

the Reporter

Vaccine liability & no-fault compensation

by Laura Hale Brockway

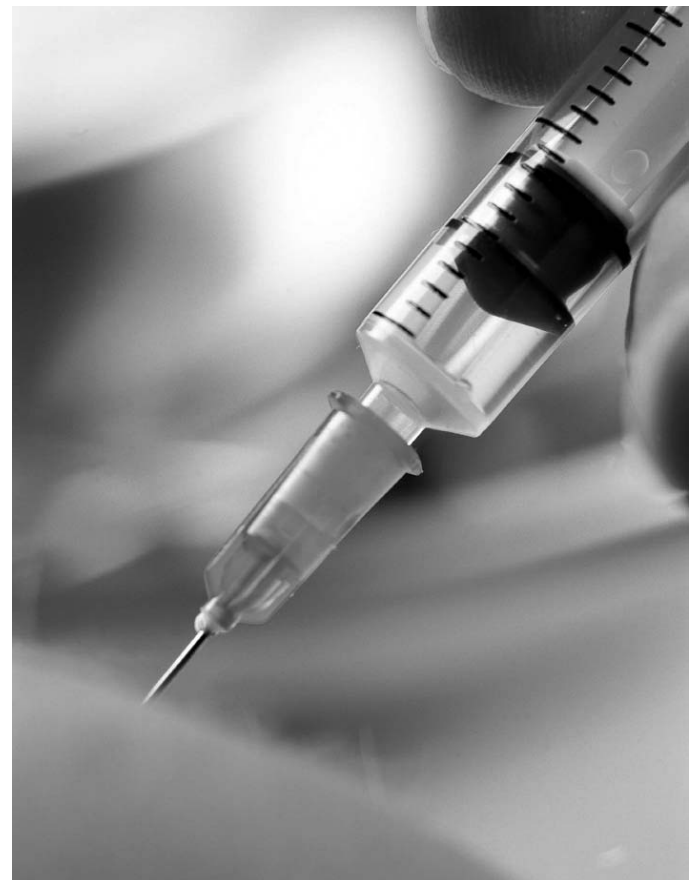
*“Pediatricians cite the development of vaccines and mass immunization programs among the most significant advances for the protection of the public’s health. Lawyers often refer to the development of modern tort law, with its expanded scope of legally enforceable standards of conduct, as a major advance for the protection of society’s interest. In recent years, these movements have at times collided, creating controversy and jeopardy for the goals of both.”*¹

A vaccine liability crisis in the 1980s led to the creation of the Vaccine Injury Compensation Program (VICP), a unique way of compensating those injured in the course of routine childhood vaccinations. In the face of a similar crisis in medical liability, observers often cite the VICP as an example of a successful no-fault dispute resolution system. They suggest that a similar program could be implemented as an alternative to the system of tort liability for medical malpractice.²

The merit of the VICP, the legal controversies surrounding its administration, and to what extent it truly protects physicians and other health care providers have been discussed at length elsewhere.³⁻⁴ This article will serve as an introduction and will acquaint readers with the organizational aspects of the program.

History and perspective

The issue of vaccine liability was uncommon prior to 1974. “It may be hard for the pediatricians of today to realize



that at one time there were seven producers of the diphtheria, pertussis and tetanus (DPT) vaccine in this country. Originally, there were three producers of the oral polio vaccine, and six producers for the measles vaccine.”⁵ Currently, four companies manufacture vaccines in the United States.

The crisis began with the landmark case *Reyes v Wyeth Laboratories*, a suit on behalf of a South Texas child who developed polio after receiving a polio vaccine. “This case was subsequently proven to be due to a wild polio virus, but the courts held that the manufacturer had a duty to warn of any possible side effects when a vaccine was given in a public program without a doctor present to assume that responsibility.”⁶

While the *Reyes* case opened the vaccine liability floodgate, more and more U.S. children were receiving vaccines, thanks to efforts by state and federal government to

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boost immunization rates. “As the widespread use of a vaccine diminishes or eliminates the risk of a disease, the public’s perception of the vaccines value paradoxically diminishes — because the public no longer observes the disease or its aftermath, and hence perceives little or no benefit.”⁷ In this environment, vaccine reactions become more noticeable and highly publicized.

“Concerns about whole-cell pertussis vaccine (DTP) started in the United States with the 1982 documentary *DPT Vaccine Roulette*. The media attention that followed led to the filing of hundreds of lawsuits against vaccine companies alleging DTP-related adverse effects.”⁸ From 1980 to 1986, damage claims for more than \$3.5 billion were filed. Jury awards in vaccine injury cases were inconsistent and the potential for liability seemed limitless.⁹

As a result, vaccine prices rose rapidly and some manufacturers ceased production. In 1985, the Centers for Disease Control and Prevention (CDC) announced that stockpiles for some vaccines were below safe levels, and called for vaccine rationing. “Observers attributed declining rates of childhood vaccination to problems with availability and cost of vaccines.”¹⁰ The American Academy of Pediatrics declared that tort litigation was a threat to pediatric immunization efforts. A large-scale public health crisis seemed imminent.

It was in this atmosphere of “urgency and compromise” that medical, legal and consumer groups worked with Congress to enact the National Childhood Vaccine Injury Act of 1986. “In taking this giant step into vaccine safety, the federal government instituted mandates for office record keeping, scientific studies of vaccine reactions by the Institute of Medicine (IOM), distributions of vaccine information for families and patients, and a national surveillance system to monitor adverse events. Liability was addressed with the creation of the VICP.”¹¹

The VICP

“The compensation program sought to provide prompt and reliable financial relief to persons who suffered unavoidable serious side effects after immunization against diphtheria, pertussis, tetanus, rubella, rubeola, mumps or poliomyelitis, and to safeguard the nation’s supply of vaccines by insulating manufacturers from tort claims arising from unavoidable injuries.”¹²

The VICP, a federal no-fault compensation system, became effective on October 1, 1988. It provides an alternative to the traditional tort system for resolving vaccine injury claims whether the vaccine was administered in the public or private sector.

All vaccine injury claims must first be filed with the VICP before litigation through the tort system can proceed. No civil claim can be made against a vaccine manufacturer or a health care provider while families are pursuing compensation through the VICP. If a claimant accepts VICP compensation, a claim cannot be brought through the tort system. Claimants can, however, reject a VICP award and pursue civil litigation. A vaccine administrator or manufacturer can also be sued if the vaccine is not covered under the VICP. The VICP covers all vaccines recommended by the CDC for routine administration to children.¹³

As part of the effort to ensure a safer vaccination program, the National Childhood Vaccine Injury Act mandated a number of legal requirements for health care providers. Each health care provider who administers a vaccine listed in the Vaccine Injury Table must:

- record immunization information in the patient’s medical record, including the date the vaccine was administered, the manufacturer and lot number, the name, title and practice address of the person administering the vaccine;

- report vaccine-related adverse reactions to the Vaccine Adverse Event Reporting System or to the manufacturer;

- give parents or guardians the appropriate and current CDC-developed Vaccine Information Statement and discuss, when appropriate, the risk and benefits of each vaccine before administration.¹⁴

The program is funded from an excise tax of 75 cents on every dose of covered vaccine. (For vaccines administered prior to October 1, 1988, awards are compensated from federal tax dollars allocated by Congress at \$110 million per year.) The fund currently has a balance of \$1.9 billion.¹⁵

The VICP is administered by the U.S. Department of Health and Human Services, the U.S. Court of Federal Claims and the U.S. Department of Justice. The 9-member Advisory Commission on Childhood Vaccines (ACCV) provides oversight of the VICP.

The Vaccine Injury Table

As a no-fault approach to compensation, the VICP relies largely on a table of compensable injuries. This Vaccine Injury Table (VIT) is available at www.hrsa.gov/osp/vicp/table.htm, and lists vaccines, associated injuries or conditions and time periods. “If the first manifestation of a named injury occurs within the stated time period following vaccination, the injury is presumed to have been caused by the vaccine. For an injury included in the table, HHS may dispute causation by proving that there was an alternate cause for the injury. Negative expert evidence demonstrating that the vaccine does not cause the injury cannot overcome the legal presumption created by the table.”¹⁶

“It is much easier to demonstrate a table injury than to prove that the vaccine caused the condition. However, if an adverse event is not listed on the table, an individual may still file a claim but must prove that the vaccine did ‘in fact’ cause the alleged injury.”¹⁷ For injuries not on the table, the claimants must prove by a preponderance of medical evidence (ie, greater than 50 percent or more likely than not) that the vaccine caused the injury.¹⁸

Since its creation, the VIT has been amended four times, as new research about the health impacts of vaccines emerges. (For a complete account of changes to the VIT, please see the VICP web site at www.hrsa.gov/osp/vicp/.)

Eligibility

To qualify for compensation, claimants must file petitions within the specified time frames and meet other conditions. For vaccines administered before October 1, 1988, the time to file claims has expired, and those claims are subject to dismissal.

For injuries resulting from a vaccine administered on or after October 1, 1988, the claim must be filed within 36 months after the first symptoms appeared, the effects must last at least six months and the injury must have resulted in hospitalization and surgical intervention. In the case of a death from a vaccine, the claim must be filed within 24 months of the death and within 48 months after the onset of the vaccine-related injury from which the death occurred.

Claimants must also provide documentation of the patient’s status before the injury, of the vaccination and of the injury and patient’s current medical status. Such documentation may include prenatal and birth records, clinic notes, growth charts, laboratory and radiological results, hospitalization and emergency treatment records, school and death records.

Adjudication

The Court of Federal Claims adjudicates claims under the VICP. The Secretary of HHS is named as respondent and

Department of Justice attorneys represent HHS. Hearings are held before a Special Master, an expert attorney appointed by the judges of the Court. The Special Master reviews the medical records, hears testimony, considers other evidence and makes an initial decision on the petition. (More than 200 published opinions of the Special Masters are available at www.uscfc.uscourts.gov/osm.htm.)

Hearings usually last from one to two days. If a claim is found eligible for compensation, a separate hearing is scheduled to assess the amount. Either party may object to the decision made by the Special Master and request review by the Court of Federal Claims. Appeals of the judgments made by the Court of Federal Claims are heard by the U.S. Court of Appeals, Federal Circuit.

HHS is responsible for all awards, including attorney's fees in both successful and unsuccessful cases, provided the case was brought in good faith and there is a reasonable basis for the claim. In all cases, a maximum of \$30,000 is set for legal expenses and the Special Master may adjust the billing. Contingency fees are not allowed.

"Successful petitioners may be compensated for medical and rehabilitative care, custodial care, special education, equipment, travel expenses and lifelong lost earnings. Pain and suffering and emotional distress are compensable to a maximum of \$250,000. Payment is in the form of an annuity awarded to the parents or guardian. Awards for vaccine-related death are limited to \$250,000." ¹⁹ Since fault is never determined, punitive damages are not awarded. ²⁰

Claim awarded

As of July 31, 2003, for vaccines administered after October 1, 1988, a total of 5,000 petitions have been filed. Of these, 983 awards have been paid for a total of \$533.3 million. The average award for fiscal year 2003 was \$1.2 million

For pre-1988 vaccinations, a total of 4,259 petitions have been filed. Of these, 1,187 cases were judged compensable, and a total of \$899.6 million has been awarded. The average pre-1988 award for fiscal year 2003 was \$2.4 million. A total of \$1.4 billion has been paid to families and individuals under the program. ²¹

In 2003, the VICP has seen an "unprecedented" increase in the number of petitions filed. As of July 31, 2003, 2,203 petitions had been filed, compared with 957 in 2002. The increase, VICP officials say, is the result of media and Congressional attention into the alleged link between the vaccine additive Thimerosal and autism. The autism claims are being processed in an omnibus claims proceeding that claimants can opt in to ". . . the Court will consider the scientific evidence first for all autism/Thimerosal related claims, make findings on causation based on the scientific evidence presented, and then consider the factual evidence in individual claims." ²²

Conclusion

Vaccine manufacturers, physicians and other health care providers view the VICP as a qualified success. "By most standards, the federal system has met its goals of compensating individuals, stabilizing the marketplace (supply and pricing), and reducing health care provider and manufacturer liability. New court cases have nearly disappeared, with only a small number of lawsuits filed annually against U.S. manufacturers, and little evidence to suggest that those who are rejected by the federal system or who chose not to accept compensation seek court remedies elsewhere." ²³

Consumer advocacy groups, however, argue the VICP is tight-fisted and overly harsh. Claimants, they say, face too many eligibility hurdles and the government is "too aggressive" in

dismissing cases based on technicalities. ²⁴

"The various eligibility requirements and deadlines can be characterized as attempts to keep control of a novel program and to prevent abuse. Indeed, the Special Masters have invoked the eligibility rules to disqualify plainly abusive participants, including applicants with incomprehensible and contradictory medical records, medical experts whose reports on the medical literature are wildly inaccurate, attorneys who have submitted multiple bills for the same work and claimants who offered false oral testimony and noncredible documentation." ²⁵

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medical liability update

Proposition 12 passes; TMLT to reduce rates

After four years of rate increases, we finally have some good news for our policyholders. The first bit of good news — which is old news by now — is that Proposition 12 passed. Passage of this constitutional amendment will ensure the medical liability reform measures enacted by the Texas legislature in 2003 will stand as passed. Accordingly and as promised, TMLT will reduce liability rates by 12 percent. The rate reduction will take effect January 1, 2004, and will be applied as physicians renew their policies.

Rate reductions

As stated above, the rate reduction is not retroactive. The effective date for the lower rates — January 1, 2004 — is the same date that TMLT has implemented rate changes in the past. Medical liability coverage renews annually and everyone has a different renewal date. Physicians who renewed in January 2003 have paid the higher rates for 10 months, and will continue to do so until January 1, 2004. Physicians renewing in October, for example, will pay the 2003 rate until they renew again in October 2004, when they will receive the 12 percent rate reduction.

“We understand that physicians are anxious to have this promised rate reduction, but we also want to implement the reduction fairly. Decreases effective in January will be applied to policyholders at their 2004 renewal date,” says Tom Cotten, president and CEO of TMLT. “Other discounts that are available for risk management activities and for good experience will remain in force and are in addition to the 12 percent rate decrease.”

The rate reduction of 12 percent is higher than the 8.5 to 11.5 percent savings range estimated by the Texas Department of Insurance. TMLT is undertaking this rate reduction before the projected savings from 2003 lawsuit abuse reforms have been realized.

“Right now, we can only approximate the effect of the damage cap. We will not

have a complete picture and hard numbers until the law has been in place for a few years. But, we realize that physicians cannot wait that long. We are decreasing rates to provide immediate relief to the medical community and to demonstrate our belief that damage caps will work,” Cotten says.

Proposition 12 success

“We owe the victory on Proposition 12 to all those physicians who spoke with their employees and their families and their patients. The medical community came together for the good of their patients and the health care system in Texas,” says Cotten. “This vote will save TMLT policyholders \$20 million — that’s \$20 million that will stay in the health care system.”

According to the Office of the Secretary of State, voter turnout for the September 13th election was 12.2 percent or 1,468,615 voters. This was the highest turnout for a constitutional amendment election since 1993. The final tally was 51.12 percent for and 48.88 percent against Proposition 12. The difference was 33,005 votes or 2.25 percent of the total vote.

The metropolitan-area counties containing Dallas, Houston and Austin voted against Proposition 12, but San Antonio, Fort Worth, El Paso, Corpus Christi, Lubbock, Brownsville and most suburban counties supported the measure. The results in smaller counties were mixed. (For a complete look at county-by-county results, visit the web site of the Office of the Secretary of state, www.sos.state.tx.us/index.html.)

Observers believe Proposition 12 did not pass in many of the urban areas because the access to care crisis was not as acute in those areas.

In the long battle to achieve medical liability reform nationwide, Texas stands out. At press time, Texas is the only state without an existing cap on noneconomic damages to pass a \$250,000 limit. Texas is

also the first state to pass a constitutional amendment on medical liability caps.

The bad news

Texas’ plaintiff attorneys, while also leading and funding the opposition to Proposition 12, have been filing claims against Texas physicians at an unprecedented rate.

“We’ve never seen claim intake jump like this in the 24-year history of TMLT,” says Bob Fields, executive vice president, claim operations. Since June 1, the number of malpractice suits filed against TMLT policyholders has increased by 250 percent. The number of claims and lawsuits rose to 1,619 (as of September 9, 2003) compared to 645 for this same period last year.

“Many of these lawsuits have been filed with no investigation of the medical facts and no regard for the costs of litigation or affects on the careers of our doctors. It appears trial attorneys are filing any case they have in their inventory just to avoid the September 1 effective date of the new tort reform,” says Fields.

“We were already successfully defending 85 percent of the claims filed against our doctors before this mad rush to the courthouse. This latest spike in suit filings confirms the seriousness of the lawsuit abuse problem we face in this state. Defending these cases will cost our doctors millions of dollars in premiums.”

This increase in claim intake following passage of tort reform was not wholly unexpected. When medical liability reform measures were passed in 1995, TMLT also experienced an increase in claims intake. “This is a very unfortunate side effect of reforming the system. We saw it in 1995, and we knew we would see it again this year. We are just stunned by the sheer volume of cases being filed,” says Fields.

The Reporter will feature a bimonthly column to answer your most frequently asked questions about asset protection. We invite you to email or write Ken Vanway with your questions, ken@vanway.org or Law Office of Ken H. Vanway, P.C., First Commercial Bank, 1110 RR 620 South, Suite B, Austin, Texas 78734.

The information provided in this article is not to be construed as legal advice and should not be relied upon without specific consultation with a professional.

5 tax saving secrets for physicians

There is one thing that you have in common with every other physician in the country — you pay 35 to 50 percent of your income to taxes. The year-end is quickly approaching and now is the time to start looking at tax-saving strategies. This article will introduce such solutions and strategies. If you have questions about the applicability of these strategies, please do not hesitate to contact my office and I will help evaluate your situation.

3. Section 79 plan

Many physicians, if they had the opportunity, would like to double up estate planning with income tax reduction (while funding supplemental retirement income). Through a Section 79 plan, a physician can fund an investment-grade life insurance policy in a tax favorable manner, deducting approximately 60 percent of the premium. The policy can be used for estate planning or for supplemental retirement income.

4. Captive insurance company

Tax deduction benefit: \$80,000 to \$349,000
CICs are great for physicians or business owners seeking tax deductible contributions of \$80,000 to \$349,000 for asset protection and risk management programs. As a physician, you are presently liable for many risks including fiduciary liability, wrongful termination, sexual harassment, discrimination, OSHA, HCFA, Medicare Fraud, etc. If you wish to contribute pre-tax dollars to pay potential future

Protecting your assets from lawsuits

By Ken H. Vanway, P.C., attorney at law, senior partner, Vanway, Thrash & Associates



About the author

Ken H. Vanway is board certified in Estate Planning and Probate Law — Texas Board of Legal Specialization. Ken has more than 20 years experience. His firm practices in many areas of estate planning and lawsuit protection including wills, living trusts, insurance trusts, family partnerships, charitable trusts, private foundations and asset protection. For more information, please visit his web site, at www.estateplanning.com/kenvanway.

1. Deductions for retirement savings

Tax deduction benefit: \$24,500 to \$40,000 (more than \$100,000 for those age 50+)

Retirement and deferred compensation plans are excellent tools when used correctly. There are many different plans: 401K, IRA, SEP, Keogh, defined benefit, etc. The federal non-discrimination rules for required contributions to staff have changed. You should have your existing plan reviewed in light of the new rule changes and compare alternative plan designs at your older age.

Beware of certain 412(i) proposals — 412(i) plans seem to be the current fad for income tax reduction. Be wary of agents promoting this concept if it is heavily funded with life insurance, particularly the use of “5-year-pay” life insurance that will be purchased from the plan after the fifth year for a very low surrender value. This article does not allow for a detailed explanation of the problem, but be cautious and have your legal and tax counsel review any proposals prior to making a final decision.

2. Equity disability trust

Tax deduction benefit: 100 percent income tax deduction \$25,000 to \$250,000

The simplest income tax reduction plan I can find is equity disability trust (EDT). With EDT, a client simply has the corporation pay premiums of \$25,000 to \$250,000 for supplemental disability coverage where 94 percent of the premium is deposited into a growth account (and hopefully grow with the market). Anytime after the fifth year, the client can exercise a refund option of the initial premium plus any growth on that premium. The EDT is completely discriminatory in that you do not have to contribute for staff or any other physician. (See www.estateplanning.com/kenvanway for more information.)

claims, the CIC may work very well. You receive a tax deduction for your contributions (premiums). If you never make a claim, your company continues to invest the funds. If structured properly, these companies can be tax-exempt and the assets inside the companies will grow tax-free. As a company owner, you have access to the funds at any time. Along with physicians, individuals with substantial (at least \$1 million) liquid assets, royalty streams, patents, or highly appreciated assets will gain significant additional benefits from the CIC.

5. Long term care insurance (LTCI) for “free”

Tax deduction benefit: \$2,500 to \$100,000

I believe every physician would buy LTCI if it were “free.” How? If structured properly, a physician can take a 100 percent tax deduction for LTCI and through a return of premium rider have every dollar paid through the corporation received by the heirs upon death. Is the insurance free? Instead of taking 60 cents home after-tax and paying for LTCI, the physician deducted the entire premium and had 100 cents out of a dollar returned to the heirs at death. The physician lost the growth on the money, but did have the LTCI in place until death and then the entire premium paid passed to the heirs tax free.

Conclusion

Judge Learned Hand once said “There is no reason to pay more taxes than the law would provide — there isn’t even a patriotic duty to do so.” I am simply trying to help you find the best ways to benefit your family within the guidelines the IRS has given us. I hope you have found this article helpful and look forward to assisting you in the future.

This article was co-authored with Rocco DeFrancesco, JD, author of *The Doctor’s Wealth Preservation Guide*.

Medication errors

A leading cause of medical liability claims



Objectives

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

1. identify the types and causes of medication errors;
2. list the type of patients who are at risk for medication errors, and the medications frequently involved; and
3. describe strategies to reduce medication errors.

Course author

Stacey Agnew is a senior risk management representative at TMLT.

Disclosure

Stacey Agnew 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 credits 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 one 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 forms 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 October 10, 2003, and expires on October 10, 2005. Please note that this CME activity does **not** meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.

According to the Food and Drug Administration (FDA), medication errors cause at least one death every day and injure approximately 1.3 million people annually in the United States. In 1999, the Institute of Medicine issued its report on medical errors entitled *To Err is Human: Building a Safer Health System*. The report highlighted medication safety as a top priority for health care organizations and gave three reasons for singling out this issue:

- the harm to patients from medication errors is great;
- the cost of such errors to society is high;
- strategies to prevent the most common kinds of errors are well known.

The report found that medication errors accounted for more than 19 percent of medical errors and called for a 50 percent reduction in medication errors over the next five years. As we approach the five-year deadline, the progress made in identifying the types and causes of medication errors and strategies to reduce these errors will be reviewed.

The National Coordinating Council for Medication Error Reporting and Prevention

(NCCMERP), an independent group comprised of national organizations, agencies, and other parties, defines a medication error as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems, including prescribing; order communications; product labeling; packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.”

A medication error is considered a preventable adverse drug event (ADE). An ADE is defined in the clinical literature as an injury resulting from medical intervention related to a drug. However, not all ADEs can be attributed to error. For example, a patient who has no history of drug allergies may develop an allergic reaction to an antibiotic. While this is considered an ADE, it is not attributable to error. An example of an error-induced ADE is a patient whose history of an antibiotic allergy is documented in the medical record and is mistakenly given that particular drug and has a reaction. In this situation, the ADE is preventable.

Medications play such an important role in the physician-patient interchange and the prescription is often viewed as an accepted medium of exchange between the patient and the prescriber. The closure of the physician-patient encounter is symbolized many times by the prescription being handed to the patient. As the practitioner considers prescribing a certain medication to a patient, the following issues should be considered:

1. Why does this patient need this prescription, and is it documented in the medical record?
2. Are there any risks present and have they been adequately explained and documented in the medical record?
3. How will I monitor the medication's effectiveness, have I told the patient, do they understand and is it documented?

Types and causes of errors

Types of medication errors are numerous and include situations such as wrong medication, wrong dose, wrong route, wrong administration technique, prescribing error, dispensing error and monitoring error. A preventable ADE may involve more than one type of error due to the multifaceted and multidisciplinary nature of medication errors.

Common causes of medication errors, according to the FDA, are poor communication; ambiguities in product names, directions for use, medical abbreviations or writing; poor procedures or techniques;

patient misuse due to noncompliance or poor understanding of directions for the product. Contributing factors may also include job stress, lack of product knowledge, or similar labeling or packaging of a product. A 1995 study published in *JAMA* looked at the proximal cause, or apparent reason, for medication errors in inpatient settings. The study's findings can also be relevant to physician practice settings. Overall, the most common proximal cause was lack of knowledge of the drug, accounting for 29 percent of 334 errors analyzed. The second-most-frequent cause was lack of information about the patient, which represented 18 percent of errors. The proximal causes for medication errors as defined in the study are listed in order of frequency of occurrence as follows.

- Lack of knowledge of the drug — inadequate knowledge of indications for use, appropriate dose and routes, and compatibilities.
- Lack of information about the patient — physician, nurse, or pharmacist was unaware of an important aspect of a patient's condition.
- Rule violations — failure to follow accepted and well established policy and procedures.
- Slips and memory lapses — errors in which the person “knew better” and could not explain why the error occurred or why they forgot.
- Transcription errors — unexplained errors associated with order transcription and verification.
- Faulty drug identity checking — pharmacists and nurses checking for errors resulted in patients receiving or nearly receiving a wrong medication.
- Faulty interaction with other services or units — problems communicating with others such as physicians as well as errors that occurred when patients were transferred between services or units.
- Faulty dose checking — failure to ensure proper dose was dispensed and administered.
- Infusion pump and parenteral delivery problems — pump setting errors; accidental tubing disconnections; confusion between central and peripheral lines.
- Inadequate monitoring — failure to adjust the dose because necessary monitoring was not carried out or changes were ignored.
- Drug stocking and delivery problems — unexplained late or missing deliveries of medications to patient care units.
- Preparation errors — calculation and mixing errors by pharmacist and nurse that results in incorrect doses.
- Lack of standardization — administration errors by nurses due to nonstandard concentrations, dosing schedules, or infusion rates.

According to research, knowing the type of error and its proximal cause is not enough information. The reason why the patient did

not obtain the correct dose or proper medication is to understand the underlying system failures, if any. The following case demonstrates how a system failure can result in a tragedy that could have easily been prevented.

Case study

(This case was taken from a publication produced by Norcal Mutual Insurance Company.)

A 47-year-old male weighing 195 pounds presented to the emergency room complaining of chest pain and shortness of breath. His history included spontaneous pneumothorax two years prior.

The ER physician ordered a chest x-ray which confirmed the presence of a left chest pneumothorax. A chest tube was placed by the ER physician which resolved the pneumothorax and resulted in 80 to 90 percent expansion. A pulmonologist was then called in for consultation. He evaluated the patient and noted that vital signs were normal with no cyanosis, clubbing or edema. A CT scan to determine the etiology of the pneumothorax was ordered to identify if it was infectious or emphysematous. The results were negative for infection so the pulmonologist recommended a pleurodesis, a procedure where a solution is administered through the chest tube into the chest cavity, causing an inflammation of the tissues, and sealing the affected lung.

The pulmonologist wrote an order for Talc 4 grams in a solution of 50 cc's of 10% lidocaine and 50 cc's of normal saline. The solution was to be mixed and placed into two 50 cc syringes. The order was transcribed by the nursing staff and sent to the hospital pharmacy.

The 10% lidocaine represents a toxic dose of 5,000 mg. According to the patient's weight, he should have received no more than 30-40 cc's of a 1% lidocaine solution. The nursing staff is the first line of defense for preventing medication errors since it is their duty to transcribe orders exactly as written by the physician. However, in this case, nobody on the nursing staff challenged the physician regarding the toxic dosage of lidocaine, and the order was sent to the pharmacy.

Due to scheduling, the pulmonologist was off the day the procedure was to be performed and his partner was asked to perform the pleurodesis. On this day, the pharmacy sent the unmixed components to the floor.

The pharmacy staff or their computer system is the second line of defense against medication errors. Many facilities have computer systems that generate warnings regarding toxic doses and potential interactions with other medications. In this case, the pharmacy staff read and filled the order without noting the toxic dosage. Normally, the pharmacy staff mixes the solution and places it in the

syringes, but not in this case. Since it was unmixed, the nursing staff returned the components to the pharmacy to have it mixed.

The nursing staff and the pharmacy each had another opportunity to verify the physician's order and note the toxic dosage. Once again, they all missed this opportunity to make the appropriate correction. The pharmacy staff mixed the components and returned two labeled 50 cc syringes to the floor.

Five minutes after the physician injected the two 50 cc syringes, the patient began twitching and then had a grand mal seizure. The patient then went into cardiac arrest and resuscitative efforts began. The patient remained unresponsive and on life support for two days until he was extubated and ultimately expired.

The patient's family sued the hospital and the two pulmonologists. The physician who originally wrote the order could not explain why he wrote the toxic dosage and believed that he might have been distracted at the time. He also felt that although he wrote this order in error, it would not have been executed since everyone involved considered it a lethal dose. He was certain there were safeguards to prevent this type of medication error from occurring, especially in the hospital.

The physician who administered the medication felt that he could trust his partner of many years to write the orders correctly. He too believed there were safeguards in place and he could rely on the nursing staff and pharmacy to prevent medication errors.

Arguments about this case could have included statements about one lost opportunity after another to correct the error, and if just one person challenged the physician's order, the patient would be alive today. Six occasions to rectify the error occurred. Since these arguments would appeal to a jury, it would have been a difficult case to win. Therefore, this case was settled out of court.

Patients at risk for medication errors

While all patients deserve thorough prescribing attention, extra caution may be warranted when prescribing medication to pediatric, pregnant and geriatric patients. Newly prescribed medications often begin at the lowest effective doses until the physician can determine the effectiveness and adjustments can be made appropriately.

When prescribing for pediatric patients, physicians consider many variables, above all age and weight. Calculation of dosages for children often falls upon the health care provider because pediatric dosages are not always listed in reference manuals, and medications are usually not packaged in pediatric doses. Physicians prescribing for children should refer to a reference source that specif-

ically lists medication dosages for children or should otherwise appropriately calculate proper dosages. To calculate proper dosage, it is important that a recent record of the child's weight is available to prevent under- or over-prescribing medication. In addition, when calculating dosage, it is also important to be aware of conditions such as fever and dehydration.

Consideration of the potential for pregnancy is important when prescribing medications for women of childbearing age. Particular attention should be directed toward prescribing a teratogenic drug to a patient who could be pregnant. Documenting the date of the patient's last period will help in determining whether a pregnancy test is needed before prescribing drugs not proven safe during pregnancy. A common situation is initiating a medication and discovering soon after that the patient is in an early stage of pregnancy and may have exposed the fetus to a potentially dangerous drug.

Elderly patients are at risk for medication errors due to receiving numerous medications, often from more than one physician. Polypharmacy combined with drug interaction potentials and side effects can produce lethal outcomes. Physical changes that affect metabolism of drugs occur in patients over the age of 65. Body fat increases while lean body mass and water decrease, along with decreased renal and liver function. Cognitive skills such as the ability to hear, read and understand instructions may also decrease with age. Therefore, physicians should try to

be aware of the patient's level of understanding as well as the spouse or caretaker's cognitive skills, who may be involved in administering the medication. Non-steroidal anti-inflammatory agents, calcium channel blockers, beta-blockers and psychotropic drugs are commonly associated with medication errors in the elderly.

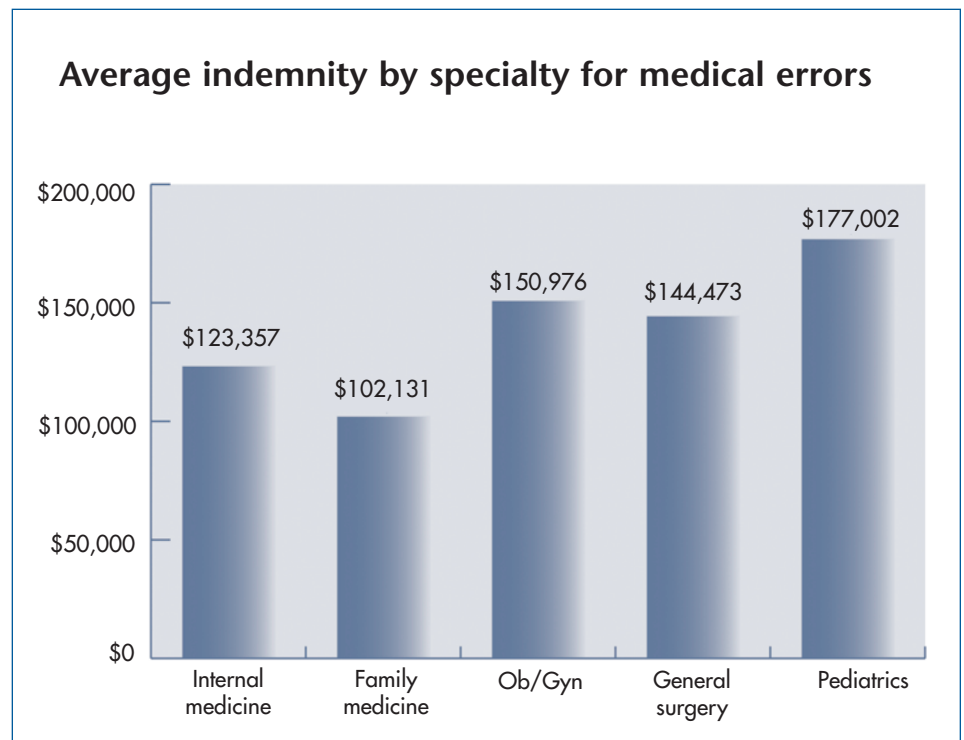
Physician specialty and medication errors

The medical specialty most frequently involved in medication error liability claims, according to the Physician Insurers Association of America (PIAA), is internal medicine, accounting for 28 percent of all medication error claims in the Data Sharing Project. Family practitioners followed with 23.2 percent of claims. However, the average amount paid in a liability claim or indemnity varied by physician specialty, with the highest average indemnity payments for medication errors involving pediatrics. (See graph below.)

High alert medications

JCAHO recommends health care facilities implement safety strategies for certain high-alert medications. Medications that are known to have high risks for causing injury if misused are as follows:

- insulin;
- opiates and narcotics;
- injectable potassium chloride concentrate;
- intravenous anticoagulant such as heparin;
- intravenous sodium chloride solutions above 0.9 percent.



According to recent contact with a PIAA representative, the drug classes involved in professional liability claims where indemnity is paid have remained steady since the 1993 Medication Errors Study. The drug classes most frequently involved were antibiotics, glucocorticoids, and narcotic/non-narcotic analgesics/narcotic antagonists. The most common errors with antibiotics are failure to note documented allergy, failure to utilize the most appropriate medication, and prescription of medication not indicated for the medical condition. With glucocorticoids, the errors include incorrect dosage, communication failure between physician and patient, and failure to monitor side effects. Errors with narcotics include prescription of a medication that is not indicated for the medical condition, and failure to monitor side effects.

Case study

A 45-year-old patient with a long history of ankle and toe fractures presented to her orthopaedic physician with an ankle fracture. The physician performed an open reduction and internal fixation and intramedullary rodding of her distal tibia fracture. Eleven days post-operatively, the patient returned to see the physician, and exhibited signs of cellulitis. The patient was asked if she had ever taken Keflex, and she advised the physician and his nurse that she had taken it previously with no ill effects. The medication was prescribed and was immediately filled by the patient. At home, approximately five minutes after ingesting the Keflex, the patient complained of difficulty breathing. EMS arrived and took the patient to the hospital. During the transfer, the patient went into asystole and could not be revived. The autopsy report indicated she died as a result of a severe anaphylactic reaction due to the ingestion of the antibiotic.

The allegation by the claimant was that the physician negligently prescribed a medication that was contraindicated due to a documented allergy to Keflex. Three years earlier, the physician documented that the patient was placed on Keflex and seemed to have an allergic reaction to it. Consultants who reviewed the case indicated that the physician had the responsibility to be familiar with the patient's allergy history. Even if Keflex was not a known allergy, it was inappropriate to challenge a penicillin allergic patient with Keflex due to the potential for cross sensitivity. This case was ultimately settled for a six-figure amount.

Some useful risk prevention activities to avoid allergic reactions include the following.

- Question the patient for allergies or suspected allergies including over-the-counter medications. Americans spend \$10 billion per year on over-the-counter medications.

- Indicate allergies in bold lettering — preferably red — in the patient's record. It is helpful if this is in the front of the chart or on each new page of the patient's progress notes.

- Educate the office staff regarding the importance of allergy notations on charts and forms.

- Radiologists: reviewing the original request for diagnostic imaging before using any contrast medium will help avoid allergic reactions.

- Check with an allergist, if possible, when the situation warrants prescribing the drug to which a patient is allergic but to whom it would be life saving.

Enlist patients and families

The patient and his or her family or caretaker are important resources often overlooked in the medication process. According to the *American Journal of Health-System Pharmacists*, "if patients are more knowledgeable . . . errors in treatment may be prevented." Telling a physician or nurse something as simple as "this pill is the wrong color" could make all the difference when preventing a medication error. Patients have the right to know about the medications they are receiving, how often the medication is to be administered, and possible side effects. Patients or their caretaker should be encouraged to speak up if they have questions about medications, and providers should listen to their concerns. For example, a hospital laboratory discovered a hidden error that affected more than 900 patients receiving warfarin after a patient questioned a change in the dose.

Technological solutions

Health care facilities are turning to technology to improve the efficiency and effectiveness of medication processes. The FDA recently proposed a regulation that would require bar codes on all single-unit packages of prescription drugs, over-the-counter drugs commonly used in hospitals, vaccines and biologics such as blood. Physician samples will be excluded from the bar coding regulations. Once the regulation is in place, the FDA will give pharmaceutical makers three years to comply. The bar code would contain the National Drug Code (NDC) number, unique identifying information about the drug to be dispensed to the patient in a linear bar code as part of the drug label. The proposed design would allow manufacturers to include additional information as the bar code standards and information technology progresses. The current proposed regulation does not require the inclusion of the medication's lot number and the expiration date in the bar code, citing the cost and the need for more evidence of the value. When bar code scanners and com-

puterized patient information systems are used, many errors can be prevented including administering the wrong drug, administering a drug to a patient with a known drug allergy, administering the wrong dose, administering the drug at the wrong time, or using the wrong route of administration.

Medication administration systems that use bar coding hold promise for reducing medication errors. After a successful pilot test at Colmery O'Neil VA Medical Center in Topeka, Kansas, the Department of Veterans Administration has implemented its Bar Code Med Admin (BCMA) system in all its medical centers. The Topeka facility found it could reduce errors during the administration stage with a bar-coding system. Based on the Topeka experience, the VA expects to eliminate more than 40,000 medication errors, including 400 serious incidents.

Although automated systems seem like the perfect solution, some caveats exist. First of all, automated systems can be time consuming to operate, especially in the beginning. Therefore, facilities must have the support of physicians and nurses in order to make the new technology work. Users of the equipment should be involved from the start in defining the facility's needs, evaluating systems, and selecting a system for the facility. To generate acceptance of the system, the users should participate in a training program. Once the system is in place, personnel should be available for the first two weeks or so to answer questions and to troubleshoot.

Facilities should also be aware that technologies can introduce new sources of errors. For example, many health care facilities use automated medication dispensing systems in certain care units to improve turnaround time for drug dispensing. Medication errors include choosing the wrong medication, selecting the wrong dose, getting medications for more than one patient and mixing them, and stocking medications in the wrong slot in the dispensing unit. Safety precautions for facilities using automated drug dispensing should be developed and should include the following:

- requirements for a pharmacy order entry prior to a nurse removing a drug from a cabinet;
- minimize the type of drugs supplied and stock drugs in the smallest doses;
- develop a system to check accurate cabinet stocking.

When an error occurs

Report medication errors even if no harm is suffered, including the near misses. Each incident can help uncover system failures leading to the error and each potential error or near miss can help identify the successful

safety nets that prevented the error from reaching the patient. Medication errors are rarely attributed to one individual but are instead the result of a series of dynamic issues along the medication-use continuum. In order to analyze errors in the systems that contribute to an incident, facilities must adopt a nonpunitive approach to error management so that practitioners are willing to reveal complete information about incidents and near misses involving medications.

Health care facilities and physicians should consider their obligation to disclose the error to the patient or patient's family when a medication error occurs. In the hospital, JCAHO requires accredited hospitals to disclose unanticipated outcomes to patients. Full disclosure can make a difference in how patients and their families respond to an incident. Some evidence suggests that patients may be less likely to pursue litigation if providers disclose errors in an honest, empathetic and timely manner. In addition to the disclosure, the facility should support the persons involved in the error with counseling; conduct an analysis of the incident; and report the incident to appropriate outside organizations such as the FDA, U.S. Pharmacopeia (USP), Institute for Safe Medication Practices (ISMP), JCAHO (if the incident is a sentinel event), and, if necessary, state agencies.

Strategies to reduce medication errors

An integral part of any hospital or physician practice risk management program should include activities to prevent or reduce the exposure to medication-related liability. The following strategies may assist in the prevention and reduction of medication errors.

- Maintain a *Physician's Desk Reference (PDR)* and its two-year supplementary issues in the physician's office or in-patient care areas in hospital settings.
- Prominently display critical patient information such as drug allergies and medication regimens, in patient records.
- "Dear Doctor" letters and other specialized information received from the device or drug manufacturer can be helpful.
- Oral recommendations received from pharmaceutical representatives or pharmacists about a drug are another source of information.
- Occasionally, medications are prescribed for purposes outside those normally seen. Documenting your rationale for such prescriptions in the medical record will help others, including other health care providers, understand this rationale.
- Develop a system for in-office and telephone monitoring for patients who receive highly toxic medications.

- Avoid refilling highly toxic prescriptions unless the patient submits to an office examination to rule out harmful toxicity and side effects.

- Chart discussions regarding a medication problem to avoid misunderstandings in the future about what information was received.

- Avoid prescribing medication to strangers by phone, patients you have not examined or others who may request a prescription not in the course of an established physician-patient relationship (hospital staff, neighbor, etc).

- Write all prescriptions so the text is legible, e.g., Digoxin v. Digitoxin. If your handwriting is beyond repair, have your staff type or legibly write the prescription and then review prior to giving it to the patient.

- Educate patients and/or family members about possible drug interactions. This may include prescription and over-the-counter medications, dietary and herbal supplements, and food-beverage-drug interactions. Document that this was done.

- Note the distribution of free samples in the record and give the patient instructions. Document in the record that instructions were given.

- If experimental drugs are prescribed or drugs prescribed in experimental dosages, obtain a signed written consent from the patient acknowledging an agreement to participate in an experiment.

The NCCMERP offers the following suggestions to correct error-prone aspects of prescription writing.

- All prescription documents must be legible. Prescribers should move to a direct, computerized, order entry system.
- Prescription orders should include a brief notation of purpose (e.g. for cough), unless considered inappropriate by prescriber.
- All prescription orders should be written in the metric system except for therapies that use standard units such as insulin, vitamins, etc. Units should be spelled out rather than writing "U."
- Prescribers should include age and when appropriate, weight of the patient on the prescription or medication order.
- The medication should include drug name, exact metric weight or concentration and dosage form.
- A leading zero should precede a decimal expression of less than one. A terminal or trailing zero should not be used after a decimal.
- Prescribers should avoid use of abbreviations including those for drug names (e.g. MOM, HCTZ) and Latin directions for use.
- Prescribers should not use vague instructions such as "take as directed" or "take/use as needed" as the sole direction for use.

Conclusion

Medication errors continue to be a hot topic in the public spotlight due to the frequency of professional liability claims, scientific studies and media reports. Claim data indicate medication error as the third or fourth most prevalent allegation filed in suits against physicians. Reducing the number of medication errors involves all persons on the health care team to identify those patients who are prone to medication errors, recognize the drug and drug classes most commonly associated with medication errors, and identify the type and cause of medication errors. Through consistent adherence to systematic strategies for prescribing and administering medications, medication errors can be drastically reduced or even eliminated.

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In case you missed it . . .

Law requires distribution of resource list to pregnant patients

Texas physicians who provide prenatal care to pregnant women are now required by law to provide these patients with a resource list of professional organizations that provide postpartum counseling and assistance. The law, passed in the form of House Bill 341, became effective September 1, 2003.

The resource list is maintained by the Texas Department of Health (TDH), and is available at <http://www.tdh.state.tx.us/mch/depression.htm>. The list includes organizations a parent can contact to receive counseling and assistance for postpartum depression and other emotional traumas associated with pregnancy and parenting. The law applies to hospitals, birthing centers, physicians, nurse midwives or midwives who provide prenatal care to a pregnant woman during gestation or at delivery. The providers must:

- provide the woman with a resource list of the names, addresses and phone numbers of professional organizations that provide

postpartum counseling and assistance;

- document that the patient received this information in the patient's medical record;
- retain this documentation for at least three years.

TDH recommends giving the information to patients at the first prenatal visit and again after delivery. For more information on HB 341 or postpartum depression, contact Chan McDermott, TDH Perinatal Health Program, 512-458-7796.

EMTALA changes implemented

The Centers for Medicare and Medicaid Services have published a final rule implementing changes to the Emergency Medical Treatment and Active Labor Act. Effective November 10, 2003, the changes are intended to make EMTALA more workable for doctors and hospitals.

Main provisions of the rule include:

- Hospitals have the discretion to develop their on-call lists in a way that best meets the needs of their communities — physicians will

be permitted to be on call simultaneously at more than one hospital and to schedule elective surgery or other medical procedures during on-call times;

- Hospital departments that are off-campus are not required to move patients to the main campus to provide the best emergency care when this would not be best for the patient;

- EMTALA does not apply to individuals who come to off-campus outpatient clinics that do not routinely provide emergency services or to those who have begun to receive scheduled, non-emergency outpatient services at the main campus. Other regulations and state laws cover the hospital's obligations under these circumstances;

- EMTALA does not apply after a patient has been seen, screened and admitted for inpatient hospital services, unless admission is made in bad faith to avoid EMTALA requirements.

The final rule was published in the September 9, 2003, *Federal Register*.