PREPARING FOR A DEPOSITION

CME ACTIVITY: PRESCRIBING ISSUES: OPIOIDS AND OFF-LABEL MEDICATIONS

CLOSED CLAIM STUDY 1: OVERPRESCRIBING NSAIDs AND FAILURE TO DIAGNOSE

CLOSED CLAIM STUDY 2: FAILURE TO CORRECTLY PRESCRIBE AND INSTRUCT IN TAKING MEDICATION

TAKING THE FIRST STEPS TO AVOID A LAWSUIT, BOARD ACTION, OR PEER REVIEW

Q3
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PREPARING FOR A DEPOSITION

For physicians involved in a lawsuit, the process can feel foreign. Attorneys use unfamiliar terms (often intentionally), the pace can be painfully slow, and it can be difficult to understand the proceedings of our legal system.

As a defendant in a case, you will also be called upon to give a deposition. In the midst of the overall unease you may feel about the lawsuit, giving a deposition may be the most difficult part.

“You may be good at public speaking, you may present at grand rounds, and yet you are going to feel like a fish out of water once you sit down, take the oath, and start answering questions,” says Austin, Texas-based defense attorney Dan Ballard. “You will become much more nervous than you expected, and it may be difficult to think clearly and present yourself in the most effective way.”

A deposition is testimony given under oath before a court reporter. In a medical malpractice case, depositions typically occur during the discovery phase of the lawsuit, after the plaintiff’s attorney and the plaintiff’s expert have reviewed the medical records.
During a deposition, the attorneys (defense attorney, plaintiff’s attorney, and co-defendant’s attorney) question the defendant physician to determine the facts of the case. Depositions allow physicians to tell their side of the story and to defend the care provided to the patient.

The testimony given during deposition can be described as “baseline testimony,” because both parties will use it at trial to further question the defendant.

“Depositions are a pivotal point in the process because both sides are evaluating the case and the defendant’s capabilities as a witness,” says Sue Mills, senior vice president of Claim Operations at TMLT. “The defendant physician is Exhibit A.”

Preparation is essential. Mills and Ballard offer the following recommendations to help physicians prepare and present themselves at deposition. The goal of your deposition is to come across as knowledgeable, credible, and respectful.

• Work with your attorney and take the time to prepare. Review all the materials you are given.
• Be familiar with your own medical records and with the medical records of the other providers that are pertinent to the case.
• Wear clothing appropriate for an important business meeting.
• Treat all persons in the deposition room with respect.
• Speak slowly and clearly.
• Tell the truth.
• Do not argue or be defensive.
• Testify only about what you remember clearly.
• Do not be concerned with the appropriateness of a particular question.
• Do not speculate or state anything as a fact that you do not know. If you do not know an answer, say so.
• Give accurate estimates.
• Do not volunteer any facts that are not specifically requested.
• Give a clear, concise answer that only addresses the question being asked.
• Beware of a question that assumes a fact.
• Be alert to paraphrasing.
• Answer all questions, unless otherwise instructed by your attorney.
• If asked, “Is that all?” respond with, “That is all I can recall at this time.”
• Do not try to memorize your testimony.
• Do not answer a question unless you clearly understand it.
• If you do not understand a question, say so and request clarification.
• If you are asked about a document, ask to see and review the document before answering.
• Do not lose your temper, get angry, or get excited.
• Do not allow the plaintiff’s attorney to misstate your testimony or put words in your mouth. Courteously correct the attorney if he or she misstates or misinterprets what you have said.
• Some of the most dangerous words you can use in a deposition are “always” and “never.” Using these qualifiers and being absolute in your testimony can be detrimental to your case because it can make irrelevant issues relevant.
• Do not give your professional opinion outside of your area of expertise.
• Do not give your professional opinion about another health care professional unless you are thoroughly familiar with the facts of the case.
• Do not explain your professional opinion unless asked.
• If you wish to take a break at any time in the deposition, ask for one.

To learn more or to view deposition scenarios, please see our CME video Successfully Navigating Your Deposition, available for purchase at https://tmlt.inreachce.com/.

**NOTES**

1. The discovery phase allows every party in the lawsuit access to the relevant information necessary to defend or prosecute a case.

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PREScribing Issues: Opioids and Off-Label medications
Upon completion of this course, the physician will be able to:
1. discuss statistics related to the opioid epidemic;
2. describe potential solutions to the problem, including the CDC guidelines for prescribing opioids for chronic pain;
3. identify patients who exhibit manipulative behaviors and discuss how to handle drug-seeking patients;
4. explain the risks of prescribing off-label drugs and drugs not approved by the U.S. Food and Drug Administration (FDA); and
5. summarize ways to limit liability exposure when prescribing off-label drugs.

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TARGET AUDIENCE
This 1-hour activity is intended for physicians of all specialties who are interested in practical ways to reduce the potential for medical liability.

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INTRODUCTION
Two of the more significant issues facing most health care professionals today are the use of opioids to treat pain and “off-label” use of medications. While opioids have their place in the treatment of chronic and recurrent pain, it has become increasingly evident that opioids are easily and often abused, and can be a gateway to even more dangerous drug use.

Stories of the opioid epidemic and its dramatic consequences are frequently in the news, so much so that our national “war on drugs” now includes prescribed opioids. Physicians also face trouble when prescribing off-label and/or drugs not approved by the U.S. Food and Drug Administration (FDA). Prescriptions in this context can open physicians up to patient complications and litigation.
This article addresses ongoing concerns and physician considerations when writing opioid prescriptions or prescribing medications for off-label, or non-FDA approved use. The article further explores the steps that health care professionals may take to reduce the risks and potential liabilities associated with these treatment options.

**THE OPIOID PROBLEM**

In 2015, 21% of all patients insured by a large national insurer filled at least one opioid prescription. In addition, the insurer reported a 493% increase in opioid-use disorder diagnoses between 2010 and 2016. The insurer also reports that women over the age of 45 were the patient population most affected by opioid use.9

As this data reveals, opioid use in the United States has climbed sharply over the last decade, resulting in what is now referred to as the opioid epidemic. Physicians unintentionally contributed to this problem, as evidenced by the finding that physicians who were more likely to prescribe opioids had more patients who went on to be long-term opioid users.8

More concerning still, the mortality rate related to opioids has also risen dramatically. Every day, 91 Americans die from opioid prescription medication and heroin.3 Preliminary data indicates that drug overdoses may have become the leading cause of death for Americans under 50.4 Rates for overdosing are highest among people aged 25 to 54 years.5 However, it is not just illegal drugs that are killing Americans. In 2015, the death rate attributed to a prescription pain medication overdose (20,101) was significantly higher than the death rate attributed to a heroin overdose (12,990).6, 7

Where are people getting prescription opioids to abuse? People who use prescription opioids non-medically for 200 or more days out of the year are “using their own prescriptions (27 percent), from friends or relatives for free (26 percent), buying from friends or relatives (23 percent), or buying from a drug dealer (15 percent).”8 In other words, a fair percentage of the problem appears to be originating in physician offices.

In addition, prescribed opioids may have become the gateway drug to heroin. Approximately four out of five new heroin users report that they abused prescription opioids before using heroin.9 An overwhelming majority (94%) of heroin users claimed that they switched from pain medication to heroin because it was much less expensive and easier to obtain.10

The social cost of this epidemic is staggering in terms of the price of the medications, the expense of addiction treatment, and the societal harm to the addicted person, that person’s family, and their community. Similar to tobacco litigation, Mississippi, Ohio, and Missouri have already filed suit against pharmaceutical manufacturers of opioids for the rising costs of battling the opioid epidemic. These states allege that the pharmaceutical companies minimized the risk of addiction and exaggerated the need for opioids in treating pain in their marketing practices. More than half of the remaining states are investigating the possibility of filing similar suits.11, 12

**THE SOLUTION**

As evidenced by the statistics cited, there is no question that an epidemic is taking place and a solution is needed. There are a number of methods that physicians can adopt to help create a solution and minimize the risk of patient drug abuse.

- **Use caution when treating overly complex patients.** If you are treating a patient with chronic pain, and the patient’s condition or treatment requirements become too complicated, consider referring the patient to a pain specialist. They have the specific training and experience to handle more complex pain issues.

  When referring a patient to a specialist, discontinue treating the patient’s pain symptoms — even if the patient fails to follow up with the specialist. Do not let a patient’s refusal to adhere to the care plan force you to continue treatment that you are not comfortable providing. Generally, if you are not comfortable providing treatment to a patient, consider ending that relationship.

- **Use caution when treating family and friends.** Physicians should avoid providing treatment to themselves, family members, or friends. According to the American Medical Association Principles of Medical Ethics, treating oneself or family members can pose “several challenges for physicians, including concerns about professional objectivity, patient autonomy, and informed consent.”13

  A physician’s personal feelings may influence his or her medical judgment if treating a family member, or lead the physician to attempt treating conditions beyond his or her expertise or training. The AMA recommends that physicians refrain from treating themselves or family members, but it may be acceptable in a limited circumstance.14 Do not prescribe an opioid medication without first establishing a formal physician-patient relationship.

- **Supervision of staff.** As a physician, you are responsible for monitoring the duties you assign to staff members. Ensure that your staff and affiliated health care professionals understand the importance of monitoring patient requests for refills and keeping a record of any interactions related to prescriptions.
• **Maintain clear documentation.** Clear, comprehensive, and up-to-date documentation of patient interactions can assist a physician’s defense in the event of a claim or medical board hearing. The extra time it takes to fully document a prescription issue could make a crucial difference in reaching a favorable outcome in a formal board action or claim.

**GUIDELINES FROM THE CENTERS FOR DISEASE CONTROL AND PREVENTION**

In 2016, the Centers for Disease Control and Prevention (CDC) introduced guidelines for prescribing opioids to chronic pain patients. These guidelines apply to physicians treating patients outside the context of cancer, palliative, and end-of-life care. The goal of the guidelines was to reduce the number of people who misuse or abuse — and ultimately overdose — from opioids, while still ensuring that patients have access to safe and effective treatment for chronic pain. Below is a summary of the CDC’s 12 recommendations.

**Considerations for determining when to initiate or continue prescribing opioids:**

1. **Opioids are not first line therapy.** Non-pharmacologic and non-opioid pharmacologic therapy is preferable when treating chronic pain. Opioids should only be prescribed if the benefits outweigh the risks. If opioids are used, they should be used in conjunction with non-pharmacologic and non-opioid pharmacologic therapy. Other treatment options include nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, cognitive behavioral therapy, and interventions.

2. **Establish goals for pain and function.** For patients who are prescribed opioids, realistic treatment goals should be established. Treatment should be discontinued if the risks ever outweigh the benefits. Treatment should be continued only if there is meaningful improvement in pain and function that outweighs the risks.

3. **Discuss risks and benefits.** The risks and benefits should be discussed with the patient before starting opioids and periodically during treatment. The physician needs to be explicit and realistic in telling patients that complete relief of pain is unlikely and there is no good evidence that long-term opioid use improves pain or function. All the risks of opioid use should be discussed, including the most serious ones, such as fatal respiratory depression and lifelong opioid use disorder.

**Drug selection, dosage, duration, and follow up:**

4. **Immediate release opioids vs. extended release.** The CDC recommends initiating opioid treatment with immediate-release prescriptions as opposed to extended release. Clinical evidence shows that there is a higher chance of overdose if patients are started on long-acting opioids.

5. **Consider prescribing the lowest effective dose.** When initiating an opioid prescription, the CDC recommends starting with the lowest effective dose. The CDC also recommends evaluating the risks and benefits if the dosage is greater than 50 MME/day (morphine milligram equivalents/day), and avoiding dosages greater than 90 MME/day without careful justification.

6. **What about the prescription durations for acute pain?** Long-term opioid use often starts with treatment for acute pain. Therefore, the CDC suggests only prescribing the lowest effective dose, immediate release, and in no greater quantity than needed for the expected duration of the pain.

7. **Evaluate the benefits and risks frequently.** CDC recommendations include evaluating the benefits and risks within one to four weeks of starting opioid treatment, and continuing to re-evaluate every three months. If the benefits fail to outweigh the risks, the CDC suggests introducing other therapies and tapering the opioids to lower doses or until they are discontinued.

**Assessing risk and addressing harms:**

8. **Use strategies to mitigate risk.** Before starting an opioid prescription, evaluate the risks of opioid therapy for your patient. Opioid management should include mitigation of risks and offering naloxone when there is an increased risk of overdose, such as a patient history of overdose, a history of substance abuse, high opioid dosages over 50 MME/day, or concurrent benzodiazepine use. Continue to periodically evaluate your patient’s risks going forward.

9. **Review prescription drug monitoring program (PDMP) data.** Physicians should review the patient’s PDMP data to determine if he or she is receiving opioids from other health care professionals. The PDMP should be checked when starting opioids and at least every three months while still prescribing opioids to the patient.

10. **Use urine drug testing.** Consider testing the patient’s urine for opioid use before initiating a treatment plan using opioids. Test annually, at minimum, while still prescribing opioids to the patient.
11. Avoid concurrent benzodiazepine use. Avoid prescribing opioids with benzodiazepines whenever possible.

12. Offer treatment for opioid use disorder. Offer or arrange treatment for a patient if he or she develops opioid use disorder.

MANIPULATIVE BEHAVIORS OF DRUG-SEEKING PATIENTS

According to one study, “approximately 56 percent of painkiller prescriptions were given to patients who had filled another prescription for pain from the same or different providers within the past month.”16 This statistic illustrates the very real problem of drug-seeking patients. Although we all know that the problem exists, it can be difficult to determine if a patient is trying to manipulate you into providing prescriptions.

The U.S. Drug Enforcement Agency (DEA) has developed the publication “Don’t Be Scammed By A Drug Abuser,” 17 which outlines several telltale signs to consider if you suspect a patient is seeking a prescription to opioid medications. A drug-seeker might:

• exhibit unusual behavior;
• have a demanding personality;
• present an unusual appearance, whether that be slovenly or over-dressed;
• demonstrate an unusual knowledge of medications;
• offer a history of textbook symptoms to an illness treated with opioids;
• evade questions regarding prior medical history;
• hesitate to give information regarding past health care providers;
• ask for a specific drug by name;
• exaggerate symptoms;
• request to be seen right away, toward the end of the day, or after hours;
• report that he or she is from out of town;
• feign physical or psychological symptoms in an effort to obtain the desired drug;
• insist that alternatives to the requested drug do not work or that he or she has an allergy to the drug alternatives offered;
• state that his or her prescription has been lost or stolen; or
• request refills more frequently than prescribed.

If a patient exhibits any of these behaviors, proceed with extreme caution before writing an opioid prescription. That caution may require spending a little extra time with the patient to better ascertain the patient’s honesty. The extra effort may prevent a tragic outcome.

DEALING WITH DRUG-SEEKING PATIENTS

Recognizing the characteristics of the drug seeker is often difficult. However, if you believe you have identified a drug-seeking patient, the DEA has pragmatic suggestions for interacting with any individual you suspect is motivated by seeking an opioid prescription.

• Request that the patient provide photo identification, a phone number, and local address. Confirm the authenticity of these identifiers if you can.
• Contact any previous provider for the patient to verify the patient’s identity, history, condition, and potential drug-seeking tendencies.
• Conduct a thorough exam of the patient, regardless of how they behave or try to rush the visit.
• Document your exam thoroughly to support your diagnosis and treatment.
• If you provide the patient with a prescription, authorize a very limited quantity.17

Another option may be to refer the patient to a pain specialist, who can more closely monitor the patient. If the patient does not comply or follow through with your referral, consider terminating this physician-patient relationship.

OFF-LABEL MEDICATIONS

Off-label drug use (OLDU) refers to a health care professional prescribing or providing an FDA-approved medication that is not intended to treat a certain disease; not approved in certain patient populations, such as pediatric or geriatric patients; or not approved at the dosage recommended on the FDA label.

When the FDA approves a medication, it signals that a careful evaluation of the product’s benefits and risks has been conducted; that the approval of the drug is supported by strong scientific data; and the drug labeling has been approved, so that physicians and other health care professionals know how to use the drug safely and effectively.18

Once the FDA approves a drug, a physician can prescribe the drug for any use as long as the physician judges the use as medically appropriate.18 Off-label prescribing is very common. A 2001 study measured prescribing patterns for 160 commonly prescribed FDA-approved drugs and found that 21% of all drug “mentions” were OLDU. Rates varied by specialty and conditions. For example, off-label use was most common among cardiac medications.19

Among specific medications, gabapentin and amitriptyline are prescribed off-label the most, approximately 80% of the time.19 Off-label prescribing may be the only option in some cases — when a drug does not exist or has not been approved for a particular medical condition and the provider believes the patient may benefit from OLDU.
Off-label prescribing is undeniably a common practice and an important part of a physician’s available treatment options. For example, even aspirin is not approved for treatment and prophylaxis against coronary disease in diabetic patients, but guidelines still recommend its use. While often a patient’s best option, OLDU is a gray area that is fraught with liability risks given the subjectivity involved in determining what is medically appropriate for a given patient.

**OLDU AND ADVERSE DRUG REACTIONS**

In 2016, a study of OLDU was conducted among 46,021 patients who received 151,305 incident prescribed drugs between January 1, 2005 and December 30, 2009. That data showed that 11.8% of the total prescriptions analyzed were off-label, and 80.9% of those off-label prescriptions lacked strong scientific evidence for use. Consequently, the most alarming finding was that adverse drug reactions occurred at a higher rate with OLDU.

The incidence rate of adverse drug reactions was 12.5 per 10,000 person-months for on-label use; 19.7 per 10,000 person-months for off-label use; and 21.7 per 10,000 person-months for off-label use that lacked strong scientific evidence. Therefore, extreme caution is recommended when prescribing any off-label use of drugs, and especially those that lack strong scientific evidence.

**LIMITING RISK EXPOSURE WHEN PRESCRIBING OFF-LABEL**

The FDA encourages patients to question health care professionals about any proposed off-label use. Those questions are basically the same questions that would be asked of a physician in a medical liability case about off-label use of drugs. It is therefore important that a physician can answer all of these questions before prescribing a drug to a patient for off-label use:

- What is the drug approved for?
- Are there other drugs that are FDA approved to treat the medical condition?
- What scientific studies support the off-label use of this drug to treat the medical condition?
- Is it likely that the off-label use of this drug will work better than an approved treatment?
- What are the risks and benefits of using this off-label drug to treat the medical condition?

In a lawsuit, the plaintiff has to show that the defendant physician acted negligently or unreasonably. The plaintiff must prove the physician failed to do what a physician of ordinary prudence would have done or not done in the same or similar circumstances. To determine what is “reasonable,” experts are consulted on both sides of the case, and the jury hears all findings on what the experts believe is reasonable action.

With that end in mind, the best protection a physician can employ against the possibility of a claim is thorough patient counseling and documentation (PCD). Patients have a right to be informed about their treatment options so that they may participate in that decision. If a patient has an adverse drug reaction to an off-label drug, the chance of the physician getting sued is much greater if the patient was not told it was off-label. Many patients will not want to take any medication that is not “approved.”

A physician or group may decide to establish a protocol for PCD that is followed by all providers in the practice. The protocol may include giving the patient comprehensive information regarding side effects and what to do if they occur. The patient may even be asked to sign a form indicating their receipt and understanding of the information. Even if you fully inform the patient of possible side effects, many forget. Therefore, documenting any patient communication is also important.

Any time a physician or health care provider deviates from the *Physicians Desk Reference*, the reason needs to be documented. Documentation starts with a thorough patient history and physical exam to determine a differential and the available treatment options. If the physician wants to treat the patient using an off-label drug, there should be documentation of the treatment options available and why this is the preferred and chosen treatment option. The documentation should include:

- other available treatment options;
- existing scientific support for the off-label drug use;
- support for the off-label drug use over the other options; and
- a brief description of the risks and benefits of the off-label drug use for this patient.

Documentation confirming that instructions were given to the patient is also critical.

**CONCLUSION**

In summary, the abuse of opioid medications is at an epidemic level in the United States. Physicians can play a part in correcting this situation by being more judicious in prescribing these medications. Avoid using opioids as the first line of treatment for pain. Opioids are to be used sparingly and in conjunction with other treatment options. Look for manipulative behaviors from patients and know how to deal with drug seekers. Train staff members on these issues as well.

In using off-label medications, counsel the patient and document accordingly. There should be strong scientific support for using off-label drugs. Otherwise, the physician runs the risk of an increased incidence of an adverse drug reaction and allegations of neglect.


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OVERPRESCRIBING NSAIDs AND FAILURE TO DIAGNOSE

PRESENTATION
A 50-year-old man came to the emergency department (ED) of a large medical center with symptoms that suggested cellulitis. He had a fever of 102.4 degrees, his blood pressure was 163/92 mm Hg, and his pulse was 132 bpm. He had a history of gout, hypertension, hyperlipidemia with triglycerides greater than 700, diabetes, acute hepatitis, kidney stones, appendectomy, degenerative disc disease, morbid obesity, and sleep apnea. He provided his home medications as twice daily allopurinol 100 mg, colchicine 0.6 mg, and indomethacin 100 mg.

In the ED, the patient’s preliminary diagnosis was acute gout with fever. He was admitted to the hospital.
PHYSICIAN ACTION
Internal Medicine Physician A examined the patient and noted erythema and swelling in the left great toe. Lab findings showed a white blood cell count of 15,330; hemoglobin at 17.1; hematocrit at 48.5; and platelet count as normal at 185,000. Her assessment was 1.) fever; 2.) gout; and 3.) hypertension. Inpatient medications included aspirin 81 mg a day, colchicine 0.6 mg twice daily, indomethacin 100 mg twice daily, and IV ceftriaxone, methylprednisolone, and vancomycin.

The following morning, the patient’s white blood cell count was 13,260 and hemoglobin had returned to within the normal range at 16.5. From blood taken the day before, the patient’s uric acid level was 10, consistent with gout. (Normal range of uric acid is 2.6 to 8.0). His glucose was high at 188 (normal is less than 110). The patient remained in the hospital for another night. He was discharged the following day. Medications at the time of discharge were allopurinol, colchicine, indomethacin, and antibiotics.

Two days later, the patient returned to the ED with rectal bleeding. He reported that he was home for only a few hours before he started having lower GI bleeding. He also reported vomiting a moderate amount of bright red material and rectal bleeding accompanied by bloody diarrhea. Labs showed the patient’s hemoglobin dropped to 10.9. He was admitted to the hospital, under the care of Internal Medicine Physician A, and a gastroenterology consult was requested.

The on-call gastroenterologist saw the patient and performed an esophagogastroduodenoscopy (EGD). The gastroenterologist noted that the esophagus appeared normal. There was some granular gastritis of the antrum and multiple linear erosions of the apices of the duodenal folds, but no deep ulcers. He also noted that there were a few hints of blood with discoloration, but no signs of active bleeding.

A colonoscopy to the terminal ileum was also performed. The gastroenterologist noted normal mucosa throughout the colon and terminal ileum and no evidence of ulcerations in the terminal ileum.

The patient was transferred to the intensive care unit (ICU) after suffering seizures. Internal Medicine Physician A ordered a CT scan of the head without contrast. Results were normal. The results from a CT of the abdomen and pelvis showed no obvious inflammatory process in the perineum or retroperitoneum. There was also no evidence of a mechanical bowel obstruction.

Internal Medicine Physician B took over the care of the patient, and requested a pulmonary consult. The patient received multiple blood transfusions, as ordered by the pulmonologist. However, the patient’s overall status declined.

He developed acute respiratory failure and required mechanical ventilation. The patient also required resuscitation after suffering a cardiac arrest. It was believed that he was in hemorrhagic shock with pulmonary edema. The patient developed absent brainstem reflexes, severe hypotoxic-ischemic encephalopathy, and multisystem organ failure. Three days after the second admission, the patient died. An autopsy was not performed.

ALLEGATIONS
The patient’s family filed a lawsuit against Internal Medicine Physician A, alleging that the patient’s death was a direct consequence of:

- overprescription of multiple nonsteroidal anti-inflammatory drugs (NSAIDs), colchicine, and corticosteroids at extremely high dosages;
- failure to diagnose gastrointestinal bleeding during hospitalization for gout and hypertension; and
- failure to prescribe GI prophylaxis upon discharge from the first hospitalization, which may have prevented the gastrointestinal bleed.

LEGAL IMPLICATIONS
Experts on both the defense and plaintiff sides reviewed the case. The overall consensus was that Internal Medicine Physician A was too aggressive in treating the patient’s gout during the first hospitalization with concurrent high-dose steroids and NSAIDs. They noted that gastrointestinal bleeding is a risk when treating gout with aspirin, NSAIDs, or high-dose steroids. When combined, the risk becomes even greater.

Several of the experts felt that the patient should have been placed on gastric prophylaxis with a proton pump inhibitor (PPI) upon discharge from the hospital. They further noted that this failure may have led to the patient’s subsequent gastrointestinal bleed and death.

Another expert believed the patient’s cardiac enzymes should have been checked in the ICU and a STAT cardiac echocardiogram performed due to the patient’s high risk of a cardiac event (diabetes, hypertension, morbid obesity, gastrointestinal blood loss). This same expert also noted that the physician’s documentation of the case was incomplete, making it hard to correlate critical events with the timing of treatments and therapies.

Other experts felt that due to the patient’s comorbidities, it was difficult to determine the exact cause of the patient’s bleeding or cardiac arrest.

DISPOSITION
Due to the defense challenges outlined above, the case was settled on behalf of Internal Medicine Physician A.
**RISK MANAGEMENT CONSIDERATIONS**

Knowing which medications to prescribe and the correct dosage is important for maintaining quality standard of care. In this case, choosing an incorrect combination of medications at high dosages may have led to the patient’s death. Failure to anticipate a potential GI bleed and prescribe a PPI at discharge was another medication error that may have been avoided.

According to the U.S. Department of Health and Human Services, some strategies for preventing adverse drug events include:

- adhere to the “five rights” of medication safety: administer the right medication, in the right dose, at the right time, by the right route, to the right patient;
- establish clear, strong policies and procedures to support strict adherence to these “five rights”;
- avoid unnecessary medications by adhering to conservative prescribing principles; and
- reconcile medications at times of transitions in care.¹

Due to the delay in diagnosing the patient’s bleed during the second hospitalization, the patient rapidly developed multiple organ failure that led to his death. More than one of the experts who reviewed the case discussed the physician’s poor documentation—missing progress notes, physician orders, and nursing documentation. While it appeared the patient received reasonable care while hospitalized (prompt GI work-up, thorough ICU care, evaluations), lack of clear documentation made it difficult to pinpoint when the diagnosis of the patient’s GI bleed should have occurred.

In this case, better documentation and communication between health care professionals may have changed the outcome. The SBAR (situation, background, assessment, recommendations) communication technique may have improved the communication process in this case by providing a logical sequence to the patient’s progress.

- **Situation:** What is the situation? What is currently happening? What is the acute condition?
- **Background:** What is the patient’s history? Vital signs? Medications? What circumstances could have led to the situation?
- **Assessment:** What is your assessment of the problem? What do you think caused the problem?
- **Recommendation:** What can be done to correct the problem? What care or treatments do you propose?²

Had Internal Medicine Physician A assessed the patient using the SBAR technique, care for this patient may have been improved. Effectively documenting these findings may also have increased communication among the health care professionals and led to more successful treatment.

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**SOURCES**


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FAILURE TO CORRECTLY PRESCRIBE AND INSTRUCT IN TAKING MEDICATION

PRESENTATION
A six-year-old girl came with her mother to a dermatology clinic for treatment of molluscum contagiosum. The lesions had been present for six months and she had 11 mollusca on her left torso and left arm. The child’s mother had treated the areas with triamcinolone, which was not effective.
PHYSICIAN ACTION
The dermatologist obtained informed consent and treated the patient with cantharidin and liquid nitrogen. The mother was instructed to leave the medicated occlusive tape on the patient’s lesions for 2 to 4 hours and then remove it. The following day, the patient and her mother returned to the dermatologist. The tape was still applied. The mother explained that the child would not let her remove it. The patient had a mild form of autism, which was a complicating factor.

The tape was removed in the office and significant blistering was revealed under the tape. Wound care was provided and a prescription for silver sulfadiazine was given with instructions on how the medication was to be used. A follow-up visit was scheduled in one week.

One week later, the patient and her mother returned to the clinic for evaluation of the scabbed lesions. There were no signs of infection or any functional limitations. The family had been applying the silver sulfadiazine, and the patient’s condition had improved. Reduced mollusca remained on the patient’s left rib cage and left proximal upper arm. A follow-up appointment in 7 to 10 days was offered, but not made. The child did not return to the clinic.

ALLEGATIONS
A lawsuit was filed against the dermatologist. The allegations included negligence in failing to maintain the standard of care in the following ways.

- Failure to appropriately apply the cantharidin causing chemical burns, scarring, and disfigurement. It was alleged that the medication was applied in a general manner rather than directly on the skin lesions.
- Failure to give proper application instructions, as instructions were given to leave the cantharidin on for a long time rather than wash it off within the time provided on the package insert.
- Failure to properly prescribe, as it was alleged that cantharidin should not be used on children under the age of 12 due to the high potency of the drug.

LEGAL IMPLICATIONS
Three defense consultants reviewed the case, and none were supportive of the dermatologist. Concern was expressed over poorly documented consent; lack of documentation of wound care and wound care instructions; and poor documentation of the physical examination of the complications.

DISPOSITION
The case was settled in mediation.

RISK MANAGEMENT CONSIDERATIONS
The patient trusts the physician to knowledgeably choose the best medication for his or her unique set of circumstances: age, history, condition, etc. Many sources are available for physicians to stay informed on new and existing medications and the associated benefits and risks of each: the medication supplier, package labeling, CME, information from colleagues, journal articles, and personal experience.

When selecting the dosage amount for a child, consider the patient’s current conditions and medications, age, weight, and physical size. The majority of drugs used in pediatric patients are dosed according to the patient’s body weight. If a physician decides to go outside of recommended dosages—for either a child or an adult—it is a best practice to document the rationale behind that decision in the patient record. Discuss the medication and the reasoning for the dose with the patient and document that conversation, as well. Clear and comprehensive documentation is a physician’s first, best defense in the event of a claim.

How is medication information communicated to patients? Tell patients how to take prescribed medications and encourage them to ask questions. In addition, tell patients to refer to the Patient Package Inserts (PPIs) if provided with the prescriptions by the pharmacy. However, be aware that PPIs are not required to be included in the package and the U.S. Food & Drug Administration (FDA) does not screen PPIs. Patients should be told to contact you with any additional questions or concerns after filling the prescription. It is always beneficial to document any patient conversation related to medications or prescriptions.

As an additional consumer aide, the FDA has posted medication guides for approximately 200 FDA-approved drugs on its website. These medication guides are short, written in plain language, and subject to FDA approval. The FDA requires that a medication guide be issued for a drug and available on the site whenever the agency determines that:

- “certain information is necessary to prevent serious adverse effects
- patient decision-making should be informed by information about a known serious side effect with a product, or
- patient adherence to directions for the use of a product are essential to its effectiveness.”

If applicable, direct your patient to use these Medication Guides and document all patient education conversations in the medical record.
SOURCES


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Even when you win, trials can take a toll.

A few days after a jury returned a verdict in favor of my client, a radiologist with years of experience, I attended a celebratory dinner in his honor. At one point in the evening, he pulled me aside to tell me that, after some soul searching, he decided to stop performing interventional radiology. The trial had been too hard on him. I said, “Hey, I defend radiologists all the time who are second guessed on their read of a study. Please don’t think you will be immune from lawsuits by getting out of interventional.” He said something that hit me hard: “Well then, I may just get out of medicine altogether.”

More recently, I defended a prominent general surgeon who performed a laparoscopic cholecystectomy that resulted in an unfortunate outcome. This was the second time the surgeon experienced this outcome, after performing almost 4,000 of these procedures without incident. Still, this lawsuit disabled him. After 25 years, he seriously considered giving up his medical practice. I asked him to reconsider. I reminded him of the thousands of patients he has helped with only a few bad results—only 3 lawsuits in 25 years.

These types of reactions are becoming more and more common. No one wants or plans to make life-changing mistakes or to be scrutinized for those errors. The rigors associated with defending yourself (or even the potential of having to defend yourself) have become almost too much for many to bear. However, there are some basic things all physicians can do to make these processes less painful and more successful.
This article provides some guidance to help physicians avoid and defend lawsuits, effectively handle state medical board matters, and manage peer reviews.

**AVOIDING LAWSUITS**

When a physician receives a letter threatening or advising of a potential legal action, it is estimated that about half of those letters will actually result in a lawsuit. Some specialties are more at risk than others. Plaintiff’s lawyers weigh cases based on potential negligence and potential damages — the amount of money they may be able to recover. Thus, the spine surgery that goes awry may be a more valuable case than one involving improper medication that does not cause long lasting harm.

If a lawsuit happens, and you are served with a citation and petition, it is a best practice to follow this standard protocol:

- contact your professional liability carrier;
- provide a copy of the lawsuit papers, either in physical or digital form to your claim representative; and
- locate and safeguard your records on the patient involved in the suit.

What is one thing you can do to increase your chances of a good result in the lawsuit? Be able to demonstrate that you initiated or followed a reasonable path of care, a path that can be backed up by experts, published guidelines, literature, or textbooks.

What can be done to avoid lawsuits altogether? Maintain excellent records. Consider that when an unhappy patient consults an attorney, the first thing the attorney will do is look at the medical records. Most plaintiff attorneys will make decisions about the case — specifically their chances to prevail — based on review of the pertinent records.

Excellent documentation is the equivalent of equipping your home with an alarm system, burglar bars, and a large dog. A burglar is typically only looking for the easy house to break into, not the difficult one. The same is true of a medical lawsuit. While complete, well-documented records are not a guarantee against a lawsuit, they can be a strong deterrent and aide in your defense if litigation is pursued.

Maintain records that are accurate, thorough, and reflect your thought process. Do not default to repetitions that indicate corners are being cut or entries are copied and pasted.

**STATE MEDICAL BOARD**

There is a special anxiety that comes from dealing with the licensing board of your profession, an entity that holds your license and can affect your life. And for most of my physician clients, state board matters are more dreaded than lawsuits.

One important thing you can do to prevail before a state board is to obtain legal counsel as early as possible. Lone Star Alliance, RRG provides coverage for expenses, fines, or penalties related to a board action. Do not hesitate to use this coverage. I have seen routine matters mushroom into major ordeals simply because the physician did not consult with legal counsel and wrote their own initial response. Having an experienced attorney is one of the best ways to prevail in a state board matter.

**PEER REVIEW**

To paraphrase Winston Churchill, a peer review is sometimes “a riddle wrapped in a mystery, inside an enigma.” There are a few different categories and scenarios that can lead to a peer review, in which colleagues are required to assess the care provided by a physician. Peer review may occur based on concerns by a hospital at the number of unfortunate outcomes attributed to one physician or a single incident in which a physician is involved.

One thing to keep in mind is that a peer review is a confidential proceeding. It is intended to allow open discussion, but this type of discussion can lead to some tricky, unexpected legal situations. Therefore — just as with a lawsuit or state medical board proceeding — it is important to seek legal counsel early on.

It has been my experience that physicians take lawsuits, board proceedings, and peer reviews very hard — understandably. But as a friend, ally, and advocate, I want to encourage all physicians to consider the good that you have done, the good you will do, and the high dues you have paid — and to carry on.

_In 1996, T. Marc Calvert, JD founded Calvert & Associates in Houston, Texas. Mr. Calvert is board certified by the Texas Board of Legal Specialization in the field of Personal Injury Trial Law._

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