

the Reporter

By Laura Brockway, ELS

A 42-year-old man came to his cardiologist with complaints of chest pain. The cardiologist wrote a prescription for 20 mg of Isordil every six hours. The pharmacist read the prescription as Plendil and dispensed the same dosage, although Plendil's maximum daily dose is 10 mg.

One day after taking what equaled a 16-fold excess dose of Plendil, the patient collapsed and died several days later. In the

Drug name confusion



malpractice suit that followed, the overall quality of care the patient received from the cardiologist was not an issue. The illegibility of the prescription became the sole focus of the case, despite evidence that the medication error had not caused the patient's death. The jury found the physician and the pharmacy equally liable for what they viewed as a fatal medication error. The jury ordered the pharmacy and the physician to pay \$225,000 each.¹

Medication errors

Medication errors present a serious threat to patient safety and a significant liability to physicians. With pharmacies filling 3.1 billion outpatient prescriptions in 2002, even a small error rate has the potential to endanger millions of patients.²

The true incidence of medication errors is difficult to obtain due to "poor reporting, differences in definitions of medication errors, lack of awareness of reporting techniques, lack of time, fear of litigation, inability to determine causality, reluctance to admit error, and cost." However, estimates for all types of medication errors range from 1.5% to 35% of all doses given to hospitalized patients.³ According to the FDA,

medication errors cause at least one death every day and injure approximately 1.3 million people annually.⁴ The costs associated with medication errors are significant and vary from expenses associated with prolonged hospitalizations to malpractice litigation costs. In an analysis of national closed claims data from 1985 to 2003, the Physician Insurers Association of America (a trade association of more than 60 liability insurance companies) found medication error to be the fifth most frequent misadventure generating medical liability claims. 6,854 medication error claims were closed, at a cost of more than \$334 million in indemnity payments.⁵

This article will discuss one type of medication error — errors related to drug name confusion, also known as look-alike and sound-alike (LASA) errors. Examples of this type of error include confusing Paxil* with Plavix (a look-alike error) and confusing Endocet with Indocin (a sound-alike error). (For information on the liability issues related to other medication errors, please see "Medication errors: a leading cause of medical liability claims" published in the September-October 2003 edition of *the Reporter*.)

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* In this article, brand names will be designated by capitalizing the first letter. Generic drug names will be written in all lower case letters.

Drug name confusion

Although there are many contributing factors, confusion between look-alike medication names and sound-alike medication names has been consistently associated with medication errors. Name confusion has been reported to cause from 12% to 25% of all medication errors in the U.S.³

U.S. Pharmacopeia (USP) receives voluntary reports of medical errors through its Medication Errors Reporting and MEDMARX programs. From January 2000 to March 2004, MEDMARX received 31,932 reports of errors related to LASA drug names, packaging, or labeling. Approximately 2.6% of these were categorized as harmful to the patient.⁶ The FDA reviews approximately 250 reports of medication errors each month. They estimate that half are due to error-prone labeling such as look-alike labels, poor package design and confusing names.⁷

“Similarity of drug names involves confusion between look-alike and/or sound-alike brand names, generic names, and brand to generic names. This confusion is compounded by illegible handwriting, lack of knowledge of drug names, newly available products, similar packaging or labeling, and incorrect selection of a similar name from a computerized list.”⁶

Confusion between drug names not only creates the potential for patient harm, but also further burdens the health care system. “Indecipherable or unclear prescriptions result in more than 150 million calls from pharmacists to physicians, asking for clarification, a time-consuming process that could cost the health care system billions of dollars a year in wasted time.”⁸

How drugs are named

There are an estimated 11,000 drug names currently in use in the United States, with dozens of new drugs and formulations added each year.⁹ The process of assigning drug names is complex and involves several different organizations. The following is a brief description.

- The drug’s chemical name is designated by the International Union of Pure and Applied Chemistry. The chemical name identifies the compound’s chemical structure and is rarely used clinically.
- The generic name (also known as the nonproprietary name) is granted by the United States Adopted Name Council (USAN). Names are assigned under specific criteria to ensure uniformity and safety, and may include the use of name stems to indicate the chemical or therapeutic characteristics of the drug. The generic name is aimed at health care providers and is commonly used to identify the drug during its clinical lifetime.
- The USP monograph title for a drug is determined by the USP Nomenclature Committee. In most cases, this title is the same as the generic name, but may include the dosage, formulation and route.
- The brand name (also called the proprietary or trademark name) is created by the company that patents the drug. This name identifies the drug during the 17 years the company has exclusive rights to sell the drug under patent law. Pharmaceutical companies want brand names that “promote brand loyalty, facilitate recognition, and since there is now direct marketing of prescription drugs to the public, imply the drug’s effects to a lay person.”³ Choosing a brand name is a serious and expensive process, with companies spending between \$75,000 and \$250,000 per drug to develop names.¹⁰
- If a brand name is to be trademarked, the U.S. Patent and Trademark Office reviews the name to prevent infringement on the commercial interests of companies holding existing trademarks.
- The FDA’s Office of Post-Marketing Drug Risk Assessment reviews brand names, including how they appear when handwritten, and regulates drug labeling that uses the generic or brand name.
- If a drug is to be sold internationally, the World Health Organization works with a nation’s nomenclature committees to recommend

a single worldwide name, the International Nonproprietary Name.³

“Despite these efforts, new names that are similar to existing names continue to be approved, and name confusion errors continue to occur. Failures in the name review process occur partially because reviewing organizations have different goals.”¹¹

Common LASA errors

The USP maintains a list of problematic drug names based on reports submitted through USP’s error reporting systems. Currently, that list contains more than 1,700 name pairs. Examples include:

- acetohexamide and acetazolamide
- Adderall and Inderal
- Advicor and Advair
- Albuterol and Acebutolol
- Avinza and Evista
- Avandia and Coumadin
- Carbatrol and Carbrital
- Celexa and Cerebyx and Celebrex
- chlorpropamide and chlorpromazine
- cisplatin and carboplatin
- clonidine and clonazepam
- DiaBeta and Zebeta
- ephedrine and epinephrine
- fentanyl citrate and sufentanil citrate
- heparin and Hesperin
- Humulin and Novolin
- Lamisil and Lamictal
- Serzone and Seroquel
- Taxol and Taxotere
- Zyprexa and Zyrtec and Xanax¹²

USP’s complete list is available at <http://www.usp.org/patientSafety/newsletters/practitionerReportingNews/prn1182004-09-10.html>.

Very rarely, drug pairs can have both generic and brand names that can be confused. Two examples include Valtrex (valacyclovir) and Valcyte (valganciclovir); Viracept (nelfinavir) and Viramune (nevirapine). “These are exceptions, and the vast majority of medications do not have proprietary and generic names that can be confused with both the proprietary and generic names of another drug.”³

Confusion is not limited to prescription drugs. Over-the-counter medications, medical devices and blood tests have been misread or misheard. Examples include Benadryl and benazepril (non-prescription versus generic medication); Lamisil and Lamitel (non-prescription medication versus prescription medical device); Arixtra and Anti-Xa (prescription medication versus blood test); and iodine and Iopidine (skin cleanser versus prescription eye drop).³

Another area of concern involves the proliferation of medications with the same active ingredient but different brand names. Patients who see different physicians and use different pharmacies may be taking multiple doses of the same medication. Examples include bupropion for depression (Wellbutrin) and smoking cessation (Zyban); finasteride for benign prostatic hypertrophy (Proscar) and male pattern baldness (Propecia); and fluoxetine for depression, bulimia, and obsessive-compulsive disorder (Prozac) and premenstrual dysphoric disorder (Sarafem).³

Preventing LASA errors

“Strategies for reducing name confusion errors must consider both preventing the approval of new names that may be confused with existing names, and dealing with existing confusable names.”¹³ Efforts in both areas have proved to be complex.

“The effort to design error-resistant drug nomenclature is complicated by the need for new drug names that simultaneously satisfy commercial, professional, and safety concerns. New names must be reasonably safe and free from confusion but must also be mean-

ingful and memorable to physicians, nurses, pharmacists, and patients. Although names need to be distinct, drugs that share an indication, mechanism of action, or chemical constituent are often intentionally given the same prefix or suffix.”¹⁴

A team from the University of Illinois in Chicago has been developing software that can screen medication names based on spelling and sound similarities. However, with an estimated 11,000 existing medications, evaluating a single new name requires 11,000 comparisons. Screening all existing names would require more than 60 million comparisons.^{9, 14}

In 1999, the USAN contracted with the University of Illinois to screen proposed generic drug names for potential confusion. However, existing generic names will not be screened retroactively. The FDA has implemented a system to review proposed proprietary names and currently rejects one-third of all proposed names due to potential LASA problems.¹⁵

Name confusion can cause enough errors that a pharmaceutical company will change a brand or generic name. In 1999, Celebra was changed to Celebrex to avoid confusion with Celexa, but Celebrex was consequently confused with Cerebyx. Amrinone had been confused with amiodarone; amrinone had its name changed to inamrinone.³ In 2005, confusion between Reminyl and Amaryl caused Reminyl to be renamed Razadyne.¹⁶

Other strategies for dealing with existing confusable names include increasing awareness of confusing drug pairs and emphasizing the differences between confusing drug pairs.

In 2001, the FDA ordered drug makers to list the names of more than 30 medications in “tall man” lettering to emphasize the differences between similar names.¹⁷ For example, dobutamine and dopamine would appear as DOBUTamine and DOPamine on product labels. Studies indicate that “tall man” lettering can make similar names easier to distinguish.¹³

Calling confusing drug names a “common system error,” the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is addressing this issue through the 2005 National Patient Safety Goals. A new requirement for 2005 states that health care organizations must identify and annually review a list of LASA drugs used in the organization and take action to prevent errors involving these drugs. JCAHO has provided a list of problematic drugs and will require that a minimum of 10 drug combinations be reviewed and addressed by the organization.¹⁸ The JCAHO list is available at www.jcaho.org/accredited+organizations/patient+safety/npsg.htm.

Risk management considerations

The following guidelines may help reduce the likelihood of look-alike, sound-alike medication errors.

- Because distraction can lead to errors, take a “prescribing moment” within each patient encounter and dedicate your attention to writing the prescription. “Temporarily delay the patient’s additional comments via verbal or nonverbal clues. For example, say ‘Let me complete your prescription, and then I’ll answer your question.’”¹⁹

- Become familiar with the list of LASA drug names, especially those medications most commonly associated with your specialty.

- Prescription drug orders should be legible. Prescribers with poor handwriting should type or print prescriptions.

- Consider electronic prescribing. Computerized medication management systems can alert physicians to potential LASA errors as the prescription is being entered. While these systems are not a panacea, they may solve one part of the overall problem. In 2000, the Institute of Safe Medication Practice (ISMP) called for the elimination of handwritten prescriptions in three years. “Prescription writing remains one of the last and perhaps most important paper transactions in our increasingly computerized society.”⁸

- When prescribing drugs orally, speak slowly, clearly and artic-

ulately to avoid confusion. Develop a specific policy for phone-in prescriptions and oral orders. For example, insist that staff spell the drug name and have the pharmacist spell the name back.

- Educate patients about the medication you are prescribing. Provide patients with written information about their medications, including the brand and generic names. Document that this information was given to the patient.

- All patient safety organizations studying medication errors (USP, JCAHO, the FDA, the ISMP) recommend that physicians use the brand name and generic name when writing prescriptions for problematic drugs. “This allows for internal error checking since it is unlikely that both the generic as well as the brand name would have a look-alike or sound-alike, as well as allowing for the opportunity to detect duplicate or redundant prescriptions.”³

- Specify the indication. “By noting the purpose, you confirm to the pharmacist the appropriate medication and remind the patient of the drug’s purpose.”¹⁹ Again, this step is highly recommended by patient safety organizations.

- When storing medication samples, do not store known problem medications next to each other. Affix “name alert” stickers to areas where known LASA products are stored.

- Help others avoid mistakes. Report any drug name issues or other medication errors to USP’s medication error reporting programs. For information, visit www.usp.org/patientSafety, email uspcaps@usp.org or call 800-23-ERROR. Reports can also be made to the FDA through MedWatch by calling 800-FDA-1088 or online at www.accessdata.fda.gov/scripts/medwatch/.

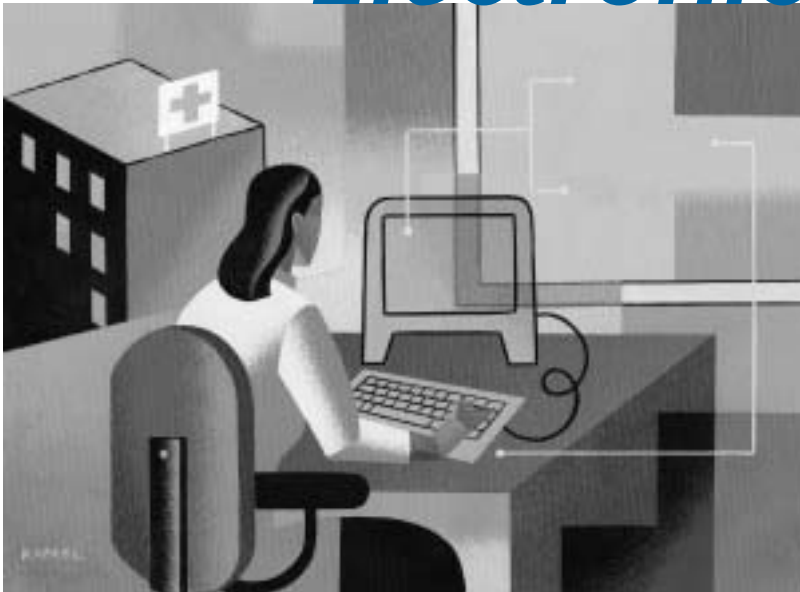
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A journey of innovation

Electronic health records



Objectives

At the conclusion of this activity, the physician will be able to:

1. Identify risk management techniques related to the use of electronic health records.
2. Discuss the problems other physicians have encountered during implementation of an electronic health record.
3. Describe areas of public concern regarding security of an electronic health record.
4. List elements of the HIPAA security rule designed to protect electronic health information.

Course author

Eldon Volk is a risk management representative at TMLT.

Disclosure

Eldon Volk has no commercial affiliations/interests to disclose related to this activity.

Target audience

This one-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for malpractice liability.

CME credit statement

TMLT is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

TMLT designates this educational activity for a maximum of 1 category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Ethics statement

This course has been designated by TMLT for 1 hour of education in medical ethics and/or professional responsibility.

Directions

Please read the entire article and answer the CME test questions. In order to receive credit, submit the completed test and evaluation form to TMLT. All test questions must be completed. Please print your name and address clearly. Allow four to six weeks from receipt of test and evaluation form for delivery of certificate.

Estimated time to complete activity

It should take approximately one hour to read this article and complete the questions.

Release/review date

This activity is released on July 29, 2005, and expires on August 1, 2007. Please note this CME activity does not meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.

Introduction

As personal computers became available in the 1980s — at a high cost and with limited use — many failed to realize the growth of this technology would occur so rapidly. Now, a mere 25 years later, it is hard to imagine not having the capabilities of a computer to assist in our jobs and daily lives. Yet, there is still one industry that lags

significantly behind the others in the adaptation of this technology . . . health care. In a recent survey of the American Academy of Family Physicians' 105,000 members, only 15% were using electronic health records (EHRs).¹ While the health care industry has embraced information technology in their billing, scheduling, and other business practices, the acceptance of EHRs is only just beginning.

In the 2004 State of the Union address, President George Bush stated "By computerizing health records, we can avoid dangerous medical mistakes, reduce cost, and improve care."² In April 2004, President Bush stated his goal to have EHRs for most Americans within 10 years.³ As physicians begin using EHRs in their practices and begin to accept a different way of documenting patient visits, the true benefits of EHRs will be realized, along with the possibility of new problems and risks.

This article will describe the use and benefits of EHRs in physician practices, government involvement and regulations, barriers to implementation, risk management considerations and look at what has been learned from early adopters of this technology.

Moving forward

As physicians contemplate the possibility of converting their record-keeping system to an EHR system, the words of Niccolo Machiavelli, Italian philosopher and statesman, resonate: "It must be considered that there is nothing more difficult to carry out, nor more dangerous to conduct, nor more doubtful in its success, than an attempt to introduce innovations. For the leader in the introduction of changes will have for his enemies all those who are well off under the existing order of things, and only lukewarm supporters in those who might be better off under the new."⁴

Physicians who have practiced with a paper-based system for either one year or 10 years must completely change their paradigm of working with their records. It is in this transition from paper to electronic records that a physician's adherence to paper-based processes can interfere with successful integration of the electronic records. In turn, this leads to the possibility of additional risk, detrimental effects on patient's health, or the possibility of a medical malpractice claim against the physician.

One physician choosing innovation

After 20 years of using paper charts, the challenge for a physician converting to an EHR is great. John McKenzie, MD, a family physician in Gilmer, Texas, decided to con-

front that challenge a little more than a year ago.⁵

After researching EHRs, Dr. McKenzie decided to purchase a software package. He felt the system was suited to a small size practice, and felt the program was well suited to his advanced computer skills. The cost of his EHR was on the lower end of the spectrum, with Dr. McKenzie spending about \$17,000 on software and hardware, which he anticipates, will be recouped in three years. He chose to do much of the start-up labor himself, spending approximately 150 hours working on the system. If he chose, about 100 hours of this labor could have been conducted by a vendor, which costs \$75 per hour in his rural community.

For Dr. McKenzie, the impetus to switch to an EHR was the hope for improved documentation via the use of templates for data entry. One area that became more efficient was his use of informed consent. By entering a short code, the system can bring up a paragraph discussing the risks and benefits of a particular treatment. This allows the physician to discuss the desired elements and enter the discussion into the patient's record.

The tracking and receipt of lab and consult reports has also improved dramatically. When Dr. McKenzie sends a patient for a consult or for lab work, the office note remains in his electronic inbox until a result is received. He no longer depends on staff to maintain a written log and notify him if the patient did not keep the consultant appointment or the consult results have not been received.

Not only has the tracking of lab results improved, but the receipt of lab results has been simplified. Now instead of waiting for a paper report to arrive at his office, the results come electronically and are imported into his inbox, coupled with the original office note waiting for his electronic signature. Once he has signed off on the results, they are removed from the inbox and he knows no further action is pending. Since he can review his inbox at anytime, he is always aware of any needed test results and can follow up to ensure the patient is compliant and the results received. This tracking system has the ability to greatly reduce the likelihood of a lost result or patient non-compliance, two underlying causes of lawsuits alleging "failure to diagnose."

Even when patients are compliant, following the patient's history and creating an accurate problem list can be a challenge, but again made easier with Dr. McKenzie's EHR. Patients often can only give a limited history when asked to recall information. In one case, Dr. McKenzie had a patient who provided a history of a myocardial

infarction in October 2004 with stent placement. Based on the patient's limited recall, he entered this information into the problem list. Next, records were requested from the patient's previous treating physicians. When received, those records were scanned into the system for review and Dr. McKenzie could easily change the problem list to: "Anterior MI 10/17/04, drug coated stent placed in LAD by Dr. Jones at All Saints Hospital."

Since implementation, Dr. McKenzie no longer needs transcription services offsetting some of the initial cost and eliminating worry about transcription errors. Notes can be spell-checked by the system before signing, helping to ensure an accurate record. "It does not look good to show a record to a jury with poor handwriting and spelling errors," says Dr. McKenzie. Another area of improvement is prescription documentation. With all prescriptions being printed, pharmacists can easily read the script decreasing the possibility of errors caused by poor handwriting.

Although Dr. McKenzie has realized many benefits with his EHR, he warns of the potential pitfalls. "I am a real computer geek, but even being a geek there were problems I encountered."

Initial problems included the time and effort involved to implement the system, train the staff, and become accustomed to documenting in the electronic format. Productivity decreased by 20% for six months in Dr. McKenzie's office during the transition. "The process was much harder than anticipated." Yet, when asked if he would ever go back to paper records, he responded with, "No way!"

When Dr. McKenzie began searching for the right system, he said "I did not know the questions to ask, now I know the questions to ask," and offers this advice to other physicians considering implementation of an EHR:

1. Look at several systems and talk to several doctors using EHRs to narrow the choices. When you identify 2 or 3 systems of interest, spend time familiarizing yourself with each before purchasing.
2. Realize that the implementation may take longer and be much more difficult than anticipated.
3. Have access to quality and trusted IT support, but make sure the physician or a small group of physicians has overall control of the network and administrative passwords. If an IT support person has complete control of the network it could have detrimental effects if the person leaves or is terminated.

Current users

Medical Economics magazine recently surveyed 10,000 physicians, asking who was using EHRs, how they were being used, and the satisfaction rate. Of those who responded (1,916 physicians), 15% were using EHRs.

The survey found that the typical EHR user is young, a generalist, and practices in a large group. Of the physicians using EHRs, 50% have implemented their use within the past two years. And, one in four physicians indicate they plan to acquire a system within one year.

The responding physicians indicated their EHR allowed them to do the following:

- 73% — transfer information between the EHR and practice management systems;
- 70% — prescribe electronically;
- 70% — generate charges electronically;
- 60% — search for patients with specific diagnosis;
- 60% — exchange electronic messages with staff; and
- 51% — import lab and hospital data by email or fax.

Regarding satisfaction, 26% of physicians were very satisfied, 39% were satisfied, and 13% experienced some degree of dissatisfaction.⁶

Initial cost versus possible savings

Many physicians are interested in implementing an EHR, but feel the costs to be prohibitive. “You need to recognize the money and time that you’re wasting now, and some doctors are curiously unaware,” says Mark Leavitt, MD PhD, medical director of the Health Information Management and Systems Society. “Doctors are not trained to look for the extra overhead and extra steps.”⁷

According to an article in *Medical Economics*, one practice consisting of 8 physicians and 2 physician assistants has eliminated extra steps and reduced overhead from 59 to 52 percent of revenues since implementing a document management program in 1999. This group has improved efficiency in these ways:

- “A lab tech sorts 300 lab reports into electronic charts in an hour; the same task would have taken more than a day in the old paper system.
- Staffers save up to 20 minutes a call — including the time required to pull a chart and return the call — when they can answer patient questions from online records.
- Staffers can computer-fax electronic referral forms to specialists and imaging centers, saving at least 10 minutes for each referral that they’d otherwise spend on the phone. That adds up to about 16 hours of staff time a day.

• About half of the 600-800 calls the practice receives each day concern prescription refills. A typical call back to the pharmacy takes six minutes, but it takes less than a minute to send a fax generated by an e-prescribing program.”⁸

The increased efficiency in using an EHR can quickly justify the cost. After investing \$100,000 in a system, a San Antonio practice of two ob-gyns lost two staff members due to attrition. With the improvements the EHR created in their practice, they realized they did not have to hire new employees, saving the practice \$50,000 per year. The yearly staffing savings alone has made the investment worthwhile. The other option with the new-found efficiency is the possibility of seeing additional patients or adding new services, which may have a great effect on revenue and overall profit.⁹

Other barriers to implementation

As the benefits begin to outweigh the costs, and the government begins to push its goal for electronic health records, what obstacles will physicians need to overcome?

As patients continue to sign HIPAA acknowledgements, stating that they are aware of their physician’s privacy practices, their knowledge of privacy and their desire for secure health information is of increasing importance.

In a Harris Interactive poll of 1,012 people, the public’s specific concerns about EHRs were shown. In this survey, 71% were unaware of the government’s goal to establish EHRs. Even though they were unaware of this goal, respondents answered in the following percentages that they were “very concerned” about the following:

- 38% — possible information leaks;
- 42% — information would be released without their knowledge;
- 29% — electronic records may increase chance of medical errors; and
- 29% — patients may be less willing to share information with their physician if it was going to be stored electronically.

Overall, 48% felt the benefits of EHRs would outweigh the risk and 47% held the opposite opinion.¹⁰

HIPAA security rule

Government regulations will also affect how physicians implement EHRs.

Physician practices worked diligently to attain compliance before the implementation of the HIPAA privacy rule in April 2003. On April 20, 2005, the HIPAA security rule also went into effect protecting the security of electronic health information. The security rule establishes laws for protecting all electronic health information and insti-

tutes the rules physicians must follow to secure their electronic health record system.

The “Security Standards for the Protection of Electronic Protected Health Information,” found at 45 *Code of Federal Regulations* Part 160 and Part 164, establish many required elements and others designated as “addressable” which a physician must consider and often follow. A partial list includes:

1. assign unique identifiers to users;
2. password protect all devices, desktops, laptops, PDAs etc;
3. install virus protection software on the server and individual workstations;
4. create an emergency plan, including back-up procedures and storage of back-up data at an offsite location;
5. protect records from inappropriate viewing by having screensavers activate after a short period of inactivity and requiring re-entry of password for access.
6. audit access to protected health information;
7. ensure protected health information is not altered or destroyed;
8. implement security measures to protect health information that is transmitted via electronic means;
9. identify an individual responsible for security;
10. ensure only appropriate staff have access to the records, and create a process to handle staff breaches of security.¹¹⁻¹³

Establishing proper security protocols is necessary when implementing an EHR, but physician practices are still working to establish HIPAA compliance. More than two years after the HIPAA privacy deadline, 20% of physicians and hospitals are not fully meeting the HIPAA privacy rule. At present, approximately 35% of physician practices and 20% of payers are not compliant with the HIPAA security rule.¹⁴

Risk management tip

The HIPAA security rule requires that patient data be backed up to ensure it can be retrieved if a hardware failure or other event causes the loss of data. More than one TMLT policyholder has reported such an event. One physician experienced a hardware failure, resulting in the loss of 600 patient records. The physician was diligently backing up the data on a regular basis and storing a copy off-site. However, once the hardware was replaced and the back-up data was set for restoration, the back-up data was unavailable. The back-up process that the physician had been following since the set up of his EHR was not adequately backing up the patient data.

The physician believed that he was com-

pletely backing up the data, and that his records would be retrievable when needed. Creating a back-up data set should only be the first step in a physician's electronic risk management efforts. The back-up record must be tested regularly to ensure that all appropriate data is being copied, and that data restoration is possible. Testing should occur for all back-up types, including in-house creation on a removable hard drive or for processes that send the information encrypted over the Internet to an offsite storage location. Even if an EHR vendor is providing offsite back-up, physicians are advised to confirm that the data is created appropriately.

In this situation, the physician's electronic records were no more secure than a physician's paper charts. A physician using paper charts could experience a fire or other disaster that could destroy all patient records. The fact that electronic records can be duplicated and stored in an offsite location makes them more secure than paper records.

Risk management tip

Before filing a malpractice suit against a physician, most attorneys request the medical records to determine the merits of the case. Many physicians using an EHR do not regularly print a patient record, and may be unaware that clicking the print button on an EHR does not always provide a complete record. If a requesting attorney receives a partial record as the result of the EHR printing protocols, this could cause the attorney to accept and file a case based on incomplete information.

After printing what one assumes to be a complete record, ask these questions:

- Does the record show the electronic signature and date the physician signed the progress note?
- Does the record indicate when entries were made by staff, showing their initials or unique identifier?
- Does the record show all lab and consult reports with the physician signature and date indicating timely review?
- Does the record show all prescription refills indicated for the patient?
- Are patient consent forms included in the printed record?
- Are patient telephone calls included in the printed record?

In some EHRs, all this information is available when viewed on the computer screen but does not show up on the printed record when the general print button is clicked. It may be necessary to go to individual phone notes, prescription refills, etc.

and print them individually to ensure they are included in the complete record that was requested. Confirming that a complete record is sent when complying with a subpoena is a prudent risk management practice.

TMLT closed claim study

Clinical presentation

A 50-year-old man was referred to a nephrologist for renal insufficiency. The patient had a history of ankylosing spondylitis and scleroderma. He had an elevated serum creatinine, low creatinine clearance, anemia and proteinuria. The patient had previously been prescribed 5 mg of Prednisone daily for treatment of his renal disease.

Physician action

The nephrologist, the defendant in this case, felt there was no evidence of acute sclerodermal crisis to account for the patient's renal failure. He placed the patient on an ACE inhibitor. After 10 weeks on the ACE inhibitor, the patient's creatinine failed to improve and proteinuria was still significant. The nephrologist believed the patient had an undefined connective tissue disorder characterized by probable membranous glomerulonephritis renal lesion. He followed the patient for several weeks. In the interim, the patient was seen by his rheumatologist, who increased the Prednisone to 10 mg daily.

When the nephrologist next saw the patient, he documented that he discussed the possibility that renal replacement therapy would be needed. According to the physician, the patient indicated he did not want to go on dialysis because he was afraid it would impair his ability to work. The patient's kidney function continued to deteriorate. During the next visit, the nephrologist decided to place the patient on 120 mg of Prednisone every other day to see if renal function would improve. The physician sent an email to his nurse stating, "Kidney function is slightly worse. As a last ditch effort to keep him off dialysis we need to have him take Prednisone 120 mg every other day."

The next day, the nurse called the prescription in to the pharmacy for Prednisone 120 mg every day, and completed the medication summary in the chart to reflect 120 mg daily. Using the practice's EHR, the nurse emailed a copy of the prescription back to the nephrologist, which reflected 120 mg daily. When the nephrologist, who had been out of town, returned 10 days later he simply signed off on several emails (including the prescription) without opening them. He clicked a signature box and deleted the

prescription from his email list.

The pharmacy's computer flagged the prescription because the dosage was too high. The pharmacist called and spoke to the nurse, who confirmed the dosage. The patient's wife also questioned the dosage, and was told by the nurse that the dosage was correct. (The nurse later testified that she confirmed the dosage in the computer system by looking at her documentation rather than the actual physician's order.)

Nine days after beginning the daily Prednisone, the patient presented to the clinic for a Procrit injection. He complained to the nurse of tremors, esophageal burning, hiccups, stomach pain and swallowing problems. The following day, the nurse emailed the nephrologist, who had just returned to the office, and told him of the patient's complaints. The physician never saw this email and may have clicked it off his email list as he had done the prescription.

Eight days later, the patient called and spoke to the nephrologist, who was unaware of the prescription error. The patient indicated he was not feeling well, and the nephrologist advised him to drop his Prednisone dose back to 10 mg per day. An appointment was scheduled for the next day. When the patient arrived the following day, he had extremely low blood pressure, elevated heart rate and was going into shock.

The patient was admitted to a nearby hospital where he was diagnosed with severe dehydration, gastrointestinal bleeding and symptoms of sepsis. Despite aggressive treatment from a number of specialists, the patient died two days later.

An autopsy performed on the patient did not identify a cause of death. However, chronic gastritis was identified with angioinvasive GMS positive micro-organisms most consistent with aspergillosis. Multiple ulcers were found in the colon with full penetration through the muscular wall with reactive peritonitis. The center of the ulcer showed prominent necrosis. The patient was also found to have interstitial lung fibrosis bilaterally.

Allegations

Allegations against the nephrologist included:

- prescribing a high dose of Prednisone;
- failure to properly order Prednisone in the correct dosage;
- failure to properly supervise staff in placing an order for Prednisone;
- failure to monitor the patient's progress; and
- failure to give appropriate medical orders to stabilize and maintain the patient's deteriorating condition.

The nurse and the practice association were also named in the lawsuit.

Legal implications

In reviewing this case, defense consultants were critical of the prescription error by the nurse and her failure to detect the error when questioned by the pharmacist and the patient's wife. There was further criticism of the nurse for not reporting the patient's symptoms of esophageal burning to a physician.

Regarding the physician's action in this case, defense experts expressed their greatest concern regarding the sign-off of the email prescription. The physician indicated that he did not read the email because the manner in which he pulled it up on the computer screen did not show the text of the email. Some experts believed the physician had a right to expect the prescription would be called in as ordered and it was not necessary to read the email sent to him regarding the prescription. However, the physician did sign off on the prescription with an official electronic signature in the record. There was speculation that a jury might hold the physician at least partially responsible for the prescription error since he signed off on it.

The plaintiff's attorney was able to retain credible experts who were critical of the physician's decision to initiate steroid therapy and who related the patient's death to the prescription error. However, the defendant's decision to place the patient on alternate-day high dose steroids was very well reasoned. One of the plaintiff's own experts agreed with this decision, as did defense experts. Defense experts also agreed with the plaintiff's assertions that daily high dose steroids likely contributed to the patient's death. Though most believed that the patient's underlying systemic sclerosis was the primary cause of his death, placing him on steroids likely caused him to become sufficiently immuno-compromised that he could not fight the infection when the perforations in his colon occurred. This led to overwhelming sepsis and organ failure.

Disposition

This case settled before trial with the physician's consent.

Risk management considerations

Twenty-eight percent of medical malpractice claims involve actions or omissions by office staff. Physicians may delegate appropriate duties to staff, but in doing so, assume responsibility for their actions with vicarious liability should a patient be harmed.

Both the nurse and physician in this claim failed to meet the standard of care in their roles as participants in this patient's health care. The information reviewed for this study did not include why the nurse did not respond to the pharmacist's appropriate query regarding the Prednisone prescription. Was the nurse too busy? With an electronic medical record, confirming the physician's order would not take long. Faced with days of email, was the physician also too busy to open and read all orders requiring his signature? Electronically signing an order is an affirmation that the order is correct.

With either paper or electronic records, standards of care and documentation requirements remain the same. There were two opportunities for the nurse to confirm the prescription with queries from the pharmacist and the patient's spouse. A third opportunity to intervene and stop the daily dose was in the physician's hands when reviewing email and signing off on orders. It is difficult for a physician to defend his/her actions if established standards are not followed. Signing off on unread orders does not meet the standard of care.

Patients not only appreciate quality care provided by physicians but also that of their staff. Realizing the important role staff plays in the delivery of care, the majority of medical malpractice claims can be avoided through the diligent efforts of the entire health care team.

Conclusion

The desire for good health is held highly by most people, as is the desire for financial prosperity. Being regarded as so important, it is easy to assume that these two desires would transcend into people's daily practices in a similar fashion. Yet they are on opposite ends of the spectrum.

If the world's daily financial activities operated under the systems used in health care today, people's lives would be much different. After going to the grocery store, payment would be made to the clerk by handwriting a note that would then be mailed to the bank asking for funds to be taken from the customer's account and mailed to the grocery store. Credit cards and debit cards would not exist, as their electronic nature would not be supported. Going online to instantly and securely transfer funds electronically from one bank account to another would also not be possible.

The entire financial system would be extremely burdened if it were forced to operate under the practices that health care currently follows — using mostly handwritten, paper-based communication. One

would not want to take away the electronic nature of our financial system, and most, although cautious, feel our financial system is secure. Yet the health care system still struggles, using a paper-based system and worrying that EHRs will not be secure. If the public can accept their money being transferred electronically, they will soon embrace the need for electronic health records.

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legislative update

An overview of the 2005 legislative session

by Mignon McGarry

The 79th Texas Legislative Session adjourned Sine Die on May 30, 2005. Although the legislature concluded its regular session, Governor Rick Perry called legislators back to Austin for a special session to address school finance reform. The special session began June 21, and can last for a maximum of 30 days.

This article will address the major health care issues that were closely monitored during the regular session.

Mandatory rate rollback legislation fizzles

Early in the session, several legislators considered legislation that would force rate rollbacks on companies that provide medical liability insurance. Discouraged by the lack of support by leadership, physicians, and the TMA, they abandoned pursuit of these bills during the session. TMLT's early leadership on premium reductions helped create an environment that discouraged these ideas.

Medical liability insurance rates and the Rose amendments

In the last days of the session, Representative Patrick Rose successfully amended two initiatives to a bill originally introduced by Representative John Smithee, House Bill (HB) 2678. In its original version, HB 2678 prohibited an insurance provider from considering certain information about Medicaid or CHIP services provided by the health care provider when determining the rates of professional liability insurance.

The Rose amendments were actually two bills that he introduced during the legislative session but subsequently added to HB 2678.

- HB 686 prohibits an insurer from using a lawsuit filed against a physician or health care provider to set premiums if the lawsuit was dismissed by the claimant or non-suit-ed; and

- HB 1532 clarifies the process by which rates are set for professional liability insurance for physicians and health care providers by the Texas Department of Insurance and increases its ability to monitor those rates.

HB 2678 passed and was signed by Gov-

ernor Perry on June 18th. The bill goes into effect on September 1, 2005.

Board of Medical Examiners Sunset bill signed

On June 6th, Governor Perry signed the Texas State Board of Medical Examiners sunset bill, Senate Bill (SB) 419. The TSBME was not "sunsetting," but among the major provisions of the bill, the TSBME was given a name change. It will now be referred to as the Texas Medical Board.

Representative Will Hartnett successfully attached to SB 419 a prohibition of third trimester abortions except in limited instances of imminent, severe, irreversible brain damage and/or death to the mother or the fetus. Rep. Hartnett was also successful in amending the bill to specify that, before receiving an abortion, a minor must obtain consent from a parent or legal conservator.

Tort reform measures

Senator Tommy Williams introduced SB 890 which relates to the amount of recovery in a civil action and effectively would take away the election of settlement credits with an exception to force a dollar for dollar credit.

This exception states that defendants in health care liability claims can still retain their election. The bill passed and was signed by Governor Perry on June 9th, taking immediate effect.

Other issues of interest

- Legislators addressed the nursing shortage by appropriating \$6 million to help recruit and retain nursing faculty at colleges and universities. In addition, \$1.9 million in financial aid was approved for nursing students.

- Changes to the scope of practice allowing various allied health care professionals to increase their responsibilities did not make headway this session.

- A prescription drug provision allowing Texans to order their prescription drugs from up to 10 approved Canadian pharmacies passed with SB 410. The approved Canadian pharmacies can sell and ship prescription drugs directly to Texas consumers once they have passed inspection by the Texas State Board of Pharmacy.

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closed claim study

Alleged failure to communicate diagnosis of abdominal cancer

by Barbara Rose and Laura Brockway

The following closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physicians' defensibility. The ultimate goal in presenting this case is to help physicians practice safe medicine. An attempt has been made to make the material less easy to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.

Presentation

A 29-year-old man came to the emergency department with complaints of abdominal pain, weakness, and fever. The symptoms began the day before, but became unbearable.

Physician action

The ED physician suspected appendicitis and requested a surgical consult. The surgeon, a defendant in this case, took the patient to the OR for an exploratory laparotomy. The surgeon discovered a ruptured appendix and a mucous-type substance around the appendix. This mucous proved to be a rare cancer called Pseudomyxoma Peritonei (PMP).

After the surgery, the surgeon told the patient that his appendix had ruptured, and that he had cleaned the peritoneal cavity. There was a dispute between the patient and the surgeon as to whether the existence of the PMP was communicated to the patient. The surgeon did not specifically document the disclosure of PMP/cancer/malignancy to the patient. The patient claimed the surgeon told him not to worry about the "jelly-like substance around the appendix" because it had been removed.

Postoperatively, the surgeon sent the patient to a gastroenterologist (also a defendant in this case) to determine if there was any pathology involving the colon. At this visit, they discussed the patient's family history of cancer, and a colonoscopy was scheduled.

A dispute existed between the gastroenterologist and the patient as to whether the diagnosis of PMP was disclosed to the patient by the gastroenterologist. The gastroenterologist later testified that the patient brought the pathology report from the surgery to the office visit. The gastroenterologist's dictated consultation report quoted language from the pathology report, but the specific disclosure of the PMP diagnosis was not documented. The patient recalled a discussion about the "jelly-like substance" with the gastroenterologist, but claims the gastroenterologist told him it was a non-issue because it had been removed. The patient also said he was never told to consult with the gastroenterologist for PMP.

The gastroenterologist performed the colonoscopy and the results were normal. These results were reviewed with the patient and forwarded to the general surgeon. The patient was told to follow up with the surgeon, and he never returned to the gastroenterologist.

There was no record of a follow-up visit between the patient and the surgeon, but both testified to such a meeting. The surgeon testified he referred the patient to his primary care physician for follow-up treatment of PMP. The patient testified the surgeon told him "I think we got it all out and if it comes back, we can get it out again." The patient maintained that neither the surgeon nor the gastroenterologist ever told him he had cancer.

Over the next four years, the patient saw his family physician for a number of unrelated complaints. During these visits, there was no mention of PMP, cancer, or any illness that would require further treatment or follow up.

Approximately five years after the appendectomy, the patient began experiencing abdominal pain again. He went to the ED and was seen by a surgeon. This surgeon performed a colectomy for a pelvic mass seen on films. The patient was again diagnosed with PMP.

The patient was seen by a number of

oncologists and ultimately went to an out-of-state surgical oncologist. He underwent surgery and chemotherapy, and the PMP has not recurred. However, the patient tested positive for signet ring cells intra-operatively, which means there is latent evidence of remaining PMP. The patient must be monitored with CTs and lab work for the next 10 years.

Allegations

Lawsuits were filed against the surgeon and the gastroenterologist alleging failure to inform the patient of the diagnosis of PMP, and failure to refer the patient to a specialist for treatment.

Legal implications

The lawsuit against the surgeon, who was not a TMLT policyholder, was settled during the discovery phase. The gastroenterologist chose to defend his care, and did not consent to settle.

At trial, the plaintiffs presented an expert gastroenterologist who testified that the defendant fell below the standard of care in failing to inform the patient about the diagnosis of PMP, and by failing to refer the patient to an oncologist. The patient's family physician — who denied any knowledge of the PMP prior to the colectomy — placed the responsibility for relaying the cancer diagnosis on both the surgeon and the defendant. He testified that one or both of these physicians "dropped the ball." An oncology expert testified that the delay in the treatment of the PMP resulted in more extensive and radical surgical procedures performed on the patient.

The defense gastroenterology expert testified that the defendant had no duty to disclose another physician's diagnosis to the patient. The defendant was specifically asked to rule out colon pathology on the patient, which he did. He sent the surgeon a letter stating the same. The surgeon clearly did not intend for the gastroenterologist to

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the Reporter



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take the lead and refer the patient to an oncologist because the surgeon told the patient to follow up with his family physician.

Patient responsibility became an issue in this case, with the defense expert testifying that the patient had a responsibility to follow up on his condition. It was suggested that the patient was in denial about the cancer, which is why he never mentioned it to his family physician. However, the patient's family physician testified that when he notified the patient of the PMP after the colonectomy, the patient seemed to be totally unaware of the diagnosis from five years earlier.

Disposition

The jury returned a verdict in favor of the plaintiffs, assigning 35 percent of the

negligence to the gastroenterologist and 65 percent to the surgeon. The defense team for the gastroenterologist planned to appeal the verdict. However, with the consent of the defendant, a settlement was reached during post-verdict mediation.

Risk management considerations

Comprehensive communication and documentation of such can serve as the foundation for an effective physician-patient and physician-physician relationship. Relying on memory may have limited relevance during discovery, deposition, and trial. Because it is almost routine for a patient to be seen by several physicians, as reflected in this case, it is extremely important for the patient to know who is directing his or her care and who will determine the next step in the course of treatment.

Responsibility for follow-up and timely

continuity of care is not to be left to chance. If a patient is not an active participant in his or her medical care, it may be caused by a lack of understanding, a reluctance to ask for clarification, or a fear of the unknown. It is expected that physicians educate their patients and verify patient understanding of the information needed to make informed decisions.

Was the patient truthful about the disclosure of PMP? That question will never be answered. Consequently, medical records need to represent an accurate chronology of patient care and communication, eliminating the potential for these types of "he-said, she-said" allegations.

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