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CME: PRESCRIBING ANTICOAGULANTS – A RISK MANAGEMENT OVERVIEW

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CME - PRESCRIBING ANTICOAGULANTS – A RISK MANAGEMENT OVERVIEW

by Wayne Wenske, Senior Marketing Strategist

OBJECTIVES

Upon conclusion of this course, the physician will be able to:

1. discuss the differences and similarities of warfarin and direct oral anticoagulants;
2. list patient conditions and risk factors to consider when prescribing anticoagulants;
3. describe best practices for patient education for self-managing anticoagulant therapy; and
4. explain the importance of follow up, tracking, and clear policies and procedures when treating patients taking anticoagulants.

COURSE AUTHOR

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DISCLOSURE

Wayne Wenske has no relevant financial relationship(s) with ineligible companies to disclose. TMLT staff, planners, and reviewers have no relevant financial relationship(s) with ineligible companies to disclose.

TARGET AUDIENCE

This 1-hour activity is intended for physicians who are interested in practical ways to increase patient safety and reduce the potential for medical liability.

CME CREDIT STATEMENT

The Texas Medical Liability Trust is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The Texas Medical Liability Trust designates this enduring material for a maximum of 1 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

PRICING

A fee of $75 will be charged when accessing this CME course online at http://lonestara.inreachce.com.

ETHICS CREDIT STATEMENT

This course has been designated by TMLT for 1 credit in medical ethics and/or professional responsibility.

TEST

To receive CME credit, physicians should complete the test questions that follow the activity. A passing score of 70% or better earns the physician 1 CME credit.

INSTRUCTIONS

the Reporter CME test and evaluation forms must be completed online. After reading the article, go to http://lonestara.inreachce.com. Follow the online instructions to complete the forms and download your certificate.

Questions about the CME course? Please call TMLT Risk Management at 800-580-8658.

ESTIMATED TIME TO COMPLETE ACTIVITY

It should take approximately 1 hour to read this article and complete the questions and evaluation form.

RELEASE/REVIEW DATE

This activity is released on March 10, 2022 and will expire on March 10, 2025.

Please note that this CME activity does not meet Lone Star Alliance RRG's discount criteria. Physicians completing this CME activity will not receive a premium discount.

DISCLAIMER

The closed claim studies included in this article are based on actual malpractice claims from Texas Medical Liability Trust. These cases illustrate how action or inaction on the part of the physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physicians' defensibility. These studies have been modified to protect the privacy of the physicians and the patients.

INTRODUCTION

Anticoagulation medication management is often at the center of medical liability lawsuits and will likely continue to be, due to the complex nature of these medications and their uses. A recent study of U.S. emergency department (ED) visits for adverse drug events (ADEs) found that the most common drug class associated with ADEs were anticoagulants, responsible for 17.6 percent of patient visits.

This percentage was driven by patients over the age of 65 who make up the leading demographic for ADEs in adults. For this age group, anticoagulants are the leading cause of ED visits. For all age groups in this study, 48.8 percent of patient visits associated with anticoagulants resulted in a hospitalization.[1, 2]

Medication errors are a significant cause of preventable adverse events. A study conducted by the Centers for Disease Control and Prevention (CDC) reported that ADEs account for nearly 100,000 hospital admissions each year for adults 65 or older. Approximately two-thirds of these admissions are related to unintentional overdoses involving commonly used medications. Almost one-third of admissions involved anticoagulant-related hemorrhages.[3]

The use and management of anticoagulants involves several factors, including appropriate prescribing;

educating patients and staff members on safety measures; and monitoring patient compliance and continuity of care. This article outlines how a physician may use different risk management practices to better manage prescribing anticoagulant medications.

ANTICOAGULANTS: THE MEDICATIONS

Anticoagulants reduce the risk of blood clots by slowing the body's cascading process of blood clotting. Anticoagulants keep blood clots from forming in an artery, a vein, or the heart; keep existing clots from getting larger; and allow the body to reabsorb the blood.

Anticoagulants are commonly used to treat patients with atrial fibrillation; venous thromboembolism, also known as deep vein thrombosis and pulmonary embolism (DVT/PE); thrombophilia; and patients at risk for blood clotting such as those after surgery or those with a mechanical heart valve. By promoting the smooth flow of blood, anticoagulants reduce the risk of blood clots that can lead to myocardial infarction or stroke.

Warfarin

Warfarin is the most commonly dispensed oral anticoagulant in the U.S. with a decades-long history of effectiveness. It is within a group of drugs referred to as Vitamin K antagonists (VKAs), drugs that antagonize the recycling of vitamin K in the blood, disrupting the blood clotting process. Warfarin takes about three days to reach its full effect; but reaching a correct dose for individual patients can take longer.[4, 5]

Warfarin has a narrow index for an effective therapeutic range, numerous drug contraindications, patient dietary restrictions, and dangerous side effects. These limitations require patients who take warfarin to diligently and frequently monitor their blood to ensure it stays in therapeutic range.

Warfarin dosages vary by patient and are based on the individual patient's prothrombin time (PT)/international normalized ratio (INR) test results. These tests are used to regularly monitor patients taking anticoagulants. The PT shows how long it takes for the patient's blood to clot, as measured in seconds. The INR is a way of expressing the PT in a standardized way to ensure the results obtained by different laboratories in different facilities are consistent. The INR is expressed as a number without units.[5]

The average time for blood to clot in a healthy patient not taking anticoagulants is between 10 and 13 seconds, and an INR of 1.1 or below is considered normal. If the patient's blood takes longer to clot, the INR will be higher. For most patients taking anticoagulants, an INR between 2 and 3 is considered an effective therapeutic range. For some patients, including those with a mechanical heart valve, the target therapeutic INR range may be higher. If the INR increases above therapeutic level (increasing the risk for bleeding), it can be corrected by adjusting the anticoagulant dose until the INR level returns to the therapeutic range.[4, 6]

Heparin

In clinical use for more than 50 years, unfractionated heparin (UFH) is administered through an IV or by injection and works quickly to prevent clotting. Heparin interferes with the body's ability to activate thrombin, an enzyme in blood plasma that facilitates clotting. It is often used in a hospital setting, such as intensive care, during surgery, and for patients with renal failure. Dosing is determined by the patient's weight.

Surgery patients on warfarin typically have their anticoagulant therapy interrupted for 10 to 12 days before their surgery to minimize bleeding. When warfarin is interrupted and its anticoagulant effect goes outside the therapeutic range, heparin is given to reduce the patient's risk for developing blood clots. This is referred to as bridging anticoagulation.[7]

Patients given UFH are monitored via blood tests several times a day. The patient's weight and activated partial thromboplastin time (aPTT) reading from the blood tests are used to determine the correct dosage for reaching and maintaining a target therapeutic range. When discontinued, the therapeutic effects of UFH diminish quickly.[8]

Some patients have the option of giving themselves injections of low molecular weight heparin (LMWH) at home. As with UFH, dosing is based on the patient's weight. LMWH does not require blood testing to monitor its efficacy and is often prescribed to pregnant women for anticoagulation, as it is considered safe for a fetus. Warfarin is considered unsafe for pregnant women.

Heparin can increase the risk of osteoporosis over time, and patients are usually switched to warfarin if long-term anticoagulant therapy is required.

Direct-acting oral anticoagulants (DOACs)

Since 1990, there have been several innovations in anticoagulation medications, leading to the development of direct-acting oral anticoagulants (DOACs). There are two classes of DOACs: factor Xa inhibitors, such as rivaroxaban, edoxaban, and apixaban; and direct thrombin inhibitors, such as dabigatran.

DOACs have been increasingly recognized as safer alternatives to warfarin for many patients. DOACs are cited for working quickly to reach desired therapeutic levels (less than 24 hours) and do not require PT/INR monitoring.

However, the lack of required monitoring – often seen as an advantage over warfarin – is of concern to some physicians. They argue that situations exist (such as during urgent surgery, trauma, or acute bleed) when having a reliable method to assess the presence of an anticoagulant effect is useful.[9]

Bleeding reversal agents and protocols for patients taking DOACs have not yet been clearly identified. Whereas, if significant bleeding occurs in a patient taking warfarin, there is a reversal agent available – vitamin K. The effect of heparin is reversed with protamine sulfate.[10, 11, 12]

Also, appropriate dosing of DOAC efficacy in morbidly obese patients or patients who have undergone gastric bypass surgery is unclear. Another study shows that the use of dabigatran in older patients with kidney dysfunction may increase the risk of intracranial bleeding. Higher cost is also a factor with DOACs, as they may be prohibitively expensive compared to warfarin.[13]

PATIENT CONDITIONS TO CONSIDER WHEN PRESCRIBING ANTICOAGULANTS

Because prescribing anticoagulants presents several potential risks to a patient's safety, established guidelines and tools exist to help physicians assess a patient's suitability for anticoagulants.

A physician may choose not to use anticoagulation if the risk of harm outweighs the benefits of treatment.

The following patient characteristics and conditions are often taken into account before prescribing oral anticoagulants:

- age of 70 or over, with the risk increasing with advancing age;
- cognitive impairment;
- fall risk or history of falls;
- excessive alcohol use;
- liver disease;
- low albumin level (less than 36g/L);
- impaired vision;
- diabetes;
- anemia;
- hypertension;
- history of congestive heart failure;
- history of transient ischemic attack;
- history of stroke;
- non-compliance with medications and other health care guidance; and
- poor diet.[12, 14, 16, 17]

The risk of bleeding is also considered along with the following patient factors:

- presence of mechanical heart valve (DOACs are currently contraindicated for use with these patients); [15]
- renal and liver dysfunction or disease;
- body weight;
- history of peptic ulcer disease;
- ability to comply with medication instructions; and
- history of success with anticoagulation therapy.[12]

HAS-BLED tool to help assess bleeding risk

Several tools exist to help physicians determine if a patient may become a higher risk for bleeding while taking warfarin. It is not yet known whether these same tools can be reliably applied to DOACs.

The HAS-BLED tool is a widely used method for assessing risk for bleeding in patients with atrial fibrillation taking warfarin. Several studies exist that suggest HAS-BLED outperforms other tools in predicting "clinically relevant bleeding." It has also been noted as being a good predictor of intracranial bleeding and perioperative bleeding.[14, 16, 17]

The HAS-BLED score is achieved by compiling points for different clinical conditions. The maximum score is 9; patients with a score greater than 3 are considered at greater risk for bleeding and may require more monitoring.[14, 17]

WARFARIN: RISK FACTORS

Warfarin is contraindicated in patients with hemorrhagic stroke or clinically significant bleeding. Other contraindications include to avoid dispensing or administering within 72 hours of major surgery with risk of severe bleeding; and to avoid dispensing or administering to a pregnant patient; and within 48 hours postpartum.[18]

Side effects

Because bleeding and hemorrhage are risks associated with warfarin, maintaining the INR within the patient's therapeutic range is critical. Instruct patients taking warfarin to seek immediate medical help if they experience any of the following:

- severe bleeding, including heavier than normal menstrual bleeding;
- blood in urine (red or brown urine);
- black or bloody stool;
- severe headache or stomach pain;
- joint pain, discomfort, or swelling, especially after an injury;
- vomiting blood or material that looks like coffee grounds;
- coughing up blood;
- unexplained or excessive bruising;
- dizziness or weakness;
- changes in vision; and
- head injury, with or without bleeding.[19]

Less serious side effects may include bleeding gums after brushing teeth; bleeding between menstrual periods; fever; and diarrhea, vomiting, or inability to eat for more than 24 hours.[19]

Medical conditions that can increase the risk of bleeding include:

- uncontrolled blood pressure;
- a history of stroke;
- stomach ulcers, gastritis, or peptic disease;
- kidney problems;
- cancer;
- alcoholism;
- liver disease; or
- increased risk of falls.

Drugs, supplements, and foods that interfere with warfarin efficacy

Common drugs that can interact with warfarin include:

- aspirin or aspirin-containing products;
- acetaminophen or acetaminophen-containing products;
- non-steroid anti-inflammatory drugs;
- antacids or laxatives;
- antibiotics;
- antidepressants;
- antifungal medications;
- cold or allergy medicines; and
- medications to treat abnormal heart rhythms, such as amiodarone.[19]

Common supplements that can interact with warfarin include:

- coenzyme Q10 (ubiquinone);
- dong quai;
- garlic;
- ginkgo biloba;
- ginseng;
- green tea;
- St. John's wort; and
- vitamin E.[19]

Common foods and drinks that might interact with warfarin include cranberries or cranberry juice, grapefruit, alcohol, garlic, and black licorice.[19] In addition, foods high in vitamin K, such as liver, broccoli, Brussels sprouts, and green leafy vegetables, can potentially interfere with anticoagulation.

CLOSED CLAIM STUDY: FAILURE TO PROPERLY MANAGE WARFARIN DOSE

The following closed claim study illustrates several challenges for physicians when managing patients taking warfarin.

Presentation

An 89-year-old woman suffered a fractured right femur requiring surgical repair. She had a complicated history and comorbidities, including coronary artery disease, myocardial infarction, congestive heart failure, atrial

fibrillation, pacemaker, diabetes with retinopathy, osteoporosis with history of compression fractures, chronic obstructive pulmonary disease, bladder cancer, and chronic kidney disease.

The patient's medications included a long-standing prescription for warfarin 5 mg daily, except 2.5 mg on Wednesdays and Sundays.

The patient was admitted to a local hospital for right hip repair. Her warfarin was suspended before surgery. Following a successful procedure, the patient's usual dosage of warfarin was increased to 10 mg to reach the patient's therapeutic range (international normalized ratio, or INR, between 2.0 and 3.0).

Physician action

Two weeks after surgery, the patient was transferred to a rehabilitation facility under the care of an internal medicine physician. Upon arrival, the patient was noted as receiving warfarin 10 mg daily, and her INR was 1.5. In the hospital discharge summary, the hospitalist indicated the patient was being transitioned off enoxaparin (an LMWH) onto warfarin. The warfarin would be continued at the current dosage until the INR was greater than 2, and then the warfarin dose should be adjusted accordingly.

During her time in the rehab facility, the patient was not treated or examined by the internal medicine physician. Instead, the patient saw the physician assistant. The patient remained on the increased dosage of 10 mg of warfarin and her repeat INR level reached 2.7.

The physician was told about the patient's therapeutic INR level, but no changes were made to the dosage. The patient's treatment plan was to continue the warfarin at 10 mg and recheck the INR in one month.

Approximately one month later, while still in the rehabilitation facility, the patient was noted to have abdominal distention, nausea, vomiting, and diarrhea. She was transferred to the hospital for evaluation, imaging studies, and lab testing.

The patient's INR was greater than 6 — twice the acceptable normal range. The imaging studies suggested bleeding in her gastric and duodenal wall. In addition to the abdominal hemorrhage, the patient developed cholecystitis, which was treated with a percutaneous cholecystostomy tube.

Although the swelling resolved, the patient was severely malnourished and did not recover. After two weeks, she was discharged to home hospice care. She died three days later.

Allegations

The family filed a lawsuit against the internal medicine physician, alleging failure to properly monitor/manage the warfarin dosage.

Legal implications

Prescribing warfarin can be challenging because its therapeutic range is narrow and its metabolism is affected by patient genetics, as well as medication interactions and diet. Warfarin dosages are individualized to account for these factors.

The PT/INR study allows the effect of warfarin to be monitored so that the patient is not over-medicated (bleeding risk) or under-medicated (clotting risk). Maintenance doses of warfarin vary widely from patient to patient, typically ranging from 2 mg/day to 10 mg/day.[20]

Defense experts who reviewed the case did not support the physician's actions, though the patient was monitored frequently after admission to the rehab facility and appropriately transferred when her condition deteriorated. The consultants stated the physician failed to meet the standard of care due to:

- failure to review the discharge instructions when the patient was admitted to the rehabilitation facility;
- failure to review the admission history and physical exam to determine why the patient was placed on warfarin (how long, usual dose, and current dose); and
- failure to question why the patient was admitted on a significantly higher dose.

According to defense experts, there were multiple times when the INR could have been tested but was not. These times include the following.

- The patient was being transitioned off enoxaparin onto warfarin. This change in medication may have required close monitoring of INR levels.
- The patient was placed on multiple antibiotics for treatment of infection. These medications often interact with warfarin and can affect INR results.
- When the patient reported GI symptoms, as GI bleeding is a known risk.

The defendant stated that this patient required a higher dosage to maintain a therapeutic INR level due to her comorbidities. Defense consultants were concerned with the defendant's decision to wait 30 days to recheck the patient's INR level, stating that the standard of care required more frequent testing of the patient's INR due to the change in dosage, the patient's physical condition, and age.

Disposition

This case was settled on behalf of the internal medicine physician.

Risk management considerations
A routine part of any post-hospitalization visit is to review the patient's history, physical examination, and medication list, along with the hospital discharge summary to determine what post-hospital care is required. The most significant medication on this patient's medication list was warfarin. Had all the steps mentioned above been taken, the patient's INR could have been monitored more closely.

MANAGING ANTICOAGULATION THERAPY

When prescribing and/or maintaining anticoagulants, consider establishing the following processes, policies, and procedures to enhance patient safety.

Medication reconciliation
Reviewing a patient's current medications, including drug names and dosages, at every encounter is a good risk management practice. Reviewing medications will help you ensure patients are taking the correct dosage and not experiencing side effects or drug interactions that would require modifications.

A comprehensive list of medications should include all prescriptions, vitamins, nutritional supplements, over-the-counter drugs, vaccines, herbal medicines, diagnostic and contrast agents, radioactive medications, parenteral nutrition, blood derivatives, and intravenous solutions.[21]

Because interactions can occur between prescribed medications, over-the-counter drugs, and/or nutritional supplements, include all medications and supplements in the patient's medication history and reconciliation process.[21]

The Institute for Healthcare Improvement suggests adopting the following three steps as a medication reconciliation process:

1. "*verify* by collecting the list of medications, vitamins, nutritional supplements, over-the-counter drugs, and vaccines;
2. *clarify* that the medications and dosages are appropriate; and
3. *reconcile and document* any changes." [21]

Update the list whenever medications are added or changed. Establish a method for documenting and flagging medication changes in the patient chart and a timeframe for resolving any discrepancies.

In addition, clearly identify team roles and responsibilities for medication reconciliation in your office's policies and procedures. Determine *who* in your office may reconcile medications and *when* this process will be completed during the patient encounter. Identify exactly *where* in the patient chart the medication history is maintained. Ensure that all staff members are instructed on where to put and refer to medication history in the patient chart. By assigning the "who," "when," and "where" to documenting medication histories, the potential for duplicating entries and documentation errors are reduced.[21]

Medication reconciliation is important in all settings, including hospitals, long-term care facilities, clinics, and home care. In the hospital setting, the medication reconciliation process is undertaken at key stages such as:

- Admission: Each of the patient's medications is evaluated to determine if they should be continued, modified, or discontinued.
- In-hospital transfer: Each of the patient's present hospital medications is evaluated to determine what should be continued, and whether medications taken at home should be resumed, modified, or discontinued.
- Discharge: To avoid duplicating, omitting, or prescribing unnecessary medications, cross-reference the patient's pre-admission medication list with the most recent hospital medication list to compare and evaluate the continuing indication and need for all:
  - pre-hospital medications;
  - medications started or modified in hospital; and
  - planned post-discharge medications.[22]

If a patient is being discharged with anticoagulant medication, the education step becomes even more important to ensure the patient properly manages their therapy at home. While still in the hospital, patient education should begin with the patient's first dose of anticoagulant and be regularly reinforced.

CLOSED CLAIM: FAILURE TO MONITOR PATIENT'S POSTOPERATIVE INR

The following closed claim illustrates the importance of patient education.

Presentation
A 54-year-old woman came to an orthopedic surgeon with complaints of chronic bilateral hip pain lasting for 30 years. She reported a history of smoking one-half pack of cigarettes per day and consuming between 2 to 4 beers per day.

Physician action
An MRI of the left hip revealed full thickness cartilage loss along the anterior aspect of the hip joint with associated subchondral cyst along the acetabulum. There was moderate to severe cartilage loss along the superior aspect of the hip joint and moderate cartilage wear posteriorly. Further, there was degeneration in the superior aspect of the labrum with non-displaced tear at the base.

The orthopedic surgeon diagnosed the patient with extensive bilateral arthritis and prescribed tramadol. He

followed her in the clinic. The patient returned a year later complaining of increasing left hip pain. A cortisone injection was administered, but the patient returned four months later and reported increasing pain. The orthopedic surgeon planned to perform a total left hip replacement.

The hip arthroplasty was performed without complications.

Postoperatively — on a preprinted form — the surgeon ordered deep vein thrombosis (DVT) prophylaxis consisting of heparin 5000 units subcutaneously every 8 hours and 4 mg of warfarin at bedtime. On this order form, the orders for warfarin and heparin were checked for DVT prophylaxis. PT/INR testing, which was included on the form, was not checked. The hospital chart did not indicate there was any PT/INR testing during the admission. The medication record indicated the patient received both heparin and warfarin postoperatively.

The patient was discharged on postop day three, a Monday. She was given discharge instructions that did not include follow up on PT/INR testing. The orthopedic surgeon wrote an undated prescription that stated "PT/INR on Tuesday" which was the day after her discharge.

The discharge summary reflects that the patient was given prescriptions for pain medication, anti-inflammatories, and warfarin for DVT prophylaxis. She was also given a plan to check her coagulation in "a couple of days" when her warfarin would be adjusted accordingly. The patient was asked to follow up in the clinic in 10 to 14 days.

The patient came to the hospital nine days after discharge and before her first postoperative appointment. She had not been to the warfarin clinic to check her coagulation. She reported diffuse abdominal pain for three days, with the pain increasing in intensity. She provided no history of hematemesis, hematochezia, or melena. She denied any dysuria, hematuria, or incontinence.

The results from a hemoccult were negative, although the patient did have pain with the rectal exam. Her skin showed bruising over the left hip area. The incision on the left hip was clean, dry, and intact. Initial lab testing showed a low sodium level of 129 with normal renal function and serum glucose. Her white blood count was elevated at 23.9 and hemoglobin was 13.0. She was admitted to the ICU.

According to the attending physician, the abdominal pain was most likely secondary to diverticulitis and small bowel obstruction. However, a physical exam revealed a severely tense abdomen. The patient's INR at the time of admission was 13.3 (therapeutic range 2.0 – 3.0).

A surgical consult was obtained. The surgeon concluded that the patient was likely bleeding into her pelvis. He felt there was no evidence of diverticulitis and that her pain was due to spontaneous hemorrhage complicated by anticoagulation that had been addressed upon admission.

A gastroenterologist ordered an abdominal CT scan that showed thickening of the sigmoid colon, possible diverticulitis, or colitis. An upper GI endoscopy was performed and found a short segment of Barrett's in the distal esophagus. There was also evidence of a Mallory-Weiss tear. There was no active bleeding in that area and no visible blood vessel. The most likely source of the GI bleed was thought to be the Mallory-Weiss tear.

The patient's hospital stay was complicated by respiratory failure, acute renal failure, and hyponatremia. She was discharged a month later.

Within a month, the patient was re-admitted and underwent an exploratory laparotomy, sigmoid colectomy, mobilization of splenic flexure, small bowel resection and anastomosis, diverting loop ileostomy and central line placement. Pathology confirmed a diagnosis of diverticulitis including an apparent perforation in a portion of the sigmoid colon. During her postoperative course, she developed a surgical open wound infection.

The patient continued to have complications and multiple admissions related to her abdominal complaints and complications of surgery.

Allegations

A lawsuit was filed against the orthopedic surgeon. The allegations included:

- failure to obtain a baseline PT/INR before initiating warfarin;
- failure to obtain PT/INR values during her admission; and
- failure to ensure PT/INR labs were timely obtained following discharge.

It was further alleged that the patient's warfarin toxicity caused a retroperitoneal hematoma and multiple complications.

Legal implications

The plaintiff 's attorney retained well-credentialed experts to testify that the orthopedic surgeon's anticoagulation management breached the standard of care, which prompted the patient's complicated course.

The subsequent treating surgeon documented a retroperitoneal bleed complicated by anticoagulation. That diagnosis was perpetuated throughout the medical records by other subsequent physicians.

Disposition

The case was settled on behalf of the orthopedic surgeon.

Risk management considerations

As stated in this article, anticoagulation therapy can have life-threatening side effects, even when the treatment plan is properly monitored. Accurate and thorough documentation of patient education and plans for monitoring the patient's coagulation levels are key components.

Performing initial and follow-up lab work to determine PT/INR levels assists the treating physician to properly prescribe anticoagulation drugs, so that some of the known complications can often be avoided.

In this claim, the only documentation that focused on anticoagulation monitoring was a discharge prescription that read "PT/INR on Tuesday." The documentation was kept by the physician but is not particularly clear or thorough. There was no monitoring of the patient's PT/INR before or during her hospital stay, and education about warfarin was missing in the hospital record.

Patient education that includes a discussion of the treatment plan and the risks and benefits of the medication is an important aspect of adequate informed consent. Providing this information to the patient and/or caregivers at the initiation of anticoagulation therapy, during the continuum of care, and upon discharge, both orally and in writing, are all ways of encouraging proper follow up. Of course, documentation of patient education and the instructions given serves as both information for physicians and nurses, as well as later evidence that the appropriate instructions were provided.

For various reasons, patients don't always retain the information given to them during hospital stays. Education articulated in simple terms, repeated often, and provided in writing can improve retention of the instructions. Studies have also shown that the more educated and knowledgeable patients are about anticoagulation therapy, the better their compliance and therapeutic outcomes.[23]

PATIENT EDUCATION

Again, patient education should start at the initiation of therapy and continue throughout the patient's use of the anticoagulant. To ensure medication instructions are understood and properly followed, it is recommended to reinforce oral instructions given to a patient or caregiver by concurrently providing written, detailed instructions.[24]

Providing written materials along with the oral instruction has been shown to improve patient outcomes.[26] Patients may feel overwhelmed by receiving too much information at once about a stressful new drug therapy. Providing them with written information and instructions gives them an opportunity to review it later and often.

A central component of patient education should be the importance of regular, scheduled PT/INR testing, either at home or at a clinic; side effects; and potential interactions. Describe emergency signs and symptoms that must be reported back to you or to a pharmacy in a timely manner. In both the oral and written instructions, emphasize that adherence to instructions is critical to the patient's safety.

It is important that education be in simple terms and include the risks and benefits of the specific medication. The information should be repeated as often as possible – at follow-up appointments and at PT/INR testing clinics.

Some strategies to help educate patients include:

- avoid using medical jargon and speak to patients using plain language;
- provide written instruction in the patient's native language to reduce any communication barriers;
- ask your patient to explain to you what he or she knows about his or her condition, diagnosis, or treatment plans and correct any misinformation; and
- ask your patient to describe (step-by-step) how he or she will explain the diagnosis and treatment plan to someone else (a spouse, parent, or friend) and, again, correct any misinformation.[25, 26]

Document the specifics of education efforts in the patient's record, including follow-up instructions or handouts provided. In Texas, documentation of patient education and specific instructions for follow up are considered standard elements of an "adequate medical record." If practicing outside of Texas, check with your state medical board for any documentation requirements.[27]

PATIENT TRACKING AND POLICIES AND PROCEDURES

As stated, the importance of regular PT/INR testing and follow up is a vital component of a patient's warfarin therapy. A patient's compliance with testing and returning for follow-up appointments can be a challenge for physicians, as it puts a great deal of trust in patients to remain an active member of the care team.

Losing track of a patient who requires careful monitoring places a physician at risk. It is recommended to schedule PT/INR testing and follow-up appointments with the patient upon prescribing the anticoagulant. If an appointment is not kept, contact the patient immediately and document this action in the medical record.[26]

Having written policies and procedures to track and follow up with lab work, testing, and referrals is essential for quality patient care. It is important to create, implement, and maintain tracking policies and procedures, with particular consideration made to critical INR test results.

These policies should include documenting a patient's baseline INR, current dosage, and INR tracked over time. Maintaining standardized policies and procedures helps to ensure that each care team member understands their responsibilities, such as medication reconciliation, patient education, and making and tracking appointments.

Consider incorporating the following rules in your policies and procedures for tracking patients prescribed anticoagulants.

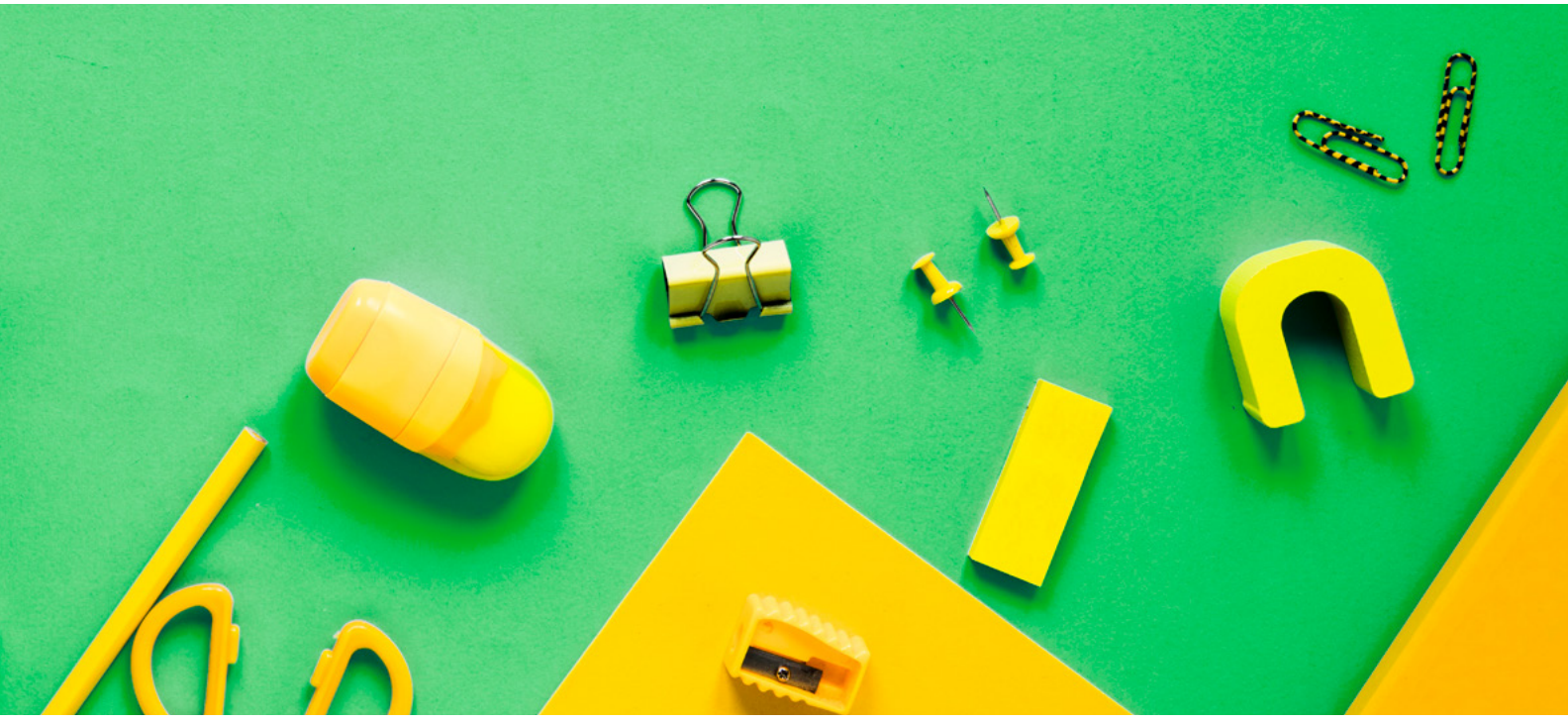
- Develop a tracking system for all labs, diagnostic studies, and referrals. This can be done via electronic order entry in the EHR, or a log.
- Identify for each patient how often to monitor PT/INR, including critical values (both high and low) for the patient.
- Identify those patients at risk for noncompliance, either due to language barrier, cognitive difficulties, repeated no-shows, etc.
- Set up an electronic reminder in your EHR or calendar to check if you have not received a pending INR test result by a specified date, or if a scheduled follow up appointment has occurred as planned or did not occur.
- Work with staff members or outside labs to orally notify you of a patient's critical INR test results.
- Initial and date or electronically sign all laboratory and diagnostic reports upon your review of the report. Develop protocols to ensure that documents are not filed before your review.
- Document follow-up actions for critical or abnormal test results.
- Document the discussion with the patient about diagnostic abnormalities. Each attempt made by a staff member to contact the patient with follow up instructions should be documented.
- Identify someone in your office to be available to receive and act upon critical results after hours.[26, 28]

If a patient regularly fails to return to your office or for PT/INR testing, contact the patient by phone, written letter, or their preferred communication method. Re-emphasize the importance of regular, scheduled testing and/or follow-up appointments. Practices using EHR may use a secure patient portal to send messages to patients. "If using a portal, attention should be given to reviewing whether messages have been opened and viewed by the patient.

If sending a letter, send it on your office letterhead via certified mail and regular mail. Retain a copy of the letter in the patient record, and document when it was sent and by what means. When the certified receipt is received, place it in the patient's record.

Sending a written or electronic message will not guarantee the patient reads it or even receives it if your office does not have correct contact information for the patient. At every patient encounter, ask your patients to confirm that their contact information is correct, including their physical address, phone number, and email address." [28]

While a physician who orders diagnostic testing or anticoagulation medication is responsible for obtaining test results and acting on them, there is also a shared responsibility of all providers to ensure results are



communicated in a timely manner. This includes timely review of critical lab results and planning appropriate follow up, such as any changes to anticoagulation dosages.

Whenever policies and procedures are updated or changed, changes should be communicated to all employees. Staff members should then be instructed to sign and date the new policies and procedures as an acknowledgement that they have read and understood the updates. This also acknowledges their understanding of any changes to their individual roles and responsibilities.

Even with clear communication, patient education, and test tracking, patients may still experience an adverse event related to anticoagulation therapy. Documenting the safe practice protocols you have put into place and the care provided by you and your staff is helpful in increasing the defensibility of a claim surrounding this high-risk class of medication.

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CLAIMS BY SPECIALTY: MPL ASSOCIATION'S 2017-2019 NATIONAL CLOSED CLAIM DATA

by Tanya Babitch, Assistant Vice President, Risk Management, and Wayne Wenske, Senior Marketing Strategist

The following is a compilation of medical malpractice claim data from 2017 to 2019, submitted by member companies of the Medical Professional Liability Association (MPL Association), a trade association of medical liability insurance companies. The MPL Association has been compiling this information since 1985 as part of its Data Sharing Project (DSP). The DSP was created as an aggregated source of claims data "to enhance risk management programs and to track claim costs." MPL Association members have shared more than 350,000 physician and dental professional liability claims with the DSP since its inception.[1]

When submitting data, member companies report data in a codified, generic manner. Names of claimants and insureds are not reported. Approximately 21,300 closed claims and lawsuits were reported to the DSP between 2017 and 2019. "The average cost to defend these claims was $50,950 and nearly one-third (28%) resulted in an average indemnity payment of $368,035 to the claimant." [2]

In addition, 65% of these closed claims were resolved but later shown to lack merit. These claims were either dropped, withdrawn, or dismissed without indemnity payment to the claimant. However, these cases still incurred an average defense cost of $32,146. In cases resolved by a judge or jury, judgement favored the defendant 91% of the time. The average cost to defend these claims was $149,470.[2]

The following report highlights the top three presenting medical conditions; chief medical factors; and outcomes per specialty. The average indemnity payment and the paid-to-closed ratio is also provided.[3]

- The ***presenting medical condition*** is the disease, symptom, complaint, or reason for the patient's visit; significant to the treatment provided at the time of the accident or incident.
- The ***outcome*** is the medical condition that occurred after a medical encounter and led to the chief medical factor named in the claim.[4]

What follows is not meant to be an in-depth analysis, but a snapshot of claims by specialty. This information is designed for use as a risk management tool to inform physicians about the nationwide risk trends for their specialty.

ANESTHESIOLOGY

Top three presenting medical conditions:
1. Pain, not elsewhere classified
2. Dorsalgia
3. Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Medication/IV fluids: Adverse Drug Reaction

Top three outcomes:
1. Cardiac arrest
2. Intraoperative and postprocedural complications and disorders of nervous system, not elsewhere classified
3. Complications of procedures, not elsewhere classified

Average indemnity: $408,884
Paid-to-closed ratio: 27.6%

CARDIOVASCULAR AND THORACIC SURGERY

Top three presenting medical conditions:
1. Chronic ischemic heart disease
2. Aortic aneurysm and dissection
3. Nonrheumatic aortic valve disorders

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Diagnostic: Incomplete/Inadequate

Top three outcomes:
1. Complications of procedures, not elsewhere classified
2. Intraoperative and postprocedural complications and disorders of circulatory system, not elsewhere classified
3. Cardiac arrest

Average indemnity: $481,156
Paid-to-closed ratio: 25.4%

DERMATOLOGY

Top three presenting medical conditions:
1. Other and unspecified malignant neoplasm of skin
2. Encounter for procedures for purposes other than remedying health state
3. Other disorders of skin and subcutaneous tissue

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Diagnostic: Incomplete/Inadequate
3. Procedure: Failure to Recognize Complication

Top three outcomes:
1. Other and unspecified malignant neoplasm of skin
2. Atrophic disorders of skin
3. Complications of procedures, not elsewhere classified

Dermatology continued

Average indemnity: $250,860
Paid-to-closed ratio: 20.8%

EMERGENCY MEDICINE

Top three presenting medical conditions:
1. Abdominal and pelvic pain
2. Pain in throat and chest
3. Dorsalgia

Top three chief medical factors:
1. Diagnostic: Incomplete/Inadequate
2. Diagnostic: Not Performed When Indicated
3. Procedure: Incomplete/Inadequate

Top three outcomes:
1. Cardiac arrest
2. Cerebral infarction
3. Paraplegia (paraparesis) and quadriplegia (quadriparesis)

Average indemnity: $464,228
Paid-to-closed ratio: 28.4%

FAMILY MEDICINE

Top three presenting medical conditions:
1. Dorsalgia
2. Encounter for general examination without complaint, suspected or reported diagnosis
3. Abdominal and pelvic pain

Top three chief medical factors
1. Diagnostic: Incomplete/Inadequate
2. Procedure: Incomplete/Inadequate
3. Diagnostic: Not Performed When Indicated

Top three outcomes:
1. Cardiac arrest
2. Pulmonary embolism
3. Complications of procedures, not elsewhere classified

Average indemnity: $333,531
Paid-to-closed ratio: 34.3%

GENERAL SURGERY

Top three presenting medical conditions:
1. Cholelithiasis
2. Cholecystitis
3. Diverticular disease of intestine

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Diagnostic: Incomplete/Inadequate

Top three outcomes:
1. Complication of procedures, not elsewhere classified
2. Intraoperative and postprocedural complications and disorders of digestive system, not elsewhere classified
3. Accidental puncture or laceration during a procedure, not elsewhere classified

Average indemnity: $382,137
Paid-to-closed ratio: 30.4%

GYNECOLOGY

Top three presenting medical conditions:
1. Leiomyoma of uterus
2. Excessive, frequent, and irregular menstruation
3. Noninflammatory disorders of ovary, fallopian tube and broad ligament

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Diagnostic: Incomplete/Inadequate

Top three outcomes:
1. Accidental puncture or laceration during a procedure, not elsewhere classified
2. Complications of procedures, not elsewhere classified
3. Emotional distress only

Average indemnity: $307,502
Paid-to-closed ratio: 29.9%

HOSPITALIST

Top three presenting medical conditions:
1. Pneumonia, unspecified organism
2. Abnormalities of breathing
3. Cerebral infarction

Top three chief medical factors:
1. Diagnostic: Incomplete/Inadequate
2. Procedure: Incomplete/Inadequate
3. Procedure: Failure to Recognize Complication

Top three outcomes:
1. Cardiac arrest
2. Other sepsis
3. Pulmonary embolism

Average indemnity: $357,461
Paid-to-closed ratio: 22.4%

INTERNAL MEDICINE

Top three presenting medical conditions:

1. Abdominal and pelvic pain
2. Pain in throat and chest
3. Abnormalities of breathing

Top three chief medical factors:

1. Diagnostic: Incomplete/Inadequate
2. Diagnostic: Unavailable/Failure to Diagnose
3. Procedure: Unavailable/Not Performed when Indicated

Top three outcomes:

1. Cardiac arrest
2. Cerebral infarction
3. Symptoms and signs specifically associated with systemic inflammation and infection

Average indemnity: $413,973
Paid-to-closed ratio: 23.9%

INTERNAL MEDICINE – SUBSPECIALITIES

Top three presenting medical conditions:

1. Encounter for screening for malignant neoplasms
2. Malignant neoplasm without specification of site
3. Chronic ischemic heart disease

Top three chief medical factors:

1. Diagnostic: Incomplete/Inadequate
2. Procedure: Incomplete/Inadequate
3. Procedure: Failure to Recognize Complication

Top three outcomes:

1. Cardiac arrest
2. Accidental puncture or laceration during a procedure, not elsewhere classified
3. Unspecified parasitic disease

Average indemnity: $322,327
Paid-to-closed ratio: 22.3%

NEUROLOGICAL SURGERY

Top three presenting medical conditions:

1. Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders
2. Dorsalgia
3. Other spondylopathies

Top three chief medical factors:

1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Diagnostic: Incomplete/ Inadequate

Top three outcomes:

1. Complications of procedures, not elsewhere classified
2. Intraoperative and postprocedural complications and disorders of nervous system, not elsewhere classified
3. Paraplegia (paraparesis) and quadriplegia (quadriparesis)

Average indemnity: $598,274
Paid-to-closed ratio: 25.6%

NEUROLOGY

Top three presenting medical conditions:

1. Dorsalgia
2. Cerebral infarction
3. Malaise and fatigue

Top three chief medical factors:

1. Diagnostic: Incomplete/Inadequate
2. Procedure: Incomplete/Inadequate
3. Diagnostic: Unavailable/Failure to Diagnose

Top three outcomes:

1. Cerebral infarction
2. Emotional distress only
3. Paraplegia (paraparesis) and quadriplegia (quadriparesis)

Average indemnity: $444,396
Paid-to-closed ratio: 32%

OBSTETRIC AND GYNECOLOGIC SURGERY

Top three presenting medical conditions:

1. Weeks of gestation
2. Leiomyoma of uterus
3. Encounter for supervision of normal pregnancy

Top three chief medical factors:

1. Procedure: Incomplete/Inadequate
2. Diagnostic: Incomplete/Inadequate
3. Procedure: Failure to Recognize a Complication

Top three outcomes:

1. Birth injury to peripheral nervous system
2. Other disturbances of cerebral status of newborn
3. Emotional distress only

Average indemnity: $471,284
Paid-to-closed ratio: 33.8%

OPHTHALMOLOGY

Top three presenting conditions:
1. Other cataract
2. Age-related cataract
3. Disorders of refraction and accommodation

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Procedure: Unavailable/Not Performed When Indicated

Top three outcomes:
1. Blindness and low vision
2. Poisoning by, adverse effect of, and underdosing of diuretics or other and unspecified drugs, medicaments, and biological substances
3. Complications of procedures, not elsewhere classified

Average indemnity: $277,239
Paid-to-closed ratio: 18.2%

ORTHOPEDIC SURGERY

Top three presenting conditions:
1. Other joint disorder, not elsewhere classified
2. Osteoarthritis of knee
3. Osteoarthritis of hip

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Procedure: Unavailable/Not Performed When Indicated

Top three outcomes:
1. Other joint disorder, not elsewhere classified
2. Complications of internal orthopedic prosthetic devices, implants, and grafts
3. Complications of procedures, not elsewhere classified

Average indemnity: $255,693
Paid-to-closed ratio: 36.8%

OTORHINOLARYNGOLOGY

Top three presenting medical conditions:
1. Chronic sinusitis
2. Other and unspecified disorders of nose and nasal sinuses
3. Encounter for procedures for purposes other than remedying health state

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Diagnostic: Incomplete/Inadequate

Top three outcomes:
1. Complications of procedures, not elsewhere classified
2. Accidental puncture or laceration during a procedure
3. Intraoperative and postprocedural complications and disorders of nervous system, not elsewhere classified

Average indemnity: $374,214
Paid-to-closed ratio: 34%

PATHOLOGY

Top three presenting medical conditions:
1. Unspecified lump in breast
2. Malignant neoplasm of breast
3. Other disorders of skin and subcutaneous tissue, not elsewhere classified

Top three chief medical factors:
1. Diagnostic: Incomplete/Inadequate
2. Diagnostic: Unavailable/Failure to Diagnose
3. Diagnostic: Wrong Patient

Top three outcomes:
1. Emotional distress only
2. Malignant neoplasm of breast
3. Malignant melanoma of skin

Average indemnity: $408,712
Paid-to-closed ratio: 31.2%

PEDIATRICS

Top three presenting medical conditions:
1. Encounter for general examination without complaint, suspected or reported diagnosis
2. Disorders of newborn related to short gestation and low birth weight, not elsewhere classified
3. Nausea and vomiting

Top three chief medical factors:
1. Diagnostic: Incomplete/Inadequate
2. Procedure: Incomplete/Inadequate
3. Diagnostic: Not Performed When Indicated

Top three outcomes:
1. Cardiac arrest
2. Emotional distress only
3. Other disorders of brain

Average indemnity: $559,603
Paid-to-closed ratio: 31.9%

PLASTIC SURGERY

Top three presenting medical conditions:
1. Encounter for procedures for purposes other than remedying health state
2. Complications of other internal prosthetic devices, implants, and grafts
3. Other disorders of breast

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Procedure: Wrong Process/Treatment/Procedure

Top three outcomes:
1. Complications of procedures, not elsewhere classified
2. Unhappy with results of plastic surgery
3. Complications of other internal prosthetic devices, implants, and grafts

Average indemnity: $246,573
Paid-to-closed ratio: 27.4%

PSYCHIATRY

Top three presenting medical conditions:
1. Bipolar disorder
2. Symptoms and signs involving emotional state
3. Major depressive disorder, single episode

Top three chief medical factors:
1. Diagnostic: Incomplete/Inadequate
2. Procedure: Incomplete/Inadequate
3. Medication/IV Fluids: Adverse Drug Reaction

Top three outcomes:
1. Emotional distress only
2. Injury of unspecified body region
3. Other anxiety disorders

Average indemnity: $258,295
Paid-to-closed ratio: 22.8%

RADIATION THERAPY

Top three presenting medical conditions:
1. Other and unspecified malignant neoplasm of skin
2. Malignant neoplasm of brain
3. Malignant neoplasm of breast

Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Procedure: Wrong Process/Treatment/Procedure

Top three outcomes:
1. Complications of procedures, not elsewhere classified
2. Other anxiety disorders
3. Radiation sickness, unspecified

Average indemnity: $577,420
Paid-to-closed ratio: 26.3%

RADIOLOGY

Top three presenting medical conditions:
1. Abdominal and pelvic pain
2. Encounter for screening malignant neoplasms
3. Dorsalgia

Top three chief medical factors:
1. Diagnostic: Incomplete/Inadequate
2. Diagnostic: Unavailable/Failure to Diagnose
3. Diagnostic: NA - Previous Format

Top three outcomes:
1. Malignant neoplasm of breast
2. Malignant neoplasm of bronchus and lung
3. Complications of procedures, not elsewhere classified

Average indemnity: $456,165
Paid-to-closed ratio: 29.7%

UROLOGY

Top three presenting medical conditions:
1. Malignant neoplasm of prostate
2. Calculus of kidney and ureter
3. Benign prostatic hyperplasia

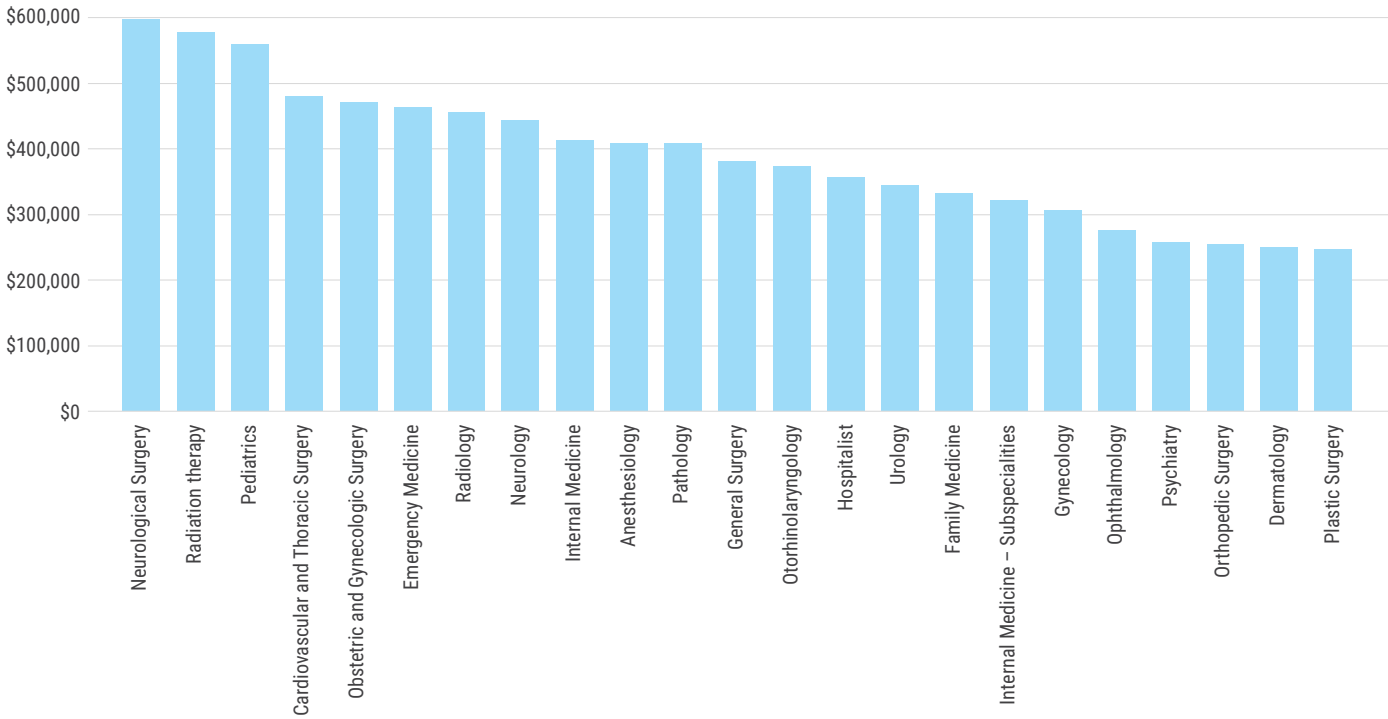
Top three chief medical factors:
1. Procedure: Incomplete/Inadequate
2. Procedure: Failure to Recognize Complication
3. Diagnostic: Incomplete/Inadequate

Top three outcomes:
1. Complications of procedures, not elsewhere classified
2. Accidental puncture or laceration during a procedure, not elsewhere classified
3. Malignant neoplasm of bladder

Average indemnity: $344,762
Paid-to-closed ratio: 27%

AVERAGE INDEMNITY BY SPECIALTY

MPL Association Claims by Specialty: Closed claims reported between 2017 – 2019[3]



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FAILURE TO COMMUNICATE AND TREAT PATIENT IN A TIMELY MANNER

by Wayne Wenske, Senior Marketing Strategist

PRESENTATION

On December 20, a 60-year-old man came to a small hospital's emergency department (ED) with pain in both shoulders, slight numbness in the left arm, nausea, and blood pressure of 224/100 mm Hg. His troponin level was measured at 0.28.

ED Physician A evaluated the patient and noted his impression as non-ST elevation myocardial infarction. He ordered a cardiac consult.

This closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of the physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. This study has been modified to protect the privacy of the physicians and the patient.

PHYSICIAN ACTION

Cardiologist A was notified and scheduled a cardiac catheterization for the patient the next morning. On December 21, Cardiologist A performed a left heart catheterization and a percutaneous transluminal coronary angioplasty and stent procedure to the mid left anterior descending artery. Cardiologist A's arterial access was performed above the inguinal ligament into the external iliac artery, not the femoral artery.

That afternoon, a nurse removed the patient's groin sheath at approximately 4:30 – 5 p.m. and the patient experienced a vagal response. The nurses responded to the drop in blood pressure by administering a fluid bolus and monitoring the response. Two hours later, the nurse paged Cardiologist A when the patient began experiencing shortness of breath and nausea and had a change in color. The patient's blood pressure was below normal. Cardiologist A ordered packed red blood cells, pressors, and fluids. An interventional radiologist (Radiologist A) and hospitalist (Hospitalist A) were also consulted.

Radiologist A requested an arterial line to confirm the patient's blood pressure. While an arterial line was being inserted, the patient passed a bloody stool. Cardiologist A ordered a colonoscopy.

At approximately 7:30 p.m., Cardiologist A consulted with a cardiothoracic and vascular surgeon (Surgeon A) and informed him the patient was hypotensive after the cardiac catheterization; that he suspected a retroperitoneal bleed; and that an arterial line was placed.

Surgeon A was employed by a group that covered the small hospital. This night was the last night of his week-long shift covering the hospital, and he was scheduled to be on-call at 7 a.m. the next day, December 22, in a nearby city. It is believed that Surgeon A was already in the nearby city when he was called and notified of the patient.

The colonoscopy was performed at 8:45 p.m. and negative for bleeding. At 11:30 p.m., a CT scan confirmed an active extravasation from the right external iliac artery contributing to the patient's bleed.

At 1:15 a.m., Radiologist A was consulted and attempted to repair the injured artery and control the bleeding by percutaneous technique using a covered stent. However, the hospital was not equipped with the appropriate-sized covered stent and the procedure was cancelled.

At approximately 3 a.m., Surgeon A arrived at the hospital and performed a repair of the iliac artery/iliac vein. Before surgery, Radiologist A informed Surgeon A of an arteriovenous fistula he encountered while attempting to repair the injured artery with the covered stent. He also informed Surgeon A that during his effort to repair the artery he discovered that Cardiologist A's catheterization procedure had been performed with a high stick via the external iliac artery.

During surgery, a large amount of free blood was found in the abdominal cavity. An open abdominal closure was done with drains and an occlusive dressing.

The patient remained in critical condition after surgery. He required hemodialysis for renal failure. He also developed additional gastrointestinal bleeding and severe metabolic acidosis. There was lab evidence of shock liver.

Radiologist A performed an angiogram and documented two pseudoaneurysms, the trigger for the bleeding. These were identified as the puncture sites that did not seal after the sheath was pulled by the nursing team. The patient was taken to surgery for a pseudo-aneurysm embolization. There were no complications from the surgery, but it was not successful.

The morning of December 22, the patient's EKG showed anterior wall myocardial infarction pattern. An echocardiogram showed ejection fraction of 40 percent, representing reduced cardiac function. Given his hemorrhagic shock, the patient was deemed a poor candidate for repeat catheterization lab management.

The patient was diagnosed with a retroperitoneal bleed following removal of an arterial catheter sheath that led to profound hypotension, cerebrovascular accident, kidney damage, and visual impairment.

He stayed in the hospital for several months, and underwent several procedures, including colostomy and inferior vena cava filter placement due to deep vein thrombosis.

Two years later, the patient received a kidney transplant. He also has loss of vision in his right eye, recurring headaches, affected balance due to lack of depth perception, and decreased cardiac function. He must also take anti-rejection medication for his new kidney.

ALLEGATIONS

The patient filed a lawsuit against Cardiologist A, Surgeon A, Hospitalist A, and the hospital. Allegations included failure to:

- timely diagnose the retroperitoneal bleed;
- administer aggressive intravascular volume resuscitation to maintain a stable blood pressure; and
- perform surgery to stop the bleeding until more than seven hours after the onset of hypotension.

LEGAL IMPLICATIONS

Consultant physicians for TMLT were mixed in their assessment of the care given in this case. Those who were unsupportive of the physician defendants pointed out the numerous delays in the care of the patient. Lack of communication between physicians was also a contributing factor in this case.

One supportive consultant stated that retroperitoneal bleeding resulting from hematoma and subsequent hypotension is a well-known complication after left heart catheterization and, if it occurs, must be treated promptly to minimize complications and morbidity.

Another consultant criticized all the defendants for failing to recognize that the femoral/iliac artery is a well-known site for bleeding complications. Ordering a colonoscopy in the face of hypotension and a bloody stool, instead of performing an immediate CT of the abdomen and pelvis resulted in a delay in definitive treatment.

However, another consultant felt that the decision to order a colonoscopy to rule out a GI bleed was reasonable. Once a GI bleed was ruled out, a CT was immediately ordered and found the source of the bleed.

Expert consultants for the plaintiff stated that the defendants violated the standard of care by failing to quickly recognize a known complication of cardiac catheterization. One consultant claimed that the physicians failed to maintain a systolic blood pressure of at least 90 via sufficient IV fluids and blood products leading to multi-organ failure including kidney failure, colon necrosis, stroke, and sepsis.

Another consultant echoed these criticisms and stated that the physicians did too little to prevent the hypotension caused by the retroperitoneal bleed after the catheter sheath was removed.

One nephrology consultant offered that the patient's kidney damage was irreversible within the first 24 hours after the catheterization procedure. He felt that the kidney recovery was complicated by delays in diagnosis and treatment. However, another nephrology consultant stated that it was impossible to determine when the kidney damage was irreversible, as there was not enough information in the patient's chart regarding his labs and urine output.

The nurses were also criticized for lacking urgency in providing resuscitative efforts to the patient and notifying the attending physicians.

DISPOSITION

This case was settled on behalf of all defendant physicians. The hospital also settled with the plaintiff.

RISK MANAGEMENT CONSIDERATIONS

Poor communication in this case led to a series of harmful delays that may have been prevented with more direct interactions between providers and improved patient hand-off policies and procedures.

Cardiologist A consulted with several specialists, often without follow up, face-to-face interactions, or phone interactions. He also did not provide full documentation or notes, as evidenced by Radiologist A discovering that Cardiologist A's catheterization was a high stick during his treatment of the patient, instead of seeing this catheterization detail provided in the patient record. When documentation or patient information is incomplete or inaccurate, the potential for mistakes during continuing or follow-up patient care can become an issue.

According to a 2017 Joint Commission alert, communication failures were found to be responsible for approximately 30 percent of all malpractice claims in U.S. hospitals and medical practices, resulting in 1,744 deaths and $1.7 billion in malpractice costs over five years.[1]

In the same alert, The Joint Commission cites "insufficient or misleading information, absence of safety culture, ineffective communication methods, lack of time, poor timing between sender and receiver, interruptions or distractions, lack of standardized procedures, and insufficient staffing" as the top contributing factors to hand-off communication breakdowns.

SOURCES

1. Inadequate hand-off communication. Sentinel Event Alert, September 12, 2017. The Joint Commission. Available at https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea_58_hand_off_comms_9_6_17_final_(1).pdf?db=web&hash=5642D63C1A5017BD214701514DA00139&hash=5642D63C1A5017BD214701514DA00139. Accessed Jan 25, 2022.

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MISDIRECTED TEST RESULTS LEAD TO DELAY IN DIAGNOSIS

by Laura Hale Brockway, ELS, Vice President, Marketing

PRESENTATION

A 67-year-old woman came to a walk-in clinic reporting a cough. The cough had persisted for a week; was made worse with exertion; was described as moderate to severe; and was productive and blood tinged. The patient also reported chills, dyspnea, dyspnea on exertion, fatigue, fever, pleuritic pain, and a sore throat.

The patient was a smoker and had a history of COPD. She was also thin, with a BMI of 16.6.

This closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of the physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician's defensibility. This study has been modified to protect the privacy of the physicians and the patient.

PHYSICIAN ACTION

An internal medicine (IM) physician saw the patient and diagnosed COPD with acute exacerbation and acute bronchitis. She ordered an HRCT scan of the thorax, a chest x-ray, and prescribed levofloxacin, dextromethorphan and guaifenesin, and a tiotropium bromide inhaler. This note was signed at 5:30 p.m. on October 17.

The chest CT was performed the next day at a nearby hospital. The indications for the procedure, as noted by the IM physician, were "COPD, smoker, 30 years, cough."

A radiologist read the scan and dictated the following in his report at 10:23 a.m. on October 18:

"Suspicious mass in the left lower lobe as above. This lesion would be amenable to CT-guided biopsy. There is a smaller subpleural soft tissue nodule in the posterior aspect of the right lower lobe. A small parapneumonic effusion is present."

The radiology report was faxed to the hospital and to the IM physician's office at 11:35 a.m. on October 18. The IM physician's office did not receive the faxed report. There was no follow-up on the October 18 CT scan, either by the patient or the IM physician.

Eighteen months passed. The patient went to another urgent-care clinic with concerns that she had pneumonia. A CT scan was ordered and the report noted the lung nodule. The patient was referred to a pulmonologist. A biopsy revealed squamous cell carcinoma of the lung. The patient was diagnosed at Stage IV and was treated with chemotherapy.

ALLEGATIONS

A lawsuit was filed against the IM physician, the hospital where the CT scan took place, the radiologist who read the CT scan, and his radiology group. The allegations were:

- failure to follow up on the patient's CT scan (IM physician);
- failure to communicate the suspicious findings on the CT to the ordering physician (radiologist);
- failure to have policies and procedures in place to ensure that critical findings are timely and appropriately reported to ordering physicians (radiology group); and
- failure to ensure the critical finding from the CT was reported to the IM physician (hospital).

The plaintiffs further alleged that the delay in the diagnosis and treatment of the patient's lung cancer resulted in limited treatment options and a less favorable outcome.

LEGAL IMPLICATIONS

Physicians who reviewed this case stated that the radiologist appropriately read the scan and timely dictated the report. The report was faxed to the hospital, as required by the contract between the hospital and the radiology group. The report was also faxed to the IM physician at the walk-in clinic. However, during the investigation of this case, it was discovered that the radiology group faxed the CT scan report to the wrong fax number. It was sent to the walk-in clinic's old fax number, so the IM physician did not receive it.

The hospital — which was contractually obligated to forward radiology reports to ordering physicians — did not attempt to forward the report to the walk-in clinic. The reason for this was unclear.

While acknowledging that the IM physician clearly did not receive the report, physician reviewers were critical that he did not follow up on the test that he ordered. The IM physician also believed that he should have followed up on the results of the CT scan.

Patient responsibility was a factor in this case. The patient did not follow up on the CT scan, as she testified that she assumed it was "okay" since she did not hear back from the walk-in clinic. Also, the patient likely had comparative responsibility for her condition relative to her long history of cigarette smoking.

Regarding causation, the defense oncology expert stated that the patient was likely at stage IV when the October 18 CT scan occurred. Consequently, earlier intervention may not have changed the patient's treatment, prognosis, or outcome. The plaintiff's oncology expert was not definitive about the patient's staging on October 18. He stated there was evidence of metastasis on the October 18 scan, and it appeared the lesion did not grow much over an 18-month period.

There was discussion among the radiologists who reviewed this case about whether the defendant radiologist should have called the IM physician to report the results of the scan. Those who stated the radiologist should have called cited the *American College of Radiology Practice Parameter for the Communication of Diagnostic Imaging Findings*.[1] Conversely, the defendant stated that the scan was a non-urgent outpatient study. The findings — in a patient with COPD and a 30-pack year smoking history — were not unexpected. She did not believe the standard of care required her to pick up the phone.

DISPOSITION

This case was settled on behalf of the IM physician. The hospital also settled their case. The case against the radiologist and the radiology group was dropped.

RISK MANAGEMENT CONSIDERATIONS

Tracking and follow up with lab/diagnostic imaging is consistently among TMLT's top 10 risk management

considerations. General risk management strategies to assist with follow-up include:

- Have written policies and procedures in place to track and follow lab work, testing, and referrals.
- Use a tracking system to ensure test results are received. A tracking system can be enhanced with dedicated personnel who schedule diagnostic testing, monitor tracking logs or pending electronic orders, make appointment reminder calls, and follow up on patients who do not keep scheduled appointments.
- When ordering a test or procedure, assist the patient with scheduling when needed. Schedule a follow-up appointment with the patient to review results.
- Engage patients in their own care and treatment plan by educating them about needed follow-up labs and testing. Include clear instructions on when to contact you if they do not receive results or hear back from you. It is important to document these conversations and any education in the progress notes.
- Avoid a "no news is good news" approach when communicating test results to patients. In this case, the patient wrongly assumed that she did not need to follow up on the CT scan and that it was "okay" since she did not hear back from the clinic.
- Communicate any change in your contact information — phone number, fax number, email, website — to all outside vendors and contacts. This includes hospitals, labs, radiology groups, physicians you refer to, etc. You may need to send your new contact information more than once.

While a physician who orders diagnostic testing or imaging is responsible for obtaining the results and acting on them, there is also a shared responsibility of all physicians to ensure results are communicated in a timely manner. According to the American College of Radiology, there are instances when it may be appropriate for the interpreting physician to contact the ordering physician directly.[1]

SOURCE

1. American College of Radiology. ACR Practice Parameter for Communication of Diagnostic Imaging Findings. Available at https://www.acr.org/-/media/ACR/Files/Practice-Parameters/CommunicationDiag.pdf.
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