug name confusion, lack of employee knowledge, and lack of patient understanding about a drug's directions. "But it's important to recognize that such errors are due to multiple factors in a complex medical system," says Paul Seligman, M.D., director of the FDA's Office of Pharmacoepidemiology and Statistical Science. "In most cases, medication errors can't be blamed on a single person."

A medication error is "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," according to the National Coordinating Council for Medication Error Reporting and Prevention. The council, a group of more than 20 national organizations, including the FDA, examines and evaluates medication errors and recommends strategies for error prevention.

A Regulatory Approach

The public took notice in 1999 when the Institute of Medicine (IOM) released a report, "To Err is Human: Building a Safer Health System." According to the report, between 44,000 and 98,000 deaths may result each year from medical errors in hospitals alone. And more than 7,000 deaths each year are related to medications. In response to the IOM's report, all parts of the U.S. health system put error reduction strategies into high gear by re-evaluating and strengthening checks and balances to prevent errors.

In addition, the U.S. Department of Health and Human Services (HHS) and other federal agencies formed the Quality Interagency Coordination Task Force in 2000 and issued an action plan for reducing medical errors. In 2001, HHS Secretary Tommy G. Thompson announced a Patient Safety Task Force to coordinate a joint effort to improve data collection on patient safety. The lead agencies are the FDA, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, and the Agency for Healthcare Research and Quality.

The FDA enhanced its efforts to reduce medication errors by dedicating more resources to drug safety, which included forming a new division on medication errors at the agency last year. "We work to prevent medication errors before a drug reaches the market and to also monitor any errors that may occur after that," says Jerry Phillips, R.Ph., director of the FDA's new Division of Medication Errors and Technical Support.

Here's a look at key areas in which the FDA is working to reduce medication errors.

Bar code label rule: After a public meeting in July 2002, the FDA decided to propose a new rule requiring bar codes on certain drug and biological product labels. Health care professionals would use bar code scanning equipment, similar to that used in supermarkets, to make sure that the right drug in the right dose and route of administration is given to the right patient at the right time.

"It's a promising way to automate aspects of medication administration," says Robert Krawisz, executive director of the National Patient Safety Foundation. "The technology's impact at VA hospitals so far has been amazing." The Department of Veterans Affairs (VA) already uses bar codes nationwide in its hospitals, and the result has been a drastic reduction in medication errors. For example, the VA medical center in Topeka, Kan., has

reported that bar coding reduced its medication error rate by 86 percent over a nine-year period.

Here's how it works: When patients enter the hospital, they get a bar-coded identification wristband that can transmit information to the hospital's computer, says Lottie Lockett, R.N., a nursing administrator at the Houston VA Medical Center. Nurses have laptop computers and scanners on top of medication carts that they bring to patients' rooms. Nurses use the scanners to scan the patient's wristband and the medications to be given. The bar codes provide unique, identifying information about drugs given at the patient's bedside. "Before giving medications, nurses use the scanner to pull up a patient's full name and social security number on the laptops, along with the medications," Lockett says. "If there is not a match between the patient and the medication or some other problem, a warning box pops up on the screen."

The FDA's proposed rule on bar code labeling was published on March 14, 2003. The rule, which would take effect in 2006, applies to prescription drugs, biological products such as vaccines, blood and blood components, and over-the-counter (OTC) drugs that are commonly used in hospitals. Manufacturers, repackers, relabelers, and private label distributors of prescription and OTC drugs would be subject to the bar code requirements. The agency continues to study whether it also should develop a rule requiring bar code labeling on medical devices.

Drug name confusion: To minimize confusion between drug names that look or sound alike, the FDA reviews about 300 drug names a year before they are marketed. "We reject about one-third of the names that drug companies propose," says Phillips. The agency tests drug names with the help of about 120 FDA health professionals who volunteer to simulate real-life drug order situations. "We're also creating a computerized program that will assist in detecting similar names and that will help us take a more scientific approach to comparing names," Phillips says.

After drugs are approved, the FDA tracks reports of errors due to drug name confusion and spreads the word to health professionals, along with recommendations for avoiding future problems. For example, the FDA has reported errors involving the inadvertent administration of methadone, a drug used to treat opiate dependence, rather than the intended Metadate ER (methylphenidate) for the treatment of attention-deficit/hyperactivity disorder (ADHD). One report involved the death of an 8-year-old boy after a possible medication error at the dispensing pharmacy. The child, who was being treated for ADHD, was found dead at home. Methadone substitution was the suspected cause of death. Some FDA recommendations regarding drug name confusion have encouraged pharmacists to separate similar drug products on pharmacy shelves and have encouraged physicians to indicate both brand and generic drug names on prescription orders, as well as what the drug is intended to treat.

The last time the FDA changed a drug name after it was approved was in 1994 when the thyroid medicine Levoxine was being confused with the heart medicine Lanoxin (digoxin), and some people were hospitalized as a result. Now the thyroid medicine is

called Levoxyl, and the agency hasn't received reports of errors since the name change. Other examples of drug name confusion reported to the FDA include:

- Serzone (nefazodone) for depression and Seroquel (quetiapine) for schizophrenia
- Lamictal (lamotrigine) for epilepsy, Lamisil (terbinafine) for nail infections, Ludiomil (maprotiline) for depression, and Lomotil (diphenoxylate) for diarrhea
- Taxotere (docetaxel) and Taxol (paclitaxel), both for chemotherapy
- Zantac (ranitidine) for heartburn, Zyrtec (cetirizine) for allergies, and Zyprexa (olanzapine) for mental conditions € Celebrex (celecoxib) for arthritis and Celexa (citalopram) for depression.

Drug labeling: Consumers tend to overlook important label information on OTC drugs, according to a Harris Interactive Market Research Poll conducted for the National Council on Patient Information and Education and released in January 2002. In May 2002, an FDA regulation went into effect that aims to help consumers use OTC drugs more wisely.

The regulation requires a standardized "Drug Facts" label on more than 100,000 OTC drug products. Modeled after the Nutrition Facts label on foods, the label helps consumers compare and select OTC medicines and follow instructions. The label clearly lists active ingredients, uses, warnings, dosage, directions, other information, such as how to store the medicine, and inactive ingredients.

As for health professionals, the FDA proposed a new format in 2000 to improve prescription drug labeling for physicians, also known as the package insert. One FDA study showed that practitioners found the labeling to be lengthy, complex, and hard to use. The proposed redesign would feature a user-friendly format and would highlight critical information more clearly. The FDA is still reviewing public comments on this proposed rule. The agency has also been working on a project called DailyMed, a computer system that will be available without cost from the National Library of Medicine next year. DailyMed will have new information added daily, and will allow health professionals to pull up drug warnings and label changes electronically.

Error tracking and public education: On March 13, 2003, the FDA announced a proposed rule that would revamp safety reporting requirements. For example, the proposal would require that reports on actual and potential medication errors be submitted to the agency within 15 calendar days. FDA's Seligman says, "This rule is part of FDA's overall effort to understand the sources of medication errors and prevent them."

The FDA reviews 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 from the Institute for Safe Medication Practices (ISMP) and the U.S. Pharmacopeia, or USP (see "Who Tracks Medication Errors?").

A recent ISMP survey on medication error reporting practices showed that health professionals submit reports more often to internal reporting programs such as hospitals than to external programs such as the FDA. According to ISMP, one reason may be health professionals' limited knowledge about external reporting programs.

The FDA receives and reviews about 250 medication error reports each month, and classifies them to determine the cause and type of error. Depending on the findings, the FDA can change the way it labels, names, or packages a drug product. In addition, once a problem is discovered, the FDA educates the public on an ongoing basis to prevent repeat errors.

In 2001, the agency released a public health advisory to hospitals, nursing homes, and other health care facilities about the hazards of mix-ups between medical gases, which are prescription drugs. In one case, a nursing home in Ohio reported four deaths after an employee mistakenly connected nitrogen to the oxygen system.

ISMP reports medication errors through various newsletters that target health professionals in acute care, nursing, and community/ambulatory care. Recently, ISMP launched a newsletter for consumers called *Safe Medicine.*

In December 2002, USP released an analysis of medication errors captured in 2001 by its anonymous national reporting database, MedMARX. Of 105,603 errors, 3,361 errors (3.2 percent) involved children. Most of the errors were corrected before causing harm, but 190 caused patient injury and of those, two resulted in death. As a result of this analysis, USP released recommendations for preventing drug errors in children in January 2003.

What Consumers Can Do

In one case reported to ISMP, a doctor called in a prescription for the antibiotic Noroxin (norfloxacin) for a patient with a bladder infection. But the pharmacist thought the order was for Neurontin (gabapentin), a medication used to treat seizures. The good news is that the patient read the medication leaflet stapled to his medication bag, noticed the drug he received is used to treat seizures, and then asked about it. ISMP president Michael Cohen, R.Ph., Sc.D., says, "You should expect to count on the health system to keep you safe, but there are also steps you can take to look out for yourself and your family."

- Know what kind of errors occur. The FDA evaluated reports of fatal medication errors that it received from 1993 to 1998 and found that the most common types of errors involved administering an improper dose (41 percent), giving the wrong drug (16 percent), and using the wrong route of administration (16 percent). The most common causes of the medication errors were performance and knowledge deficits (44 percent) and communication errors (16 percent). Almost half of the fatal medication errors occurred in people over 60. Older people are especially at risk for errors because they

often take multiple medications. Children are also a vulnerable population because drugs are often dosed based on their weight, and accurate calculations are critical.

- Find out what drug you're taking and what it's for. Rather than simply letting the doctor write you a prescription and send you on your way, be sure to ask the name of the drug. Cohen says, "I would also ask the doctor to put the purpose of the prescription on the order." This serves as a check in case there is some confusion about the drug name. If you're in the hospital, ask (or have a friend or family member ask) what drugs you are being given and why.
- Find out how to take the drug and make sure you understand the directions. If you are told to take a medicine three times a day, does that mean eight hours apart exactly or at mealtimes? Should the medicine be stored at room temperature or in the refrigerator? Are there any medications, beverages, or foods you should avoid? Also, ask about what medication side effects you might expect and what you should do about them. And read the bottle's label every time you take a drug to avoid mistakes. In the middle of the night, you could mistake ear drops for eye drops, or accidentally give your older child's medication to the baby if you're not careful. Use the measuring device that comes with the medicine, not spoons from the kitchen drawer. If you take multiple medications and have trouble keeping them straight, ask your doctor or pharmacist about compliance aids, such as containers with sections for daily doses. Family members can help by reminding you to take your medicine.
- Keep a list of all medications, including OTC drugs, as well as dietary supplements, medicinal herbs, and other substances you take for health reasons, and report it to your health care providers. The often-forgotten things that you should tell your doctor about include vitamins, laxatives, sleeping aids, and birth control pills. One National Institutes of Health study showed a significant drug interaction between the herbal product St. John's wort and indinavir, a protease inhibitor used to treat HIV infection. Some antibiotics can lower the effectiveness of birth control pills. If you see different doctors, it's important that they all know what you are taking. If possible, get all your prescriptions filled at the same pharmacy so that all of your records are in one place. Also, make sure your doctors and pharmacy know about your medication allergies or other unpleasant drug reactions you may have experienced.
- If in doubt, ask, ask, ask. Be on the lookout for clues of a problem, such as if your pills look different than normal or if you notice a different drug name or different directions than what you thought. Robert Krawisz of the National Patient Safety Foundation says it's best to be cautious and ask questions if you're unsure about anything. "If you forget, don't hesitate to call your doctor or pharmacist when you get home," he says. "It can't hurt to ask."

Who Tracks Medication Errors?

The Food and Drug Administration

Accepts reports from consumers and health professionals about products regulated by the FDA, including drugs and medical devices, through MedWatch, the FDA's safety information and adverse event reporting program.
1-800-332-1088
www.fda.gov/medwatch/how.htm

Institute for Safe Medication Practices

Accepts reports from consumers and health professionals related to medication. Publishes *Safe Medicine,* a consumer newsletter on medication errors.
1800 Byberry Rd., Suite 810 Huntingdon Valley, PA 19006-3520
215-947-7797
www.ismp.org/Pages/Consumer.html

U.S. Pharmacopeia

MedMARX is an anonymous medication error reporting program used by hospitals.
www.medmarx.com
12601 Twinbrook Parkway Rockville, MD 20852
1-800-822-8772
www.usp.org

Patient Safety Proposals

In March 2003, Health and Human Services Secretary Tommy G. Thompson announced two proposed rules from the FDA that will use state-of-the-art technology to improve patient safety. Here is a snapshot of each rule:

- **Bar codes:** Just as the technology is used in retail and other industries, required bar codes would contain unique identifying information about drugs. When used with bar code scanners and computerized patient information systems, bar code technology can prevent many medication errors, including administering the wrong drug or dose, or administering a drug to a patient with a known allergy.
- **Safety Reporting:** The proposed revamping of safety reporting requirements aims to enhance the FDA's ability to monitor and improve the safe use of drugs and biologics. The rule would improve the quality and consistency of safety reports, require the submission of all suspected serious reactions for blood and blood products, and require reports on important potential medication errors.

Hospital Strategies

Hospitals and other health care organizations work to reduce medication errors by using technology, improving processes, zeroing in on errors that cause harm, and building a culture of safety. Here are a couple of examples.

Pharmacy intervention: It was a challenge for health care providers, especially surgeons, at Fairview Southdale Hospital in Edina, Minn., to ensure that patients continued taking their regularly prescribed medicines when they entered the hospital, says Steven Meisel, Pharm.D., director of medication safety at Fairview Health Services. "Surgeons are not typically the original prescribers," he says. The solution was to have pharmacy technicians record complete medication histories on a form. In a pilot program, the technicians called most patients on the phone a couple of days before surgery. A pharmacist reviewed the information and then the surgeon decided which medications should be continued. After three months, the number of order errors per patient dropped by 84 percent, and the pilot program became permanent.

Computerized Physician Order Entry (CPOE): Studies have shown that CPOE is effective in reducing medication errors. It involves entering medication orders directly into a computer system rather than on paper or verbally. The Institute for Safe Medication Practices conducted a survey of 1,500 hospitals in 2001 and found that about 3 percent of hospitals were using CPOE, and the number is rising. Eugene Wiener, M.D., medical director at the Children's Hospital of Pittsburgh, says, "There is no misinterpretation of handwriting, decimal points, or abbreviations. This puts everything in a digital world."

The Pittsburgh hospital unveiled its CPOE system in October 2002. Developed by the hospital and the Cerner Corporation in Kansas City, Mo., Children'sNet has replaced most paper forms and prescription pads. Wiener says that, unlike with adults, most drug orders for children are generally based on weight. "The computer won't let you put an order in if the child's weight isn't in the system," he says, "and if the weight changes, the computer notices." The system also provides all kinds of information about potential drug complications that the doctor might not have thought about. "Doctors always have a choice in dealing with the alerts," Wiener says. "They can choose to move past an alert, but the alert makes them stop and think based on the specific patient indications."

For More Information

Agency for Healthcare Research and Quality Brochures:
"20 Tips to Help Prevent Medical Errors" and "20 Tips to Help Prevent Medical Errors in Children"
1-800-358-9295

Food and Drug Administration
"Think it Through: A Guide to Managing the Benefits and Risks of Medicines"
1-888-878-3256