

## Legal Issues



By Janet K. Feldkamp, JD, RN, LNHA

# Anticoagulant Therapy: Stem the Bleeding

**A**nticoagulant therapy has increased over the past few years for residents of long-term care facilities as it is put to use in diseases such as atrial fibrillation to prevent strokes.

Accompanying the undeniable benefits of anticoagulant drugs are the increased risk of bleeding and fluctuations in clotting. In addition, anticoagulants can interact with other drugs in dangerous ways. Particularly concerning are antibiotics, which may increase an anticoagulant's effect, resulting in elevated risk of clinically significant patient bleeding.

Significant injury and death have occurred among long-term care residents receiving anticoagulants, but whose facilities have not monitored blood clotting times of residents receiving this therapy in a timely fashion. The tests used to do so measure the international normalized ratio (INR) and the prothrombin time (PT). Recent civil and regulatory cases based on these failures demonstrate that facilities must take responsibility for monitoring the patients' blood clotting times and must question attending physicians who do not order frequent monitoring.

In April, the federal Health and Human Services Departmental Appeals Board upheld a finding of immediate jeopardy and the imposition of a civil penalty in excess of \$143,000 based on an Arkansas nursing home's violation of professionally recognized standards in administering warfarin (Coumadin). The board found that the facility had violated the "quality of care" regulation 42 C.F.R. § 483.25.

The resident had a history of cerebrovascular accidents and atrial fibrillation, for which the resident's attending physician had prescribed the warfarin. The government's evidence in the case indicated that the facility had failed to monitor the patient's INR and PT monthly, as ordered by the attending physician. In addition, the board found that the facility's staff had failed to comprehend signs of warfarin toxicity in the resident and to take into account in managing her care that she was also receiving antibiotics.

Finally, the board found that the facility's consultant pharmacist had failed to discharge a responsibility to evaluate the resident's use of warfarin in conjunction with her antibiotic regimen. As a result of the facility's errors, the resident developed a hemorrhage so severe that she required hospitalization and multiple transfusions to treat the consequent anemia.

Although the nursing staff noted the resident's bruising and bleeding in her chart, the board held that they should

have realized that these were signs of warfarin toxicity and, at the very least, determined whether her blood clotting times were being monitored appropriately. This would have alerted the staff that they were not in conformance with the physician's orders.

In addition, the board held that the facility's nursing staff should have recognized the potential of the antibiotics to heighten the effects of the warfarin and that they should have taken special precautions such as increased INR and PT testing to guard against the possible adverse effects of the woman receiving warfarin with the antibiotics.

### Question Authority

In a 2005 decision, the HHS board indicated that a facility's nursing staff should recognize the need for increased monitoring of a resident's blood clotting parameters and should question the resident's physician if the physician has not ordered adequate monitoring. In the case triggering that ruling, the physician of a resident receiving Coumadin ordered an INR checked every 2 weeks. However, when the physician subsequently prescribed an antibiotic in addition to the warfarin, the pharmacist sent to the physician and the facility a written warning that the resident's INR should be checked 3 days after beginning the antibiotic because of the potential for drug interaction.

However, the physician did not order the facility to monitor the resident's INR as suggested. Five days after he began receiving the antibiotic, a nurse noted a scant amount of rectal bleeding with a bowel movement, which the nurse attributed to hemorrhoids. The next day, the resident had two bouts of rectal bleeding, and the facility sent the resident to the emergency room, where his INR was too high to measure, as was his PT.

The resident was hospitalized for 3 days and required blood transfusions. The government and the board faulted the facility for failing to intervene when it appeared that the physician had ignored the pharmacist's warning and failed to order the INR monitoring according to that warning. The board held that, at a minimum, the facility should have consulted the physician to ensure that he had received and understood the warning and had made an informed decision not to monitor the resident's INR as recommended by the pharmacist.

In addition to subjecting a facility to survey deficiencies and civil money penalties, failure to properly monitor residents receiving warfarin or other anticoagulation drugs can result in civil malpractice lawsuits against the facility.

In 2005, a Massachusetts facility entered into a \$170,000 settlement agreement with the estate of a deceased resident when the resident, who received warfarin and was later prescribed the antibiotic Rocephin (ceftriaxone) for a urinary tract infection, suffered an intracranial bleed and died. The resident's estate alleged that the facility had failed to monitor the resident's clotting time and failed to administer the medications properly in order to maintain proper INR levels. The facility denied the allegations but ultimately settled with the resident's estate out of court.

Because of the risk that anticoagulants present, nursing facilities should:

- ▶ Ensure that blood clotting parameters of patients receiving anticoagulants are monitored in accordance with physician's orders and, in any case, not less than once every 30 days.
- ▶ Carefully track changes of medication dosages, with particular follow-up after dosages have been changed because of either increased or decreased clotting times.
- ▶ Monitor residents' blood clotting times more frequently if anticoagulant drugs are used in conjunction with antibiotics or other drugs with anticoagulant effects.
- ▶ Ensure that nursing staff recognize the signs of excessive anticoagulation—such as bruising, bleeding gums, and blood in the urine or stool—and closely monitor

a resident's blood clotting parameters if the resident exhibits such signs.

▶ Ensure that checks and balances are built into the system for tracking samples sent to the laboratory. Establish mechanisms for prompt notification by the laboratory to the facility and the facility to the physician.

▶ Keep vitamin K in the emergency kit so that it can be given when appropriate for markedly elevated INRs.

▶ Consider using a protocol for managing anticoagulant dosing. Many facilities have arrangements with their contracted pharmacies or their physician groups' "Coumadin clinics" to provide appropriate prescribing and monitoring orders in response to lab results.

▶ Make patients and families aware of the risks of anticoagulant usage, which include increased bleeding, and document informed consent to their use. Patients can have adverse events even with INRs that are within therapeutic range. 

*This column is not to be substituted for legal advice. The writer, Janet K. Feldkamp, practices in various aspects of health care, including long-term care survey and certification, certificate of need, health care acquisitions, physician and nurse practice, managed care and nursing related issues, and fraud and abuse. She is affiliated with Benesch Friedlander Coplan & Aronoff LLP of Columbus, Ohio.*

## Medical Expert Perspective

**M**ost of us are well aware that anticoagulant drugs, especially warfarin, are among the greatest sources of serious medication-related adverse events and medical errors.

The cases mentioned here are not uncommon. When a patient has a bad outcome and there is evidence of repeated abnormally elevated lab values (INRs) without appropriate action, it is difficult to defend a lawsuit—as it should be, considering that multiple entities have had an opportunity to intervene: laboratory, pharmacy, nursing, and physicians or other practitioners. Keep in mind that risks of bleeding are increased when multiple drugs are used—including aspirin and other antiplatelet agents (clopidogrel, prasugrel, ticlopidine), NSAIDs, and heparin and heparinoid drugs.

We need to be sure we have reasonably consistent practices with respect to (1) changing a warfarin dose, (2) rechecking the INR, (3) how long

to keep a patient on warfarin and other blood thinners, and (4) what to do when starting antibiotics or other drugs that are likely to interact with warfarin. All these considerations are on top of ensuring that we have obtained informed consent and that the patient or family is aware of the risks associated with bleeding.

There are good protocols that we can use, but in my experience they are very conservative and take a long time to get warfarin to a therapeutic dosage. That delay frequently necessitates prolonged bridging therapy.

New drugs are in the pipeline that will not require monitoring of labs, but it will probably be years before they are in the mainstream. So in the meantime, be vigilant and be sure you have processes in place to provide checks and balances when a patient is receiving warfarin or other anticoagulants.

—Karl Steinberg, MD, CMD,  
Editor in Chief