

Evaluate liability risks in prescribing

Dear Dr. Mossman,

I prescribed topiramate for Mr. B, a patient with no history of kidney stones. Many months later he developed back pain. During the medical workup for a possible kidney stone, Mr. B and I revisited the risk of kidney stones with topiramate, which we had discussed at the beginning of therapy. Mr. B was adamantly opposed to stopping topiramate, even if he had a kidney stone. Testing revealed that Mr. B did not have a stone, but I wasn't sure how to proceed. I worried that I might be found liable if Mr. B stayed on topiramate and did develop a kidney stone.

Submitted by Dr. A

When a patient develops a medical problem from a drug you prescribed, it is natural to feel responsible—after all, your treatment caused the adverse event. But did you commit malpractice? To answer this, let's review the concept of "medical negligence."

Malpractice law applies legal principles of negligence to professional conduct.¹ The elements of a negligence case (*Table 1*) can be summarized as "breach of duty causing damages." Therefore, when you wonder whether possible harm to a patient might be considered malpractice, ask yourself, "Did I breach my professional duty?"

Physicians have a duty to practice within their specialty's standard of care, and if they do this, they should not be held liable even if their treatments cause adverse effects. Each jurisdiction defines the standard of care differently, but the gen-

Table 1

Elements of a successful negligence case

- Defendant owed the plaintiff a duty of care
- Defendant breached that duty
- Defendant's conduct harmed the plaintiff
- Defendant's conduct was a "proximate cause," meaning it had a significant relationship to the harm
- Legally recognized damages, such as a physical injury, occurred

Source: Reference 1



Douglas Mossman, MD

eral expectation is "that physicians acting within the ambit of their professional work will exercise the skill, knowledge, and care normally possessed and exercised by other members of their profession. . . in the relevant medical community."¹

It's impossible to describe all the skills, knowledge, and care a psychiatrist normally employs when prescribing a drug, but elements of good practice include reasonable efforts to:

- make an appropriate diagnosis
- offer appropriate treatment
- monitor effects of treatment.

Further, treatment should occur only when a patient gives informed consent. Let's examine each of these elements as they apply to Dr. A and Mr. B.

Appropriate assessment

Despite the availability of guidelines for psychiatric evaluation,^{2,3} it is tough to

» Do you have a question about possible liability?

■ Submit your malpractice-related questions to Dr. Mossman at douglas.mossman@dowdenhealth.com.

■ Include your name, address, and practice location. If your question is chosen for publication, your name can be withheld by request.

■ All readers who submit questions will be included in quarterly drawings for a \$50 gift certificate for Professional Risk Management Services, Inc's online market-place of risk management publications and resources (www.prms.com).

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Malpractice minute

We give you facts of an actual malpractice case. Submit your verdict at CurrentPsychiatry.com and see how your colleagues voted.

Did the patient know the risks of risperidone?

THE PATIENT. A 53-year-old woman hospitalized for depression and suicidal thoughts was prescribed risperidone.

CASE FACTS. The patient developed excessive mouth and tongue movement—including pursed lips, protruding tongue, and biting the inside of her mouth—and uncontrollable urges to move her extremities. She was diagnosed with probable tardive dyskinesia (TD), and risperidone was tapered and discontinued.

THE PATIENT'S CLAIM. The psychiatrist failed to adequately monitor her and recognize early symptoms of TD and did not tell the patient to look for signs of TD.

THE DOCTOR'S DEFENSE. None

What's your verdict?

LIABLE NOT LIABLE



Submit your verdict and find out how the court ruled at CurrentPsychiatry.com. Click on "Have more to say about this topic?"

to comment. Go to page 98 to see how your colleagues voted in February's Malpractice Minute.

Cases are selected by CURRENT PSYCHIATRY from *Medical Malpractice Verdicts, Settlements & Experts*, with permission of its editor, Lewis Laska of Nashville, TN (www.verdictslaska.com). Information may be incomplete in some instances, but these cases represent clinical situations that typically result in litigation.

Clinical Point

A prudent clinician must judge whether the potential benefit of topiramate outweighs the risk of adverse effects

summarize everything psychiatrists do when assessing patients. But—focusing on Dr. A's question—it is reasonable to ask: Did the psychiatric evaluation provide reasonably good evidence that Mr. B had a condition that topiramate might alleviate? Mr. B's strong desire to keep taking the drug suggests that the answer is "yes."

Another part of assessment is considering whether a patient has medical conditions that might contraindicate topiramate or affect prescribing. Typically, psychiatrists learn about these matters by careful history-taking and laboratory testing. In addition to kidney stones, topiramate is associated with increased risk for secondary angle closure glaucoma, hyperthermia, metabolic acidosis, cognitive dysfunction, mood changes, and sedation.⁴

Dr. A also should consider potential interactions between topiramate and any other medications that Mr. B is taking. A prudent clinician must judge whether the potential benefit of topiramate for Mr. B outweighs the risk of adverse effects. If Mr. B actually had developed a kidney stone, Dr. A might seek a nephrologist's advice about how to minimize the risk of recurrence.

Appropriate treatment

Topiramate is FDA-approved only for treating seizures and for prophylaxis against migraine headaches. However, FDA approval limits only how pharmaceutical companies can promote a medication.⁴ Physicians may prescribe drugs for unapproved "off-label" uses, and doing so is accepted medical practice. Peer-reviewed publications support using topiramate to treat agitation,⁵ alcohol dependence,⁶ binge-eating disorder,⁷ and other conditions that psychiatrists often manage. A tendency to promote weight loss has made topiramate an attractive add-on medication for patients whose weight problems are causing other health difficulties.⁸

Table 2

Evaluating a patient's capacity to consent to treatment

Is this patient able to?	Questions to ask
Express a clear treatment preference	What treatment have you chosen?
Understand basic information communicated by caregivers	Can you tell me in your own words about your condition and the treatment options I have told you about?
Appreciate his or her medical condition and how information about treatment applies	What do you think is wrong with your health now? Do you think you need some kind of treatment? What do you think treatment will do for you?
Reason logically when choosing treatment options	Why did you choose this treatment? Why is it better than your other treatment options?

Source: Adapted and reprinted with permission from Appelbaum PS. Assessment of patients' competence to consent to treatment. *N Engl J Med* 2007;357:1834-40

Assuming that Mr. B is taking topiramate for an off-label purpose, an appropriate question to ask is, "Does professional literature support use of topiramate in Mr. B's circumstances?" Also, given everything known about Mr. B up to this point, is topiramate a good treatment choice?

Appropriate monitoring

As every clinician knows, medications can cause problems. Monitoring topiramate therapy involves periodic lab testing and assessment of effectiveness. Dr. A should feel reasonably sure that Mr. B—assisted by a family member or close friend, if necessary—can and will cooperate with monitoring requirements. Dr. A also should verify that Mr. B can grasp and follow instructions designed to avert complications—such as ample hydration to reduce risk of nephrolithiasis—and will promptly address problems if they occur.

Informed consent

Informed consent is especially important when a patient receives a treatment that has a known risk. Although the *Physician's Desk Reference* does not list previous kidney stones as a contraindication to topiramate therapy, it urges caution under these circumstances.⁴ Therefore, if

Dr. A wishes to prescribe topiramate for a patient with a history of kidney stone, the patient should meaningfully collaborate in the treatment decision.

Informed consent for treatment requires that patients not feel coerced by the doctor or setting and have the mental capacity or competence to give consent. Under the conceptualization developed by Appelbaum and Grisso,⁹ competent patients can:

- express a consistent choice
- understand medical information provided to them
- appreciate how this information applies to them and their condition
- reason logically about treatment.

Most psychiatric outpatients have capacity to consent to treatment, but if you have doubts, assess the patient's capacity systematically. Appelbaum¹⁰ provides a superb summary of these concepts and suggested questions to ask your patient (Table 2).

What information should patients receive before giving consent? The legal standard varies, but in most U.S. jurisdictions, patients "are entitled to material information about the nature of any proposed medical procedure. For example, patients are entitled to information about the risks of the procedure, its necessity, and alternate procedures that might be preferable."¹¹ Topiramate's manufacturer

Clinical Point

Verify that your patient can grasp and follow instructions designed to avert complications

instructs physicians to question and warn patients about the risk of kidney stones—which Dr. A did in Mr. B’s case. When you prescribe a drug off-label, you may want to tell patients this, but explain why the drug is appropriate nonetheless.

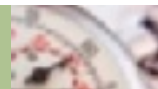
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Clinical Point

Most outpatients have capacity to consent to treatment, but if you have doubts, assess the patient’s capacity systematically

February POLL RESULTS



Was the patient still suicidal?

A 30-year-old police officer reported thoughts of suicide. He was voluntarily hospitalized for 4 days and received medication and inpatient psychotherapy. When discharged, a psychiatrist prescribed follow-up outpatient psychotherapy and antidepressant and antipsychotic medication. The next day, the officer fatally shot himself. Was the psychiatrist liable for the patient’s suicide?

LIABLE: 38% **NOT LIABLE:** 62%

What did the court decide?

A defense verdict was returned
Data obtained via CurrentPsychiatry.com, February 2008

THIS MONTH’S CASE (from page 96)

Did the patient know the risks of risperidone?

A \$1,206,000 verdict was returned

Bottom Line

If the benefits of topiramate for Mr. B appear to outweigh the risks of nephrolithiasis and other adverse effects, if Mr. B will cooperate with monitoring, and if he competently weighs and accepts the risks, Dr. A’s prescribing of topiramate appears to meet the standard of care.