

# 1.

## ***Medical Errors: The Scope of the Problem***

### **An Epidemic of Errors**

The November 1999 report of the Institute of Medicine (IOM), entitled *To Err Is Human: Building A Safer Health System*, focused a great deal of attention on the issue of medical errors and patient safety. The report indicated that as many as 44,000 to 98,000 people die in hospitals each year as the result of medical errors.

Even using the lower estimate, this would make medical errors the eighth leading cause of deaths in this country—higher than motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516). About 7,000 people per year are estimated to die from medication errors alone—about 16 percent more deaths than the number attributable to work-related injuries.

### ***Where Errors Occur***

Errors occur not only in hospitals but in other health care settings, such as physicians' offices, nursing homes, pharmacies, urgent care centers, and care delivered in the home. Unfortunately, very little data exist on the extent of the problem outside of hospitals. The IOM report indicated, however, that many errors are likely to occur outside the hospital. For example, in a recent investigation of pharmacists, the Massachusetts State Board of Registration in Pharmacy estimated that 2.4 million prescriptions are filled improperly each year in the State.

### ***Costs***

Medical errors carry a high financial cost. The IOM report estimates that medical errors cost the nation approximately \$37.6 billion each year; about \$17 billion of those costs are associated with preventable errors. About half of the expenditures for preventable medical errors are for direct health care costs.

### ***Not a New Issue***

The serious problem of medical errors is not new, but in the past, the problem has not gotten the attention it deserved. A body of research describing the problem of medical errors began to emerge in the early 1990s with landmark research conducted by Lucian Leape, M.D., and David Bates, M.D., and supported by the Agency for Health Care Policy and Research, now the Agency for Healthcare Research and Quality (AHRQ).

The final report of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, released in 1998, identified medical errors as one of the four major challenges facing the nation in improving health care quality.

### ***Public Fears***

While there has been no unified effort to address the problem of medical errors and patient safety, awareness of the issue has been growing. Americans have a very real fear of medical errors. According to a national poll conducted by the National Patient Safety Foundation:

- Forty-two percent of respondents had been affected by a medical error, either personally or through a friend or relative.
- Thirty-two percent of the respondents indicated that the error had a permanent negative effect on the patient's health.

Overall, the respondents to this survey thought the health care system was “moderately safe” (rated a 4.9 on a 1 to 7 scale, where 1 is not safe at all and 7 is very safe).

Another survey, conducted by the American Society of Health-System Pharmacists, found that Americans are “very concerned” about:

- Being given the wrong medicine (61 percent).
- Being given two or more medicines that interact in a negative way (58 percent).
- Complications from a medical procedure (56 percent).

Most people believe that medical errors are the result of the failures of individual providers. When asked in a survey about possible solutions to medical errors:

- Seventy-five percent of respondents thought it would be most effective to “keep health professionals with bad track records from providing care.”
- Sixty-nine percent thought the problem could be solved through “better training of health professionals.”

This fear of medical errors was borne out by the interest and attention that the IOM report generated. According to a survey by the Kaiser Family Foundation, 51 percent of Americans followed closely the release of the IOM report on medical errors.

### ***It's a Systems Problem***

The IOM emphasized that most of the medical errors are systems related and not attributable to individual negligence or misconduct. The key to reducing medical errors is to focus on improving the systems of delivering care and not to blame individuals. Health care professionals are simply human and, like everyone else, they make mistakes. But research has shown that system improvements can reduce the error rates and improve the quality of health care:

- A 1999 study indicated that including a pharmacist on medical rounds reduced the errors related to medication ordering by 66 percent, from 10.4 per 1,000 patient days to 3.5 per 1,000 patient days.
- The specialty of anesthesia has reduced its error rate by nearly sevenfold, from 25 to 50 per million to 5.4 per million, by using standardized guidelines and protocols, standardizing equipment, etc.
- One hospital in the Department of Veterans Affairs uses hand-held, wireless computer technology and bar-coding, which has cut overall hospital medication error rates by 70 percent. This system is soon to be implemented in all VA hospitals.

### ***Types of Errors***

The IOM defines medical error as “the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim.” An adverse event is defined as “an injury caused by medical management rather than by the underlying disease or condition of the patient.” Some adverse events are not preventable and they reflect the risk associated with treatment, such as a life-threatening allergic reaction to a drug when the patient had no known allergies to it. However, the patient who receives an antibiotic to which he or she is known to be allergic, goes into anaphylactic shock, and dies, represents a preventable adverse event.

Most people believe that medical errors usually involve drugs, such as a patient getting the wrong prescription or dosage, or mishandled surgeries, such as amputation of the wrong limb. However, there are many other types of medical errors, including:

- ❑ Diagnostic error, such as misdiagnosis leading to an incorrect choice of therapy, failure to use an indicated diagnostic test, misinterpretation of test results, and failure to act on abnormal results.
- ❑ Equipment failure, such as defibrillators with dead batteries or intravenous pumps whose valves are easily dislodged or bumped, causing increased doses of medication over too short a period.
- ❑ Infections, such as nosocomial and postsurgical wound infections.
- ❑ Blood transfusion-related injuries, such as giving a patient the blood of the incorrect type.
- ❑ Misinterpretation of other medical orders, such as failing to give a patient a salt-free meal, as ordered by a physician.

### **Preventing Errors**

Research clearly shows that the majority of medical errors can be prevented:

- ❑ One of the landmark studies on medical errors indicated 70 percent of adverse events found in a review of 1,133 medical records were preventable; 6 percent were potentially preventable; and 24 percent were not preventable.
- ❑ A study released last year, based on a chart review of 15,000 medical records in Colorado and Utah, found that 54 percent of surgical errors were preventable.

Other potential system improvements include:

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- ❑ Use of information technology, such as hand-held bedside computers, to eliminate reliance on handwriting for ordering medications and other treatment needs.
- ❑ Avoidance of similar-sounding and look-alike names and packages of medication.
- ❑ Standardization of treatment policies and protocols to avoid confusion and reliance on memory, which is known to be fallible and responsible for many errors.

### **Five Steps to Safer Health Care**

<p>1. <b><i>Ask questions if you have doubts or concerns.</i></b> Ask questions and make sure you understand the answers. Choose a doctor you feel comfortable talking to. Take a relative or friend with you to help you ask questions and understand the answers.</p>	
<p>1. <b><i>Keep and bring a list of ALL the medicines you take.</i></b> Give your doctor and pharmacist a list of all the medicines that you take, including nonprescription medicines. Tell them about any drug allergies you have. Ask about side effects and what to avoid while taking the medicine. Read the label when you get your medicine, including all warnings. Make sure your medicine is what the doctor ordered and know how to use it. Ask the pharmacist about your medicine if it looks different than you expected.</p>	

<p>4. <b>Get the results of any test or procedure.</b> Ask when and how you will get the results of tests or procedures. Don't assume the results are fine if you do not get them when expected, be it in person, by phone, or by mail. Call your doctor and ask for your results. Ask what the results mean for your care.</p>	
<p><b>Talk to your doctor about which hospital is best for your health needs.</b> Ask your doctor about which hospital has the best care and results for your condition if you have more than one hospital to choose from. Be sure you understand the instructions you get about follow-up care when you leave the hospital.</p>	
<p><b>Make sure you understand what will happen if you need surgery.</b> Make sure you, your doctor, and your surgeon all agree on exactly what will be done during the operation. Ask your doctor, "Who will manage my care when I am in the hospital?" Ask your surgeon: "Exactly what will you be doing? About how long will it take? What will happen after the surgery? How can I expect to feel during recovery?"</p>	

Tell the surgeon, anesthesiologist, and nurses about any allergies, bad reaction to anesthesia, and any medications you are taking.

### More Information

Select for more information about medical errors. A Federal report on medical errors can be accessed online, and print copies (Publication No. OM 00-0004) are available from the AHRQ Publications Clearinghouse: phone, 1-800-358-9295 (outside the United States, please call 410-381-3150) or E-mail: [ahrqpubs@ahrq.gov](mailto:ahrqpubs@ahrq.gov).

U.S. Department of Health and Human Services  
 American Hospital Association  
 American Medical Association

AHRQ Publication No. M007  
 Current as of July 2003 Internet Citation Five Steps to Safer Health Care. Patient Fact Sheet. July 2003. AHRQ Publication No 03-M007. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/consumer/5steps.htm>

## 2. **20 Tips to Help Prevent Medical Errors**

Medical errors are one of the nation's leading causes of death and injury. A recent report by the Institute of Medicine estimates that as many as 44,000 to 98,000 people die in U.S. hospitals each year as the result of medical errors. This means that more

people die from medical errors than from motor vehicle accidents, breast cancer, or AIDS.

Government agencies, purchasers of group health care, and health care providers are working together to make the U.S. health care system safer for patients and the public. This fact sheet tells what you can do.

### ***What Are Medical Errors?***

Medical errors happen when something that was planned as a part of medical care doesn't work out, or when the wrong plan was used in the first place. Medical errors can occur anywhere in the health care system:

- Hospitals
- Clinics
- Outpatient surgery centers
- Doctors' offices
- Nursing homes
- Pharmacies
- Patients' homes
- Errors can involve:
  - Medicines
  - Surgery
  - Diagnosis
  - Equipment
  - Lab reports

They can happen during even the most routine tasks, such as when a hospital patient on a salt-free diet is given a high-salt meal.

Most errors result from problems created by today's complex health care system. But errors also happen when doctors and their patients have problems communicating. For example, a recent study supported by the Agency for Healthcare Research and Quality (AHRQ) found that doctors often do not do enough to help their patients make informed decisions. Uninvolved and uninformed patients are less likely to accept the doctor's choice of treatment and less likely to do what they need to do to make the treatment work.

### ***What Can You Do?***

#### ***Be Involved in Your Health Care***

1. ***The single most important way you can help to prevent errors is to be an active member of your health care team.***

That means taking part in every decision about your health care. Research shows that patients who are more involved with their care tend to get better results. Some specific tips, based on the latest scientific evidence about what works best, follow.

#### **Medicines**

2. ***Make sure that all of your doctors know about everything you are taking. This includes prescription and over-the-counter medicines, and dietary supplements such as vitamins and herbs.***

At least once a year, bring all of your medicines and supplements with you to your doctor. "Brown bagging" your medicines can help you and your doctor talk about

them and find out if there are any problems. It can also help your doctor keep your records up to date, which can help you get better quality care.

3. ***Make sure your doctor knows about any allergies and adverse reactions you have had to medicines.***

This can help you avoid getting a medicine that can harm you.

When your doctor writes you a prescription, make sure you can read it.

If you can't read your doctor's handwriting, your pharmacist might not be able to either.

***Ask for information about your medicines in terms you can understand—both when your medicines are prescribed and when you receive them.***

What is the medicine for?

How am I supposed to take it, and for how long?

What side effects are likely? What do I do if they occur?

Is this medicine safe to take with other medicines or dietary supplements I am taking?

What food, drink, or activities should I avoid while taking this medicine?

***When you pick up your medicine from the pharmacy, ask: Is this the medicine that my doctor prescribed?***

A study by the Massachusetts College of Pharmacy and Allied Health Sciences found that 88 percent of medicine errors involved the wrong drug or the wrong dose.

***If you have any questions about the directions on your medicine labels, ask.***

Medicine labels can be hard to understand. For example, ask if “four doses daily” means taking a dose every 6 hours around the clock or just during regular waking hours.

***Ask your pharmacist for the best device to measure your liquid medicine. Also, ask questions if you're not sure how to use it.***

Research shows that many people do not understand the right way to measure liquid medicines. For example, many use household teaspoons, which often do not hold a true teaspoon of liquid. Special devices, like marked syringes, help people to measure the right dose. Being told how to use the devices helps even more.

***Ask for written information about the side effects your medicine could cause.***

If you know what might happen, you will be better prepared if it does—or, if something unexpected happens instead. That way, you can report the problem right away and get help before it gets worse. A study found that written information about medicines can help patients recognize problem side effects and then give that information to their doctor or pharmacist.

## ***Hospital Stays***

***If you have a choice, choose a hospital at which many patients have the procedure or surgery you need.***

Research shows that patients tend to have better results when they are treated in hospitals that have a great deal of experience with their condition.

If you are in a hospital, consider asking all health care workers who have direct contact with you whether they have washed their hands.

Handwashing is an important way to prevent the spread of infections in hospitals. Yet, it is not done regularly or thoroughly enough. A recent study found that when patients checked whether health care workers washed their hands, the workers washed their hands more often and used

***When you are being discharged from the hospital, ask your doctor to explain the treatment plan you will use at home.***

This includes learning about your medicines and finding out when you can get back to your regular activities. Research shows that at discharge time, doctors think their patients understand more than they really do about what they should or should not do when they return home.

## ***Surgery***

***If you are having surgery, make sure that you, your doctor, and your surgeon all agree and are clear on exactly what will be done.***

Doing surgery at the wrong site (for example, operating on the left knee instead of the right) is rare. But even once is too often. The good news is that wrong-site surgery is 100 percent preventable. The American Academy of Orthopaedic Surgeons urges its members to sign their initials directly on the site to be operated on before the surgery.

## ***Other Steps You Can Take***

14. ***Speak up if you have questions or concerns.***

You have a right to question anyone who is involved with your care.

15. ***Make sure that someone, such as your personal doctor, is in charge of your care.***

This is especially important if you have many health problems or are in a hospital.

16. ***Make sure that all health professionals involved in your care have important health information about you.***

Do not assume that everyone knows everything they need to.

17. ***Ask a family member or friend to be there with you and to be your advocate (someone who can help get things done and speak up for you if you can't).***

Even if you think you don't need help now, you might need it later.

18. ***Know that "more" is not always better.***

It is a good idea to find out why a test or treatment is needed and how it can help you. You could be better off without it.

19. *If you have a test, don't assume that no news is good news.*

Ask about the results.

20. *Learn about your condition and treatments by asking your doctor and nurse and by using other reliable sources.*

For example, treatment recommendations based on the latest scientific evidence are available from the National Guidelines Clearinghouse at <http://www.guideline.gov>. Ask your doctor if your treatment is based on the latest evidence.

## More Information

Select for more online information about medical errors. A Federal report on medical errors can be accessed online, and a print copy (Publication No. OM 00-0004) is available from the AHRQ Publications Clearinghouse: phone, 1-800-358-9295 (outside the United States, please call 410-381-3150) or E-mail: [ahrqpubs@ahrq.gov](mailto:ahrqpubs@ahrq.gov).

AHRQ Publication No. 00-PO38 Current as of February 2000

## Internet Citation

20 Tips to Help Prevent Medical Errors. Patient Fact Sheet. AHRQ Publication No. 00-PO38, February 2000. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/consumer/20tips.htm>

## Ways You Can Help Your Family Prevent Medical Errors!

### *What Are Medical Errors?*

Medical errors are mistakes that can happen with medicine, surgery, tests, and other parts of your healthcare. Here is an example of a medical error:

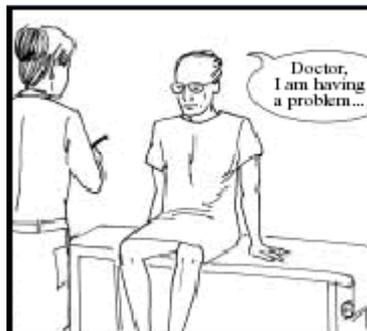
- Getting the wrong medicine is a medical error.



### What Can You Do?

You can help protect yourself and your family from medical errors. The most important way you can do this is to talk. Talk to your doctor, nurse, and other health care workers.

- Tell them important things about your health.
- Ask them questions
- Make decisions about your health care with them.



## 3. Helpful Hints for Preventing Medication Errors

The Problem Medical mistakes are a huge problem according to a 1999 report by the Institute of Medicine (IOM) entitled *To Err is Human: Building a Safer Health System*. The IOM announced that 44,000 to 98,000 Americans die from mistakes each year in hospitals. The wide range of number of errors was extrapolated from two large studies, one in Colorado and Utah, and the second one in New York. The number of adverse events ranged from 2.9%-3.7% in New York to 8.8%-13.6% in Colorado/Utah. When these percentages are extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the result is an estimated 44,000 to 98,000 Americans who die as a result of medical errors at a cost of \$17 to \$29 billion. This figure puts medical error as the eighth cause of death in this country.

Based on sentinel events that have been reported to the Joint Commission at this time, some of the most common error problems are related to medication delivery. Reviewing your medication delivery process to reduce the risk of errors is a timely quality process improvement and a cost-effective strategy for performance improvement. A focus on systemic processes is one of the most effective ways to address problems and sustain improvement.

Drug-related morbidity and mortality have been reported to cost \$136 billion per year according to a study by Johnson and Bootman. While reports vary, medication mishaps have been reported to affect about 2 million hospital patients a year with some research indicating that nearly 30% of mistakes are preventable. Other researchers estimate that 3 million such mistakes occur every year. A Louis Harris poll of 1,500 adults conducted by the National Patient Safety Foundation found that one in three Americans has been affected by serious medical mistakes. Of those, 28% are related to a medication error.

In a 1990 study about the frequency and cause of medication errors the overall detected rate was 3.13 errors for each 1,000 orders written. The most frequent medication error found in this study was overdosing. Several well publicized cases about overdoses of chemotherapy in adults as well as children point to the need for prevention and risk reduction strategies rather than trying to correct processes after the fact.

## **Prevention Tips**

The best strategies should focus on medication error prevention. These strategies should be undertaken in an interdisciplinary approach to ensure all disciplines impacted by the medication system are working together. There are multiple articles and resources that can be utilized to help hospitals evaluate their medication delivery processes to improve outcomes. Lucian Leape is widely known for his study of adverse drug events and the IHI has recently published a guide after a breakthrough series on adverse drug events. Recently the National Patient Safety Foundation was developed by the AMA to focus on safety and create resources to focus on prevention.

### ***Ways to Minimize Errors***

1. Design the medication system to prevent/reduce errors.
2. Design procedures to make errors more visible when they occur.
3. Design procedures to mitigate the effects of errors when they occur and are not trapped before they reach the patient.
4. Create the climate that fosters systemic and process changes without blame and punitive approaches.

◆ *Reduce reliance on memory*

Design processes with automatic prompts and less reliance on fallible processes.

Examples:

- Computerized order-entry
- Computerized profiling of patient data
- Computerized drug information
- Computerized alerts
- Preprinted orders
- Robotic dispensing
- Barcode drugs
- Label boldly and clearly
- Print recommended rate of administration on label

◆ *Simplify*

Reduce the number of steps and hand-off in work processes. Reduce nonessential elements of equipment, software, and rules of procedure.

Examples

- Limit the choice of drugs
- Limit the doses for each drug
- Limit the number of administration times
- Institute a pharmacy IV admixture program
- Repackage drugs to eliminate look-alikes
- Allow automatic drug dispensing on the nursing unit

◆ *Standardize*

Limit unneeded variety in drugs, equipment, supplies, rules, and processes of work. Especially helpful are prescribing conventions and protocols for complex medications such as heparin and chemotherapy.

Examples:

- Standardize (doses, dosing times, storage locations, concentrations, packaging, labels, delivery times)
- Institute an IV admixture program
- Use protocols for hazardous or high-alert drugs
- Conduct systematic review of each order

◆ *Use constraints and “forcing functions”*

Forcing a function and the use of constraints prevent actions from occurring until certain conditions are met. This method eliminates reliance on memory and checklists.

Examples

- Program computer not to process order unless key information has been entered
- Dispense epidural medications only in unique spinal syringes
- Remove hazardous or high-alert drugs of limited value from the formulary
- Use automatic dose reduction for the elderly and patients with renal failure

◆ *Use protocols and checklists wisely*

Use repetition, standard vocabularies, and clear communication. Use these tools as reminders but allow judgment and critical thinking to be applied rather than adherence to rigid models.

Examples:

Use protocols for hazardous or high-alert drugs  
Require double check by a second person for hazardous or high-alert drugs

◆ *Improve access to information*

Make information readily available to all users including patients.

Examples:

Computerized order-entry  
Computer profiling of patient data  
Computerized drug information  
Make formulary available online  
Computerized alerts  
Preprinted orders  
Print IV administration guidelines and compatibility charts  
Online laboratory data  
Critical information posted on drug labels

◆ *Decrease reliance on vigilance*

Design processes so that the safe channel is the one requiring the lowest energy. Make doing the right things the easiest thing to do. When designing tasks and work systems, keep in mind issues of stress, workload, circadian rhythm, time pressure, limits to memory, and properties of human vigilance. Design for normal human behavior and capacity.

Examples:

Automatic, daily monitoring of doses of toxic drugs, such as chemotherapy  
Eliminate look-alike drugs  
Store look-alike drugs separately  
Develop systems to differentiate sound-alike drugs  
Enlist patient and family vigilance tasks

◆ *Reduce handoffs*

Reducing the number of steps, persons involved and handoffs will reduce the risk of errors.

Examples:

Computerized order-entry  
Computerized order transfer  
Satellite pharmacy  
Computerized medication administration record  
Robotic dispensing  
Unit dosing  
Automatic dispensing

◆ *Decrease multiple entry*

Duplication of documentation increases the risk for errors.

Examples:

Computerized order entry  
Computerized medication administration record

◆ *Eliminate look-alikes and sound-alikes*

Similarity of packaging and labeling can increase the risk of choosing the wrong medication, dose, or route.

Examples:

Repackage to differentiate  
Store separately  
Alert staff and post information  
Avoid stocking them

◆ *Automate cautiously*

Automation can add alerts and messages to identify potential problems and interactions and thereby reduce errors. Use care to avoid over-automating systems and equipment. Make sure that operators can know the true state of the system, can override automation effectively and can maintain proper vigilance.

Examples:

Computerized order entry  
Robotic dispensing  
Train staff  
Bar code labels

◆ *Optimize the work environment for safety*

Let the environment and equipment “speak,” informing the user about proper use. Use visual controls. Minimize translation steps between instructions and their effects. Design physical shapes and flows to guide proper use.

Examples:

Workloads within acceptable range  
Reduce unnecessary time pressures  
Accommodate diurnal sleep rhythms  
Adjust environment to increase light, decrease noise, and decrease clutter  
Critical equipment available, in good repair, uniform storage  
Reduce distractions

◆ *Increase feedback*

Feedback can modify or correct behaviors leading to errors.

Examples:

Equipment designed to indicate problem and source  
Monitor effectiveness of protocols  
Make staff aware of responses to errors

◆ *Train the team*

An effective team will make fewer errors so training can enhance teamwork.

Examples:

Nonauthoritarian/nonpunitive style  
Team training  
Interdependence  
Train for safety

◆ *Drive out fear and facilitate error reporting “Culture Change”*

Assume the requirement of anonymity until otherwise proven. Reward reports.  
Build a culture that celebrates the increase of knowledge on the basis of which  
error rates can be reduced and risks mitigated.

Examples:

Safe havens for reporting  
Confidential reporting  
Make it easy to report  
Group discussion re-prevention  
Collect and disseminate reports  
Display improvements

◆ *Obtain leadership commitment*

A focus on system improvement is needed rather than a focus on individual  
performance to create change.

Examples:

Increase cooperation  
Interdisciplinary teams  
Thank staff  
Commit resources

◆ *Improve direct communication*

Direct communication among all members of the team is essential to work  
towards continuous improvement in the medication delivery system.

Examples:

Direct communication style  
Repeat verbal orders verbatim  
Role play to deal with conflicts  
Feedback on communication

## Thorough and Credible Root Cause Analysis

The following areas are suggested by the Joint Commission as minimal areas for analysis in a root cause analysis of a medication error.

- Patient identification process
- Staffing levels
- Orientation and training of staff
- Competency assessment/credentialing process
- Supervision of staff
- Communication among staff members
- Availability of information
- Common Error Types and “High-Alert” Medications

### *Target Drugs*

These drugs are frequently associated with medication errors and they are likely to cause significant impact on the patient. Medications that have the highest risk of causing injury when misused are known as “high-alert” medications (Cohen, 1999). Examine policies and procedures in which these drugs are administered to reduce the likelihood of an error occurring.

- Adrenergic agonists
- Aminophylline-theophylline
- Benzodiazepines
- Chemotherapy
- Digoxin
- Dextrose 50%
- Anticoagulants (Heparin)
- Insulin and oral hypoglycemics
- Lidocaine
- Neuromuscular blockers
- Parenteral narcotics and opiates
- Vasoactive drugs
- Concentrated electrolytes (especially potassium chloride and phosphate and sodium chloride solutions above .9%; also magnesium sulfate)
- Warfarin

Source: Sentinel Event Alert, November 1999

### *Target Procedures*

These procedures are commonly associated with medication errors and these aspects of the medication delivery system should be carefully examined to ensure safe medication administration. When you evaluate processes focus on areas that may be more problematic in order to correct deficiencies.

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- Dose calculations and dose check systems (have check systems for calculations and high-alert drugs) • Proximity of look-alikes, sound-alikes which lead to mix-ups of drugs

- ❑ Telephone and oral orders which may lead to confusion of orders
- ❑ Handwritten orders and use of abbreviations that lead to confusion (use of “U” instead of “units”; leading and trailing zeros according to decimal point; reason for medication; clarify amount; avoid abbreviations that are unclear)
- ❑ Choosing proper items from storage (types of drugs, look-alikes, sound-alikes)
- ❑ Administering oral meds via tube to patients with central IV lines
- ❑ Electronic infusion devices using sets that allow free flow (program correct rates and have check systems to ensure correct calculations/concentrations and rate)
- ❑ Limit the available opiates and narcotics in floor stock (review hydromorphone and morphine re mix-ups)
- ❑ Unusual requests/concentrations of meds (standardize and limit drug concentrations; remove concentrated potassium chloride and phosphate from floor stock)
- ❑ Move drug preparation off of nursing units to designated pharmacy area and use premixed solutions.
- ❑ Separate drugs known to cause mix-ups (separate heparin and insulin; standardize concentrations and use premixed solutions; use only single-dose containers)

Source: Institute for Safe Medical Practices

### ***Points in the Process Where Errors Can Occur***

As you examine target medications and target procedures, also examine the point in the process where these errors occurred to help pinpoint problems. Certain problems are more likely at certain phases.

- ❑ Choosing a medication, its dose and schedule
- ❑ Ordering a medication
- ❑ Dispensing and distributing a medication
- ❑ Administering a medication
- ❑ Monitoring for medication response
- ❑ Monitoring for adverse reactions
- ❑ Operating and recovery rooms

Source: Healthcare Benchmarks

### **Resources at a Glance**

Institute for Safe Medication Practices (ISMP)  
 300 W. Street Road  
 Warminster, PA 18974-3236 215-956-9181  
<http://www.fda.gov/medwatch>

MedWatch - FDA Medical Products Reporting Program 12601 Twinbrook Parkway  
 Rockville, MD 20852-1790  
 800-FDA-1088  
<http://www.ismp.org>

Institute for Healthcare Improvement (IHI)  
 135 Francis Street  
 Boston, MA 02215  
 617-754-4800  
<http://www.ihl.org>

National Patient Safety Foundation (at the AMA)  
 515 North State Street

Chicago, IL 60610  
312-464-4615  
<http://www.ama-assn.org/>

American Society of Hospital Pharmacists  
7272 Wisconsin Avenue  
Bethesda, MD 20814  
301-657-3000  
<http://www.ashp.org>

Agency for Health Care Policy and Research (AHCPR)  
2101 East Jefferson Street  
Rockville, MD 20851  
301-594-1364  
<http://www.ahcpr.gov>

National Coordinating Council for Medication Error Reporting (NCCMERP)  
12601 Twinbrook Parkway  
Rockville, MD 20852  
301-816-8215  
202-822-8405  
<http://www.usp.org/>

Joint Commission on Accreditation of Healthcare Organizations  
One Renaissance Boulevard  
Oakbrook Terrace, IL 60181  
630-792-5000  
[www.jcaho.org](http://www.jcaho.org)

National Council on Patient Information and Education  
1201 16th Street NW, Box 39  
Washington, D.C. 20036  
202-223-7195  
<http://www.talkaboutrx.org>

Institute of Medicine Report: To Err is Human: Building a Safer Health System  
[www.national-academies.org](http://www.national-academies.org)

Numerous articles and resources can be found on medication processes and error reduction including:

- National Patient Safety Foundation at <http://www.ama-assn.org/med-sci/npsf/bibliogr.htm>
- Joint Commission at [http://www.jcaho.org/ptsafety\\_frm.html](http://www.jcaho.org/ptsafety_frm.html)
- Institute for Safe Medication Practices
- Institute for Medicine: To Err is Human: Building a Safer Health System <http://www.national-academies.org>
- Video "Beyond Blame" available free from Bridge Medical Inc., 120 South Sierra, Solana Beach, CA 92075; 619-30-0100; [www.mederrors.com](http://www.mederrors.com)

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## **4.**

# ***Improving Medication Safety***

## **Background**

Most of what has been learned in recent years about how to reduce medication errors and increase patient safety is based on two principles. First, individuals, by the very nature of being human, are vulnerable to error. Although individuals are the focus of the error, errors happen because of the systems in which those individuals work. As a result, reducing error will require us to design and implement more error-resistant systems. Second, we have to create an environment in which we can learn from failure— a safe, nonpunitive environment that supports candid discussion of errors, their causes, and ways to prevent them.

These principles have a common denominator—they require the leadership and commitment of senior executives, medical, nursing, and clinical staff to create change within our organizations.

## **Common Sources of Error**

Medication systems in hospitals are complex and multilayered, involving many steps and many individuals. According to experts, this complexity increases the probability

of failure. While many errors are caught before they can cause harm, it can be tragic whenever a patient's safety is compromised. Error can occur at any stage—prescribing, ordering, dispensing, administering, or monitoring the effects of a medication. According to the Institute for Safe Medication Practices, some common sources of medication error in health systems include:

***Unavailable patient information:*** Critical patient information (diagnoses, lab values, allergies, drug contradictions, etc.) is often unavailable to pharmacy, nursing, and medical staff prior to dispensing or administering drugs.

***Unavailable drug information:*** Pharmacists often are not readily available on patient care units and written resources may not be up-to-date, which can lead to dose miscalculations or ignorance of drug interactions. Because errors occur most often during the prescribing and administration stages, accessible drug information must be readily available and close at hand for all staff who prescribe and administer drugs.

***Miscommunication of drug orders:*** Failed communication is at the heart of many errors. This includes poor handwriting, confusion of drugs with similar names, careless use of zeroes and decimal points, confusion of metric and apothecary systems, use of inappropriate abbreviations, ambiguous or incomplete orders, and, sometimes, conflicts between practitioners.

***Problems with labeling, packaging and drug nomenclature:*** Most drugs are dispensed through unit dose systems that parse medications into smaller-sized doses. These systems, however, do not always provide for thorough preparation, packaging, and labeling of medications, with screening and checking by both nursing and pharmacy personnel, and they may not be available throughout every unit in the hospital (e.g., ERs and ICUs). Drug administration procedures often do not ensure that medications remain labeled until they reach the patient's bedside, a frequent source of error.

***Drug standardization, storage, and stocking:*** Stocking multiple concentrations of the same drug, or storing drugs in look-alike containers or in ways that obscure drug labels, may contribute to error. Lack of safety procedures for use of automated dispensing technology or inadequate check systems may also contribute to errors.

***Drug device acquisition, use and monitoring:*** Lack of standardization in drug delivery devices, improper default settings, unsafe equipment (e.g., free-flow infusion pumps), and the lack of independent check systems for verifying dose and rate settings can all contribute to device-related errors.

***Environmental stress:*** Environmental factors like lighting, heat, noise, and excessive interruptions, can affect individual performance. The process of transcribing orders is particularly vulnerable to distractions in the environment, as staff transcribing orders are exposed to noise, interruptions, nonstop unit activity, and too-long or double shifts.

***Limited staff education:*** Many practitioners are not as aware as they should be of situations within their own organizations that have been reported as error-prone, or of similar information published in professional literature.

***Limited patient education:*** Medication use is a multi-step, multidisciplinary process that begins and ends with the patient. Patient education about medications—what they are taking, why they are taking it, and how they should take it – is essential to successful medication administration. Patients can be partners in the prevention of error while hospitalized and need to be educated to safely self-administer medications when they go home. Quality improvement processes and risk management: Health facilities need systems for identifying, reporting, analyzing, and correcting errors and identifying trends, and measurement systems for tracking the effect of system

changes. Also, organizations need to take into consideration information from outside sources about errors that have occurred elsewhere. But above all, health organizations need to cultivate a nonpunitive approach to error that will encourage frank identification and analysis of errors when they occur.

### ***Steps for Improving Medication Safety***

These potential sources of error can be controlled if we design safer systems. With this in mind, the AHA has attached to this advisory a list of successful practices for improving medication safety and for improving overall patient safety within our hospitals and health systems. We encourage your team to review this list of recommendations, plan for implementation, and begin to track your progress.

### ***Our Sources***

The recommendations were culled from several reliable sources that are leaders in the effort to reduce and prevent medication errors, and we are grateful for their pioneering efforts. This list includes those organizations, as well as other resources for your organization's efforts.

- ❑ American Society of Health-System Pharmacists ([www.ashp.org](http://www.ashp.org))
- ❑ American Society for Healthcare Risk Management ([www.ashrm.org](http://www.ashrm.org))
- ❑ Institute for Healthcare Improvement ([www.ihl.org](http://www.ihl.org))
- ❑ Institute of Medicine ([www.national-academies.org](http://www.national-academies.org))
- ❑ Institute for Safe Medication Practices ([www.ismp.org](http://www.ismp.org))
- ❑ Joint Commission on Accreditation of Healthcare Organizations ([www.jcaho.org](http://www.jcaho.org))
- ❑ Massachusetts Hospital Association ([www.mhalink.org](http://www.mhalink.org))
- ❑ Massachusetts Coalition for the Prevention of Medical Errors ([www.macoalition.org](http://www.macoalition.org))
- ❑ National Coordinating Council on Medication Error Reporting and Prevention ([www.nccmerp.org](http://www.nccmerp.org))
- ❑ National Patient Safety Foundation ([www.npsf.org](http://www.npsf.org))
- ❑ U.S. Pharmacopeia ([www.usp.org](http://www.usp.org))

### **Books**

1. Cohen, Michael R., Ed. *Medication Errors*. Washington, D.C. American Pharmaceutical Association. 1999. (Contains a special chapter on high-alert medications and dangerous abbreviations; rich with insight and practical advice on reducing the risk of error.)
2. Corrigan, Janet, et al. *To Err is Human: Building a Safer Health System*. Washington, D.C. National Academies Press. 1999. (Comprehensive overview of medical error, containing many practical suggestions and recommendations from several trusted sources.)
3. Leape, Lucian, et al. *Reducing Adverse Drug Events*. Boston, MA: Institute for Healthcare Improvement. 1998. (Concepts to reduce adverse events and a model for improvement.)

### **Patient Information Brochures**

1. *Your Role in Safe Medication Use: A Guide for Patients and Families* is available from the Massachusetts Hospital Association at [www.mhalink.org](http://www.mhalink.org)
2. *Partners in Quality: Taking an Active Role in Your Health Care* is available from the Hospital & Healthsystem Association of Pennsylvania at [www.haponline.org](http://www.haponline.org)
3. *How to Take Your Medications Safely* is available from the ISMP at [www.ismp.org](http://www.ismp.org)
4. *Just Ask!* is available from the U.S. Pharmacopeia at [www.usp.org](http://www.usp.org)

### **Information on Safe Medication Practices**

From the Institute for Safe Medication Practices

- ❑ ISMP Medication Safety Alert!
- ❑ Urgent Error Advisories

From the U.S. Pharmacopeia

- ❑ Dangerous Abbreviations
- ❑ Practitioner Reporting Alerts
- ❑ Drug Quality Alerts
- ❑ Look-alike Sound-alike Name Lists

From the Joint Commission on Accreditation of Healthcare Organizations

- ❑ Sentinel Event Alerts

## Successful Practices for Improving Medication Safety

**Easily Implemented Changes (Process Redesign)** The following steps can be implemented immediately by hospitals and health systems. They focus on standardization and simplification of medication system processes.

### *Fully implement unit dose systems*

- ❑ Maintain and systematically use unit-dose distribution systems (either manufacturer-prepared or repackaged by the pharmacy) for all non-emergency medications throughout the hospital. Unit dose systems should include, in addition to packaging, systems for labeling and order screening.
- ❑ Stress the need for dose adjustment in children, older persons, and patients with renal or hepatic impairment.

### *Limit the variety of devices and equipment*

- ❑ For example, limit the types of general purpose infusion pumps to one or two.

### *Develop special procedures and written protocols for high-alert drugs*

- ❑ Use written guidelines, checklists, dose limits, preprinted orders, double-checks, special packaging, special labeling, and education.
- ❑ Remove concentrated potassium chloride/phosphate from floor stock.
- ❑ Limit the number of possible concentrations for a drug, particularly high-alert drugs like morphine and heparin. Such standardization will allow the use of premixed solutions from manufacturers or centralized preparation of IV medications in the pharmacy.
- ❑ Review JCAHO Sentinel Events Alert #11, Nov. 19, 1999. Also, review Chapter 5 of Michael Cohen's 1999 book, "Medication Errors," published by the American Pharmaceutical Association.

### *Ensure the availability of up-to-date drug information*

- ❑ Make updated information on new drugs, infrequently used drugs, and non-formulary drugs easily accessible to clinicians prior to ordering, dispensing, and administering medications (e.g., have pharmacists do rounds with doctors and nurses; distribute newsletters and drug summary sheets; use computer aids; and provide access to formulary systems and other internal resources).
- ❑ Review error potential for all new products, including a literature review, before any drug or procedure is approved for use; reassess six months to one year later.

### *Educate staff*

- Provide physicians, nurses, pharmacists, and all other clinicians involved in the medication administration process with orientation and periodic education on ordering, dispensing, administering, and monitoring medications.
- Distribute information about known drug errors from outside organizations like the Institute for Safe Medication Practices (ISMP) and the U.S. Pharmacopeia (USP).

### *Educate patients*

- Patients should be educated in the hospital, at discharge, and in ambulatory settings about their medications, what they are taking, why they are taking it, and how to use it safely.
- Encourage patients to ask questions about their medications.
- Encourage health care providers to work with pharmacists on patient education when patients receive certain classes of medications or are discharged on more than five medications.

### *Ensure the availability of pharmacy expertise*

- Have a pharmacist available on-call when pharmacy does not operate 24-hours a day.
- Make the pharmacist more visible in patient care areas — consider having pharmacy personnel make daily rounds on units, or enter orders directly into computer terminals on patient care units.

### *Standardize prescribing and communication practices*

- Avoid certain dangerous abbreviations (see ISMP and USP for examples); identify a list of unacceptable abbreviations that will not be used in your institution.
- Include all elements of the order — dose, strength, units (metric), route, frequency, and rate.
- Use full names (preferably generic).
- Use computerized reminders for look-alike and sound-alike drug names.
- Use metric system only.
- Use preprinted order sheets whenever possible in non-computerized order systems.

### *Standardize multiple processes, such as:*

- Doses
- Times of administration (for example, antibiotics)
- Packaging and labeling
- Storage (for example, placing medications in the same place in each unit)
- Dosing scales (for example, insulin, potassium)
- Protocols for the use and storage of high-alert drugs

### *Longer-Term Changes (Systems Redesign)*

The following steps will require substantial changes to existing organizational systems; they will likely require a longer-term implementation plan and a continual focus on improvement. Many of the recommendations rely on computerization in the physician order-entry and pharmacy dispensing processes.

Develop a voluntary, nonpunitive system to monitor and report adverse drug events

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The following steps will require substantial changes to existing organizational systems; they will likely require a longer-term implementation plan and a continual focus on improvement. Many of the recommendations rely on computerization in the physician order-entry and pharmacy dispensing processes.

*Develop a voluntary, nonpunitive system to monitor and report adverse drug events*

- Review policies for how your organization encourages reporting and analyzing errors throughout the institution.
- Encourage candid communication and feedback.
- Ensure no reprisals for reporting of errors. Reports will increase if you make it safe to report.

*Increase the use of computers in the medication administration system*

- Encourage the use of computer-generated or electronic medication administration records.
- Plan for the implementation of computerized prescriber order entry systems.
- Consider the use of machine-readable code (i.e., bar coding) in the medication administration process.
- Use computerized drug profiling in the pharmacy.
- Be a demanding customer of pharmacy system software; encourage vendors to incorporate and assist in implementing an adequate standardized set of checks into computerized hospital pharmacy systems (e.g., screening for duplicate drug therapies, patient allergies, potential drug interactions, drug/lab interactions, dose ranges, etc.).

*Institute 24-hour pharmacy service if possible ...*

... alternatively, use night formularies and careful drug selection and storage procedures. To facilitate medication distribution after hours, develop policies and procedures to ensure access to consultation with a pharmacist if a pharmacist is not available on-site.

Source: American Hospital Association, December 7, 1999; [hospitalconnect.com](http://hospitalconnect.com)

## 5.

### ***Reducing Errors in Health Care***

Medical errors are responsible for injury in as many as 1 out of every 25 hospital patients; an estimated 44,000-98,000 patients die from medical errors each year. Errors in health care have been estimated to cost more than \$5 million per year in a large teaching hospital, and preventable health care-related injuries cost the economy from \$17 to \$29 billion each year.

AHRQ research has shown that medical errors may result most frequently from systems errors—organization of health care delivery and how resources are provided in the delivery system.

#### **Patients at Risk**

Medical errors may result in:

- ❑ A patient inadvertently given the wrong medicine.
- ❑ A clinician misreading the results of a test.
- ❑ An elderly woman with ambiguous symptoms (shortness of breath, abdominal pain, and dizziness) whose heart attack is not diagnosed by emergency room staff.

Errors like these are responsible for preventable injury in as many as 1 out of every 25 hospital patients<sup>1</sup>.

Errors in health care have been estimated to cost more than \$5 million per year in a large teaching hospital<sup>2</sup>. According to a recent report by the Institute of Medicine (IOM)<sup>3</sup>, preventable health care-related injuries cost the economy from \$17 to \$29 billion annually, of which half are health care costs.

The IOM report<sup>3</sup> estimates that 44,000 to 98,000 people each year die from medical errors. Even the lower estimate is higher than the annual mortality from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516), thus making medical errors the eighth leading cause of death in the United States.

These and other findings of the IOM report are based on research sponsored by a variety of organizations, including the Agency for Healthcare Research and Quality (AHRQ).

For example, a study by AHRQ<sup>4</sup> found that just one type of error—preventable adverse drug events—caused one out of five injuries or deaths per year to patients in the hospitals that were studied.

## How Errors Occur

Errors can occur at any point in the health care delivery system, AHRQ-supported research has revealed.

### *Medication Errors*

These are preventable mistakes in prescribing and delivering medication to patients, such as prescribing two or more drugs whose interaction is known to produce side effects or prescribing a drug to which the patient is known to be allergic.

Research by AHRQ-supported investigators is helping to characterize these errors (called preventable adverse drug events, or ADEs) and suggest how to prevent them.

- ❑ In a study of inpatient care in two tertiary care hospitals<sup>5</sup>, errors in ordering and administering medicines accounted for 56 and 34 percent, respectively, of preventable adverse drug events.
- ❑ Findings from a second study<sup>6</sup> showed that dosage errors, in particular, were primarily due to the physician's lack of knowledge about the drug or about the patient for whom it was prescribed.
- ❑ An attempt to identify risk factors for preventable adverse drug reactions among patients admitted to medical and surgical units at two large hospitals<sup>7</sup> found few such factors, which suggested to the researchers that a focus on improving medication systems would prove more effective.

### Surgical Errors

In contrast to ADEs, surgical adverse events (1 in 50 admissions in Colorado and Utah hospitals during 1992)<sup>8</sup>, accounted for two-thirds of all adverse events and 1 of 8 hospital deaths in a recent retrospective study of these institutions by an AHRQ fellow. **Diagnostic Inaccuracies** Incorrect diagnoses may lead to incorrect and ineffective

treatment or unnecessary testing, which is costly and sometimes invasive. Also, inexperience with a technically difficult diagnostic procedure can affect the accuracy of the results. Here, too, AHRQ-funded researchers have made major contributions.

- ❑ One study<sup>9</sup> showed that physicians who performed 100 or more colposcopies (a test used to follow up abnormal Pap smears) a year had more accurate findings than physicians who performed the procedure less often.
- ❑ Another study<sup>10</sup> demonstrated that measuring blood pressure with the most commonly used type of equipment often gives incorrect readings that may lead to mismanagement of hypertension.

### ***System Failures***

Although errors in medication, surgery, and diagnosis are the easiest to detect, medical errors may result more frequently from the organization of health care delivery and the way that resources are provided to the delivery system. Research by AHRQ-supported scientists is helping to identify the systemic factors contributing to preventable adverse events.

- ❑ Investigators in a major study<sup>6</sup> discovered that failures at the system level were the real culprits in over three-fourths of adverse drug events.
- ❑ Failures in disseminating pharmaceutical information, in checking drug doses and patient identities, and in making patient information available are system errors that accounted for adverse drug events in over half of the hospitals studied.
- ❑ One system-level factor, staffing levels of nurses (adjusted for hospital characteristics), was found in a study<sup>11</sup> to influence the incidence of adverse events following major surgery, such as urinary tract infections, pneumonia, thrombosis, and pulmonary compromise.

This research on systemic problems leads investigators to conclude that any effort to reduce medical errors in an organization requires changes to the system design, including possible reorganization of resources by top-level management.

### **Improving Patient Safety**

Research funded by AHRQ and others has been important in identifying the extent and causes of errors. Now, additional research is needed to develop and test better ways to prevent errors, often by reducing the reliance on human memory. Some areas of past research that have shown promise in helping to reduce errors include computerized ADE monitoring, computer-generated reminders for follow-up testing, and standardized protocols.

#### ***Computerized ADE Monitoring***

Although chart review was found in an AHRQ-funded study<sup>12</sup> to be more accurate than computer tracking and voluntary reporting in identifying adverse drug events, it required five times more personnel time. Researchers concluded that the computerized method was the most efficient means of tracking drug errors.

#### ***Computer-Generated Reminders for Follow-up Testing***

Some diagnostic tests must be repeated to follow up certain conditions, but a small number of such repeat tests are done too early to yield useful results. In contrast, laboratory results showing that a patient needs critical care may not be communicated in a timely manner.

One study funded by AHRQ<sup>13</sup> found that a computerized reminder system to alert physicians to the proper timing of repeat tests reduced the number of patients who were subjected to unnecessary repeat testing.

The same research group subsequently reported<sup>14</sup> that an automatic alerting system for communicating critical laboratory results reduced the time until appropriate treatment when compared with the existing hospital paging system.

### ***Standardized Protocols***

An AHRQ-sponsored study<sup>15</sup> of patients in intensive care units who had severe respiratory disease found a fourfold increase in survival rate with the use of computerized treatment protocols.

Still other investigators are testing computerized decision support systems in various patient populations. All of these research efforts reflect AHRQ's commitment to improving patient safety by providing new tools to augment provider judgment.

AHRQ-funded research continues to create and test methods to help clinicians avoid errors in health care delivery. An investigation funded by AHRQ and the National Institute on Aging will address the incidence and preventability of adverse drug events in elderly patients receiving ambulatory care.

The Agency has recently funded four Centers for Education and Research in Therapeutics (CERTs)<sup>16</sup> as part of a 3-year demonstration program. The CERTs will conduct research to increase understanding of ways to improve the appropriate and effective use of drugs, biologicals, and devices in treatments and to avoid adverse events. These centers will also add to our knowledge of the possible risks of new uses of drugs, and combinations of drugs, as they are prescribed in everyday practice.

In addition, the Agency has recently announced<sup>17</sup> that it will enter into cooperative agreements with nonprofit and for-profit health care organizations to test the effectiveness of the transfer and application of systems-based best practices to reduce medical errors and improve patient safety. This research will help identify high-risk patients or patient groups, providers, health care processes and settings, as well as developing generalizable methods for error reduction.

### **Promoting Safety**

AHRQ (then known as AHCPH, the Agency for Health Care Policy and Research) supported the conference "Enhancing Patient Safety and Reducing Errors in Health Care," which launched the National Patient Safety Foundation.

AHRQ also works with partners, such as the National Committee on Patient Information and Education (NCPIE), to promote patient awareness of medication safety. In 1997, AHCPH and NCPIE cosponsored the publication of a consumer guide, *Prescription Medicines and You*, to help consumers understand how to avoid errors in taking medicines.

Currently, AHRQ serves as the lead agency on medical errors within the Quality Interagency Coordination Task Force (known as the QuIC), which developed the Federal response to the IOM report.

In sum, AHRQ's contributions have resulted in a broader understanding of the nature of patient safety problems and where they occur in the delivery of health care. AHRQ-supported research is in the forefront of a rethinking of health care systems to reduce medical errors.

More information on AHRQ medical errors research is online. You also may contact:

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Source: AHRQ Publication No. 00-PO58

Replaces AHCPR Publication No. 98-PO18 Current as of April 2000

Internet Citation

## Recommendations for Identifying and Learning From Errors in Pediatrics

1. Pediatricians are committed to bringing about the best possible health outcomes for children and their families. Because all medical interventions involve known and unknown risks, pediatricians should work with health care teams to create safe patient care environments and prevent medical errors.
2. Efforts to improve patient safety and prevent errors should focus on a systems approach. Existing research on hospital-based care reveals that medical errors rarely represent the failure of an individual care-giver. Most errors in medical care are systems errors related to equipment, complex processes, fragmented care, and lack of standardized procedures.
3. Systems should be developed to identify and learn from errors. These error learning systems should be open, promote discussion of errors without blame, and provide contextual data about the error. The Institute of Medicine has called for a 50% decrease in the rate of medical errors over the next 5 years, which can be realized only by researching the underlying causes of medical errors, creating effective interventions, and addressing future prevention. These efforts must be completely separate from punitive strategies. Peer review protections should be extended to encourage participation in efforts to decrease the rate of medical errors. Currently, state and federal laws provide legal protection so health professionals can be candid during peer review without fear of legal action. This should also apply to situations in which a medical error occurs.

Error reporting systems are one part of an error learning system. We can identify and learn from errors through reporting programs aimed at ensuring the systems are safe for patients. To do so, reporting systems should:

- Be nonpunitive;
- Require that only the most critical events be subject to mandatory reporting;
- Require that information reported to internal and external patient safety review groups should not be discoverable in civil or criminal legal action;
- Allow individuals involved in the events to remain anonymous whether or not error is involved;
- Recognize that adverse events may or may not be caused by errors;
- Focus on systems failures; and
- Support the key role that organizational leadership plays in systems improvement.

4. Most research on medical errors is hospital based. It may not be appropriate to extrapolate the number or types of errors found in hospitals to the number or types of errors that might be found in ambulatory health care settings. Because most health care is delivered in ambulatory care settings, and in pediatrics, many medications are taken outside of the home (in schools and child care settings), research on errors in ambulatory care settings should be a priority, particularly for unique patient populations, such as infants, children, adolescents, young adults, and children with special needs. The problem of drug dose calculation errors for pediatric patients, in particular, should be explored.

## 6.

### *Root Cause Analysis*

## Background

Historically, medicine has relied heavily on quantitative approaches for quality improvement and error reduction. For instance, the US Food and Drug Administration (FDA) has collected data on major transfusion errors since the mid-1970s.<sup>1,2</sup> Using the statistical power of these nationwide data, the most common types of errors have been periodically reviewed and systems improvements recommended.<sup>3</sup>

These epidemiologic techniques are suited to complications that occur with reasonable frequency, but not for rare (but nonetheless important) errors. Outside of medicine, high-risk industries have developed techniques to address major accidents. Clearly the nuclear power industry cannot wait for several Three Mile Island-type events to occur in order to conduct valid analyses to determine the likely causes.

A retrospective approach to error analysis, called root cause analysis (RCA), is widely applied to investigate major industrial accidents.<sup>4</sup> RCA has its foundations in industrial psychology and human factors engineering. Many experts have championed it for the investigation of sentinel events in medicine.<sup>5-7</sup> In 1997, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) mandated the use of RCA in the investigation of sentinel events in accredited hospitals.<sup>8</sup>

The most commonly cited taxonomy of human error in the medical literature is based on the work of James Reason.<sup>4,9,10</sup> Reason describes 2 major categories of error: active error, which generally occurs at the point of human interface with a complex system, and latent error, which represents failures of system design. RCA is generally employed to uncover latent errors underlying a sentinel event.<sup>6,7</sup>

RCA provides a structured and process-focused framework with which to approach sentinel event analysis. Its cardinal tenet is to avoid the pervasive and counterproductive culture of individual blame.<sup>11,12</sup> Systems and organizational issues can be identified and addressed, and active errors are acknowledged.<sup>6</sup> Systematic application of RCA may uncover common root causes that link a disparate collection of accidents (i.e., a variety of serious adverse events occurring at shift change). Careful analysis may suggest system changes designed to prevent future incidents.<sup>13</sup>

Despite these intriguing qualities, RCA has significant methodologic limitations. RCAs are in essence uncontrolled case studies. As the occurrence of accidents is highly unpredictable, it is impossible to know if the root cause established by the analysis is the cause of the accident.<sup>14</sup> In addition, RCAs may be tainted by hindsight bias.<sup>4,15,16</sup> Other biases stem from how deeply the causes are probed and influenced by the prevailing concerns of the day.<sup>16,17</sup> The fact that technological failures (device malfunction), which previously represented the focus of most accident analyses, have been supplanted by staffing issues, management failures, and information systems problems may be an example of the latter bias.<sup>17</sup> Finally, RCAs are time-consuming and labor intensive.

Despite legitimate concerns about the place of RCA in medical error reduction, the JCAHO mandate ensures that RCA will be widely used to analyze sentinel events.<sup>8</sup> Qualitative methods such as RCA should be used to supplement quantitative methods, to generate new hypotheses, and to examine events not amenable to quantitative methods (for example, those that occur rarely).<sup>18</sup> As such, its credibility as a research tool should be judged by the standards appropriate for qualitative research, not quantitative.<sup>19,20</sup> Yet, the outcomes and costs associated with RCA are largely unreported. This chapter reviews the small body of published literature regarding the use of RCA in the investigation of medical errors.

## Practice Description

To be credible, RCA requires rigorous application of established qualitative techniques. Once a sentinel event has been identified for analysis (e.g., a major chemotherapy dosing error, a case of wrong-site surgery, or major ABO incompatible transfusion reaction), a multidisciplinary team is assembled to direct the investigation. The members of this team should be trained in the techniques and goals of RCA, as the tendency to revert to personal biases is strong.<sup>13,14</sup> Multiple investigators allow triangulation or corroboration of major findings and increase the validity of the final results.<sup>19</sup> Based on the concepts of active and latent error described above, accident analysis is generally broken down into the following steps:<sup>6,7</sup>

1. **Data collection:** establishment of what happened through structured interviews, document review, and/or field observation. These data are used to generate a sequence or timeline of events preceding and following the event.
2. **Data analysis:** an iterative process to examine the sequence of events generated above with the goals of determining the common underlying factors:
  - i. Establishment of how the event happened by identification of active failures in the sequence.
  - ii. Establishment of why the event happened through identification of latent failures in the sequence which are generalizable.

In order to ensure consideration of all potential root causes of error, one popular conceptual framework for contributing factors has been proposed based on work by Reason. Several other frameworks also exist.<sup>21,22</sup> The categories of factors influencing clinical practice include institutional/regulatory, organizational/management, work environment, team factors, staff factors, task factors, and patient characteristics. Each category can be expanded to provide more detail. A credible RCA considers root causes in all categories before rejecting a factor or category of factors as noncontributory. A standardized template in the form of a tree (or “Ishikawa”) may help direct the process of identifying contributing factors, with such factors leading to the event grouped (on tree “roots”) by category. Category labels may vary depending on the setting.<sup>23</sup>

At the conclusion of the RCA, the team summarizes the underlying causes and their relative contributions, and begins to identify administrative and systems problems that might be candidates for redesign.<sup>6</sup>

### ***Prevalence and Severity of the Target Safety Problem***

JCAHO’s 6-year-old sentinel event database of voluntarily reported incidents has captured a mere 1152 events, of which 62% occurred in general hospitals. Two-thirds of the events were self-reported by institutions, with the remainder coming from patient complaints, media stories and other sources.<sup>24</sup> These statistics are clearly affected by under reporting and consist primarily of serious adverse events (76% of events reported resulted in patient deaths), not near misses. The number of sentinel events appropriate for RCA is likely to be orders of magnitude greater.

The selection of events for RCA may be crucial to its successful implementation on a regular basis. Clearly, it cannot be performed for every medical error. JCAHO provides guidance for hospitals about which events are considered “sentinel,”<sup>8</sup> but the decision to conduct RCA is at the discretion of the leadership of the organization.<sup>12</sup>

If the number of events is large and homogeneous, many events can be excluded from analysis. In a transfusion medicine reporting system, all events were screened after initial report and entered in the database, but those not considered sufficiently unique did not undergo RCA.<sup>25</sup>

## ***Opportunities for Impact***

While routine RCA of sentinel events is mandated, the degree to which hospitals carry out credible RCAs is unknown. Given the numerous demands on hospital administrators and clinical staff, it is likely that many hospitals fail to give this process a high profile, assigning the task to a few personnel with minimal training in RCA rather than involving trained leaders from all relevant departments. The degree of under reporting to JCAHO suggests that many hospitals are wary of probationary status and the legal implications of disclosure of sentinel events and the results of RCAs.<sup>12,26</sup>

## ***Study Designs***

As RCA is a qualitative technique, most reports in the literature are case studies or case series of its application in medicine.<sup>6,27-30</sup> There is little published literature that systematically evaluates the impact of formal RCA on error rates. The most rigorous study comes from a tertiary referral hospital in Texas that systematically applied RCA to all serious adverse drug events (ADEs) considered preventable. The time series contained background data during the initial implementation period of 12 months and a 17-month follow-up phase.<sup>13</sup>

## ***Study Outcomes***

Published reports of the application of RCA in medicine generally present incident reporting rates, categories of active errors determined by the RCA, categories of root causes (latent errors) of the events, and suggested systems improvements. While these do not represent clinical outcomes, they are reasonable surrogates for evaluation. For instance, increased incident reporting rates may reflect an institution's shift toward increased acceptance of quality improvement and organizational change.

**Evidence for Effectiveness of the Practice** The Texas study revealed a 45% decrease in the rate of voluntarily reported serious ADEs between the study and follow-up periods (7.2 per 100,000 to 4.0 per 100,000 patient-days,  $p < 0.001$ ).<sup>13</sup> Although there were no fatal ADEs in the follow-up period, the small number of mortalities in the baseline period resulted in extremely wide confidence intervals, so that comparing the mortality rates serves little purpose.<sup>13</sup>

The authors of the Texas study attribute the decline in serious ADEs to the implementation of blame-free RCA, which prompted important leadership focus and policy changes related to safety issues. Other changes consisted of improvements in numerous aspects of the medication ordering and distribution processes (e.g., the application of "forcing" and "constraining" functions that make it impossible to perform certain common errors), as well as more general changes in organizational features, such as staffing levels.

The significance of the decline in ADEs and its relationship to RCA in the Texas study is unclear. As the study followed a highly publicized, fatal ADE at the hospital, other cultural or systems changes may have contributed to the measured effect. The authors were unable to identify a control group, nor did they report data from serious ADEs in the year preceding the study. Their data may reflect under reporting, as there is no active surveillance for ADEs at the study hospital, leaving the authors to rely on voluntary reports. The decline in reported ADEs may actually call into question the robustness of their reporting system as other studies have found that instituting a blame-free system leads to large increases in event reporting.<sup>5</sup> On the other hand, it seems unlikely that serious ADEs would be missed in a culture of heightened sensitivity to error.

In a separate report, an event reporting system for transfusion medicine was implemented at 2 blood centers and 2 transfusion services.<sup>25</sup> Unique events were subjected to RCA, and all events were classified using a model adapted from the petrochemical industry.<sup>21</sup> There were 503 events reported and 1238 root causes identified. Human failure accounted for 46% of causes, 27% were due to technical failures, and 27% were from organizational failures. This distribution was very similar to that seen in the petrochemical industry, perhaps an indication of the universality of causes of error in complex systems, regardless of industry.

### ***Potential for Harm***

The potential for harm with the use of RCA has received only passing mention in the literature, but might result from flawed analyses.<sup>31</sup> The costs of pursuing absolute safety may be the implementation of increasingly complex and expensive safeguards, which in themselves are prone to systems failures.<sup>4,16</sup> Ill-conceived RCAs which result in little effective systems improvement could also dampen enthusiasm for the entire quality improvement process. Arguably the harm caused by pursuit of incorrect root causes must be offset by the costs of not pursuing them at all.

### ***Costs and Implementation***

No estimates of costs of RCA have appeared in the literature, but as it is a labor-intensive process they are likely significant. Counterproductive cultural norms and medicolegal concerns similar to those seen in incident reporting may hinder implementation of RCA.<sup>12,26</sup> The authors of the Texas study note the importance of clear expressions of administrative support for the process of blame-free RCA.<sup>13</sup> Other studies note the receptiveness of respondents to blame-free investigation in the name of quality improvement, with one health system reporting a sustained 10-fold increase in reporting.<sup>25,27</sup>

### ***Comment***

Root cause analyses systematically search out latent or system failures that underlie adverse events or near misses. They are limited by their retrospective and inherently speculative nature. There is insufficient evidence in the medical literature to support RCA as a proven patient safety practice; however, it may represent an important qualitative tool that is complementary to other techniques employed in error reduction. When applied appropriately, RCA may illuminate targets for change, and, in certain healthcare contexts, may generate testable hypotheses. The use of RCA merits more consideration, as it lends a formal structure to efforts to learn from past mistakes.

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## 7.

# ***Fatigue, Sleepiness, and Medical Errors***

## **Introduction**

Fatigue may contribute to the human error component of medical errors.<sup>1-3</sup> Hospitals function around the clock, which necessitates shift work for many personnel. Physicians, especially those in training, typically work long hours and are often sleep deprived.<sup>4</sup> Personnel who work during evenings and at night experience disruptions in circadian rhythms, which may aggravate fatigue. Although little research has focused specifically on fatigue in hospital personnel and its relationship to medical error, studies outside the medical field demonstrate the intuitive link between fatigue and degradation in performance and suggest some safety practices that may be adopted in medicine. Although both acute and chronic fatigue may have detrimental effects on the health of medical practitioners,<sup>5-7</sup> this chapter focuses on fatigue's direct effects on patient safety. We review the literature on problem sleepiness among medical personnel, its impact on performance, and interventions to address sleep deprivation: limiting work hours, changes in shift scheduling, napping, and pharmaceutical aids. Although beyond the scope of this chapter, factors that contribute to fatigue beyond sleepiness, such as job stress and work load, should be considered as part of a multifaceted strategy to combat fatigue. Background Fatigue and sleepiness may affect patient safety in several ways. Physicians and nurses need good attention, sound judgment, and often quick reaction time, especially in emergency situations. Whether evaluating an electrocardiogram for signs of myocardial ischemia or monitoring a patient during general anesthesia, degradation of attention, memory, or coordination may affect performance and lead to adverse events. Research suggests that sleep requirements and patterns are idiosyncratic, with wide variation across populations. In order to design interventions that will effectively decrease or prevent these events, it is important to understand the signs, prevalence, and impact of sleep deprivation and problem sleepiness.

## ***Sleep Deprivation***

Individuals differ in their optimal sleep requirements. Most sleep experts agree that adults typically need between 6 and 10 hours of sleep per 24-hour period, with most people requiring approximately 8 hours of sleep per day.<sup>8,9</sup> When adults get less than 5 hours of sleep over a 24-hour period, peak mental abilities begin to decline.<sup>2</sup> For short periods of time (2-3 days), adult who get 4 hours of sleep can function reasonably well, but below peak levels.<sup>2</sup> However, even with sleep deprivation of just a couple of days, slower response times and decreased initiatives are observed.<sup>10</sup> After one night of missed sleep, cognitive performance may decrease 25% from baseline.<sup>11,12</sup> After the second night of missed sleep, cognitive performance can fall to nearly 40% of baseline.<sup>12</sup>

With ongoing sleep deprivation (getting 2 to 3 hours less sleep than optimal), people develop a sleep debt.<sup>2</sup> If the sleep debt continues over 5 to 10 days, they are rarely maximally alert and at some point general performance, and particularly cognitive performance, become verifiably worse. Sleep debt also leads to slower response times, altered mood and motivation, and reduced morale and initiative. A meta-analysis of the

effect of sleep deprivation on performance by Pilcher et al found that humans who are chronically sleep deprived function at the 9th percentile of non-sleep-deprived subjects. Further, sleep deprivation affected mood more than it did cognitive function; both were more affected than motor function.<sup>9</sup>

### ***Night Shifts and Shift Rotation***

Shift work usually refers to a schedule in which some employees begin work at times other than the morning. In hospitals, up to 35% of nurses may be required to work at times other than the day shift.<sup>13</sup> A report by the Association of Professional Sleep Societies concluded that nighttime operators' fatigue contributed to 4 well known disasters: Exxon Valdez, Bhopal, Chernobyl, and Three Mile Island.<sup>14</sup> Fatigue has also been implicated in aircraft accidents<sup>15</sup> and in poor driving and accidents among truck drivers.<sup>16</sup> It is well documented that shift workers have disturbances in their circadian rhythm, as measured by changes in their melatonin and cortisol levels.<sup>7</sup> Sleep after night work tends to be shorter than sleep after day work, leading to greater cumulative sleep deprivation.<sup>18-20</sup> Shift workers have poorer quality of sleep, marked by less REM sleep, and are less likely to feel refreshed after awaking. Between 60 and 70 percent of shift workers complain of sleeping difficulties or problem sleepiness.<sup>21</sup> Several surveys of shift workers have found that those who work during night shifts are more likely to report sleepiness at work.<sup>18,19,22,23</sup> Alertness on the job is also affected, with employees showing less alertness during nighttime shifts.<sup>24</sup> In addition, shift workers tend to perform less well on reasoning and non-stimulating tasks than non-shift workers.<sup>22,23</sup>

### **Prevalence and Severity**

Fatigue and sleep deprivation are common among medical personnel. Long work hours are a tradition during residency,<sup>25</sup> with most interns and residents working 80 to 100 hours a week, often 36 hours at a time.<sup>26</sup> During these shifts their sleep is limited, and is usually interrupted.<sup>27</sup> In a 1991 national survey, second-year residents reported an average of 37.6 hours as the largest number of hours without sleep during their first postgraduate year and roughly 25% of the residents reported being on call in the hospital over 80 hours per week.<sup>26</sup> A movement in the late 1980s, prompted partly by the death of a young woman,<sup>28</sup> led to regulations in New York State dictating that residents could work a maximum of 80 hours per week, with a maximum of 24 consecutive hours of patient care, and a minimum of 8 hours off duty between shifts.<sup>29</sup> Despite these regulations, unannounced inspections of 12 teaching hospitals in New York State in March 1998 found 37% of all residents worked more than 85 hours per week, 20% of all residents and 60% of surgical residents worked more than 95 hours per week, and 38% of all residents and 67% of all surgical residents worked more than 24 consecutive hours.<sup>30</sup> In 2000, 8% of programs and institutions reviewed by the Accreditation Council for Graduate Medical Education were cited as being in violation of their work-hour requirements.<sup>31</sup> Work-hour violations were noted in general surgery (35%), pediatrics (16%), internal medicine (10%) and other training programs as well.<sup>31</sup>

Long hours and sleep deprivation continue after residency. Healthcare providers, particularly those still in training or who have recently completed training, occasionally work extra shifts to increase their income ("moonlighting"). One recent survey found that nearly half of all emergency medicine residents moonlight.<sup>32</sup> As many as 65% of internal medicine residents and fellows moonlight<sup>33</sup> and moonlighting is common among other residencies and fellowships.<sup>34, 35</sup> These shifts are often at odd hours, and therefore are disruptive to normal sleep patterns. Among surgical staff, fatigue is common, especially since surgical teams can be involved in long, complicated operative cases that can take 12 to 20 hours at a time.<sup>36,37</sup>

Multiple studies have documented the impact of fatigue on medical personnel performance.<sup>38</sup> However, these studies have been limited by poor study designs or outcomes that may not correlate well with medical error. One study of nursing fatigue

suggests that it may play a role in increased error. Gold and colleagues administered a questionnaire to nurses at a large academic hospital and found that nurses who worked a rotating schedule, when compared with nurses who predominantly worked day shifts, were more likely to fall asleep at work and get less sleep over all, and were nearly twice as likely to report committing a medication error.<sup>39</sup>

Using standardized testing, investigators have found that after a night of call, sleep deprived physicians may have worse language and numeric skills,<sup>40</sup> retention of information,<sup>41</sup> short-term memory,<sup>42</sup> and concentration.<sup>43</sup> Performance on standardized tests may not reflect performance in medical situations. Taffinder et al studied the impact of sleep deprivation on surgical residents previously trained on a simulator and found that after a night without sleep, surgeons were slower and more prone to errors on the simulator than those who had a normal night of sleep.<sup>44</sup> Similarly, Denisco et al studied anesthesia residents after a night of sleep deprivation and found that those who had been on call and were sleep deprived scored less well on simulated critical events.<sup>45</sup> Smith-Coggins et al compared cognitive and motor performance of emergency physicians and found that, as the 24-hour study period progressed, physicians were more likely to make errors during a simulated triage test and while intubating a mannequin.<sup>19</sup> However, other studies have failed to find an effect of sleep deprivation on cognitive performance by resident physicians.<sup>46-48</sup> Simulators may not reflect actual medical performance. Though psychomotor performance seems to be affected by sleep deprivation, data are inconsistent as to fatigue's impact on cognitive function and there are inadequate data assessing its impact on clinical performance.

Few studies have looked at the impact of fatigue in hospital personnel on adverse events. A retrospective study by Haynes et al of 6371 surgical cases, found that the risk of postoperative complications among patients undergoing surgery was not increased when the surgical resident was sleep deprived.<sup>49</sup> These results may not be surprising for several reasons. First, the authors did not measure the residents' error rate, which may have been higher with sleep deprivation. Second, the study did not measure the role attending physicians or other operating room personnel may have played in averting adverse events when residents erred. The supervisory aspect of system design can (and should) reduce both the frequency of individual mistakes (error prevention) and the likelihood of adverse events given that errors are inevitable (error absorption).<sup>1</sup> Finally, the rate of adverse events, including those that did not result in operative complications ("near misses"), may have been higher but under reported. Well-designed studies that evaluate the effects of fatigue among medical personnel on rates of medical errors or adverse events would be useful. In the meantime, the lack of convincing data linking fatigue with poor patient outcomes should not deter us from tackling the issue of fatigue among medical personnel.

## Practice Descriptions

**Hours of Service** We reviewed the evidence for two potential safety practices concerning hours of service: 8-hour versus 12-hour length shifts and regulations limiting maximum shift length and/or total hours worked. Most observational studies on optimal shift length to reduce fatigue and maximize performance are in nonmedical settings and present inconsistent findings. In a study of workplace accidents in Germany, Hanecke et al found accident risk increased exponentially after the 9th hour at work and was highest among workers whose shift began in the evening or night.<sup>50</sup> The authors concluded that shifts that last longer than 8 hours might lead to more worker fatigue and higher risk of accidents. Axelsson and colleagues studied workers at a power plant and found no difference in sleepiness or performance between those who worked 8-hour shifts and those who worked 12-hour shifts.<sup>51</sup> Another group found that switching from 8- to 12-hour shifts led to increased alertness on the job and improved recovery time after night shifts.<sup>52</sup> Overland has proposed that work that requires complex cognitive tasks may be ill suited for longer shifts, whereas work with limited cognitive demands may be well suited for longer shifts.<sup>53</sup> Because the

components of work vary dramatically within and across industries, shift durations that maintain performance in one setting may be ineffective in another.

We identified nine observational studies comparing 8- versus 12-hour shifts for medical personnel. Two studies of nursing care on 10 wards found that quantity<sup>54</sup> and quality<sup>55</sup> of care were significantly lower with 12-hour shifts. Six studies of nurses<sup>56-61</sup> and one of physicians<sup>62</sup> measured outcomes including self-reported alertness, self-reported performance, and/or worker satisfaction. While two nurse studies found that self-reported alertness, performance, and satisfaction wane with longer shifts,<sup>56,57</sup> Urgovics and Wright found that ICU nurses reported higher job satisfaction and subjectively improved clinical performance with 12-hour shifts.<sup>60</sup> The three remaining studies in nurses found no difference in either satisfaction or self-reported performance between 8- and 12-hour shifts.<sup>58,59,61</sup> A survey of emergency department physicians found that those who worked 12-hour shifts were less likely to be satisfied than those who worked 8-hour shifts.<sup>62</sup> The relationship between these subjective outcomes measures and medical error is not clear.

Hours of service regulations as an effort to reduce errors due to fatigue are standard in some nonmedical fields. Truck drivers are typically allowed to work no more than 10 hours at a time and no more than 60 hours in one week. Airline pilots and air traffic controllers work regulated hours and some data suggest waning performance as work-hours increase.<sup>24,63-65</sup> Although most healthcare personnel are not subject to work-hour standards, many physicians-in-training are, either by statutory regulations or by being in an accredited training program. In a retrospective cohort study, Laine and colleagues found the aforementioned New York State regulations limiting resident work-hours had no effect on patient outcomes such as mortality or transfers to the intensive care unit but were associated with increased rates of medical complications and delays in diagnostic tests.<sup>66</sup> These negative effects may have been related to discontinuity of care and/or fewer physician-hours per patient. As the authors noted, "better care may be provided by a tired physician who is familiar with the patient than by a rested physician who is less familiar with the patient."<sup>66</sup> In a case-control study, Petersen and colleagues found that when patients were cared for by a physician other than their primary resident, they were 6 times as likely to suffer a preventable adverse event.<sup>67</sup> Thus, fewer physician work hours may lead to more physician discontinuity and potentially, more adverse events and poorer outcomes for patients.

On the other hand, Gottlieb studied changes in a medical service staffing schedule that allowed for reduced sleep deprivation, improved distribution of admissions throughout the week, and improved continuity of inpatient care.<sup>68</sup> After these changes were instituted, patients had shorter lengths of stay, fewer ancillary tests, and fewer medication errors. Although it is difficult to ascribe the improvements to changes in work-hours because several other changes were made as well, it does appear that changes in work-hours can be made without adversely affecting patient outcomes. Any effort to change duty hours for healthcare personnel in an effort to reduce fatigue should factor in and continuously monitor numerous variables, including the potential costs of discontinuity, medical complications and unnecessary hospital days, to ensure that the measures do not compromise patient care. The costs needed to maintain adequate staffing in face of lost physician work-hours has been estimated to be \$360 million in New York State alone.<sup>69</sup> However, the difficult task of estimating other costs and potential savings from implementing these regulations has not been accomplished.

Finally, some authors have expressed concern that restriction of resident physician work-hours may lead to poorer quality training and decreased professionalism among doctors.<sup>70</sup> They argue that restricted working hours will decrease a sense of obligation to patients and will sanction self-interest over the well-being of patients. However, there are no data to substantiate these concerns.

## **Direction and Speed of Rotation of Shift Work**

The direction of shift rotation may impact worker fatigue. For workers who change from one shift to another, a forward rotation of shift work (morning shifts followed by evening shifts followed by night shifts) may lead to less fatigue on the job than backward rotation (day shift to night shift to evening shift).<sup>71-74</sup> Forward rotation appears easier to tolerate physiologically since the natural circadian rhythm tends to move forward and it is more difficult to fall asleep earlier than the normal bedtime. Several studies in nonmedical personnel have shown that forward rotation allows for better acclimation of the circadian rhythm.<sup>2,12,75</sup> However, two other studies found no significant difference in forward versus backward shift rotation.<sup>76,77</sup> None of these studies measured worker performance or error rates and we found no studies that evaluated direction of shift work rotation among medical personnel.

Another variable in scheduling is the speed of shift work rotation. Studies suggest that slow rotation (e.g., changing from one shift to another every one to two weeks) may allow for better adaptation of the circadian rhythm than fast rotation (e.g., changing shifts every 2-3 days).<sup>71,73,78,79</sup> Slow shift rotation results in greater sleep length at home, less sleepiness on the job, better self-reported performance, and fewer errors.<sup>74,79</sup> In some cases, fast rotation may increase worker satisfaction<sup>80</sup> but the effects of such satisfaction on safety have not been assessed. Shift rotation at an extremely slow rate approximates fixed, non-rotating shifts (permanent night shifts, permanent day shifts). Permanent shifts are associated with better adaptation to changes in the circadian rhythm<sup>78</sup> and better performance than rotating shifts.<sup>79</sup> However, daytime commitments and social obligations often prevent workers from completely adapting to permanent night shifts and worker satisfaction is poor.<sup>71</sup>

## Improving Sleep: Education About Sleep Hygiene

Good sleep hygiene, including the avoidance of alcohol and caffeine before bedtime, and maintaining a healthy sleep environment, may aid in decreasing sleep debt and fatigue. Studies of sleep hygiene have focused on treatment of persons with insomnia or other chronic sleep disorders.<sup>81-83</sup> We found no clinical studies that measure the efficacy of good sleep hygiene among shift workers. Generally, most employers cannot dictate how their workers spend their hours off-duty and compliance with recommendations may be poor. One study of law-enforcement officers working rotating shifts found significant increases in awareness and knowledge after a training session on sleep hygiene practices but no change on a post-sleep inventory assessed at one-month follow-up.<sup>84</sup> The effectiveness of educational programs about sleep hygiene to improve shift worker performance requires further study.

### *Lighting at Work*

The body's regulation of circadian rhythm is mediated by the effects of light and darkness. A 1986 survey found that 7.3 million Americans work at night.<sup>71</sup> These employees, who work during dark hours and sleep during daylight hours, are often chronically sleep deprived and may suffer adverse health effects,<sup>85</sup> partially due to poor synchrony of circadian rhythm to work schedule. Since scheduled light exposure can produce a phase shift in the endogenous circadian rhythm,<sup>71, 86</sup> investigators have studied changes in lighting at work and home to improve adjustment to the shift cycle. Foret et al studied 8 young men in a sleep lab and found exposure to bright lights during the night produced a beneficial effect on subjective alertness.<sup>87</sup> Czeisler and colleagues found that subjects who were exposed to bright light at night and nearly complete darkness during the day had better cognitive performance and subjective alertness, and longer daytime sleep (7.7 vs. 5.7 hours,  $p=0.01$ ).<sup>88</sup>

Manipulation of light and dark is much easier in sleep labs than in the field,<sup>89</sup> where unintended exposure to bright light is common and may adversely impact attempts to alter workers' circadian rhythm.<sup>90</sup> The National Aeronautics and Space Administration (NASA) has studied the efficacy of bright lights on shuttle astronauts. Their

encouraging results suggest that alterations in circadian rhythm can be obtained upon exposure to light at night.<sup>89,91</sup> The United States Nuclear Regulatory Commission has also implemented bright lighting for its night workers and found less fatigue and better alertness on the job.<sup>92</sup> Field studies are needed to determine how bright artificial light affects objective measures of performance in healthcare workers and medical error. Bright light may not be appropriate for all areas of the hospital. For example, Bullough and Rea have noted that while bright light might help workers in neonatal care units, it may also be detrimental to patients.<sup>93</sup>

Nonetheless, lighting can be a relatively inexpensive intervention using existing equipment. Keeping lights bright at night, and educating workers about using heavy shades at home may have an important impact on worker performance on night shifts.

## ***Napping***

Napping is common among shift workers and is perceived as a way to combat fatigue.<sup>94,95</sup> One study of shift workers in a steel plant found that over half reported napping at home either before or after their shifts.<sup>94</sup> The efficacy of naps has been studied in three settings: prior to periods of sleep deprivation (prophylactic naps), during periods of sleep deprivation (therapeutic naps) and during work hours (maintenance naps). Most studies have been conducted in sleep labs in healthy, young, male subjects.

A number of studies in the non medical literature have studied the efficacy of prophylactic napping. Gillberg and colleagues studied eight male subjects who were allowed only 4 hours of sleep at night. When subjects took a 30 minute nap in the middle of the prior day, they had better subjective alertness, 20% improvement in vigilance performance, and less overall sleepiness than when they had not been allowed to nap.<sup>96</sup> Others have also found benefits of prophylactic naps on subjective and objective measures of alertness and performance in healthy volunteers undergoing extended periods of sleep deprivation.<sup>97-100</sup> Bonnet and Arand studied prophylactic versus therapeutic naps in 12 healthy young men who underwent 24 hours of sleep deprivation to simulate sleep patterns of medical housestaff.<sup>101</sup> One group of subjects had a 4 hour prophylactic nap in the evening and caffeine during the 24 hours, while the second group had four, 1-hour naps during the 24 hour work period and no caffeine. Those in the prophylactic nap and caffeine group had a 15% increase in reasoning and overall improved subjective alertness compared with the group that had only short naps. There was no impact on mood. We identified one study of napping by medical personnel. Harma and colleagues studied 146 female hospital nurses and nurses' aides and found that those who napped prior to their night shifts were less likely to report on the job fatigue.<sup>95</sup>

Most studies evaluating the efficacy of therapeutic napping during prolonged periods of sleep deprivation have found beneficial effects when compared with no napping.<sup>102-108</sup> On the other hand, Gillberg and colleagues found no difference in simulated driving between the two groups of sleep deprived truck drivers, one group having taken a 30 minute nap during the middle of the previous night.<sup>109</sup>

Maintenance naps are naps that occur on the job, during the shift. These naps could compensate for daytime sleep deprivation or could bridge the nighttime low point in circadian somnolence.<sup>110</sup> Many Japanese industries have provided their employees with the option of on the job napping and nearly half of nighttime shift workers take advantage of this opportunity.<sup>111</sup> Though no systematic studies of the impact of maintenance naps exist in shift workers, one investigation found that short naps in the middle of the night improved performance for the rest of the shift.<sup>98</sup> Napping over several successive shifts has not been studied.<sup>110</sup>

An important consideration in napping is the phenomena of sleep inertia, a period of transitory hypovigilance, confusion, disorientation of behavior and impaired cognitive performance that immediately follows awakening.<sup>112</sup> Sleep inertia is well documented<sup>112-116</sup> and lasts up to 30 minutes after awakening.<sup>116-118</sup> The duration of deep sleep and the time of the nap, relative to the circadian cycle, seem most related to the severity of sleep inertia.<sup>8</sup> Strategies for napping on the job to reduce fatigue should be designed to avoid possible detrimental effects of sleep inertia. Another potential negative effect of lengthy naps is that they can disrupt the quantity and quality of later sleep periods.<sup>119</sup>

In summary, there is strong evidence that therapeutic naps and maintenance naps combat the effects of fatigue and sleep loss. They can help subjects adapt better to circadian rhythm disturbances and perform better during acute sleep deprivation. Their application in the medical field is not well known. While prophylactic and therapeutic napping result in loss of social time at home, maintenance napping results in loss of work time. Costs associated with naps have not been reported. The financial impact of reduced worker fatigue due to napping has not been evaluated in medicine.

### ***Medical Therapies***

Melatonin is the major hormone responsible for circadian rhythm regulation. James et al studied the effect of oral melatonin supplementation on circadian rhythm and adaptation to night shifts among medical personnel.<sup>120</sup> They and others have found no effect among medical shift workers.<sup>121-123</sup> Though melatonin continues to be studied for chronic insomnia and other conditions, there currently is insufficient evidence to recommend its use to combat the fatigue associated with changing workshifts.

Some studies have looked at the potential benefits of benzodiazepines and other sedatives for short-term insomnia associated with shift work, but no data exist on long-term use. Stimulants and caffeine can boost performance acutely but do not address the underlying sleep deprivation,<sup>124</sup> and thus are not a viable long-term solution. Furthermore, concern over side effects, addiction, and performance degradation with current pharmacologic interventions makes their use as a safety practice unlikely.

### ***Comment***

Sleep deprivation and disturbances of circadian rhythm lead to fatigue, decreased alertness, and poor performance on standardized testing. Although data from non-medical fields suggest that sleep deprivation leads to poor job performance, this link has not yet been established in medicine. Although the link with fatigue seems intuitive, promoting interventions designed to combat medical errors should be evidence-based. Limits on physician duty hours must account for potentially detrimental effects of discontinuity in patient care. Forward rather than backward shift rotation, education about good sleep hygiene, and strategic napping before or during shifts may reduce fatigue and improve performance. High face validity, low likelihood of harm, and ease of implementation make these promising strategies, although more evidence of their effectiveness in medicine is warranted. Studies on the use of bright light in the medical workplace are needed before it can be embraced.

As Gaba points out,<sup>125</sup> in most high-hazard industries the assumption is that fatigue and long, aberrant work hours lead to poor performance, and the burden of proof is in the hands of those who believe that such work practices are safe. In medicine, concerns over discontinuity of care, and difficulties in changing medical culture have pushed the burden of proof into the hands of those who wish to change the status quo. Given that medical personnel, like all human beings, probably function suboptimally when fatigued, efforts to reduce fatigue and sleepiness should be undertaken, and the

burden of proof should be in the hands of the advocates of the current system to demonstrate that it is safe.

Finally, fatigue among medical personnel may not be fully remediable and human errors are, in the end, inevitable. The ultimate solution for healthcare organizations will likely require a systems-based approach that both limits the potential for human error and intercepts errors that do occur before they reach patients.

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## 8.

### ***Mental Health Professionals***

Most people believe that medical errors usually involve drugs, such as patient getting the wrong prescription or dosage, or mishandled surgeries, such as amputation of the wrong limb. However, there are many other types of medical errors, including improper diagnosis, failure to comply with mandatory abuse reporting laws, inadequate assessment of potential for violence (e.g., suicide, homicide), failure to detect medical condition presenting as a psychological/psychiatric disorder.

Mental health professionals, such as counselors, psychologists, and marriage and family therapists, and social workers, are most likely to face two kinds of situations where they will be called upon to exercise personal judgment between their duty of confidentiality to their client and moral and legal obligation to prevent or stop harm to innocent third parties.

- Duty to protect third parties from actions by a client believed to be dangerous;
- Statutory duty requiring the reporting of child abuse and neglect.

## The Duty to Protect

In 1976, the California Supreme Court handed down a decision in *Tarasoff v. Board of Regents of the University of California* that signaled a trend toward protection of the public's safety preference to client confidentiality in psychotherapy. The case involved a client who threatened during therapy to kill his girlfriend and did so two months later:

In August 1969, Prosenjit Poddar, a voluntary outpatient at the student health service on the Beverly campus of the University of California, informed the therapist, a psychologist, that he was planning to kill a young woman. He did not name the woman, but as was established later, the psychologist could have easily inferred who she was. The murder was to be carried out upon the woman's return to the university from her summer vacation. Following the session during which this information was given, the therapist telephoned the campus police, requesting that they observe Poddar for possible hospitalization as a person who was "dangerous to himself or others." The therapist followed up his telephone call with a formal letter requesting assistance from the chief of the campus police. The campus police did take Poddar into custody for the purpose of questioning, but later released him when he gave evidence of being "rational." Soon afterward, the therapist's supervisor asked the campus police to return the letter, ordered that the letter and the therapist's case notes be destroyed, and directed that no further action be taken to hospitalize Poddar. No warning was given to the intended victim or her parents. The client, understandably, did not resume therapy. Two months later Poddar killed Tatiana *Tarasoff*. Her parents filed suit against the Board of Regents of the University, several employees of the student health service, and the chief of the campus police plus four of his officers for failing to notify the intended victim of the threat. A lower court dismissed the suit, the parents appealed, and the California Supreme Court upheld the appeal and later reaffirmed its decision that failure to warn the intended victim was irresponsible.

In *Tarasoff* the court held that a therapist who knew, or by the standards of his or her profession should have known, that his or her client posed a threat to another, had a duty to exercise reasonable care to protect the intended victim. Several other courts across the country have since adopted the *Tarasoff* reasoning, subsequently further narrowing and refining it.

The court established three factors that would define a therapist's duty to protect. Generally, one person does not have a duty to control the conduct of another person unless that person has a "special relationship" either to the person whose conduct needs to be controlled or to the foreseeable victim of that conduct. The therapist-client relationship meets this definition of special relationship.

Such a relationship may support affirmative duties for the benefit of third persons. Thus, for example, a hospital must exercise reasonable care to control the behavior of a patient which may endanger other persons. A doctor must also warn a patient if the patient's condition or medication renders certain conduct, such as driving a car, dangerous to others. A doctor is liable to persons infected by his patient if he negligently fails to diagnose a contagious disease or, having diagnosed the illness, fails to warn members of the patient's family.

The second condition required to create a duty to protect is a determination that a client's behavior "needs to be controlled."

The third and final condition that gave rise to the duty to protect was a "foreseeable" victim. Tatiana *Tarasoff*, while not specifically named, was readily identifiable as the proposed victim. Thus, the facts of *Tarasoff* satisfied the three conditions creating a duty to protect for the therapist: a special relationship, a reasonable prediction of conduct that constituted a threat, and a foreseeable victim.

In another case involving a dangerous mental patient the Veterans Administration arranged for the patient to work on a local farm, but did not inform the farmer of the man's background. The farmer consequently permitted the patient to come and go freely during nonworking hours; the patient borrowed a car, drove to his wife's residence and killed her. Notwithstanding the lack of any "special relationship" between the Veterans Administration and the wife, the court found the Veterans Administration liable for the wrongful death of the wife.

Within the broad range of reasonable practice and treatment in which professional opinion and judgment may differ, the therapist is free to exercise his or her own best judgment without liability; proof, aided by hindsight, that he or she judged wrongly is insufficient to establish negligence. Once a therapist does in fact determine, or under applicable professional standards reasonably should have determined, that a patient poses a serious danger of violence to others, he bears a duty to exercise reasonable care to protect the foreseeable victim of that danger.

In *McIntosh v. Milano* (1979) a New Jersey court ruled on a factual situation similar to that found in *Tarasoff* and similarly addressed a therapist's duty to protect:

In this case, the client was an adolescent boy referred by a school counselor to the therapist, a psychiatrist. The boy informed the therapist of several fantasies he had including a fear of others, being a hero or important villain, using a knife to threaten those who might intimidate him, and having sexual experiences with Kimberly, the girl living next door to him. The boy also informed the therapist of having shot at Kimberly's car with a BB gun when she left for a date and showed the therapist a knife he had bought. The therapist was well aware of the boy's possessive feelings for Kimberly. The boy further told the therapist that he wanted Kimberly "to suffer" as he had and showed anger when Kimberly moved out of her parents' home. He was hateful toward Kimberly's boyfriends and upset when he could not obtain her new address. The boy killed Kimberly. Although the therapist had spoken to his client's parents on a number of occasions about their son's relationship to Kimberly, he never addressed the issue with either Kimberly or her parents.

By entering into a doctor-patient relationship a therapist becomes sufficiently involved to assume some responsibility for the safety, not only of the patient himself, but also of any third person whom the doctor knows to be threatened by the patient. Although it is often difficult to predict violence, mental health professionals similar to physicians must conform to the standards of the profession and must often make diagnoses and predictions based upon available facts and assume responsibility for these actions. The therapist is not required to render a perfect performance; the therapist need only exercise "that reasonable degree of skill, knowledge, and care ordinarily possessed and exercised by members of the professional specialty and under similar circumstances."

In *Davis v. Lhim* (1988), the Michigan Supreme Court specified factors that should be considered by a mental health professional in seeking to determine whether a client might act on a threat to a third party. These included the client's clinical diagnosis, manner and context in which the threat was made, opportunity to act on the threat, history of violence, factors provoking the threat and whether threats are likely to continue, relationship with the potential victim, and the client's response to treatment.

## **Child Abuse and Neglect**

The Child Abuse Prevention and Treatment Act of 1974 (PL 93-247) defines abuse and neglect as follows:

Physical or mental injury, sexual abuse or exploitation, negligent treatment, or maltreatment of a child under the age of eighteen or the age specified by the child

protection law of the state in question, by a person who is responsible for the child's welfare, under circumstances which indicate that the child's health or welfare is harmed or threatened thereby.

Mental health professionals may become involved in child abuse and neglect cases in several ways. Their juvenile patients may disclose that they are currently being or have been abused or neglected, or other patients (parents, spouses, relatives, or friends) may report that the child is being abused by someone with whom they are involved. Abusers may report their own acts of maltreatment, although this is the exception rather than the rule. And finally, protective service agencies may refer children for counseling or for psychological testing. As discussed earlier, many states classify emotional abuse as child abuse and therefore require the treating professional to report these cases to the appropriate agency.

The law does not require that the person reporting child abuse be absolutely certain before filing a report of abuse or neglect; all that the law requires is that the person has "reason to believe" or "reasonable cause to believe or suspect" that a child is subject to abuse or neglect. The applicable standard here is what a reasonable professional would believe under similar circumstances.

Further, the law provides immunity from civil suit and criminal prosecution to those who report suspected child abuse or neglect. Such immunity applies to all mandatory or permissible reporters who act "in good faith." On the flip side of the coin, counselors, therapists, psychologists, and other mental health professionals may face criminal liability for a "knowing" or "willful" failure to report suspected abuse or neglect in a majority of states.

Adapted from Huber, C.H. (1999). *Ethical, Legal, and Professional Issues in the Practice of Marriage and Family Therapy*. Upper Saddle River, NJ: Prentice Hall, Inc.