Incorrect medication prescribed to patient

by Stacey Agnew
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This closed claim study is based on 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 physicians’ defensibility. The ultimate goal in presenting this case is to help physicians practice safe medicine. An attempt has been made to make some of the material difficult to identify. If you recognize your own claim, please be assured it is presented solely to emphasize the issues of the case.

Presentation

A 34-year-old woman came to her family physician for the first time to request a prescription for oral contraceptives. The patient had four children, and she reported that she did not use any form of birth control.

Physician action

The patient was examined, and her vital signs were reported to be normal. A pap smear was performed, and the patient was given a prescription for oral contraceptives. Because the patient did not fill the prescription until 11 days after the visit, it was thought that the physician gave the patient samples along with the prescription. However, this was not clear in the medical records. The prescription was refilled one month later.

Two months passed and the patient contacted the family physician’s office. She reported experiencing adverse effects from the oral contraceptives. The physician’s medical assistant wrote a prescription for a hormone replacement patch to be changed every week with 11 refills available. The medical assistant used the physician’s signature stamp on the prescription.

The patient filled the prescription for the patch and claimed that the physician told her via telephone to stop taking the birth control pills. The patch was actually hormone replacement therapy instead of oral contraceptives. The patient later went to a gynecologist for complaints of amenorrhea and it was discovered that she was 7 weeks pregnant. She later gave birth to twins by cesarean delivery and had a tubal ligation at that time.

Allegations

A lawsuit was filed against the family physician. The allegations included:

• failure to provide appropriate birth control;
• failure to disclose the risks of engaging in sexual activity while not being appropriately protected by birth control; and

continued on page 2
• incorrect prescription of hormone replacement medication instead of oral contraceptives resulting in an unplanned twin pregnancy.

Legal implications
Consulting physicians who reviewed this case were critical of the care provided by the family physician. The medical assistant wrote a prescription for hormone therapy and not oral contraceptives. This prescription was written without the family physician’s permission and using a signature stamp. It was clearly the wrong prescription and was inappropriate for the patient.

Documentation was also a concern in this case. The patient’s medical records were incomplete. There was no documentation of any phone calls made by the patient or of any conversations between the patient and family physician.

Disposition
This case was settled on behalf of the family physician.

Risk management considerations
Missing or incomplete medical records can complicate the defense of a medical liability claim. In keeping with the Texas Medical Board Rule 165.1 on medical records, an “adequate medical record” should meet the following standards and include:

• reason for the encounter and relevant history, physical examination findings and prior diagnostic test results;
• an assessment, clinical impression, or diagnosis;
• plan of care (including discharge plan if appropriate);
• the date and legible identity of the observer; and
• past and present diagnoses should be accessible to the treating and/or consulting physician.

Additionally, the medical record should include:

• the rationale for and results of diagnostic and other ancillary services;
• the patient’s progress, including responses to treatment, change in diagnosis, and patient’s noncompliance should be documented; and
• relevant risk factors should be identified.

The written plan of care should include the following, when appropriate:

• treatment and medications (prescriptions and samples) specifying amount, frequency, number of refills, and dosage;
• any referrals and consultations;
• patient/family education;

• specific instructions for follow up; and
• any written consents for treatment or surgery requested from the patient/family by the physician. 1

The medical assistant wrote the prescription for a hormone replacement patch on the physician’s prescription pad, and there was no documentation of this prescription in the medical record.

Both the prescription pad and the signature stamp were available to office personnel. When office staff refill standard prescriptions, physician co-signature in the medical record can reduce the opportunity for conjecture about authorization to prescribe medications. If co-signature is not possible, it is suggested that physicians implement a policy outlining the circumstances in which prescriptions can be refilled by staff and when the patient should be seen before a refill. Having such a policy in place may alleviate questions about authorization to prescribe medications should an adverse outcome occur.

The use of a signature stamp in place of a physician signature was also an issue in this claim. The physician’s signature validates the entry and authenticates the documentation or order. Stamps used in lieu of physician signatures may pose problems when defending some medical liability claims.

The medical records for this patient did not include documentation of patient phone calls. The phone call from the patient about the adverse effects of the oral contraceptives and the phone conversation the patient claims she had with the physician about the discontinuation of oral contraceptives were not documented. Documenting patient phone calls and the instructions given to patients is recommended. This information can serve physicians and subsequent caregivers in providing patient care. It also provides evidence that the instructions were in response to specific medical complaints.

In order to defend against allegations of failure to adequately supervise, protocols and standing delegation orders are recommended. Standing delegation orders or guidelines may be authorized for the performance of acts and duties that do not require the exercise of independent medical judgment for nurses and unlicensed assistive personnel.

Sources

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Gadolinium, renal failure, and NSF: a potentially dangerous combination

by Jay Henderson, JD

Physicians and patients are familiar with the imaging modality we know as magnetic resonance imaging (MRI). MRI is an imaging technique in which radio waves and a powerful magnet linked to a computer are used to create detailed images of areas inside the body. MRI images are often enhanced by the use of a contrast media, which is injected in the body to permit greater visualization of the organs and structures under scrutiny.

Gadolinium is a paramagnetic metal ion contrast agent that was developed in the 1980s. Gadolinium has been used in imaging procedures since 1988, when the first gadolinium-based contrast agent (GBCA) was approved for use in the United States. Gadolinium provides improved lesion sensitivity and improved lesion characterization. Millions of patients have received injections of GBCAs, including patients on dialysis or with compromised renal function.

GBCAs were historically thought to be safe for use in patients with renal compromise. There was no indication in the medical literature or the product labeling that use of gadolinium in these patients might result in a systemic autoimmune disorder. As of 2004, the American College of Radiology (ACR) observed that “[g]adolinium agents are considered to have no nephrotoxicity at approved dosages for MR imaging.” The 2006 ACR Practice Guidelines and Technical Standards offered numerous scenarios in which “intravenous contrast may be useful,” including vascular abnormalities, infections, masses, and tumors. As a result, millions of imaging procedures were performed using this presumably safe agent.

The first public indication that GBCAs might pose a potential health hazard in susceptible patients occurred in June 2006. At that time, the Food and Drug Administration (FDA) obtained reports of an unusual cluster of adverse events from Europe. The disease in question was known as Nephrogenic Systemic Fibrosis (NSF). The FDA issued a Public Health Advisory on this subject. The advisory offered two recommendations to health care professionals and patients: (1) gadolinium-containing contrast agents, especially at high doses, should be used only if clearly necessary in patients with advanced kidney failure; and (2) it may be prudent to institute prompt dialysis in patients with advanced kidney dysfunction who receive a gadolinium contrast Magnetic Resonance Angiography (MRA). Thus, this first advisory was limited in scope and contrary to two decades of experience of physicians familiar with this compound.

Many physicians, including radiologists, did not become aware of this initial advisory. Among those who did, the prevailing view was that the FDA advisory did not warrant a drastic change in existing medical practice. There was no definitive guidance from industry or professional organizations initially, which left practitioners to their own devices. As a result, most physicians continued to order contrast-enhanced studies in the same circumstances as they had for years.

The FDA issued a second Public Health Advisory in December 2006. This second advisory stated: “When a patient with moderate to end-stage kidney disease needs an imaging study, select imaging methods other than MRI or MRA with a gadolinium-based contrast agent for the study whenever possible. If these patients must receive a gadolinium-based contrast agent, prompt dialysis following the MRI or MRA should be considered.”

Again, the information in this advisory did not initially gain wide distribution or acceptance.

One critical flaw in our drug and medical device regulatory system is that there was no reliable way to ensure that information on NSF would come to the attention of physicians. The FDA advisories were not widely circulated. Manufacturers of GBCAs did not revise their labeling to reflect the contents of the advisory. Communications from industry and professional associations were not well disseminated and were vulnerable to subjective interpretations. The practical effect of this divergence of information was that practice standards varied dramatically among prescribers and radiologists. This was not an urban-rural dichotomy or one dictated by the sophistication of the practice. The author has first-hand knowledge that tertiary care centers in major metropolitan areas of Texas did not begin to screen patients for renal dysfunction until the spring and summer of 2007 or thereafter. In any event, many radiology centers did not alter their gadolinium screening protocols in response to the FDA advisories.

In May 2007, the FDA announced that it would require a black box warning for all marketed GBCAs to alert prescribers to the risk of NSF in patients with renal compromise. The product labeling for GBCAs was not modified until after this announcement, and the revised labeling was not formally distributed to the medical community until September 2007. This series of events explains why many physicians did not implement new gadolinium protocols in the early days of this episode.

Today, all marketed GBCAs are subject to a black box warning. This warning states that gadolinium-based contrast agents increase the risk for nephrogenic systemic fibrosis (NSF) in susceptible patients. The ACR issued formal screening recommendations on gadolinium-based MR contrast agents in July

continued on page 4
continued from page 3

2007. GBCA product labeling also contains screening criteria for physician consideration.

Physicians who order contrast-enhanced MRIs, as well as radiologists, must take heed of the new black box warning that accompanies gadolinium-based contrast agents. While its occurrence is rare, nephrogenic system fibrosis is a tragic disease for which there currently is no cure. GBCAs remain a useful tool for the vast majority of patients undergoing MRIs, but candidates who are susceptible to NSF should be screened and assessed under current medical guidelines. In the end, the appropriate course of care is left to the sound discretion of the physician and should include the informed consent of the patient.

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