

the Reporter

An ultimate risk management challenge:

anticoagulation therapy

By Laura Brockway

Warfarin is the most frequently prescribed anticoagulant, the fourth most prescribed cardiovascular agent and, overall, the 11th most prescribed drug in the U.S. It is a “high-alert” medication, a medication known to cause severe injury to patients when administered incorrectly. Warfarin is one of the most common drugs associated with medication errors and appropriate use has been identified as an important indicator of high-quality health care and patient safety.^{1,2}

“Of all available pharmaceutical therapies, coumarin anticoagulants such as warfarin represent some of the most difficult-to-manage and dangerous drugs prescribed to patients.”³

Conversely, the use of warfarin has been shown to reduce the risk of ischemic stroke significantly (68 percent by intention-to-treat analysis, 83 percent risk reduction by on-treatment analysis) in patients with atrial fibrillation.^{4,5} Its use is also indicated in the prevention of venous thromboembolism and in the prevention of acute myocardial infarction (AMI) in patients with peripheral arterial disease.⁶

Despite the evidence of its efficacy in the prevention of thromboembolic disease in a significant patient population, warfarin therapy is underused. Only one-third to a little more than half of patients with atrial fibrillation, who would be good candidates for warfarin therapy, receive it, with elderly patients the least likely to be treated.^{7,8} In 1995, the Agency for Health Care Policy and Research publicized a study showing

the underuse of warfarin in patients with atrial fibrillation costs \$600 million annually for 40,000 preventable strokes. The study further claimed a deterrent to warfarin use was that physicians feared its side effects.⁹

The side effects and risks include “a risk of other major hemorrhage of approximately 1.2 percent per year, a narrow therapeutic margin necessitating frequent coagulation monitoring to ensure appropriate dosing, and interactions with numerous foods and drugs.”

It is not only physicians who hesitate when it comes to the use of anticoagulation therapy. A study in the *British Medical Journal* found that fewer than 50 percent of patients with atrial fibrillation who were eligible to take warfarin for stroke prevention accepted it as treatment after the risks and benefits were explained.¹⁰

From a risk management standpoint, the use of anticoagulation therapy represents an ultimate challenge. Initiating anticoagulation therapy requires a thorough risk versus benefit analysis and patient discussion, meticulous patient monitoring, charting and follow up.

Risk versus benefit

“Because warfarin has a narrow therapeutic index and complex pharmacology, insufficient monitoring or errors in dosing can lead to severe and possible life-threatening bleeding and clotting in patients receiving it.”¹¹



The goal of anticoagulant therapy is to administer the lowest possible dose to prevent clot formation or expansion. The necessary degree of anticoagulation continues to change as studies provide up-to-date information on the efficacy and safety of lower doses. Current therapeutic goals for various disease states are available in the medical literature.¹²

“The safety and effectiveness of warfarin therapy depends critically on maintaining the INR (International Normalized Ratio) within the therapeutic range.” Research has shown a sharp increase in the risk of bleeding when the INR is higher than the upper limit of the therapeutic range and the risk of thromboembolism increased when the INR fell to less than 2.0.¹³

“After treatment is started, the INR response is monitored frequently until a stable dose-response relationship is obtained; thereafter, the frequency of INR testing is reduced. When dose adjustments are required, frequent monitoring is resumed.

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Some patients on long-term warfarin experience unexpected fluctuations in dose-response due to changes in diet, concurrent medication changes, poor compliance or alcohol consumption.”¹³

Long-term monitoring guidelines, algorithms for warfarin dose adjustment, and guidelines for the management of pregnant patients, elderly patients and patients requiring surgery are available in the medical literature.^{13, 14}

Medication errors and drug interactions

“In determining whether to treat a patient with warfarin, one of the major concerns is the risk of potential drug interactions. Drug interactions of varying severity have been identified with warfarin therapy. In most instances, the interacting drugs either inhibit or induce warfarin metabolism.” Warfarin can interact with a number of commonly prescribed and over-the-counter medications, such as acetaminophen, antibiotics, antifungal agents, NSAIDs, thyroid hormones, and oral contraceptives.¹⁴

In addition to drug interactions, travel, changes in diet, environment, and physical state may also influence how a patient responds to warfarin. “It is generally good practice to monitor the patient’s response with additional PT/INR determinations in the period immediately after discharge from the hospital, and whenever other medications are initiated, discontinued or taken irregularly. Medications of unknown interaction with coumarins are best regarded with caution. When these medications are started or stopped, more frequent PT/INR monitoring is advisable.”¹⁵

Medication errors involving warfarin can have devastating effects, as the following example illustrates. For a seven-week period in the summer of 2001, a hospital laboratory in Pennsylvania reported INRs that were falsely low. Some physicians who received these reports increased their patients’ doses of warfarin, and two deaths were associated with the laboratory error. An investigation later revealed the source of the falsely low INRs to be a calculation error.

“Laboratories should provide and physicians should consider using both the PT and the INR when contemplating a change in a patient’s warfarin dose. Incorrect laboratory reporting of INR results further contributes to the risk for complications of warfarin use.”¹⁶

Laboratory error should be considered if an otherwise stable patient experiences fluctuations of the INR that cannot be attributed to changes in diet, poor compliance, suspected drug use, alcohol consumption, and self-medication.¹⁷

Anticoagulation management

“Even though four decades have passed since warfarin was first used to prevent thrombo-embolic disease, studies continue to discover and refine techniques that make therapy with this agent safer and more effective.”¹⁷

Problems in the management of anticoagulation commonly arise when physicians and other providers attempt oversight without regularly scheduled anticoagulation appointments.

“Standing orders, which pay no attention to alterations in patient risk factors or the introduction of potentially interacting medications, direct laboratory technicians to run labs without clinical assessments. Lab results are then telephoned or mailed to the ordering office, and a physician orders therapeutic changes based primarily on INR results. With this type of anticoagulation care, adverse warfarin effects are addressed after they happen and the focus of care is diverted from patient symptoms and concerns to modifying laboratory results.”

In order to alleviate some of the most common problems in anticoagulation care, some larger group practices and health care systems use anticoagulation clinics to arrange and manage therapy. There is even some indication in the medical literature that patients treated at anticoagulation clinics spend more time within their therapeutic range and have fewer adverse outcomes than patients receiving “usual care.”¹⁸

For practices that do not have access to anticoagulation clinics or if they are not applicable, an article published in *Family Practice Management* offers some real-world solutions:

- Create a low-cost tracking system using a flow sheet and reminder notes. The flow sheet tracks the patient’s PT, INR, recommended dosage and date for rechecking the PT. Use scheduling software to create a reminder system for follow up.

- Designate one staff member as the person to make sure patients come in as scheduled and to track down no-shows.

- Consider the use of a hand-held, point-of-care anticoagulation device, which requires a finger stick instead of a blood draw. The test can be performed in the office and the results are available in minutes. The results can then be added to the patient’s chart for the physician to review and discuss with the patient.

- Visit anticoagulation clinics for ideas on improving systems within practices.¹⁹

Guidelines on the indications for warfarin use and the management of patients on warfarin are available from the American College of Chest Surgeons,¹⁸ the American Heart Association/American College of Cardiology Foundation,⁶ Bristol-Myers Squibb Pharma Company²⁰, and Barr Laboratories.²¹

Risk management considerations

“For any patient on long-term medication therapy, including anticoagulants, it is important to stay patient-focused. Lab results are important and continued monitoring is vital, but remember the patient behind all those lab results,” says Jane Holeman, vice president, risk management. “Consider what is happening with the patient’s entire health status when reviewing lab work and adjusting regimens.”

Other risk management considerations:

- Have tools in place to establish a process for tracking patients on anticoagulation therapy. These tools may include tracking logs, computer appointment software, dedicated personnel, etc.

- When a patient is on long-term anticoagulation therapy and changes in health status or life situation occur, frequent monitoring can help avoid problems. Significant changes can include hospital or nursing home admission, surgery, changes in diet or self-medication.

- Good communication between caregivers is another valuable tool for better management of patients on anticoagulation therapy. Problems can occur when a patient is admitted to the hospital or is scheduled for surgery. Determining and documenting who will manage the anticoagulation while the patient is in the hospital and who will resume the management after discharge will help avoid misunderstandings of who is in charge of that therapy at any given time.

- Patients appreciate open communication about their therapy. Documenting patients’ understanding of what they need to do, both routinely and after any changes (such as after a hospital discharge) is important for future reference.

- If you know your patient is scheduled for surgery, discussing anticoagulation therapy with the surgeon can provide valuable information that could impact his or her decisions and care.

- When first initiating anticoagulation therapy, educating patients can assist them in understanding the potential risks and benefits, in deciding to start therapy, and in complying with your instructions once therapy has begun. They will also better understand the need for monitoring, the need to get approval before taking other drugs, and any possible reactions they may experience. When indicated, including the patient’s family in the discussions is also a benefit. As always, documentation of your discussions will be a beneficial reference tool.

Sources

1. Summary of 2000 information submitted to MedMARx: a national database for hospital medication error reporting. Rockville, Maryland:

risk management consult

Q: I'm being sued. How do I report this claim to TMLT?

Answer: First and foremost, you must contact the TMLT claim department if you have received any of the following:

- **Notice of Claim** letter is a letter that refers to Chapter 74 of the Civil Practice and Remedy Code or indicates the intention to serve as a Notice Of Claim. The law provides that, upon receipt of a Notice of Claim, a physician and his or her insurer have 60 days to investigate and evaluate the claim before suit may be filed. Not all plaintiff's attorneys abide by this mandated abatement.

- **A lawsuit** will contain a citation, which informs you that you have been sued, and a petition, which lists the plaintiff versus the defendant(s), and provides narrative information about the allegations in the case. Once you are served with a citation and petition, there is a limited time to respond to the suit by retaining a defense attorney to file an answer on your behalf.

Even if you have previously reported a Notice of Claim, TMLT will have no way of knowing that suit has been filed until you report it. Your TMLT policy contains very specific reporting requirements, including but not limited to, immediately reporting the lawsuit by telephone and delivering the suit papers to TMLT within 10 days, obtaining written receipt of such delivery. Failure to timely report a lawsuit can result in a default judgment against you, which places your coverage in jeopardy.

- **A records request** may come from the patient, the patient's spouse, an attorney, or a record retrieval service either with an authorization or in the form of a subpoena. Requests for records should include a HIPAA-compliant medical authorization signed by the patient or by the patient's legal representative. It is best to respond to a records request as soon as possible.

- **A deposition** is testimony given under oath before a court reporter. You may be served with a subpoena for oral deposition, or you may be contacted by an attorney directly. If you are asked to give testimony regarding a patient, particularly if that patient is suing another health care provider, or if

you suspect that such litigation may later ensue, please contact the TMLT claims department immediately. Because deposition testimony you provide can prompt a plaintiff attorney to name you as a defendant in the suit, you may need legal representation before and/or during your deposition.

Reporting to TMLT

If you have received a Notice of Claim, a lawsuit, a medical records request or a request for deposition, please immediately do the following:

1. Report the matter to the TMLT claim department by calling 800-580-8658. Please allow about 20 minutes for the report and have whatever notice you have received, as well as the pertinent medical records, available for reference.

2. Fax and send via certified mail, return receipt requested, a copy of the Notice of Claim letter or the lawsuit, subpoena or other documents. Do not fax your medical records.

3. Gather a complete and unaltered copy of all pertinent medical records, including hospital and prior or subsequent treatment records, if available. Forward a copy of these records to TMLT as soon as possible.

It is essential that you contact the TMLT claim department immediately upon receipt of the documents. In many cases, we will have limited time to investigate and evalu-

ate claims prior to suit being filed. Any delay in reporting could compromise your defense.

What to do after reporting to TMLT

- Do not discuss the case with anyone except a TMLT claims representative or the attorney assigned to defend you.

- Maintain your original medical records in a secure place for future reference. Do not make any additions, deletions, or any other type of alteration to the medical records. Secure any other pertinent information or items in your possession, such as billing records, x-rays, hospital charts, etc.

- All correspondence to and from TMLT and your assigned attorney should be kept in a separate and secure file. These items should not be co-mingled with the original medical chart on the patient. Do not release these materials to anyone unless cleared through your assigned attorney or the TMLT claim department.

The TMLT claims representative assigned to your case will keep you informed as the case proceeds, both directly and through your assigned attorney. If you have questions, do not hesitate to call your claim supervisor or your defense attorney.

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

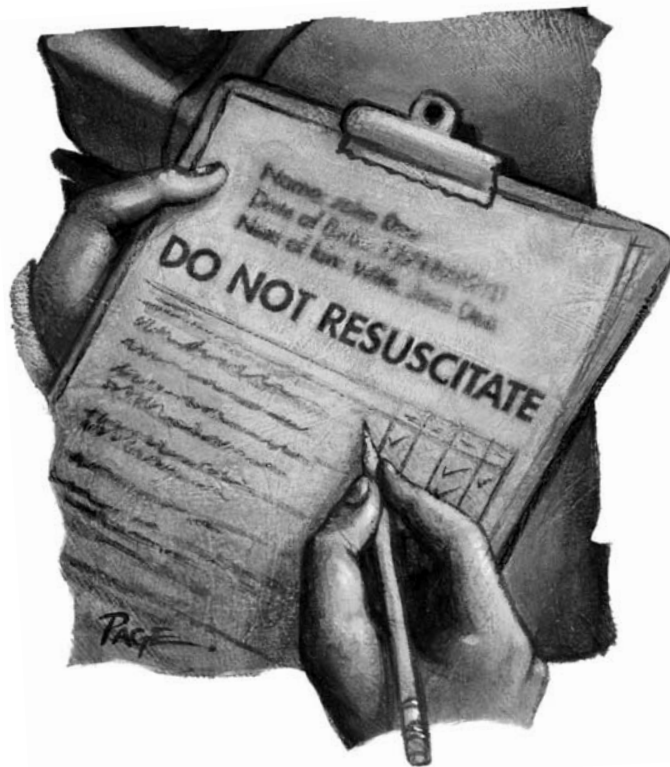
The short answer — reporting a claim to TMLT

1. If a Notice of Claim letter or demand from a patient is received, immediately notify the TMLT claim department by telephone at 800-580-8658. Follow up by providing written notice of a potential claim and a copy of the Notice of Claim letter as soon as possible. A copy of the patient's medical records should also be provided. Do not fax the medical records.

2. If a lawsuit is received or served, immediately notify the TMLT claim department by telephone 800-580-8658. Within 10 days of such service or receipt, deliver all lawsuit papers to the Trust's claim department, obtaining delivery receipt from the Trust. This might be accomplished by certified mail, return receipt requested, or by personal delivery or by messenger. A copy of the patient's medical records should also be provided.

End-of-life decisions:

protecting your patients and yourself



Objectives

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

1. Differentiate between “Advance Directives” and other actions **not** condoned by the Advance Directive Act.
2. List the three advance directives recognized by Chapter 166 of the Texas Health and Safety Code.
3. Recall three risk management techniques when managing patients during their end of life.
4. Identify resources available to assist the patient and physician with execution of advance directives.

Course author

S. Catherine Stidham is a risk management representative at TMLT.

Disclosure

S. Catherine Stidham 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 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 February 10, 2004, and expires on February 10, 2006. Please note that this CME activity does **not** meet TMLT’s discount criteria. Physicians completing this CME activity will not receive a premium discount.

Introduction

As Baby Boomers — those born between 1946 and 1964 — reach retirement age, the growth of the proportion of those older than 65 is expected to accelerate rapidly. The proportion of Texas’ population classified as elderly is expected to increase from 10.2 percent in 1995 to 16.1 percent in 2025.¹ The

Medicare and Health Care Chartbook created for the members of the Committee on Ways and Means further estimates that, by the year 2030, 19.8 percent of the national population will be over 65 years of age.² Diligence in adhering to end-of-life decisions is becoming more imperative as physicians care for a growing population of those over 65.

According to *Texas Medicine*, “80 percent of Americans die in medical institutions or under some other organized health care service, and 80 percent of those deaths are preceded by specific decisions to limit life-sustaining medical treatment.”³ One can hypothesize that this percentage will increase, positively correlating with the growth of the elderly population. That is, more and more hospital patients seen by physicians will be elderly and facing inevitable end-of-life decisions.

However, case after prominent case concerning young patients has brought the importance of end-of-life decisions and corresponding medical record documentation, to the forefront of the practice of medicine. Many times cases involving the younger patient have sparked great controversy and legislative action.

From the sensational headlines, “. . .denied Last Rites, Catholic monsignor forbidden to put crumb of holy wafer in dying woman’s mouth,”⁴ to “the Florida state legislature steps in to save a woman whose husband is trying to kill her,”⁵ the fierce battle over Terri Schiavo rages. What would Terri want? Feeding tube? No feeding tube? Cardiopulmonary resuscitation upon arrest? As *USA Today* stated, “That mystery could have been solved with a simple piece of paper.”⁶ Had Terri put her health care preferences in writing, the medical community and her family would not be guessing.

As stated in the *AMA News* editorial of December 15, 2003, “at few other times in recent history has the interest in advance directives been so high; such receptiveness should not be squandered.” Physicians may be interested in reviewing the Virtual Mentor, the AMA’s online ethics journal that includes a short tutorial on advance care planning. This can serve as a guide for physicians engaging in these discussions for the first time and as a refresher course for those more familiar with the process. The address is www.ama-assn.org/ama/pub/category/3717.html.

By engaging both young and elderly patients in discussions regarding end-of-life decisions, and documenting those discussions, physicians can help protect themselves and the rights of their patients.

The evolution of “advance directive”

In 1967, attorney Luis Kutner first suggested the concept of a “living will.” His goal was to advocate for “the rights of dying people

to control decisions about their own medical care.” Later in 1968, a physician elected to the Florida legislature named Walter F. Sackett introduced the first living will legislation. It failed then, and again in 1973 after Dr. Sackett reintroduced it. Simultaneously, Barry Keene presented a similar bill to the California senate in 1974. It failed as well.⁷

On the night of April 15, 1975, 21-year-old Karen Ann Quinlan ceased breathing for at least two episodes lasting 15 minutes. She received ineffectual resuscitation from friends, was taken to Newton Memorial Hospital, and was described as comatose with evidence of decortication. Later, at age 22, Karen lay in Saint Claire’s Hospital where physicians described her as being in a “chronic persistent vegetative state,” and as a “subject who remains with the capacity to maintain the vegetative parts of neurological function but who . . . no longer has any cognitive function.”⁸

After a lengthy struggle, the Quinlans won their battle to allow their daughter to die naturally. On March 31, 1976, the Supreme Court of New Jersey and Chief Justice Richard Hughes issued a ruling allowing the Quinlans to turn off Karen’s respirator. They did. Karen lived nine more years in a long-term care nursing facility.⁹ The Quinlans’ struggle and eventual court victory raised awareness and set the national tone for the right-to-die debate.

Several months later, in September 1976, Senator Keene tried again. This time his bill was passed and California was “the first state in the nation to legally sanction living wills.” Perhaps Senator Keene succeeded because it was personal. His mother-in-law fought unsuccessfully to limit her treatment for her terminal illness, even after the execution of a power of attorney.¹⁰

The Quinlan case facilitated many additional court cases, including another landmark decision in 1990. The U.S. Supreme Court ruled that the Constitution does allow individuals to direct their own medical care. Therefore, the parents of Nancy Cruzan, a patient having sustained permanent brain damage from a motor vehicle accident, were permitted to discontinue artificial feeding based on clear and convincing evidence of her wishes expressed prior to the accident. Health care directives became more popular, particularly following this Supreme Court decision.¹¹

In December 1991, the federal Patient Self-Determination Act became effective, requiring all hospitals, nursing facilities, home health agencies, hospice programs, and certain health maintenance organizations participating in Medicare and Medicaid to inquire about and document a patient’s advance directive status. All states were obligated to comply.¹² Although this act did not create or legalize advance directives, it required health

care institutions to validate their existence. Most states quickly followed suit, passing their own advance directive legislation. By 1992, all 50 states, as well as the District of Columbia, had passed legislation to legalize some form of advance directive.¹³

What about Texas?

Advance directives themselves are hardly new to Texas. Shortly after the Quinlan case, the Texas legislature passed the “Living Will” legislation in 1977. The Durable Power of Attorney for Health Care legislation followed in 1989, and the Do-Not-Resuscitate (DNR) order legislation was passed in 1995.

The “Living Will,” or Directive to Physicians, was developed to allow the competent patient with a terminal condition to express a preference for no treatment once the individual became unable to communicate his or her wishes. The Durable Power of Attorney for Health Care permitted a competent patient to designate any person of his or her choice to make all health care decisions on his or her behalf. The DNR order allowed a “patient with a terminal condition and a physician to execute an order instructing emergency medical personnel and other health care professionals to withhold cardiopulmonary resuscitation (CPR) in the event of cardiac or respiratory arrest.”¹⁴

Current status of advance directives

In 1999, the 76th Texas Legislature (SB 1260) attempted to reduce the confusion surrounding prior decentralized legislation on advance directives by consolidating the three previous applicable chapters, setting more uniform provisions governing the execution of advance directives and eliminating inconsistencies. The current definition of advance directive reads:

“an instruction to administer, withhold or withdraw life-sustaining treatment in the event of a terminal or irreversible condition [A Directive to Physicians and Family or Surrogates]; or an out-of-hospital DNR order; or a medical power of attorney.”¹⁵

Directive to physicians

The Advance Directives Act allows patients to execute or issue a directive and leave instructions to physicians and family or surrogates regarding their wishes to administer, withhold, or withdraw life sustaining treatment in the event the person is in a terminal or irreversible condition and is unable to make his or her wishes known. The directive may take one of three forms; (1) a written execution by a competent adult, (2) an oral directive issued by a competent adult, or (3) a written directive executed on behalf of a qualified patient younger than 18 years of age.¹⁶

Written directives

A written directive may be executed at any time and must be signed by the patient in the presence of two qualified witnesses (qualified witnesses may not be related by blood or marriage). It is effective whether or not the document has been notarized, and no health care professional or facility may require the patient to utilize a provided form. Patients should inform the physician of their decision. At this point, the attending physician must make the directive part of the patient's medical record. A written directive may include directions other than those provided in the standardized forms. For example, Jehovah's Witnesses may direct that they receive no blood transfusion by simply writing that statement in a standard form.¹⁶

Oral directives

An oral directive must be issued by the patient in the presence of the attending physician and two qualified witnesses. The physician must in turn note the execution, existence of the oral directive, and the names of the witnesses in the medical record.¹⁶

Directives issued for patients under age 18

These directives may be done by (1) the spouse, if the spouse is an adult, (2) the patient's parents, or (3) the patient's legal guardian. The directive must be in writing, although it is unclear as to whether the Act requires witnessing.¹⁶

Directive to Physicians remain effective until revocation. A patient may revoke a directive at any time through canceling the directive, (destroying the directive, signing and dating a written revocation which becomes effective only upon the communication to the attending physician), or by oral expression by the patient of his or her intent to revoke the directive. In addition, if the patient has been diagnosed as pregnant, and that diagnosis is known to the attending physician, the directive is not effective during the course of pregnancy.¹⁶

Out of hospital-do not resuscitate (OOH-DNR)

An OOH-DNR order is a legally binding order prepared and signed by the patient's attending physician on a form specified by the Board of Health that documents the patient's (or legal patient representative's) instructions directing health care professionals acting in out-of-hospital settings not to initiate or continue life sustaining procedures. Life sustaining procedures include cardiopulmonary resuscitation, artificial ventilation, defibrillation, and transcutaneous cardiac pacing.¹⁶

Health care professionals may include physicians, physician assistants, nurses, emergency medical services personnel, and

hospital emergency department personnel. The OOH-DNR is also void if the patient is diagnosed as pregnant. An OOH-DNR order does not include authorization to withhold any medical intervention deemed necessary to provide comfort care, to alleviate pain, the provision of water, and the provision of food.¹⁶

Requirements for the execution of the OOH-DNR order include the use of a specific standardized Board of Health form obtained from the Texas Department of Health. The patient must sign the order in the presence of two witnesses, who must also sign the form. The attending physician must then sign the order and note the existence of the order in the patient's medical record.¹⁶

An OOH-DNR order remains effective until revoked either in writing or orally. Patients may revoke the order at any time by destroying the order and identification device, if any, and/or orally stating their intent to revoke.¹⁶

Medical power of attorney

A Medical Power of Attorney is a document that delegates the authority to make health care decisions to a designated agent. The designated agent's authority commences upon the declaration from the attending physician that the patient is incompetent. In order to declare a patient incompetent, the attending physician must certify the opinion in writing and file the certification in the patient's medical record.¹⁶ At this point, the agent is obligated to make decisions on behalf of the patient that are consistent with the agent's understanding of the patient's religious and moral beliefs, or according to the agent's assessment of the patient's best interest. An agent may not consent to voluntary inpatient mental health services, electroconvulsive treatment, psychosurgery, abortion, or the omission of care primarily intended to provide for the comfort of the patient.¹⁶

The Medical Power of Attorney is valid until revoked or until the patient becomes competent. The patient may revoke the Medical Power of Attorney at any time through an oral or written notification to the agent or health care provider or through any other act evidencing a specific intent to revoke the power without any regard to whether the patient is competent. The current agent may also revoke the power and execute a subsequent Medical Power of Attorney. The power is also revoked through the divorce of the patient and agent.¹⁶

Afforded protection

The Texas Advance Directives Act specifically addresses legal liability issues for health professionals honoring a valid directive. It states that physicians, health care professionals, and health care facilities will not be

held civilly or criminally liable or guilty of unprofessional conduct "unless they fail to exercise reasonable care when applying the patient's advance directive." The standard of care is defined as "that degree of care that a professional in the same or similar circumstances in the same or similar community would exercise."¹⁷

Texas Medical Jurisprudence states, "a physician, health care facility, or health care professional who has no knowledge of a directive is not civilly or criminally liable for failing to act in accordance with the directive. Furthermore, an attending physician who refuses to comply with a patient directive, for whatever reason, must provide life-sustaining treatment to the patient until a reasonable opportunity has been afforded to transfer the patient to another physician who is willing to comply with the directive."¹⁸ However, "A physician, or health care professional acting under the direction of a patient, is subject to review and disciplinary action by the appropriate licensing board for failing to effectuate a qualified patient's directive in violation of the ACT."¹⁸

A case study

Unfortunately, practicing good medicine alone does not necessarily protect against medical malpractice litigation. The following case illustrates the importance of physicians engaging patients in discussions regarding end-of-life decisions, encouraging patients to put their wishes in writing, and documenting pertinent information in the medical record.

A 76-year-old female patient was admitted to the hospital for complaints of lower back pain "going down her left leg to her thigh." The pain apparently started after a fall at a senior citizen clinic approximately six months earlier. The family practice admitting physician recorded that the family said that the patient was in so much pain that she could not void, stand, sit, or move her legs.

Pursuant to the Self-Determination Act effective December 1, 1991, the patient's daughter signed a "Receipt of Information" form along with other admitting paperwork upon the patient's admission to the hospital, indicating that she did receive information about advance directives. Nursing admission notes also indicated that the patient reported having a Living Will. No copy of the Living Will was found in the medical record and no further discussion or clarification regarding the patient's specific end-of-life wishes was documented in the medical record.

Evaluation by an orthopedic surgeon indicated a problem with the left hip. The patient had lost a considerable amount of internal and external rotation, aggravating her symptoms. She was scheduled for a total left hip replacement.

On initial examination for preoperative clearance, the attending physician thought she appeared to be in “good shape.” Past medical history was positive for hypertension and a low potassium level. Current medications included K-Dur twice daily, Procardia KL 60 mg daily, Prozac 20 mg mornings, and Vicodin 7.5, APAP prn for pain. A review of systems revealed a sensitive stomach and muscular pains in her lumbar back, left hip, and left thigh area. He reported that her heart, lungs and electrocardiogram showed no acute changes. A chest x-ray, a complete blood count, a urinalysis, and SMA were all within normal limits. She was cleared for surgery.

The patient then began to complain of abdominal discomfort. She was given Dulcolax and enemas for complaints of constipation. Her constipation was relieved but she began to have some diarrhea and vomiting and intravenous fluids were administered. Her abdominal pain was not alleviated.

Three days after admission, the total left hip replacement was cancelled by the orthopedic surgeon and the attending physician ordered a consult with a gastroenterologist who suspected diverticulitis and ordered antibiotics and a CT scan of the abdomen. The CT scan was completed at approximately 5:30 p.m. A note from the gastroenterologist at approximately 7 p.m. indicated “GI films negative. CT with collection in lower abdomen most likely abscess with increased white blood count, thickened bowel wall, but density most consistent with bleeding. Her hemoglobin is elevated however, which makes a bleed unlikely.”

The defendant physician, a colon-rectal specialist, was called by the attending doctor with a request for consultation. At approximately 9 p.m., the colon-rectal specialist examined the patient and recorded the increased complaints of abdominal pain for the last “day or two.” He interpreted that the CT scan of the abdomen . . . “showed thickening of left colon with some arch of attenuation suggestive of possible abscess.” He further noted that the attending physician’s previous attempts to manage conservatively including NPO and antibiotics had failed and the patient had increased fever and abdominal pain. Abdominal tenderness was noted upon palpitation of the LLQ without masses. His impression was that the patient suffered from acute diverticulitis with a possible abscess. He recommended surgical exploration the following morning. At this point, he clearly documented the patient’s desire to proceed with the operation, stating “Have discussed this with patient and she is agreeable to this. Will plan to proceed with OR tomorrow.”

Furthermore, at 9:25 p.m., the patient signed a written “Disclosure and Consent for Medical and Surgical Procedures” for a

“subtotal colectomy with ileo-rectal anastomosis.” The same date, an “Agreement for Blood Transfusion” was signed by the daughter. Again, no documentation was found regarding the patient’s living will.

At approximately 11 p.m., the patient was found on the floor by nursing staff. Nursing notes indicated that she had apparently tried to use the rest room and fainted. The note also reflected notification of the primary physician, who then ordered an immediate EKG, blood gasses and a peripheral line.

At 11:30 p.m., the defendant, as well as the other physicians involved in this patient’s care, were informed of her condition. An on-call hospital physician was also notified of the patient’s fall and ordered labs STAT including a CBC with differential and a SMA7.

At 12:53 a.m., the lab results on the CBC were reported. The patient’s hemoglobin had dropped from 16.3 to 11.2. Her hematocrit went from 48.9 to 33.12. The impression was that the patient suffered acute bleeding with hemorrhagic shock. Contrary to previous impressions, the patient was thought to be bleeding internally and required immediate medical intervention.

At 1:40 a.m., the physicians and family were present at the patient’s bedside. Heart rate and blood pressure were stable. Repeat CTs were obtained to determine the nature and location of the bleed. At 3:30 a.m., a “Disclosure and Consent for Medical and Surgical Procedures” form was signed by the daughter for an “exploratory laparotomy with possible resection of abdominal aortic aneurysm.”

At 8:15 a.m., a nurse’s note indicated that the physicians, including the defendant, were paged STAT and that surgery was pending. A nurse’s note recorded at 8:45 a.m. documented the receipt of a Living Will and that the Living Will was in the medical record. At 9:35 a.m., a nurse’s note indicated that the defendant was at the bedside of the patient with the patient’s family. It further stated that the family expressed their desire to allow the patient to die naturally. The defendant also documented the patient’s DNR status and the family’s wishes.

The last entry made by the defendant was the pronouncement of death at 5:10 p.m. At 6 p.m., the chaplain was called in to counsel the family.

Analysis

The defendant physician spent considerable time discussing the patient’s condition with the family. The documentation reflects a caring, involved physician who was available to the patient and family throughout the decision-making process. In addition, it is also clear that the defendant was aware of the importance of honoring the patient’s wishes regarding her end-of-life care preferences. He

also clearly attempted to involve the family appropriately when needed.

Unfortunately, the defendant neglected to document all detailed discussions with the patient and her corresponding oral remarks regarding preferences for care. In deposition, the physician was able to describe in detail the unwitnessed informed consent conversation he had with the patient regarding the initially proposed surgical procedure and the patient’s objections to the colostomy under any circumstance. The physician and patient made a health care decision to then proceed with a subtotal colectomy. Although an appropriate consent was signed, the physician did not proceed with the surgery due to his belief that the patient would not want it. In deposition he further explained his thinking process; if the patient did not want a colostomy, she certainly would not want a feeding tube or to be put on a ventilator, both distinct possibilities if he were to proceed with the proposed surgery. He also elaborated on this discussion with the family. At least partially due to this conversation, the family made the decision to execute a DNR for their mother. The absent and unread Living Will was referenced again in his note in the medical record. Undocumented conversations on which decisions are made are far less defensible than complete medical record entries documenting the physician, patient, and family decision-making process.

As mentioned above, despite nurses’ notes indicating that a Living Will existed and was in the medical record, ultimately no Living Will was filed in the record. In order for the providers to know what each individual Living Will dictates, the Living Will must be collected, read, and put in the medical record for all providers to access. The Living Will not only provides the physicians with written guidance and support for their decisions, but will also allow the physician and family to better understand and agree to the patient’s wishes. In this case, the physician understood that the patient wanted no colostomy and no heroic measures. In deposition, the family stated that their impression was that . . . “all measures necessary to save her life” . . . would be taken if she had . . . “any chance for survival.”

Additionally, the family testified that they felt the nurses were being very rude and were giving them “dirty looks.” Furthermore, they overheard a nurse saying “the daughters are just going to let their mother bleed to death.” Impertinent remarks such as these can be very damaging in the event of litigation. “Health care professionals can and do incite patients to file lawsuits.”¹⁹

Physician reviewers for the plaintiff were critical, stating that this physician deviated from the standard of care. The physician

failed to perform the exploratory laparotomy to identify the etiology of the patient's drop in hemoglobin and hematocrit and subsequently treat the source of intra-abdominal bleeding, thereby leading to the death of the patient. Defense experts argued that, even if the patient had survived the surgery, she would have required I.V. feedings and would most likely have died of necrosis of the bowel.

The claim filed against this physician and others included an allegation of failure to undertake an exploratory laparotomy for intra-abdominal bleeding. The case was ultimately settled for an amount in the mid five figures.

What is *not* an advance directive?

Advance Directive issues can be confusing for everyone — patients, families and health care providers. Nothing in the Advance Directive Act condones, authorizes, or approves of mercy killing or euthanasia. It does not, in any circumstance, permit any affirmative or deliberate act or omission to end life. It only permits the natural process of dying.²⁰ The physician can be instrumental in educating patients about the execution of a directive regarding their wishes for health care should they be unable to communicate. It is important that patients understand it is not a wish to die. Rather, it is instruction explaining the process by which they wish to face life's ultimate reality.

Risk management techniques

1. Empathically engaging your patients in discussions regarding end-of-life issues and their desires will help them make their difficult and necessary decisions. Misunderstandings can be avoided by having witnesses present who are unemotionally involved when patients are making oral directives to you regarding their wishes, and by documenting their wishes in the chart at the time the decisions are made.

2. Patients who have chosen to die naturally will be unavailable to testify later regarding your conversations. Understandably, their families were most likely very emotional and stressed when the conversations and decisions took place. Complete and contemporaneous documentation of the discussions is the best way to avoid disputes later.

3. You can abide fully with the patient's wishes by acquiring and reading previously executed advanced directives, and by placing those in the patient's chart. The written document can be useful when communicating with family members about the patient's wishes.

4. Negative and/or inflammatory comments by staff members serve no useful purpose and often prove distressing to patients and their family members. Such

comments should be avoided. If they do occur, they should be reported to the appropriate supervisors or staff members.

5. Many ancillary services and other interdisciplinary professionals are available to assist you. Such professionals include social workers, religious advisors and patient representatives. These professionals are trained to assist patients and their families with problems and difficult decision-making. Calling on them early can enable them to facilitate the end-of-life decision-making, and can lead to better understanding among all parties.

Conclusion

Legally, physicians have no choice but to honor patient executed advance directives or transfer the care of that patient to another physician who will. Directives to physicians come in all shapes and sizes. The options for patient direction are limitless. No uniform directive exists. Patients may direct that they wish for no colostomy under any circumstance, but that they do indeed wish to have a ventilator, if needed.

Unclear communication between patient, family, and physician makes the difficult situation even more challenging. Obtaining any previously executed documents and attempting physician, patient, and family consensus on understanding will help avoid misunderstandings. Payout on this claim may have been prevented or reduced through more comprehensive documentation. By utilizing sound risk management techniques, one may be afforded increased defensibility against allegations from regretful family members. By accurately determining your patient's end-of-life decisions, and through conscientious and careful documentation of such, you may also protect yourself from unwarranted litigation.

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closed claim study

Improper management of anticoagulation therapy

by Barbara Rose and Laura Brockway

The following closed claim study is based on an actual malpractice claim from TMLT. 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 for the purpose of emphasizing the issues of the case.

Presentation

A 72-year-old man presented to a general surgeon with a one-week history of pain in the right groin with a reducible mass. Physical examination confirmed a reducible right inguinal hernia. The patient's medical history included a CVA four years earlier. During the evaluation for CVA, an arteriogram revealed "1) the right vertebral artery was occluded; 2) the left vertebral artery was relatively normal; 3) the left internal carotid artery had a 40 to 50% stenosis in the neck portion, but an 80% stenosis in the cavernous portion; 4) the right internal carotid artery had a very long, irregular stenosis in the neck . . . he also had a 95% distal internal carotid artery stenosis, again in the cavernous portion." Due to the severity of the disease, the patient was placed on long-term anticoagulation therapy with warfarin. The patient continued to smoke one pack of cigarettes daily.

Physician action

The physician recommended surgical repair of the hernia. The patient was in considerable pain, and the surgeon felt he was at risk for incarceration, bowel obstruction and strangulation. Further, if such a complication developed, the patient would require emergent surgery which would occur while the patient was anticoagulated.

The risks and benefits of the elective surgery were explained and the patient consented to the procedure. The surgeon also told the patient that he could not operate while the patient was taking warfarin. The surgeon instructed the patient to discontinue warfarin

five to seven days before the hernia surgery. The patient complied and stopped taking warfarin for seven days.

The patient underwent a repair of his right inguinal hernia with mesh. The surgery went well, but in the recovery room the patient was slow to awaken, was unable to speak and had right-sided weakness. Neurology consultation concluded the patient had suffered either an intraoperative or postoperative thrombotic ischemic infarct of his brain. The patient was anticoagulated with heparin, but developed a severe right-sided stroke with flaccid hemiparesis and global aphasia.

The patient was transferred to a skilled nursing facility and later to a nursing home where he died from sepsis five months later.

Allegations

The plaintiffs alleged the surgeon fell below the standard of care by failing to discuss the surgery and interruption of anticoagulation with the patient's neurologist and by failing to initiate alternative anticoagulation therapy. It was further alleged the interruption in anticoagulation was a significant contributing cause of the patient's stroke.

Legal implications

The plaintiffs were able to locate experts supportive of their allegations regarding standard of care and causation. They claimed that alternative coagulation therapy could have been arranged that would have reduced the chances of intraoperative stroke. One expert stated that the "safest" alternative would have been to perform the surgery while the patient was in a "heparin window." For this, the patient is hospitalized for intravenous Heparin infusion several days between discontinuing the Coumadin and the scheduled surgery. The expert also maintained the stroke occurred because the patient was not anticoagulated.

Defense experts were supportive of the surgeon's action regarding the interruption of anticoagulation. This expert stated the "heparin window" was not the standard of care for patients on long-term anticoagulation. It is only recommended in extreme cases, specifically in patients who have suffered a recent

acute venous thromboembolism in the three months before surgery. Additionally, the expert stated there was no medical literature to support the fact that the warfarin was preventing the patient from having a stroke and discontinuing it was the cause of the stroke.

Defense experts pointed out that even if alternative anticoagulation had been arranged, the patient would still have been at high risk for developing a stroke. One expert stated the patient was a "stroke waiting to happen" due to the severity of his disease and the fact that he continued to smoke.

One area of weakness identified in this case was the fact that the surgeon did not contact the neurologist before surgery. The surgeon testified he did not contact the neurologist about discontinuing warfarin because he felt the surgery was necessary, and he would not operate as long as the patient was anticoagulated. Therefore, he did not feel the need to discuss options with the neurologist. While the experts did not assert the surgeon was negligent, they did state it would have been better if he had contacted the neurologist.

Disposition

This case was settled with the consent of the surgeon for an amount in the low six figures. While the surgeon disputed the claim, he opted for a compromise settlement to avoid the risk, inconvenience and expense of litigation.

Risk management considerations

With a patient history indicating increased risk of peri- or postoperative complications, it is prudent for a physician to exercise extra caution and to solicit the input of a patient's treating doctors for preoperative clearance and management decisions. Further discussion regarding choice of anesthesia may allow the physicians involved to make a decision with the lowest risk for the patient. The team concept of care requires additional planning and time, but a commitment to this "style" may affect patient outcomes in a positive way.

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medical liability update

TMLT awarded Accreditation with Commendation by ACCME

by Lesley Viner, MS, education program manager

TMLT has been surveyed by the Accreditation Council for Continuing Medical Education (ACCME) and awarded Accreditation with Commendation for 6 years as a sponsor of continuing medical education (CME) for physicians.

ACCME accreditation seeks to assure both physicians and the public that CME activities sponsored by TMLT meet the high standards specified by the ACCME. The ACCME evaluates the CME programs of institutions according to standards adopted by all seven sponsoring organizations of the ACCME. According to the ACCME, only 8 percent of CME providers achieve Accreditation with Commendation status.

TMLT CME history

TMLT became interested in providing CME in 1991 when the risk management department began implementing programs in conjunction with the Texas Medical Association, an accredited CME provider. As TMLT began to insure large physician networks, physician members voiced a desire for CME programs with an emphasis on risk management. In 1996, TMLT elected to pursue CME accreditation through the ACCME. TMLT was initially awarded provisional accreditation for two years and in November 1999 became a fully accredited CME provider. TMLT currently offers CME activities focused on risk management issues to its 10,800 policyholders.

TMLT CME activities

TMLT's programs are based on demonstrated needs originating from data on malpractice claims frequency and severity. Content areas are designed to meet the challenges of emerging technologies, medical advances, the practice of medicine, and the medical-legal needs of physicians. Expected results involve attitudinal and behavioral changes related to risk management practices that will help lower the incidence of malpractice suits.

TMLT's CME program includes live seminars, online courses, enduring mate-

rials, and practice-based CME activities that focus on reducing a physician's liability risks. Most CME activities meet TMLT's premium discount criteria; however, there are activities offered that do not meet the discount criteria, usually because they offer fewer than 3 hours of education.

Live seminars

Live seminars are offered to TMLT policyholder groups at no cost. They address specific risk management issues identified as problematic after a review of the group's claim history, as well as issues the group has identified. Topics currently available include documentation, HIPAA, and physician/patient communication.

Online CME

TMLT's online courses are found at www.tmlt.org. They offer risk management education for policyholders who prefer computer-based learning or who live in rural areas where there is limited opportunity to attend live CME offerings. A complete list of courses is available at www.tmlt.org.

The cost to register and complete one of the online courses is \$50 for policyholders, and credit hours range from 3 to 6. All online courses meet the discount criteria.

the Reporter CME

TMLT has recently begun to explore CME as an enduring material in *the Reporter*, which is mailed to all TMLT policyholders on a bimonthly basis at no cost. The newsletter features articles on the latest trends in medical liability, ways to reduce risk, TMLT and industry news, and closed claim studies. The CME articles published in *the Reporter* offer 1 hour of CME credit but **do not** meet TMLT's discount criteria.

Practice review

TMLT's practice-based CME activities are also offered at no cost to policyholders and take place on a per-request basis. The practice-based CME activity is a part of TMLT's practice review process, which

includes an examination by a risk manager of the physician's office; a review of the practice's policies and procedures; an evaluation of medical record documentation; and a confidential, written summary of the findings and recommendations for the physician's review.

In order to receive 2 hours of CME credit, the physician must first complete a self-assessment of the practice. The physician must then participate in a 1-hour discussion with the risk manager regarding identified areas of potential liability, recommended risk management interventions, and other issues. The practice review offers a 3 percent discount, following verification the review recommendations were met. An additional 2.5 percent discount is available if the policyholder has fully implemented electronic prescribing or an electronic medical record for a minimum of one year.

Risk management education discount

The risk management education discount (3 percent discount, not to exceed \$1,000) is awarded for risk management CME courses that are at least 3 hours in length. The discount is awarded per course, not per hour. A physician can take two CME courses per year and qualify for up to a 6 percent discount, not to exceed \$2,000.

Effective January 1, 2001, physicians cannot receive credit for the same course twice, unless the course has been revised or updated. Physicians must take new or revised courses each year to receive the discount, unless otherwise approved by the risk management department.

Discounts are applied to the upcoming policy period. If more than two risk management courses are taken per year, the courses can be applied to the following policy period but not to any policy periods thereafter.

Non-TMLT activities

TMLT does offer the risk management discount for non-TMLT activities. The criteria

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the Reporter



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TMLT CME . . . continued from page 11

qualifying outside programs for the risk management discount include:

- the sponsoring organization is an accredited provider of CME for physicians;
- the activity has been designated as a CME activity;
- the activity is at least three hours;
- the activity contains substantial risk management content; and
- the physician submits the course materials, including course objectives, course length, and course outline to the risk management education program manager for review and approval.

Specialty-specific risk management courses are recommended.

To request a risk management program, or for more information about TMLT's CME activities and discount options, please call 800-580-8658, ext. 5911 or visit the TMLT web site at www.tmlt.org.

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Correction

In the November/December 2003 issue of the Reporter, Physicians Insurance Companies was inadvertently described as a California-based company. The company is based in Seattle, Washington.

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