

the Reporter

Sticker shock

the high cost of legal defense

By Laura Brockway

“To date, \$12,292 has been paid in expense costs related to the defense of this matter. These costs may include (but are not limited to) such things as independent medical consultant reviews of the records, defense attorney fees, record retrieval and document copying services, court reporting services, defense expert fees and any costs associated with mediation of this matter.”

At the conclusion of every TMLT claim, the defendant physician is sent a letter detailing the final resolution of the claim, informing the physician how much was paid in indemnity to the plaintiff (if an indemnity payment was made), and how much was spent to defend the claim. Physicians seeing this final amount often react the same way patients do when they open a hospital bill and see the \$5 charge for an aspirin. Legal defense “sticker shock” is common, and has led many to ask why it costs so much to defend malpractice claims.

This article will discuss what legal expenses are, what factors affect legal expenses and what TMLT does to control costs. Please note, for purposes of this article, “legal expenses” includes all costs associated with defense of a claim and does not include costs for indemnity payment.

Legal expenses

Legal expenses — just like all of life’s expenses — add up. Generally, legal expenses include court costs and legal fees. Court costs include record retrieval fees, court reporting fees for depositions, filing fees, ad litem fees, and mediation fees.

Legal fees include the hourly fees for the defense attorney and his or her staff to perform tasks such as preparing for and taking depositions; researching appropriate law; reviewing medical records, expert witness and codefendant depositions; attending conferences and interviews; corresponding with clients; preparing for mediation; preparing for and trying the case; and handling mandamus actions and appeals (when necessary). There are also travel expenses, delivery expenses, costs for paralegal services, expert fees, and costs to create trial exhibits.



Bill Abernethy, a Corpus Christi defense attorney, has been working with TMLT for 15 years. In defending medical malpractice cases, Abernethy says the most time-consuming aspect involves reviewing the medical records and understanding the medicine. “I like to have a good understanding of what’s going on so I can discuss the issues with my doctor and come up with the defense plan. That initially is the most time consuming — getting into the chart and understanding the medicine,” he says.

For Dallas defense attorney Bill Chamblee, who has been working with TMLT since 1988, some of the most time-consuming activities occur during the “second stage” of the lawsuit. “This middle stage of a lawsuit is depositions, supplementation of discovery, obtaining information on the plaintiff and plaintiff’s experts — their prior depositions, their qualifications, their prior lawsuits — and reviewing all that material. You may get in 20 depositions,” he says. “You have to obtain and review all this information to cross examine the witnesses at their depositions. You then have to prepare all of your witnesses for their depositions.”

continued on page 2

Preparing for trial can also be an arduous and time expending process.

"You're two weeks away from trial and you've got a file that's taken a year or two to accumulate. You may have 15 to 25 boxes of information to reabsorb and redigest. You have to read every single word of every single deposition, read all the medical records, read all the expert's prior depositions. You also have to reread the medical literature which might be 2,000 pages," Chamblee says. "Once you have reabsorbed and focused on that information, you have to write out your questions for voir dire and your opening statement. You have to prepare and put together your questions for the cross examination of plaintiffs, cross examination of experts and other witnesses, and prepare your witness. You have to do all this correctly and do it thoroughly and without fail to be in the courtroom and defend your physician against someone who has just done the same thing."

What affects legal expenses

Defending malpractice claims can be a costly and complex task. TMLT tracks the cost of legal defense from year to year based on average loss adjustment expenses (LAE). In 2003, average LAE per medical malpractice claim was \$23,244, up from \$22,485 in 2002. Any number of factors can affect these costs, and not all of these can be easily controlled.

- Cases involving multiple codefendants (other physicians, nurses, hospitals) are generally more complicated and cost more to defend. All defendants and all experts must be deposed. "We had one case where the plaintiff named 12 experts, the hospital named 18 and we named two. This invoked a tremendous amount of time to get those depositions from experts from all over the country," says Abernethy.

- The length of the life of a claim also affects costs. At TMLT it costs an average of \$1,376 in legal expenses to close a case in the claim stage before it goes into suit, and it costs an average of \$28,032 in legal expenses to close a claim once it moves to suit phase. "The difference in cost is from the time spent investigating the claim and preparing a defense," says Bob Fields, executive vice president, claim operations.

- Cases can also be prolonged when judges grant unwarranted or unwanted continuances. Each continuance represents time spent preparing for trial. "It is very seldom that we can get to trial on the first setting. The courts are too busy and you get bumped," says Abernethy.

- The style of the plaintiff's attorney and his or her discovery practices affects defense costs. "Some attorneys do not cooperate during discovery and we must go before the judge to get even the things we are unquestionably entitled to have. This takes time and costs money," says Jill McLain, vice president, claim operations.

- Another variable that affects legal expenses is the difficulty encountered obtaining medical records. "We cannot conduct a thorough investigation without the medical record," says Sue Mills, assistant vice president, claim operations. "In some cases, we need copies of records from the hospital, from previous physicians, and from subsequent physicians. Any delay in securing these records means the defense of the case is delayed."

- Finding independent medical consultants and expert witnesses can also take time and money. "Finding and locating the right expert witness is very time-consuming, and I emphasize the word 'right,'" Chamblee says. "Lots of people use experts who do not have the right background or who testify too much. In most of our cases, we want experts who have never been experts before, who do not know the doctor or our firm, and who are local. You have to recreate the wheel each time."

"Why don't you just settle?"

Any discussion involving legal expenses and how much it costs to defend physicians invariably leads to the question "wouldn't it be cheaper to just settle claims?" The answer to that question is a simple and resounding "no."

"Our experience over 25 years is a philosophy of looking to defend before we look to settle. We do not pay nuisance settlements and we do not pay early just to get rid of claims and reduce legal expenses," says McLain. "Settling nonmeritorious cases takes all the risks of litigating those cases out for the plaintiff's attorneys. If they face no financial downside to suing, they will be encouraged to sue more doctors."

TMLT's "look to defend" philosophy also saves money. "We defend claims that we believe should be defended but if we opt to settle, we don't pay outrageous demands. If we paid what was initially demanded of us, we would not be here for our policyholders," says Fields.

In 2002, TMLT conducted the "demands project" which involved gathering information on the initial, highest and lowest demands for claims closed in 2002. Of the 1,552 claims closed, TMLT paid \$44.9 million in indemnity on 223 files. The demands on these same 223 files were: \$81.1 million (total initial demand); \$103.2 million (total highest demand); and \$46.1 million (total lowest demand). On the remaining files that closed with no indemnity payment, the demands were: \$102.6 million (initial demand); \$108.1 million (highest demand); \$62.2 million (lowest demand).

There are also other practical reasons for not settling claims early. "We cannot always settle in the beginning without incurring legal expenses. We must perform a thorough investigation, which often involves obtaining medical records, expert opinions, depositions, etc., to determine whether our defendant doctor's treatment met the required standard of care," says Mills.

Additionally, TMLT cannot settle a claim without the consent of the policyholder. "There are serious consequences that occur when we make a claim settlement. That information is reported to the National Practitioner Databank and the Texas State Board of Medical Examiners. It can also adversely affect the doctor's future credentialing and insurability. We have to keep that in mind when considering settlement," says Fields.

Controlling costs

After 25 years and 33,000 claims, the TMLT claim department has developed a successful system to keep defense costs in check. "We control legal expenses better than other carriers. Our legal expenses per policyholder are less than our competitors, and we pay less in indemnity settlements per policyholder," says Fields.

Specifically, TMLT controls legal costs by auditing all legal bills; working with experienced law firms; paying fair and reasonable legal fees; and having claim supervisors work as a team with defense attorneys.

"With our claim supervisors and attorneys, we have developed experienced defense teams. These teams are talented and experienced and they are the reason for our successful trial record and the reason we are able to achieve optimal resolution of so many of our cases," says McLain.

TMLT defense attorneys value and appreciate the experience TMLT claim supervisors bring to the process. "It is very refreshing to work with TMLT. They keep up with the medicine and understand all aspects of the case and keep on top of it. That makes our job easier," says Abernethy. "TMLT likes to have experienced lawyers working for them who have learned what needs to be done and what does not need to be done. This saves everyone time and money."

continued on page 12

TMLT risk alert



FDA UPDATE ON THE USE OF ANTIDEPRESSANTS

June 2004

On March 22, 2004, the Food and Drug Administration took action to modify the labeling for antidepressant medications to include a warning statement to encourage close observation of adult and pediatric patients treated with these agents for worsening depression or the emergence of suicidality. The FDA Public Health Advisory included the following comments regarding guidelines for the use of these medications.

- Health care providers should carefully monitor patients receiving antidepressants for possible worsening of depression or suicidality, especially at the beginning of therapy or when the dose either increases or decreases. Although the FDA has not concluded that these drugs cause worsening depression or suicidality, health care providers should be aware that worsening of symptoms could be due to the underlying disease or might be a result of drug therapy.
- Health care providers should carefully evaluate patients in whom depression persistently worsens, or emergent suicidality is severe, abrupt in onset, or was not part of the presenting symptoms, to determine what intervention, including discontinuing or modifying the current drug therapy, is indicated.
- Anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia (severe restlessness), hypomania, and mania have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although FDA has not concluded that these symptoms are a precursor to either worsening of depression or the emergence of suicidal impulses, there is concern that patients who experience one or more of these symptoms may be at increased risk for worsening depression or suicidality. Therefore, therapy should be evaluated, and medications may need to be discontinued, when symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.
- If a decision is made to discontinue treatment, certain of these medications should be tapered rather than stopped abruptly (see labeling for individual drug products for details).
- Because antidepressants are believed to have the potential for inducing manic episodes in patients with bipolar disorder, there is a concern about using antidepressants alone in this population. Therefore, patients should be adequately screened to determine if they are at risk for bipolar disorder before initiating antidepressant treatment so that they can be appropriately monitored during treatment. Such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.
- Health care providers should instruct patients, their families and their caregivers to be alert for the emergence of agitation, irritability, and the other symptoms described above, as well as the emergence of suicidality and worsening depression, and to report such symptoms immediately to their health care provider.

The complete Public Health Advisory and FDA Talk Paper are available at the FDA web site:
<http://www.fda.gov/cder/drug/antidepressants/default.htm>.

Physicians' duty to inform:

a guide to informed consent



Objectives

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

1. Recognize physician responsibility related to the doctrine of informed consent.
2. Identify barriers to informed consent and methods to overcome them.
3. Assess areas of vulnerability inherent in patient informed consent.
4. List prudent risk management practices relevant to informed consent.

Course author

Jane Holeman is the vice president of risk management at TMLT.

Disclosure

Jane Holeman 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 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 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 June 1, 2004, and expires on June 1, 2006. Please note this CME activity does **not** meet TMLT's discount criteria. Physicians completing this CME activity will not receive a premium discount.

Introduction

The right of self-determination has become increasingly prevalent in the law. The concept of "disclosure" goes beyond medicine. It is evident in many forms, from new labeling requirements for food products to financial statements issued by Fortune 500 companies. The concept presupposes that people should make decisions based upon a full understanding of all material information. Whether it is buying a box of cereal or consenting to a surgical procedure, the intent of the law is to create an opportunity for people to be fully informed. Therefore, providing information regarding treatments and procedures, including an explanation of the risks and benefits, will help prepare patients and improve physician defensibility in the event of litigation.

Studies have shown that patients, when questioned about preoperative informed consent discussions, remember little following their surgeries. More remember the promised benefits but few remember the risks.¹

In the context of medical malpractice, historically the patient deferred to his physician with respect to all treatment and did not question what was needed. With the expansion of the concepts of self-determination, patient's rights, consumer advocacy, etc., it should come as no surprise that the historical notion of total deference to the physician has been abandoned. In its place has come the doctrine of consent, followed by a more sophisticated and refined definition of informed consent.

Physicians are often overburdened and work in an unpredictable environment. That unpredictability can create unrealistic patient expectations that may lead to medical malpractice claims. According to attorney Linda Crawford, who has taught trial advocacy at Harvard Law School, "... lawsuits are not about bad outcomes . . . they are about expectations."²

A claim alleging lack of consent begins with patients stating that they had not consented to the treatment rendered by their physician. The law traces these complaints to the turn of the last century. For example, in 1906, an Illinois woman sued her doctor contending she had never given permission for the removal of her uterus (*Pratt v. Davis*). Eighty-four years ago, a Texas doctor was held to account for operating on a child without parental consent (*Moss v. Rishworth*). These and other cases treated the doctrine of consent like a light switch. It was either on or off. Consent had either been given or it had not.

Consent is no longer so simple. It is not enough that the patient gives consent to a procedure or treatment. The patient must now give consent based upon facts and information necessary to render an intelligent decision. Hence was born the concept of "informed" consent. The hallmark case of *Salgo v. Leland Stanford, Jr. University Board of Trustees* recognized the duty of a doctor to tell the patient all the facts necessary to render his decision. As a consequence, informed consent litigation burgeoned and physicians quickly became the targets of claims that the consent obtained was not informed and, therefore, tantamount to no consent at all.

Informed consent in Texas

Texas recognizes that consent for treatment must be obtained and that consent be "informed." In 1977, the Medical Liability and Insurance Improvement Act (referred

to as "article 4590i") became law. This statute was passed by the Texas legislature and was an attempt to put in writing the legal requirements of Texas physicians regarding informed consent. As will be explained later, the statute has since been the subject of many interpretations by the courts, further refining our understanding of this statute. In September 2003, the informed consent statute that was codified in article 4590i was moved to Chapter 74, Subchapter C of the Texas Civil Practice and Remedies Code.

The informed consent statute itself is rather simple. It states the following:

"In a suit against a physician or health care provider involving a health care liability claim that is based on the failure of the physician or health care provider to disclose or adequately disclose the risks and hazards involved in the medical care or surgical procedure rendered by the physician or health care provider, the only theory on which recovery may be obtained is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent."

The statute views informed consent as a negligence issue. The law focuses on a hypothetical, reasonable physician and what that physician normally would or would not tell a patient regarding any treatment. This is not to say, however, that the statute has abolished any claims other than those alleging negligence. For example, a battery claim could still be filed if the physician got no consent whatsoever. It is important to note the difference between consent and informed consent. It requires that the physician properly inform the patient.

Focusing on the concept of the adequacy of the consent (informed consent), a Texas physician needs to know what the patient must be told in order to satisfy the duty to properly inform that patient. It is often difficult and complex to know what is enough information to tell the patient so that their decision is now "informed."

Article 4590i created the Texas Medical Disclosure Panel, composed of six physicians and three attorneys. It is an administrative attachment to the Texas Department of Health (TDH). The panel is supposed to review all treatments and procedures to determine which procedures require disclosure and which do not. Those matters requiring disclosure are put on List A. Those matters that do not require disclosure are identified in List B. The panel periodically examines new treatments or procedures and assigns them to a particular list. A current list is published in the *Texas Register* and in the Texas Administrative Code, accessi-

ble on the internet at www.sos.state.tx.us.

As stated above, List A represents those treatments or procedures which the panel has decided require disclosure to the patient. The panel identifies the particular risks that should be disclosed to the patient. The panel also identifies the manner in which the risks are to be disclosed to the patient.

The panel created consent forms that must be utilized for certain List A procedures. Specifically, the Medical Disclosure Panel created consent forms for 1) General Disclosure and Consent (25 Texas Administrative Code, Section 601.4); 2) Radiation Therapy (Id, section 601.5); 3) Electroconvulsive Therapy (Id. Section 601.7); and 4) Hysterectomy (Id, section 601.8). Additionally, as of January 1, 2004, a patient contemplating an abortion must be provided informational materials created by the TDH. Prior to obtaining an abortion, a patient must sign the informed consent form created by TDH.

The statute states that consent is effective if it is:

- in writing;
- signed by the patient or person authorized to give consent;
- signed by a competent witness; and
- the consent specifically states the risks and hazards involved in the care or procedure in the form and to the degree required by the panel.

If the physician complies with the panel's requirements as to List A procedures, there is a substantial legal benefit derived. The statute states that the jury will be made aware of this law and instructed that the law presumes in favor of the physician who has properly obtained consent. By the same token, a physician who does not comply with the requirements of disclosure for List A procedures will be in the unfortunate position of hearing the jury told that the law presumes he did not comply with Texas law regarding informed consent.

List B procedures require no written consent. If a proposed treatment or procedure is on List B, there is no requirement that disclosure of risks be made to the patient. While there is no statutory requirement for physicians to disclose various risks to procedures on List B, it is usually prudent to discuss the risks and benefits of those procedures with patients and document that discussion in the medical record.

Many treatments or procedures do not appear on either List A or List B. The law states the physician is under the duty of disclosure "otherwise imposed by law." The law is very vague in this regard and most lawyers refer to this as the hypothetical "List C" procedures. Although there is no

“List C,” it is convenient to refer to it for all those procedures and treatments not specifically identified on List A or List B. These include medical treatment as well as surgical procedures. Any material risk associated with medical treatment should otherwise be disclosed to the patient.

The difficult questions are: what disclosure needs to be made for a “List C” procedure and what is the duty “otherwise imposed by law?” The law provides only a little guidance. It states that a physician should disclose what a reasonable person would want to know in giving or withholding consent. In *Peterson v. Shields*, the Texas Supreme Court held that this means the physician must identify “the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.” It is extremely important for the physician to understand the focus of this law. It is on the patient, not the physician. In other words, it is not what the physician thinks the patient should know. It is what a reasonable patient would want to know in making the decision. Therefore, a benevolent physician seeking to spare patients from a discussion of grisly, but remote risks cannot avoid liability by saying the information was withheld for the patient’s benefit. Disclosure is important, indicating that the risk could have influenced a reasonable patient in making a decision, not whether a reasonable doctor should or should not disclose the risk to the patient.

Only “material” risks must be disclosed (*Barclay v. Campbell*). This means two things. The risk must be inherent to the procedure undertaken, and it has to be the type of risk that could influence a person in making a decision. Therefore, if a reasonable person could be influenced in the decision to undergo a treatment or procedure by disclosing a risk inherent to that treatment or procedure, then that risk must be disclosed.

What could influence a reasonable person must be determined on a case-by-case basis. A risk of one in a million probably need not be disclosed. However, a risk of one out of a thousand probably should. It is generally best to err on the side of caution and let each patient decide what is, or is not, material to him.

In summary, Texas informed consent practice is now governed by statute; Sections 74.101-74.107 of the Texas Civil Practice and Remedies Code. When offering any treatment or procedure to a patient, the physician must make these determinations:

- if the treatment or procedure appears on List A, then the disclosure specified by the panel must be followed.
- if the treatment or procedure appears

on List B, no disclosure is legally required.

- if they appear on neither List A nor List B, the physician must then disclose all material and inherent risks, which could influence a patient in making a decision.

Although List A procedure disclosures must be in writing, nothing is specified regarding List B and “List C” procedures. Physicians may choose to follow the List A approach to the List B and “List C” procedures and document the disclosure in writing. This may be accomplished either with a consent form witnessed by a competent adult, or with a physician note documenting the risk/benefit discussion in the medical record.

Obtaining informed consent is a non-delegable responsibility of the physician. Documentation of the informed consent discussion will assist in the physician’s defense in the event of litigation. The note should indicate that the physician personally conferred with the patient, explained the risks and benefits, as well as alternatives to the procedure or consequences in failing to authorize the procedure. It is important to note that hospital consent forms do not replace the physician’s informed consent discussion with the patient.

Closed claim study: failure to obtain informed consent

The following closed claim study illustrates the importance of obtaining informed consent, including the discussion and documentation of the risks, benefits and any alternatives available to the patient.

Clinical presentation

A 36-year-old man with a history of excessive sweating on his hands presented to a thoracic surgeon for treatment of his hyperhidrosis. The patient had seen an ad in a magazine in which the surgeon indicated several treatment options for persons with hyperhidrosis. The patient told the physician the condition had been a life long problem, which affected him socially and professionally. The patient said he had tried numerous medical therapies with no success, and he came to the physician to learn more about sympathectomy.

Physician action

The physician told the patient what a sympathectomy was, and recommended a bilateral T2-T3 thoroscopic sympathectomy be performed. The procedure was performed by the thoracic surgeon. Postoperatively, the patient developed severe hyperhidrosis of his hands, axillae and feet.

The patient consulted a dermatologist who told him the sympathectomy was irreversible, and he would be combating this condition for the rest of his life. The patient was referred to a neurologist for a second opinion, and the neurologist was unable to help him. The patient then went to see his cousin, a general practitioner, who told the patient having the surgery was a mistake.

Allegations

Allegations in this case included:

- failure to offer other non-surgical treatments for hyperhidrosis;
- failure to inform the patient of the risks and complications of the bilateral T2-T3 thoroscopic sympathectomy; and
- alteration of the medical record.

Legal principle

The plaintiff’s attorney made it clear during mediation that he would suggest that the physician was operating a surgery mill, cranking out dozens of these operations. In this regard, there is some indication that the plaintiff’s attorney intended to make the physician’s web site an issue. In addition, there was the magazine ad that initially brought the patient to the physician’s office.

The plaintiff’s expert was also critical of the physician’s failure to obtain informed consent. One of the physician’s own articles on sympathectomy states that compensatory sweating occurs. The expert felt this was a significant complication, one that required full discussion with the patient.

Informed consent is defined by two legal doctrines — fiduciary relationship and self-determination. Fiduciary relationship requires a physician to inform and advise the patient in an understandable manner of the risks and treatment. Self-determination is the patient’s right to agree to or refuse treatment to the extent the law allows. A physician may be liable for damages proximately caused by the failure to obtain informed consent, or if the patient does not receive adequate information which is necessary to make a truly informed decision.

Further complicating this case was an alteration of the patient’s medical chart by the physician. Some time after the surgery occurred, the physician made a late entry on the page referencing the risks and complications involved with the bilateral thoracic sympathectomy.

Disposition

Although the patient most likely did suffer from compensatory hyperhidrosis, a known complication of this type of surgery, it can be argued that this type of injury does not have a persuasive, visceral appeal to a jury that would result in a large award.

In this particular case, it was principally the alteration of records that weighed against the physician. The record was changed expressly to add an indication that the patient was warned preoperatively about the very surgical complication he developed. It could be persuasively argued that, since the physician admitted altering the medical records, there is a strong possibility that he did not advise the patient of the complications or inform him of other nonsurgical treatments available.

This case was settled prior to trial.

Risk management considerations

The physician's duty to obtain informed consent prior to a treatment or procedure is nondelegable. In order to protect against an allegation of failure to obtain informed consent, physicians must both educate patients as to known complications and alternative forms of treatment as well as document these efforts. Regarding discussions between physician and patient, the physician should at minimum make a reference to this conversation in his office notes. A suggested method of documentation is:

"Advised patient of the need for () due to (). Discussed risks, benefits and alternatives. Patient reviewed educational materials/instructions and states he/she understands and agrees to proceed. It is my judgment that the patient does understand and accept the treatment plan."

In addition to face-to-face interaction, patient education can take the form of pamphlets, handouts, videos, and pre- and post-treatment instructions. Any form of patient education should be documented in the medical record to verify the patient was provided pertinent information regarding his/her care and was given information needed to make informed decisions. If your practice routinely provides certain education materials, you may want to consider making a standardized list of such materials to incorporate into patients' charts. In addition, consider having the patient sign a form acknowledging that he/she has been provided these materials and had the opportunity to ask questions.

In some situations, it may be obvious there is a direct relationship between the procedure and the resulting complication. Preprocedure documentation of the true necessity for the procedure may protect against a challenge to consent. For example, assume an appendectomy carries a one percent risk of infection, and a patient presents with clear appendicitis on the verge of rupture. The appendix is removed. The patient develops an infection resulting in a stormy postoperative course. The patient files suit alleging they did not understand

the significance of the one percent risk of infection.

In this situation, a jury would be asked to determine whether or not the patient would have refused the procedure if he had been informed of that one percent risk. Would a reasonable person rather take the near 100 percent certainty of a ruptured appendix, peritonitis and an agonizing death over the one percent chance of a post-operative infection? Any reasonable patient would have willingly agreed to the appendectomy. Therefore, the jury would likely find in favor of the physician even if the patient convinced them that he was not informed or not adequately informed about the risk of the appendectomy. The jury would likely conclude that, had the patient been informed, most likely he would have consented. The actual legal test is not whether this particular patient would have consented, but would a "reasonable patient" have consented.

It is important that physicians document in the medical record the necessity of any treatment or procedure prior to its administration or performance. Documenting that other reasonable or viable options, if any, were considered is beneficial to both patient and physician. This is applicable in emergent situations as well as in those situations in which it can be shown the patient has exhausted other options.

Barriers to informed consent

In complying with Chapter 74 of the Texas Civil Practice and Remedies Code, physicians are presumed to have obtained informed consent. However, this presumption can be overcome if the patient produces evidence to the contrary i.e., that he was not properly informed even though his signature appears on the permit. There are barriers to informed consent that patients may use to establish that their permission was truly not informed and, therefore, permission had not been given.

Impaired mental status

Lawsuits have been filed in which the patient contends his mental status was such that he was not in a position to comprehend the explanation of risks and benefits. This mental handicap may be permanent (as in the form of retardation), transient (as in the form of intoxication or drug impairment), or somewhere in between (as in the form of a severe but treatable mental illness). In these cases, the plaintiff interjects doubt as to his mental acuity at the time the consent was signed.

Patients may sign the operative permit while under the influence of narcotics or other mind-altering drugs administered

during their inpatient stay. Even patients seen in the office may be on medication known to cause cognitive impairment. To protect against those contentions, a physician can reduce risk by considering the following measures:

- Document the patient's mental acuity at the time of the risks/benefits discussion. A brief note reflecting that the patient was awake, alert, participated in the discussion and asked appropriate questions, comprehended the discussion, etc., will assist in defense in the event of litigation.

- Involve family members in the informed consent discussion. This is especially important when the patient is cognitively impaired or under the influence of medication known to cause cognitive impairment. In certain situations, it may be necessary to obtain consent from a family member or designated legal representative.

- Consider incorporating a brief statement within your forms that the patient fully comprehends the risks of the procedure and is not subject to any medication, illness, or other impairment which might affect his ability to comprehend or understand.

- Consider including an addendum above the witness' signature in which the witness certifies that the patient signed the document and that the patient was alert, comprehended the discussion and voluntarily signed the permit.

Language

Understandably, it is difficult to maintain the presumption of disclosure when the patient presents evidence that he cannot speak English, and the permit is entirely in English. The jury may believe the patient just signed whatever was placed in front of him.

Texas law requires that the consent form for hysterectomy be available in both English and Spanish. The Spanish version is available from the TDH. The Consent Form and Informational Materials for abortion must also be in English and in Spanish. The TDH must provide these materials at no cost on request. The forms and materials are also available on the TDH web site, www.tdh.state.tx.us. Although these are the only two procedures that statutorily require bilingual consent, the law requires that informed consent be obtained in accordance with the Medical Disclosure Panel specifications.

Illiteracy

It is dangerous to assume that all patients can read. Be observant for indications of illiteracy. It may be more than a simple "X" instead of the patient's signature. Did the patient complete the forms himself? Do the answers on a new patient questionnaire

appear to be in a different handwriting? Does the patient sign the form without even looking at its contents? Claims have been filed in which patients allege they cannot read or write, regardless of the language, and signed the consent form only because they were too embarrassed to admit illiteracy. Again, it is difficult to convince the jury that the patient was adequately informed of the risks as evidenced by the signed permit when the patient and his entire family come into court and establish the patient has never learned to read.

In these situations, the permit must be read to the patient in the appropriate language. The person who reads the permit should also sign the permit certifying that they accurately and completely read the form to the patient who then expressed his comprehension.

Disability

Physicians frequently encounter hearing-impaired and vision-impaired patients. Some may contend that it was too difficult to read the small print on the consent permit. Since most juries understand the concept of “fine print,” they may be receptive to the notion that the patient really was not informed because the print was too small and not easily seen. Likewise, the Americans with Disabilities Act (ADA) prohibits discrimination against disabled individuals.

Overly-complex forms

Consent forms have been challenged on the basis that the contents were too technical and beyond the scope of the patient’s understanding. A patient may understand the consequences of “infection,” but not the significance of an “electrolyte” imbalance. A patient might understand that a cardiac medicine may “cause more arrhythmias” but not understand that the medicine might be “proarrhythmic.”

Techniques to overcome barriers

- Use bilingual consent forms. Bilingual forms and interpreters are both appropriate methods to use in obtaining informed consent from non-English speaking patients. However, the physician remains responsible for ensuring that the patient understands the information presented on the forms. When interpreters are used, they should certify in writing that the form was accurately and orally translated and read in the language of the patient, who expressed comprehension of the translation.
- Use large print forms.
- Give the consent form to a couple of

sixth graders. After they have read it, ask what they understand about the procedure.

- Be aware of the timing of the patient’s signature. Verify the patient has not recently received any medication that might adversely affect the patient’s cognitive abilities. Office notes or hospital chart progress notes should document the patient’s mental status at the time the permit is signed.

- Interpreters for hearing-impaired patients may be legally required under the ADA. The fact that the expense of an interpreter may not be cost effective is legally irrelevant. Generally, the law requires that an interpreter be provided. When using handwritten notes to communicate with patients, include the notes in the patient’s record. Also document that the patient was satisfied with that mode of communication, did not request an alternate form of communication, and expressed comprehension of your written communications.

Patient education materials

Many physicians use brochures, other printed material or videotapes to supplement the informed consent discussion. It is important to review such materials to ensure that they appropriately convey the likelihood and severity of all inherent risks. Caution should be exercised in using materials that tend to downplay or otherwise understate the significance of the risks to which the patient is being exposed. Some risks may be characterized as too remote or more of an annoyance as opposed to a potentially life threatening development. Overly optimistic brochures may give patients the opportunity to argue that they would not have signed the consent if they had known the risks were more likely or more serious than what had been portrayed.

Good risk management strategies suggest that you or your staff document the receipt of printed material by the patient or the viewing of a videotape in the office or hospital. Documenting the receipt of such information by each individual patient may improve defensibility by indicating that the patient was properly informed.

General risk management

In assessing risks related to informed consent, the following checklist may be helpful. It is not all-inclusive, but represents common areas of vulnerability.

- Do you personally counsel each patient regarding the risks of a procedure as opposed to a nurse or physician’s assistant?
- Do your office notes or hospital progress notes collectively suggest that a reasonable

person would, in all likelihood, consent to the offered treatment?

- Do your office or hospital progress notes clearly indicate that the patient was informed of the risks, benefits and alternatives of the offered treatment, and that the patient expressed a desire to proceed?

- Do you know the content of the forms used at the hospital to which you admit your patients? Have you read them within the past year?

- If you use consent forms in your practice, are they easy to understand? Can a person with less than a high school education easily read and comprehend the contents?

- Do you use the consent forms required by the state of Texas?

- Do you have bilingual forms for non-English speaking patients? If not, do you always have a translator certify in writing that the form was accurately translated for the patient?

- Does your informed consent process go beyond merely surgical or invasive treatment but also extend to any medical treatment that has inherent risks?

- Do you have written documentation establishing the mental competency of the patient at the time consent is given?

- Does all auxiliary information made available to your patients (brochures, videotapes, etc.) fairly and accurately portray the risks of the procedure rather than understate such risks?

- Do you regularly review the Texas Medical Disclosure Panel List A to verify that your forms comply with the Panel’s most recent requirements?

Informed consent is not a static legal principle. This doctrine continues to evolve and change as new laws and new cases further shape the parameters and content of what constitutes informed consent.

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risk management consult

Q: A colleague of mine recently had a lawsuit dismissed “with prejudice.” What does this mean?

Answer: *Black’s Law Dictionary*, 6th edition, defines “dismissal with prejudice” as a term meaning a formal judgment and final disposition, barring the plaintiff the right to bring or maintain an action on the same claim or cause. It is a final judgment as to every allegation by the plaintiff because they have been found untrue or insufficient to entitle the complainant to the relief sought.

A “dismissal without prejudice” means the plaintiff may sue again on the same cause of action. There is no barrier to a subsequent suit.

Q: If I close my practice and move to another state, what is my responsibility for maintaining medical records?

Answer: It is the physician’s responsibility to secure records for future accessibility and assure their retention in accordance with state guidelines. In Texas, the adult record must be kept for seven years from the date of the last encounter. The record of a minor (a person under 18) must be retained for seven years from the date of the last encounter or to age 21, whichever is longer. The records of deceased patients should be kept for a minimum of two years. Hospitals are required to keep records for 10 years. Consequently, physicians may choose to keep office records for 10 years as well. Medical records that relate to any civil, criminal or administrative proceeding may not be destroyed until the physician knows the proceeding has been fully resolved.

Medical records that satisfy retention requirements may be destroyed by shredding or incineration. Do not dispose of records in dumpsters or landfills. If a vendor is used for disposing of medical records, have a HIPAA nondisclosure agreement signed.

To avoid issues of abandonment relevant to continuity of care, adequate notice should be given to the patients to select another physician and sign an authorization for release of the record to their new physician. The notice should include where the records are maintained and how to make future requests after your move. **Do not** give original records to a patient! You may establish a custodian for the records. The county medical society may know of companies that provide this service.

Whether a physician retires, sells or closes his/her practice, and/or moves out of state, the process can be complicated and time-consuming. The TMA Office of General Counsel has developed a booklet to serve as a guide to physicians, their lawyers and accountants. Visit the TMA web site at www.texmed.org. The title of the booklet is *Transitions: Legal Considerations in Selling or Closing a Medical Practice*.

Q: What constitutes abandonment?

Answer: “Actionable abandonment” occurs when the physician unilaterally terminates the physician-patient relationship without a period of notice that affords that patient a reasonable opportunity, under the circumstances, to locate another physician; and, the patient is able to prove damages caused by the physician’s wrongful conduct.

The key issues here are a lack of reasonable notice and the necessity of continuing medical treatment.

Q: I am a surgeon and some of my patients want medical advice that is outside my specialty. They want to see me about everything since I have been “their” doctor for 20 years. I know they need advice, but

they are reluctant to find the proper physician. What is the best way to help these patients?

Answer: You can put yourself in a risky situation by practicing outside your specialty. You and your office staff should be very clear with patients about the limits of your practice. Advise patients and provide resources to find physicians in appropriate specialties, such as county medical societies or physician referral services. Instruct patients on the importance of follow up for the condition in question and the potential consequences of delaying treatment. Document this information in the patient’s chart.

The situation could be handled like this:

“Mr. Smith, I appreciate the trust you have in me, but I do not treat stomach problems. I want you to get the right treatment from the right doctor. Let me give you the number to the doctor’s referral service at the hospital.”

Q: If we receive a request for medical records, does this include billing records?

Answer: According to the TSBME, in response to a proper request for release of medical records, a physician shall not be required to provide copies of billing records pertaining to medical treatment of a patient unless specifically requested pursuant to the request for release of medical records.

Please email your risk management consult questions to barbara-rose@tmlt.org.

closed claim study

Failure to diagnose meningitis

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 physician's 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 case, please be assured it is presented solely to emphasize the issues of the case.

Presentation

A 14-year-old girl presented to her family physician complaining of nausea, vomiting, bodyaches and fever. The patient had been receiving treatment from this physician for five years. Her medical history included upper respiratory tract infections, ear infections, skin rash and episodic fevers.

Physician action

The patient was first examined by a third-year medical student who was on rotation in the physician's office. The family physician then examined the patient and determined her complaints were consistent with a flu-like syndrome and/or gastritis. The chart reflects absent signs of meningismus (pain on flexion of chin to chest) and negative Brudzinski and Kernig's signs. The patient had redness and swelling of the pharynx, mild tachycardia, and a temperature of 101.4 degrees. A CBC revealed a white blood count of 15,800. The patient was sent home with prescriptions for zanamivir, cefprozil and promethazine. The patient's mother was instructed "go to the ER if headache pain worsened. Discussed with patient and mother the need for follow up if pain, headache or other symptoms worsen."

In his later testimony, the physician recalled that he recommended a lumbar puncture to rule out meningitis, but the mother declined to have the test performed. This exchange was not noted in the chart.

The medical student, who was present during the exam, later remembered the discussion about taking the patient to the ER for a lumbar puncture. He recalled there was a money or insurance problem and the mother was reluctant unless it was necessary. The physician had the mother agree to take the child to the ER if her symptoms worsened or did not improve the following day.

Two days later, the patient experienced a clonic-type seizure at home and became unresponsive. She was taken to the ER, and was unresponsive upon arrival with agonal respirations. Her left pupil was fixed and dilated, and her temperature was 105 degrees. She coded in the ER, was intubated, put on ventilator support and admitted to ICU. A head CT revealed diffuse cerebral edema. She never regained consciousness.

Consultations were obtained from infectious diseases, neurology, pulmonology and nephrology. The initial diagnosis was meningococcal meningitis and septicemia. All blood cultures showed no growth and viral cultures were negative. Serum antigen tests for *Neisseria meningitidis*, *Escherichia coli*, *Haemophilus influenzae*, *Streptococci pneumoniae* and group B streptococci were negative. An EEG revealed no brain activity. The patient was declared brain dead and, after parental consent, was removed from the ventilator.

A limited autopsy of the central nervous system revealed brain stem herniation, necrosis of the pituitary gland and yellow exudate in the left frontal region, meninges, and cerebrum. Special stains for bacteria and viruses were negative. It was unclear which type of meningitis the patient had, and the pathologist noted the cause of death to be "acute pyogenic meningitis."

Allegations

The allegations in this case included:

- failure to perform a neurological exam;
- failure to insist on a lumbar puncture, which would likely have caught the patient's bacterial meningitis;

- improper administration of antibiotics prior to performing a lumbar puncture;
- failure to diagnose and treat meningitis.

Legal implications

The plaintiffs were able to locate expert testimony to support their allegations. The expert claimed that it was below the standard of care for the physician not to insist on a lumbar puncture. If the physician suspected meningitis, then he failed to adequately counsel the patient's mother that the test was necessary to rule out meningitis. If a lumbar puncture had been performed on the day of the office visit, according to the plaintiff's expert, it would have been diagnostic of bacterial meningitis and led to appropriate, immediate hospitalization and definitive intravenous antibiotic therapy. "At this stage of the disease process, the illness is usually curable and this is the reason that LP and/or hospitalization is necessary when meningitis is suspected."

The expert also indicated the physician fell below the standard of care when he prescribed an antibiotic and an antiviral without identifying the etiology of the illness. The antibiotic, which made the patient feel better, masked the meningitis and contributed to the family's inability to determine that the patient was acutely ill until it was too late. (The patient's condition improved the day after the office visit, according to the mother.)

The expert also faulted the physician for not performing a complete neurological exam and for failure to document the results of his examination of the patient's neck.

Overall, defense experts were supportive. The physician's examination and diagnosis were reasonable and within the standard of care. Because it is difficult to differentiate viral syndromes from meningitis, it is the physician's clinical impression at the time of the exam that determines whether a lumbar puncture or further diagnostic work up is necessary. The patient presented with non-

continued on page 12

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In memoriam: Presley Howard Chalmers, MD

On May 4, 2004, TMLT lost one of its most beloved founders, Presley Howard Chalmers, MD, who died after a short illness. He was a TMLT board member for a total of 18 years, beginning his service with TMLT's organizational meeting in 1978. After his retirement in 1996, he continued to serve on both the claims and underwriting review committees. Dr. Chalmers was a very special man — patient, caring, and wise — who will be missed by all who had the privilege and pleasure of knowing him.

closed claim study . . . continued from page 11

specific symptoms suggestive of viral illness. She did not have a rash or a stiff neck; she was not photophobic; there was no neurologic deficit or signs of meningeal irritation. Based on these facts, it was reasonable not to have ordered a lumbar puncture.

Disposition

With the consent of the physician, this case was settled before trial for an amount in the low six-figures. While disputing the claim, he agreed to a compromise settlement to avoid the uncertainty of litigation.

Risk management considerations

The complete, comprehensive medical record is a chronological document of a patient's health status and care. In this claim, a consultant reviewer indicated the medical student took the history and performed the physical examination. The reviewer further indicated there was no documentation of another history and physical performed by the defendant, or it is unclear "who did what in the record" since the encounter form for the visit included three different writers. The physician signature line was signed by the student and the defendant in the style of a co-signature, medical student name/attend-

ing physician. Medical records need to reflect the identity of each person and clearly reveal what is done by those who are allowed to document information in the chart. If the physician repeated the physical exam, that is unclear in the encounter notes.

The failure to document the recommendation for a lumbar puncture and the refusal became a significant weakness in this claim. A complete medical record should include all the physician's advice. When a patient refuses a test or any medical advice, include that response in the notes. In situations where a refusal has potentially serious consequences, it is appropriate to have the patient sign an informed refusal form. When there is an adverse outcome, plaintiffs may subsequently claim they were not given enough information about a proposed test to make an informed decision and would not have refused.

Because lawsuits may not be filed immediately after the event, and the events surrounding the allegation of malpractice or negligence can recede from memory, timely, accurate and complete documentation on a consistent basis may become the physician's best defense.

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legal expenses . . . continued from page 2

The future

The exact effect Texas' medical liability reforms will have on legal costs is unknown. While all malpractice claims will incur costs, many predict the reforms will help weed out nonmeritorious cases early.

"We are going to see fewer cases filed because the recovery is not what it used to be," Abernethy says. "We may also see lawyers pursue these cases who don't know the rules and mess up with their expert reports. This will lead to a lot more dismissals where we don't have to defend . . . just move to dismiss."

TMLT has seen this in a number of cases. "During last summer's rush to the courthouse, 1,228 cases were filed. Of those, about 600 have already been dismissed because plaintiff's attorneys cannot find experts to certify the case. They filed suit without adequately verifying that they had legitimate cases. Legal expenses averaged under \$10,000 for each case," says Fields. "The new reforms will definitely have an effect. We are looking forward to defending our doctors under the new law."

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