The following closed claim study is based on an actual malpractice claim from Texas Medical Liability Trust. This case illustrates how action or inaction on the part of physicians led to allegations of professional liability, and how risk management techniques may have either prevented the outcome or increased the physician’s defensibility. An attempt has been made to make the material less easy to identify. If you recognize your own case, please be assured it is presented solely for the purpose of emphasizing the issues presented.

Clinical presentation
A 39-year-old man presented to the emergency room with a serious response to a recent puncture wound on his back.

Physician action
The patient was diagnosed with cellulitis in the puncture area and was hospitalized. During the course of the hospitalization, he received Ancef which was discontinued due to an adverse reaction. The patient was then started on Vancomycin, but developed a reaction to that medication. The Vancomycin was discontinued, and the patient was placed on oral Augmentin with instructions to continue this regimen when he was released from the hospital.

After being discharged from the hospital, the patient began follow-up treatment with his internal medicine physician (the defendant in this case), who at that time continued the Augmentin. The physician saw the patient again 11 days later. At this visit, the physician gave him an injection of Rocephin and placed the patient on oral Ciprofloxacine. This treatment was continued for five days, at which time the physician ordered home health care to administer the Cipro by infusion through a PICC line. The patient presented to another emergency room with an apparent reaction to the IV Cipro. The Cipro was discontinued after a consult between the emergency department and the internal medicine physician.

The patient returned to the internal medicine physician two days after this emergency room visit. The doctor ordered Vancomycin to be administered every six hours by ambulatory infusion pump. The following day, the patient’s wife took him to see the physician because of nausea and vomiting after the Vancomycin infusions. The physician reviewed infusion protocol for Vancomycin and prescribed Reglan to be given prior to the infusions to reduce the nausea and vomiting. The patient was found dead in his home that evening.

Allegations
• The plaintiffs alleged the patient died as a result of a cardiac arrhythmia caused by a histamine release due to an allergic reaction to Vancomycin.
• Record fabrication and alteration

Legal principle
In this case, proximate cause was one of the main issues to address. TMLT experts felt this case was medically defensible, and were willing to testify that the internal medicine physician did not cause the patient’s death by prescribing medication the patient was allergic to. The consultants believed the patient died as a result of a coronary artery spasm totally unrelated to any treatment by the internal medicine physician. The plaintiffs, likewise, had retained experts to support their theory of liability.

While this case was defensible from the medical standpoint, it was severely compromised by an alteration of the patient’s medical record by the defendant physician. During the physician’s deposition, the plaintiff’s attorney presented different versions of the patient’s medical record. Long before the possibility of a malpractice claim was known, a copy of the medical record was sent to the plaintiff’s counsel, unknownst to the defense, in connection with a workers’ compensation claim filed by the patient due to the puncture wound. Once the physician was in receipt of the malpractice claim, he produced a dictated version of the medical record to the defense council. Handwritten notes existed as well and the record had suspicious entries throughout. The copies of the medical record provided before the physician was noti-
fied of a claim and the copies of the medical record provided in defense of the claim were significantly different. The existence of more than one version of the medical record significantly undermined the physician’s credibility.

Disposition
This case was settled for $115,000 on behalf of the internal medicine physician. The physician’s alteration of the medical record was a major factor in the settlement of this case.

Risk management analysis
Patients tend to be poor historians; therefore, it is pertinent that physicians obtain medical records from hospital admissions. It is recommended that physicians review the records to ensure they are aware of what took place in the hospital. To demonstrate these records have been reviewed, it is good practice to initial and date the copies obtained or document in the medical record that they were reviewed.

Medication errors continue to account for a significant percentage of indemnity paid claims. The Physician Insurers Association of America conducted a Data Sharing Project which found medication errors to be the fifth most prevalent misadventure. At TMLT, medication errors are the fourth most prevalent misadventure. (For more information on medication errors, please see below.) In many cases, the patient or pharmacy may catch the error, but often they do not. When prescribing medications, it is imperative to review the medical record as well as question the patient regarding any known allergies or sensitivities. Records must be continually updated regarding new allergies and sensitivities and this information must be entered in all places where allergy documentation is routinely found. The use of a medication flow sheet is recommended to serve as a quick reference for allergy documentation. Placing the date beside the allergy will help indicate when the patient was questioned about allergies to medications.

Altering the medical record seriously jeopardizes a physician’s credibility. Upon reviewing the medical record when served with a notice of claim or lawsuit, physicians may be tempted to add information they believe will assist in their defense. While the information itself may be accurate, the addition of such information after the event is always detrimental to the defense of the case. Plaintiff’s attorneys will use this information to discredit the physician by suggesting that he/she did something wrong and are trying to cover for it. Experts have advanced technology to pinpoint when an entry was made. In many cases, this is not necessary since most alterations can be seen clearly with the naked eye. The message is clear: if a physician alters medical records, this will be discovered. While there may have been no breach of the standard of care, situations such as this are difficult to defend at trial and frequently result in settlements out of court. It is recommended, upon notice of a claim or lawsuit, that the medical record be placed in a secure location to protect the authenticity and avoid any possible temptations to alter information.

PIAA Medication Error Study
Medication error claims are a significant source of loss for malpractice carriers and the physicians they insure. The Physician Insurers Association of America Data Sharing Project began in 1985 with the goal of providing member companies with current and credible data on medical malpractice claims. The data collected includes loss description and causation information; expense and indemnity payments; and demographics of policyholders, claimants and institutions. The Medication Error Study conducted in 2000 intended to better define the nature of these claims and means by which they may be prevented.

Medication error claims by specialty

![Medication error claims by specialty](image)

Most frequent medication errors: antibiotics

- Failure to note documented allergy
- Most appropriate drug not used
- Drug inappropriate for condition
- Inadequate medical history
- Failure to read medical record

54 Total Claims
Don’t be a sitting doc
by Jane Mueller, Assistant Vice President, Risk Management

The health care industry is the target of outside organizations as never before. Pressure from third party payors, government agencies and large employers to provide cost effective and quality care are some of the many reasons physicians and administrators should implement a risk management program. Additionally, physicians increasingly find they are the target of plaintiff attorneys hoping to bag their limit in contingency fees from settlements or jury verdicts in medical malpractice cases.

The majority of medical malpractice claims can and should be avoided. It does not require evolutionary changes or that you elevate yourself to a higher standard of care. The public is largely unaware that approximately 80% of medical malpractice claims nationally are closed with no indemnity paid. TMLT closes approximately 87% of claims without indemnity payment. Implementing basic risk management processes and systems will decrease the risk of a liability claim and improve the defensibility of those who are involved in litigation.

The following risk management strategies will facilitate the practice of safe, quality medicine and help maintain a standard of care to which physicians have always been held accountable. These areas consistently rank among the top five concerns when defending a claim.

Medical records documentation

When involved in litigation, documentation can be your best ally or your worst enemy. Juries typically believe physicians when appropriate information is documented in the medical record. Conversely, a physician’s credibility is challenged when essential elements of the patient encounter are absent or incomplete. Following these guidelines can strengthen defensibility.

• Documentation of each patient encounter should be complete. According to AMA guidelines, documentation should include:
  • chief complaint and/or reason for the visit and, as appropriate, relevant history, examination findings and prior diagnostic test results
  • assessment, clinical impression or diagnosis
  • plan of care, follow-up visits and/or referrals

• Do not make any additions, deletions, or any other type of alteration to the medical records. Anything added to a previous note is considered a late entry. If you need to elaborate or clarify a previous note, the note should say “LATE ENTRY” and be dated. The relationship to a previous note should be explained, such as “addendum to note of 8/23/2000,” or “see 2/15/2000 note.” The reason for the late entry should be explained. A late entry should appear in its normal chronological position in the chart, not squeezed into space near the previous note. After-the-fact entries may be viewed as alterations to the medical record and damage the credibility of the physician.

• How late is a late entry? Once a note is finished, anything else is a late entry. When in doubt, a late entry that is clearly identified and properly referenced is always preferable to adding anything to an existing note.
  • Blank lines or large blank spaces in the medical record may invite some individuals to make changes or additions to a note. It is wise to mark the medical documentation from such alteration by not leaving blank lines or by marking through spaces in a manner that prevents alteration.
  • Illegible handwriting in medical records is a common weakness, and the documentation can be subject to broad interpretations of actual meaning as well as the quality of patient care.

Physician-patient relationship

The physician-patient relationship is the result of a contract, express or implied, between physician and patient that is voluntary and arises when a patient requests and is supplied medical information and/or treatment. Generally, once established, the physician-patient relationship continues as long as medical treatment is required, unless the physician or patient terminates it. Advice given during a telephone conversation or casually at a social gathering may be construed as establishing a physician-patient relationship.

• Create policies and procedures regarding the acceptance of new patients. Educate your staff and ensure they adhere to these policies. Communicate to staff the dangers of trying to accommodate walk-in patients.

• Physicians need to follow a process of proper documentation and adequate notice when deciding to terminate the physician-patient relationship. Where appropriate, physicians should verbally advise the patient of the decision and document this in the record. In every case, the physician should send a letter by regular mail and also by certified mail, return receipt requested, with the notice. Refer the patient to the county medical society or their managed care organization for a list of physicians. It is not advisable to refer patients to specific physicians. Enclose an authorization for release of the medical record and advise the patient to designate his/her new physician as soon as determined, sign the form and return it to your office. Place a copy of the letter in the patient’s record.

• When terminating a physician-patient relationship, the patient should be given a reasonable amount of time to find a new physician. The time limit for finding a new physician will depend on several factors, such as physician specialty, size of community and availability of other practitioners. The current physician should remain available for acute and emergency care until the patient finds a new physician.

• When deciding whether or not to terminate a physician-patient relationship, consider the patient’s medical status and needs. For example, pregnant patients, patients in a post-op recovery period and patients undergoing a continuous course of treatment, might need assistance in making sure continuity of care is not disrupted.

Informed consent

Texas recognizes that consent for treatment must be obtained and that such consent be “informed.” By statute, the process
of obtaining informed consent is a non-delegable responsibility of the physician.

- Even minor procedures carry the risk of an unexpected outcome. A separate consent form is not required by law for procedures not on the Medical Disclosure list. However, a protocol should be written to either use a consent form for minor procedures or document the informed consent discussion with the patient as well as the patient’s understanding and consent to do the procedure.

- Be aware of the timing of a signature when obtaining informed consent. Patients can contend their mental status was impaired when they consented. When obtaining consent in a hospital, try to make sure the consent was not signed 15 minutes after a mood-altering medication had been given.

- Document the patient’s mental acuity at the time of the risk/benefits discussion or when obtaining informed consent. A brief note reflecting that the patient was awake, alert, participated in the discussion and asked appropriate questions could protect against allegations of failure to obtain informed consent.

- Consider including on your informed consent form a statement that the patient fully comprehends the risks of the procedure and is not subject to any medication, illness or other impairment which might affect the patient’s ability to comprehend. Include any family members who witnessed the discussion.

- Supply patients with supplemental information about a procedure, such as a brochure, and document the receipt of the brochure by the patient. Ensure all the information made available to your patients fairly and accurately portrays the risks of the procedure.

- A patient’s decision to decline treatment, evaluation or testing should be documented in the patient record. “Informed refusal” should be obtained with respect to any treatment or procedure, which could have either diagnostic or therapeutic consequences. “Informed refusal” should be obtained in writing or at the very least, a note in the chart should be made. The documentation of informed refusal should contain:
  - description of the treatment offered
  - the reasons the treatment was offered
  - the potential benefits of the procedure
  - a statement that the patient has been informed of the risks in not accepting the treatment
  - a clear statement that the patient has unequivocally and without condition declined the treatment
  - reasons the patient refused treatment

Health information release

- With few exceptions, health care information should not be released without a valid authorization signed by the patient or a subpoena signed by a judge.

- Document each release of medical information in the medical record.

- Medical information should only be faxed for urgent or emergent care. If you do fax health information, identify who will receive the information and relay when you will send the fax so the person will be available to secure the fax. Use a fax cover sheet indicating the need to maintain confidentiality. Avoid faxing sensitive health information such as HIV, mental health or alcohol/drug abuse records.

Additional considerations

- Notify the TMLT Claim Operations Department immediately if you receive a notice or subpoena which involves the delivery of medical care as an issue in a claim where you may be the defendant.

- Design a tickle file or a log of patients referred for tests, appointments with other physicians, etc., in order to identify those that are not completed in the time frame scheduled.

- Give patients a return appointment as a method of determining that orders were followed. For “no show” patients, develop a protocol to contact the patient and document your conscientious efforts to determine why the appointment was not kept. Triage the patient conditions, and if of a serious nature, call again, document again and then send a certified letter with your concerns. Place a copy of the letter in the patient record.