

Special issue – includes a 3-hour CME activity



*the*

# Reporter

TEXAS MEDICAL LIABILITY TRUST  
November-December 2009

## Challenges in managing **anticoagulation**

### therapy

**informed consent,  
patient monitoring, and  
documentation among  
the risk management  
issues**

**by Laura Brockway, ELS**



### **Closed claim study: failure to discharge patient on warfarin**

#### **Presentation**

A 63-year-old woman with an extensive history of cardiac disease came to a rural hospital emergency department (ED) with complaints of shoulder, jaw, and back pain. The patient's EKG was abnormal, so she was transferred to a regional hospital under the care of Cardiologist A.

#### **Physician action**

A cardiac catheterization by Cardiologist A revealed critical aortic stenosis, mild aortic insufficiency, closed right coronary artery with collateral flow from the left system, mild to mod-

*continued on page 2*

erate right disease of the left anterior descending coronary artery and left circumflex coronary artery, left ventricular hypertrophy with inferior hyperkinesis, overall satisfactory left ventricular function, and severe pulmonary hypertension. Cardiologist A requested a cardiovascular surgery consult. The cardiovascular surgeon performed an aortocoronary bypass and aortic valve replacement the next day.

The cardiovascular surgeon and Cardiologist A started the patient on warfarin with daily protime studies. A pulmonologist was consulted when the patient exhibited symptoms of fluid overload. The cardiovascular surgeon and Cardiologist A then began altering the warfarin orders as the patient's protimes and international normalized ratio (INR) fluctuated.

For three days, Cardiologist A wrote orders to "hold" warfarin as the patient's INR was greater than 3. Cardiologist A then left town, handing the patient off to Cardiologist B. Cardiologist A's last note indicated that he expected the patient to be discharged within two days. The cardiovascular surgeon also saw the patient that day and wrote an order to decrease the warfarin dosage but to "hold" the warfarin as her INR was greater than 3.

The next day, the patient's INR was 2.31. Cardiologist B saw the patient at 6:50 a.m., noting that the patient was to be discharged that day. He wrote an order for "home health" which meant that he intended for a home health agency to perform INR checks so that he could follow the patient's anticoagulation. The pulmonologist and the cardiovascular surgeon both saw the patient that day. The surgeon wrote the patient's discharge instructions, which were to return to the surgeon for staple removal and return to Cardiologist A in a month. The patient's discharge instructions did not mention warfarin. Her last dose of warfarin had been three days earlier.

The patient came to the cardiovascular surgeon's clinic nine days later, and she was seen by the nurse practitioner. She listed her medications, but warfarin was not included on the list. Three weeks later, the day before she was to return to Cardiologist A, she came to the ED with right-sided weakness and aphasia. A CT scan of the head revealed a left middle cerebral artery cerebrovascular accident. After a lengthy hospital stay, she was discharged to a rehabilitation facility, and ultimately to a long-term care facility where she currently resides. She is densely hemiparetic, aphasic, and unable to swallow. She has a PEG tube for feeding.

### Allegations

Lawsuits were filed against Cardiologist A, Cardiologist B, the cardiovascular surgeon, and the hospital. The allegations included failure to ensure that the patient was discharged on warfarin therapy to prevent clot formation from her artificial valve.

### Legal implications

The plaintiff's expert cardiologist was critical of all of the defendants in the case, saying they violated the standard of care in failing to ensure the patient was discharged on warfarin therapy. Regarding Cardiologists A and B, these physicians should have scheduled the patient for a post-discharge follow-up appointment to monitor her anticoagulation.

Cardiologists who reviewed this case for the defense expressed concern that the patient was discharged without warfarin. According to these physicians, the patient should have had repeat INR 3-5 days after her discharge and should have been followed by her cardiologist or primary care physician 10 to 14 days after discharge.

The defense pointed to the home health order written by Cardiologist B to demonstrate that the hospital failed to perform on the order to ensure home health care after discharge to monitor the patient's INR values. However, the plaintiff's expert testified that the "home health" order was too vague and, therefore, insufficient.

### Disposition

This case was settled on behalf of Cardiologist B and the cardiovascular surgeon. Cardiologist A was dropped from the case. The outcome of the case against the hospital is not known.

### Anticoagulation therapy

With approximately 30.6 million outpatient prescriptions dispensed in the United States in a single year, warfarin is among the most commonly prescribed drugs in the United States.<sup>1</sup> Warfarin and other anticoagulants (such as heparin, unfractionated heparin, low molecular weight heparin, fondaparinux, or direct thrombin inhibitors: argatroban, bivalirudin, lepirudin) are also considered "high-alert" medications — medications known to cause severe injury to patients when administered incorrectly.<sup>2</sup> Anticoagulants have also been identified as one of the top five drug types associated with medication errors and their appropriate use has been identified as an important indicator of high-quality health care and patient safety.<sup>3</sup>

From 2001 to 2006, a total of 59,316 medication errors related to anticoagulants were reported to the United States Pharmacopeia MEDMARX database. Of these errors, 59.8% reached the patient and 2.9% resulted in harm or death. Administration was the most common cause of adverse events relating to anticoagulant medications. The product group most associated with errors was heparin, which accounted for 35% of anticoagulant errors, followed by warfarin at 29.1%.<sup>4</sup>

"Of all available pharmaceutical therapies, coumarin anticoagulants such as warfarin represent some of the most difficult-to-manage and dangerous drugs prescribed to patients."<sup>5</sup>

Conversely, the use of anticoagulants 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.<sup>6,7</sup> Their use is also indicated in the prevention of venous thromboembolism, arterial thromboembolism, prosthetic valve thrombosis, and acute myocardial infarction in patients with peripheral arterial disease.<sup>8</sup>

Despite the evidence of its efficacy in the prevention of thromboembolic disease in a significant patient population, anticoagulation therapy continues to be under-used. Only 30 to 50 percent of patients with atrial fibrillation — who would be good candidates for warfarin therapy — receive it. Elderly patients are the least likely to be treated.<sup>9,10</sup>

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 moni-

toring to ensure appropriate dosing, and interactions with numerous foods and drugs.”<sup>10</sup>

“Three main objections are often raised as barriers to the use of warfarin: that it may not be a safe treatment for elderly patients who are presumed to be at greater risk for a major hemorrhage, that the proven benefits of warfarin derived from trials of highly selected patients may not be realized in routine clinical practice, and that therapeutic control is difficult.”<sup>11</sup>

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% 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.<sup>12</sup>

From a risk management standpoint, the use of anticoagulation therapy represents an ultimate challenge. Initiating anticoagulation therapy calls for a thorough risk versus benefit analysis and patient discussion, meticulous patient monitoring, charting, and follow up. According to the Joint Commission, “Patients under consideration for receiving anticoagulant drugs must be carefully screened for contraindications and drug interactions. While receiving anticoagulants, patients must be monitored closely to ensure effectiveness and to prevent side effects or overdosing. Heparin and warfarin in particular have narrow therapeutic ranges and a high potential for complications, so there is a great risk of patient harm.”<sup>3</sup>

Fortunately for physicians, guidelines exist to address many of the challenges physicians face when treating patients with anticoagulation therapy. In June 2008, the American College of Chest Physicians published new evidence-based guidelines to address the prevention, treatment, and management of thrombotic disorders. The guidelines were developed by an international panel of 90 experts and include more than 700 comprehensive recommendations, including chapters on preventing and treating thrombosis in children and pregnant women, managing peri- and postoperative patients, and the routine use of preventive therapies. The guidelines are currently available at [www.guideline.gov](http://www.guideline.gov) or in the June 2008 issue of *Chest*, available at [www.chestjournal.org](http://www.chestjournal.org).<sup>13</sup>

Guidelines are also available from American Heart Association/American College of Cardiology (available at <http://www.acc.org/qualityandscience/clinical/topic/topic.htm>, search topic anticoagulants), European Society of Cardiology (available at <http://www.escardio.org/guidelines-surveys/esc-guidelines/Pages/GuidelinesList.aspx>) and the British Committee for Standards in Haematology (available at [www.bcsghguidelines.com](http://www.bcsghguidelines.com)). Several national specialty societies have also published guidelines related to anticoagulation in specific patient populations. These guidelines are available at [www.guideline.gov](http://www.guideline.gov).

### 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.”<sup>14</sup>

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 addressed in the published guidelines.<sup>15</sup>

“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.<sup>15</sup>

“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. 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.”<sup>15</sup>

### 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, herbal substances, NSAIDs, thyroid hormones, and oral contraceptives.<sup>16</sup>

In addition to drug interactions, travel, changes in diet, environment, and overall health 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.”<sup>17</sup>

Incorrect laboratory reporting of INR results further contributes to the risk of complications of anticoagulant use. 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.<sup>16</sup>

### 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.”<sup>16</sup>

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.”<sup>16</sup>

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. Self-management, in which patients are given small portable devices that enable them to measure their own degree of anticoagulation, may also be an option for outpatient management.

However, there are limitations to the self-management approach. “Self-monitoring is not feasible for all patients, and requires identification and education of suitable candidates as well as an underlying institutional policy for providers of this service.”<sup>18</sup>

“No matter how the management of oral anticoagulation is accomplished, patients still spend a considerable proportion of time with their targeted degree of anticoagulation outside of the recommended INR range.”<sup>19</sup> An analysis of 67 studies involving 50,208 patients followed for a total of 57,155 patient years was published in *Chest*. For these patients, the INR was in the therapeutic range an average of 64% of the time. The study also found that the rate varied with study setting:

- self-management: 72%
- randomized trials: 66%
- anticoagulation clinics: 66%
- community physicians: 57%<sup>19</sup>

“In the worst subgroup, namely, patient groups treated with warfarin by community physicians without self-monitoring, patients spent half of their time outside of the therapeutic range. Unfortunately, it is likely that this is the most common subgroup in North America since self-management is relatively uncommon, warfarin is used almost exclusively, and anticoagulation monitoring is most commonly followed by community physicians.”<sup>19</sup>

For practices that do not have access to anticoagulation clinics or if self-monitoring is not available, an article published in *Family Practice Management* offers the following suggestions:

- Consider creating 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.
- Consider designating one staff member as the person to make sure patients come in as scheduled and to track 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.
- Consider visiting anticoagulation clinics for ideas on improving systems within practices.<sup>5</sup>

### Special considerations: anticoagulation in older adults

“Many of the common cardiovascular disorders in the elderly have a relationship to thrombosis, including ischemic

heart disease, atrial fibrillation, valvular disease, and atherosclerotic vascular disease. Many of these patients require antithrombotic therapy, which raises questions regarding the appropriate use and safety of antithrombotic therapy in this setting.”<sup>20</sup>

Concerns about the use of warfarin in the elderly include poor compliance, difficulty monitoring patients in remote areas, recurrent falls, cognitive impairment, history of gastrointestinal bleeding, hypertension, cerebral hemorrhage, and potential interactions with other drugs elderly patients may be taking.<sup>20</sup>

“It is important to caution elderly persons about the importance of warfarin drug interactions any time their medication list is altered. The decline in cognitive function in some elderly patients may result in the lack of realization that some medications may interact with anticoagulants and in failure to mention the use of oral anticoagulants to their doctors or pharmacists.”<sup>20</sup>

Clinical practice guidelines for the use of anticoagulants in the elderly have been issued by the American Geriatrics Society and abstracted from the guidelines produced by the American College of Chest Physicians.<sup>(15,21)</sup>

A review article published by *UptoDate* offered useful questions to ask when considering anticoagulation in elderly patients:

- “Is there a definite indication for anticoagulation?”
- “Is there a high risk of bleeding or strong contraindication against anticoagulation?”
- “Will concurrent medications or disease states significantly increase bleeding risk or interfere with anticoagulation control?”
- “Are patient education, drug compliance, and attendance at an anticoagulant clinic for monitoring likely to be problems?”
- “Will there be regular discussions with the patient, especially with regard to a full understanding of the risks and benefits of anticoagulation?”<sup>20</sup>

Suggestions to reduce the bleeding risk in elderly patients include:

- “Meticulous attention to the degree of anticoagulation, especially during the early phase (i.e., first 90 days as well as the first year) of therapy, as well as in warfarin-naïve patients.
- Aggressive treatment of excessive anticoagulation, if present.
- Control of hypertension, if present.
- Interventions to reduce the risk of falls.”<sup>20</sup>

### Special considerations: management before and after elective surgery

“Although anticoagulation increases the risk of bleeding following surgical procedures, interruption of anticoagulant therapy, on the other hand, increases the risk of thromboembolism.”

The risk of bleeding occurring with surgery in patients taking anticoagulant therapy is dependent on a number of factors, such as “patient age, presence of other disease states, the type of surgery, the anticoagulant regimen and intensity, the length of warfarin therapy, the use of other drugs that affect hemostasis (eg, heparin, aspirin, antiplatelet agents), the

stability of anticoagulation, and the degree of anticoagulation as measured by the INR.”<sup>22</sup>

“By contrast, cessation of oral anticoagulation used to treat acute thrombosis may exacerbate the condition, which may itself be life-threatening. Appropriate use of alternative strategies, such as intravenous heparin, [or other low molecular weight heparins such as enoxaparin] to provide antithrombotic coverage (i.e., ‘bridging’ anticoagulation) during the period when warfarin is withdrawn or reintroduced will minimize the risks involved.”<sup>22</sup>

Special attention should be paid to patients who require bridging anticoagulation. “Interdisciplinary teams should develop, implement, and evaluate evidence-based guidelines to manage patients who require bridging. Errors can and do occur when clinicians attempt to manage bridging without a clear understanding of the goals of treatment or how to safely adjust the medications and doses.”<sup>23</sup>

Clinical practice guidelines for the management of anticoagulation in surgical patients have been issued by the American College of Chest Physicians. *UptoDate* also published the following guidelines:

- For patients at low risk for perioperative bleeding, oral anticoagulation with a vitamin K antagonist can probably be maintained at or below the low end of the therapeutic range (INR  $\leq$  2.0).

- For patients with a high risk of bleeding, the INR should be  $\leq$  1.5. Within this group, patients at low risk for thrombosis can stop warfarin two to five days preoperatively; patients at high risk for thrombosis can stop warfarin but should probably be treated with intravenous or subcutaneous heparin when the INR is subtherapeutic.

- Warfarin and/or heparin can be restarted postoperatively when there is no contraindication to anticoagulation.”<sup>22</sup>

### Special considerations: anticoagulation in acute pulmonary embolism

Approximately 200,000 new cases of pulmonary embolism (PE) resulting from deep vein thrombosis (DVT) are diagnosed each year in the United States. An estimated 60,000 deaths are attributed to PE and the cost of treating PE amounts to \$1.5 billion annually.<sup>24</sup>

The management of DVT/PE involves the use of anticoagulants, which have the potential for complications such as bleeding and heparin-induced thrombocytopenia. Failure to use anticoagulants in an optimal manner can contribute to poor patient outcomes. The Joint Commission has recognized DVT/PE as a preventable cause of morbidity and mortality for hospitalized patients.<sup>24</sup>

“Widespread failure to diagnose PE, and to administer prophylaxis when necessary, means that this condition has become the most common cause of unexpected death in hospitalized patients, and one of the primary reasons for medical litigation.”<sup>25</sup>

Recent research indicates that DVT/PE is not just a condition that affects surgical patients. According to a review article in *Nature Reviews Cardiology*, the vast majority of hospitalized patients with symptomatic DVT/PE had not undergone surgery recently. Approximately 70 to 80 percent of in-hospital fatal PEs occur in nonsurgical patients. Other studies have shown that at least half of all patients who developed DVT/PE were outpatients, and many had been recently hospitalized. “The trends in medical practice toward shorter hospital stays, and the availability of outpatient therapies, have made outpa-

tient prophylaxis of acute DVT/PE a necessity.”<sup>25</sup>

Evidence-based guidelines for the prevention and management of DVT/PE are available, but underuse of preventative therapy is widespread. “In DVT FREE, 14.5% (395 of 2,726) inpatients were identified as having PE, and only 42% of those diagnosed with DVT had received prophylaxis within the preceding 30-day period. In the outpatient setting, the median time to diagnosis of DVT was 3 days after commencement of symptoms, and 80% of patients diagnosed with DVT as outpatients were subsequently hospitalized for treatment of DVT.”<sup>25</sup>

The importance of closely following post-surgical patients who have been placed on anticoagulants is illustrated by the following closed claim study.

### Closed claim study: failure to confirm diagnosis of pulmonary embolism

#### Presentation and physician action

On April 7, a 62-year-old man was admitted to a local hospital for complaints of severe, persistent back pain. On the day of admission, an orthopedic surgeon performed a three-level laminectomy with dural repair for a diagnosis of spinal stenosis. The surgery lasted more than six hours and resulted in blood loss of 1,850 cc. Postoperatively, the patient developed hypotension, tachycardia, low central venous pressure, and respiratory failure. A nephrologist, the defendant in this case, was consulted for medical management of the patient.

The nephrologist’s diagnosis was shock, acute respiratory failure, and hypoxia. His differential diagnosis included hypovolemia and pulmonary embolism (PE). The nephrologist ordered phenylephrine and dopamine and re-intubation of the patient. He also ordered a 2D echocardiogram. Although there is no echocardiogram report in the records, according to the nephrologist, a cardiologist interpreted the echocardiogram as showing a collapsed left ventricle, potentially caused by a PE. In response to this report, the nephrologist ordered a heparin bolus and drip “per protocol” for the treatment of a presumptive PE. He subsequently signed the preprinted Heparin Intravenous Protocol orders. The patient’s laboratory values were periodically measured and the PTT was always elevated, even to “panic” values, indicating a propensity for bleeding.

On April 8, a dark brown fluid was discharged from the patient’s NG tube, a probable symptom of gastrointestinal bleeding. The patient was given multiple blood transfusions. Two days later, April 10, symptoms of neurologic deficits were documented. The orthopedic surgeon ordered an EMG, but this was not done because the patient was on a ventilator and there was no neurologist available in the hospital. The patient began to experience weakness and a decreased sensation in his legs. On April 13, the patient was unable to move his legs. The nephrologist’s documentation did not address this issue. The administration of heparin continued and the patient required additional blood transfusions.

The nephrologist ordered a CT scan of the abdomen and a Doppler study of the legs on April 14. (Other diagnostic tests such as a lung VQ scan, spiral CT, and CT angiography were not available at this hospital.) The Doppler study did not show evidence of DVT. The CT scan was not performed, but an ultrasound found no evidence of PE. The patient’s NG tube continued to drain dark brown material and the neurologic deficits continued. The orthopedic surgeon documented

a hematoma at the surgical site. He noted the possibility that it was applying pressure to the nerve roots, however, due to the PE and heparin, it was not safe to take the patient to surgery. On April 17, it was documented that the patient could not stand or void.

Heparin and blood transfusions continued. The results from Doppler studies of the legs and a CT scan of the chest were negative. CT scans revealed a spinal hematoma in the surgical area and a large abdominal hematoma. Heparin was discontinued on April 19, but enoxaparin was started for continued PE prophylaxis. On April 21, a gastroenterologist saw the patient and ordered an EGD. The results from the EGD indicated bleeding stomach ulcers. Nursing documentation from April 22 stated that the patient is a paraplegic with no motor or sensory function. The enoxaparin was continued.

The patient was transferred to a regional hospital for an MRI of the lumbar spine on April 24. (This MRI had been recommended by the radiologist who interpreted the CT scans 10 days earlier.) On April 25, the orthopedic surgeon documented that the MRI confirmed a spinal hematoma compressing the nerve root “secondary to heparin anticoagulation which was needed to save the patient’s life.” He further documented that surgery was not an option to excise the hematoma because of the patient’s “other medical reasons.”

The nephrologists continued to manage the patient medically until his discharge on May 7. The patient was discharged to a long-term acute care facility, where he remained for one month. He never regained the use of his legs. He died approximately one year later. According to the autopsy report, the cause of death was bilateral pneumonia.

### Allegations

Lawsuits were filed against the nephrologist, the orthopedic surgeon, and the hospital. The allegations included inappropriately starting and continuing heparin with no definitive testing to confirm pulmonary embolism. The unnecessary and prolonged use of heparin led to the formation of the hematoma which caused the patient’s paralysis and death.

### Legal implications

The plaintiff’s expert was a critical care specialist who stated that anticoagulants should be used judiciously in post-spine surgery patients due to the risk of bleeding at the surgical site. According to this physician, the nephrologist breached the standard of care in the following ways:

1. by not definitively diagnosing pulmonary embolism via diagnostic tests, such as spiral CT, CT angiography or lung VQ scan, prior to initiating heparin therapy;
2. after heparin therapy was initiated, by not immediately performing definitive tests to confirm the diagnosis of pulmonary embolism;
3. by not ruling out other diagnostic possibilities, such as blood loss and hypovolemia, prior to initiating heparin therapy;
4. by failing to discontinue heparin until April 19, given the patient’s symptoms of bleeding, hematoma, and neurologic deficits; and
5. by failing to place an inferior vena cava filter if pulmonary embolism was suspected.

Physicians who reviewed this case for the defense supported the nephrologist’s decision to initiate heparin. However, all reviewers stated that further testing should have been

ordered to confirm the diagnosis. There was also concern about the continuation of the heparin in light of the patient’s bleeding and neurologic deficits. There was no documentation in the medical records of consideration of transfer to another facility for appropriate diagnostic testing. Though it could be argued that the patient was not stable enough to transfer to another facility for several days, transfer for further testing should have been ordered by April 15.

The defense of this case was further weakened by the orthopedic surgeon’s failure to investigate the suspected spinal hematoma in a timely manner and the hospital’s lack of medical specialists and equipment.

### Disposition

This case was settled on behalf of the nephrologist. The orthopedic surgeon received a summary judgment and the hospital was non-suited due to its bankruptcy status.

### Risk management considerations

Physicians can consider the following guidelines to help reduce liability in the area of anticoagulation therapy.

- Become familiar with anticoagulation guidelines and consider how following these guidelines will affect your patient.
- 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.
- Frequent monitoring can help avoid problems when a patient is on long-term anticoagulation therapy and changes in health status or life situation occur. Significant changes can include hospital or nursing home admission, surgery, changes in diet, or medication (including herbal and OTC products).
- 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. Ensure the patient knows who to contact to manage their anticoagulation therapy once they leave the hospital.
- 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.

"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 of risk management at TMLT. "Consider what is happening with the patient's entire health status when reviewing lab work and adjusting regimens."

## Sources

1. Wysowski DK, Nourjah P, Swartz L. Bleeding complications with warfarin use: a prevalent adverse effect resulting in regulator action. *Arch Intern Med.* 2007; 167:1414-1419.
2. The Institute for Safe Medication Practices. High-alert medication feature: anticoagulant safety takes center stage in 2007. Available at <http://www.ismp.org/Newsletters/acute-care/articles/20070111.asp>. Accessed October 22, 2009.
3. The Joint Commission. Preventing errors relating to commonly used anticoagulants. *Sentinel Event Alert.* Issue 41, September 24, 2008. Available at [http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea\\_41.htm](http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_41.htm). Accessed October 22, 2009.
4. U.S. Pharmacopeia. Paying Attention to Anticoagulant Medication Errors: What Have We Learned? USP Patient Safety CAPSLink. January 2008. Available at <http://www.usp.org/pdf/EN/patientSafety/capsLink2008-01-01.pdf>. Accessed October 22, 2009.
5. Caffee AE, Teichman PG. Improving anticoagulation management at the point of care. *Fam Pract Manag.* February 2002.
6. Atrial fibrillation investigators. Risk factors for stroke and efficacy of antithrombotic therapy in atrial fibrillation: analysis of pooled data from five randomized controlled trials. *Arch Intern Med.* 1994; 154:1449-1457.
7. Atwood JE, Albers GW. Anticoagulation and atrial fibrillation. *Herz.* 1993; 18:27-38.
8. Hirsh J, Fuster V, Ansell J, Halperin JL. American Heart Association/American College of Cardiology Foundation guide to warfarin therapy. *J Am Coll Cardiol.* 2003 May 7; 41(9): 1633-52.
9. Lip GYH. Anticoagulation in older adults. *UpToDate.* Available at [www.uptodate.com](http://www.uptodate.com). Accessed on October 2, 2009.
10. Chiquette E, Amato MG, Bussey HI. Comparison on an anticoagulation clinic with usual medical care. *Arch Intern Med.* 1998; 158:1641-1647.
11. Gattellari M, Worthington J, Zwar N. Warfarin an inconvenient truth. *Stroke.* 2009; 40:5-7.
12. Howitt A, Armstrong D. Implementing evidence based medicine in general practice: audit and qualitative study of antithrombotic treatment for atrial fibrillation. *BMJ.* 1999; 318: 1324-7.
13. American College of Chest Physicians. Thrombosis guidelines emphasize difficult choices for pregnant women. June 2008 Press Release. Available at <http://www.chestnet.org/about/press/releases/2008/080624.php>. Accessed October 9, 2009.
14. Bush J. Reducing risks for patients receiving warfarin. *Fam Pract Manag.* July/August 2002.
15. American College of Chest Physicians. Antithrombotic and Thrombolytic Therapy: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). *Chest.* June 2008. 133:67S-968S. Available at [www.chestjournal.org](http://www.chestjournal.org). Accessed October 22, 2009.
16. Horton JD, Bushwick BM. Warfarin therapy: evolving strategies in anticoagulation. *Am Fam Physician.* February 1, 1999.
17. Ansell J, Hirsh J, Dalen J, et al. Managing oral anticoagulant therapy. *Chest.* 2001 Jan;119 (1 Suppl):22S-38S.
18. Valentine KA. Outpatient management of oral anticoagulation. *UpToDate.* Available at [www.uptodate.com](http://www.uptodate.com). Accessed October 2, 2009.
19. van Walraven C, Jennings A, Oake N, Fergusson D, Forster AJ. Effect of study setting on anticoagulation control. *Chest.* 2006; 129:1155-1166.
20. Lip GYH. Anticoagulation in older adults. *UpToDate.* Available at [www.uptodate.com](http://www.uptodate.com). Accessed October 2, 2009.
21. The Use of Oral Anticoagulants (Warfarin) in Older People. *J Am Geriatr Soc.* 2002; 50:1439.
22. Lip GYH. Management of anticoagulation before and after elective surgery. *UpToDate.* Available at [www.uptodate.com](http://www.uptodate.com). Accessed October 2, 2009.
23. Beyea S. Anticoagulants: Be alert for errors. *AORN Journal.* January 2009. 89(1): 203-205.
24. Haines ST. Challenges in managing venous thromboembolism and acute coronary syndrome: case studies of the use of antithrombotic and antiplatelet therapies. *Am J Health-Syst Pharm.* 2008; 65 (Suppl 7):S3-4.
25. Stashenok GJ, Tapson VF. Prevention of venous thromboembolism in medical patients and outpatients. *Nat Rev Cardiol.* 6, 356-363 (2009).

Laura Brockway can be reached at [laura-brockway@tmlt.org](mailto:laura-brockway@tmlt.org).