

# ED Legal Letter™

The Essential Monthly Guide to Emergency Medicine Malpractice Prevention and Risk Management  
From the publishers of *Emergency Medicine Reports* and *ED Management*



## Non-Traumatic Low Back Pain: Avoiding Liability for Missed Cord Compression

By Robert A. Bitterman, MD, JD, FACEP, Contributing Editor

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Low back pain (LBP) is a common (more than 3 million ED visits per year in the United States) yet typically benign ED complaint.<sup>1</sup> In approaching the back pain patient presenting to the ED, the emergency physician should determine, based on the patient's age and nature of complaints, whether the patient has an abdominal aortic aneurysm (AAA), spinal cord compression syndrome (SCCS), fracture, infection, benign LBP, or some other atypical etiology — an even half dozen possibilities to consider.<sup>2,3</sup> The work-up of the patient, if any is indicated, and the documentation in the chart should reflect that thought process. Most patients will fit into the large category of mechanical/non-specific/non-serious LBP. Consider it the category for all patients with the “garden variety” LBP routinely seen in our EDs, but also note that it includes patients with an acute herniated disc if no new or acute neurological impairment is present. The logic for this is that the immediate management from our perspective in the ED, and the outpatient referral for all patients in this category, is initially the same.<sup>1,3</sup>

Epidural, spinal, or cauda equina compression syndrome, often referred to as spinal cord compression syndrome (SCCS) is one of the few true surgical emergencies that can present as LBP (AAA is another).<sup>4,5</sup> (See box, below.) Etiologies of epidural mass that can produce cord compression include tumor, metastasis, epidural hematoma, epidural abscess, recent back procedure or epidural anesthesia, and herniated disc.<sup>2,3,5,6</sup>

This article will concentrate on the recognition, management, and the malpractice liability issues related to these cord compression syndromes.

Lawsuits for misdiagnosis of spinal cord compression syndrome (SCCS), delay in diagnosis, or delay in consultation with neurosurgery are becoming increasingly common (for example, the insurance company I'm affiliated with has had 5 cases in the last three years alone), and the catastrophic patient damages can lead to correspondingly large financial losses for emergency physicians and/or their insurance companies.<sup>7,8</sup>

Technically, “epidural compression syndrome” is the collective term encompassing spinal cord compression, conus medullaris syndrome, and cauda equina syndrome. Cauda equina syndrome differs in that it occurs below the level of the cord and involves the spinal nerve roots of the cauda equina.

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## Patient History

The typical elements that should be addressed in the history of an ED patient complaining of non-traumatic LBP, and documented in the medical record, include the following:<sup>2,3,9</sup>

- Characterization of the pain, including onset, location, nature, radiation/sciatica, duration, recent changes, ameliorating or exacerbating factors, and severity;
- Associated symptoms, including fever, chills, night sweats, weight loss, bowel or bladder problems, and numbness-tingling-weakness in perineum or lower extremities;
- Past back history (previous back pain, injury, surgery, herniated disk(s), etiology, treatments, and response to prior therapy);
- Past medical history, including malignancy, tuberculosis, immunosuppression, diabetes, recent infections, hypertension (HTN), AAA, urinary tract stones);
- Medications, particularly warfarin sodium, steroids, and current pain medications; and
- Social history (IVDA [intravenous drug abuse], smoking).

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### Questions & Comments

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Risk factors for possible spinal infections, such as epidural abscesses, include fever, IVDA, immunosuppression (including chronic steroid use), and urinary infection. Fever and back pain in the IVDA patient should be considered spinal infection until proven otherwise (epidural abscess, osteomyelitis, or endocarditis).<sup>4</sup>

Cancer risk factors include age older than 50, prior history of cancer, unexplained weight loss, and failure to improve after 4-6 weeks of conservative LBP therapy (chronic LBP). If all four of these risk factors for cancer are absent, studies suggest that the possibility of cancer causing the patient's LBP is essentially zero.<sup>1,10</sup>

Documentation of urinary bladder function is crucial. Cauda equina syndrome, by definition, only exists if the patient has bowel or bladder dysfunction (usually urinary retention or urinary incontinence).<sup>5,7,8</sup> Urinary retention typically precedes incontinence. "No bowel or bladder problems" is a mandatory, pertinent negative history that must be documented on the chart of any patient discharged from the ED who presented with a complaint of LBP (or radicular pain down one leg).

True sciatica (LBP with radiation of the pain past the knee, not just into the posterior thigh) has such a high sensitivity (95%) that its absence makes nerve root compression from lumbar disc herniation unlikely.<sup>1,3,10</sup>

Recent back procedure, epidural anesthesia, warfarin sodium, or heparin therapy raise suspicion for an epidural hematoma as a cause of pain or SCCS.<sup>2-4</sup>

## Physical Examination

The typical elements of the physical exam of the LBP patient include the following:<sup>2,9</sup> vital signs; palpation of the back for vertebral tenderness, flank tenderness; abdominal palpation for AAA or other entities that refer pain to the back; range of motion of the back and lower extremities; straight leg raise testing; neuromuscular testing of lower extremities (motor, sensory, and reflexes); gait; perineal/perirectal sensation; and rectal tone.

The abdomen of every patient with LBP should be examined, not only in consideration of AAA, but also to identify the many intraabdominal conditions that can refer pain to the back.<sup>9</sup>

The emergency physician must pay special attention to the neurological exam of the lower extremities, including detailed motor, sensory, and reflexes exam and a check for saddle/perianal anesthesia.

It is not necessary to perform a digital rectal exam on every patient with LBP (though if done routinely it might cut down the number of ED visits). However, it should be done whenever patients present with bowel or bladder complaints, lower extremity neurological symptoms, or perineal paresthesias. Weak rectal tone and saddle anesthesia are indicative of SCCS.<sup>1,9,10</sup> (See Table 1.)

Straight leg raise (SLR) should be assessed to evaluate

**Table 1**

**Clinical Indicators of Spinal Cord Compression Syndrome (SCCS)**

- Sudden onset or otherwise unexplained loss or changes in bladder or bowel control (retention or incontinence).
- Sudden onset or otherwise unexplained lower extremity weakness.
- Saddle numbness, hypoesthesia, or anesthesia.

for nerve root impingement, which is usually but not always due to lumbar disc herniation. Positive SLR is defined as pain in the posterior lateral lower extremity that radiates below the knee with the patient lying supine and the hip flexed 60 degrees or less. It is suggestive of disc herniations, which in more than 95% of cases occur at the L4-5 or L5-S1 levels. Increased back pain alone, without radiation below the knee, does not constitute a positive SLR test. A negative SLR rules out surgically significant disc herniation with more than 95% specificity.<sup>1-3,10</sup>

A positive crossed straight leg test (radicular pain down the symptomatic leg when elevating the asymptomatic leg) is highly specific for a herniated disc.<sup>1,10</sup>

Approximately 2.5-6% of patients with disk herniations ultimately suffer cord compression syndrome, which is why discharge instructions for the many patients we see with potential disc disease are so important.<sup>1,10</sup>

**Laboratory Studies**

The laboratory is not very useful in the evaluation of patients with LBP.<sup>6</sup> A CBC and erythrocyte sedimentation rate (ESR) may help if there is a suspicion of cancer, ankylosing spondylitis, or infection as the etiology. Blood cultures are indicated for presumed epidural abscess or osteomyelitis; as they will often identify the infecting organism. Prothrombin time and INR (international normalized ratio) are indicated for patients on warfarin sodium anticoagulation.

**Imaging Studies to Evaluate LBP / Possible Cord Compression**

**Lumbosacral [LS] Spine X-rays (LS-Spine).** Most patients with low back pain do not require any imaging.<sup>1,10,11</sup> Consider LS x-rays in patients presenting with new LBP and a history of trauma (including relatively minor trauma in the elderly), unexplained fever or weight loss, immunosuppression, cancer, prolonged steroid use, osteoporosis, or age older than 70. The purpose of LS radiographs is to exclude malignancy/metastasis, fracture, or infection (osteomyelitis).<sup>1,10,12</sup>

Otherwise, x-rays are of no use and are not indi-

cated in the evaluation of patients presenting with LBP, including patients with sciatica, ruptured discs, and/or cauda equina.<sup>1,10,11</sup>

The ordering of LS x-rays for “medical legal” reasons to avoid litigation also is not recommended. It is better to explain to the patient why they don’t need x-rays and the unnecessary potentially harmful radiation, and then document your reasoning in the medical record. (This also mitigates the inevitable subliminal incompetence question from the family of “You mean they didn’t even do any x-rays?”)

LS-spine AP (anteroposterior) and lateral x-rays deliver a high dose of radiation, which is about 40 times the dose of a routine chest x-ray. The ovarian dose of radiation to a woman is equivalent to having a chest x-ray daily for more than 6 years.

Also, oblique view x-rays are not recommended since they add minimal information in a fraction of cases and more than double the radiation exposure.<sup>13</sup>

**CT Scan of LS-spine.** There is no reason to do a CT scan of the LS-spine in an ED patient to rule out an acute herniated disk. The initial management is the same for the first few weeks, regardless of whether the patient has simple undifferentiated LBP or a new ruptured disc as the cause of the acute LBP.<sup>1,10</sup> Explain to the patient that imaging studies may be indicated later, at the discretion of their physician, if his/her symptoms don’t resolve over the next few weeks.

Furthermore, CT scan is not the modality of choice to evaluate patients presenting with suspected spinal cord compression. An MRI (magnetic resonance imaging) is a much better diagnostic tool to identify cord compression, its etiology, and the extent or disease.<sup>2,6,8</sup> CT scan can be used in patients who are not candidates for MRI, such as those with implanted electrical devices, the morbidly obese, or those who cannot lie still or cooperate for MRI. A CT myelogram (dye is injected into the thecal space) can be useful in facilities that do not have MRI capabilities on site or within a reasonable transfer radius.<sup>5,11</sup>

A CT scan also is not the right choice for a suspected ruptured AAA. Best is a bedside ultrasound. It’s fast, easy, cheap, nearly 100% sensitive, and does not take the patient out of the ED. Only truly stable patients should go to CT.

Any time a non-contrast helical CT scan is ordered to rule out urinary tract stone/obstruction in a patient older than age 50, the radiologist should always view the aorta to detect an “unsuspected” AAA.

**MRI of the Spine.** MRI is the indicated study to evaluate all of the epidural compression syndromes, including cauda equina syndrome, epidural abscess, epidural hematoma, neoplasm, or infection.<sup>1,8</sup>

The advantages of MRI over CT scanning include the following:<sup>1,8</sup>

- Better visualization of soft tissue pathology, such as epidural abscesses or ruptured discs;
- Direct visualization of spinal cord and nerve roots;
- Improved sensitivity for cord pathology or intrathecal masses;
- Better sensitivity for infection and neoplasm;
- No radiation exposure;
- Safer for pregnant women, especially in the first trimester, because there is no radiation exposure.

### **Medical Decision Making, Consultation Issues**

Studies indicate malpractice suits related to SCCS are primarily for failure to recognize the disease on a timely basis, failure to obtain a stat MRI to make the diagnosis, and failure to consult an appropriate spine surgeon on a timely basis.<sup>7,8</sup> Not surprisingly, most often the delays in imaging or consultation came on nights, weekends, and holidays. It's important that clinicians know in advance if an MRI is available, and if not, that they know where to transfer the patient to obtain one promptly. Clinicians also should be aware of the capabilities of the surgical staff. If there is not a neurosurgeon or spine surgeon with the expertise to operatively relieve a cord compression, clinicians should know where to transfer the patient.

Whenever the LBP patient is complaining of any uri-

nary troubles, the emergency physician should catheterize the patient to obtain a post-void residual urine measurement. Ultrasound measurement of post void residual is a reasonable alternative. An amount greater than 50-100 cc is indicative of urinary retention and should prompt immediate consideration of SCCS and initiate the process of obtaining the MRI and appropriate consultation.<sup>4,5,7</sup>

The emergency physician and the nursing staff should be vigilant in observing for changes in the LBP patient's neuromotor symptoms or findings while the patient is still in the ED, particularly for patients with a prolonged ED stay due to an overwhelmed department, delay in obtaining an imaging study, awaiting consultation, or lack of in-patient bed availability. More than 85% of patients develop SCCS over a period of only a few hours, which may be while the patient is in the ED!<sup>5,8</sup> Any significant or progressive neuromotor deficit requires immediate surgical consultation.

The treatment for developing SCCS is surgery, and the speed of surgical decompression directly correlates with outcome (e.g., avoiding paraplegia, permanent bladder or bowel incontinence, or sexual dysfunction).<sup>5,7,8</sup>

Controversy exists over the relationship between outcomes and the timing of surgery, particularly in the first 24-48 hours, but there is near universal agreement that earlier is better than later.<sup>4,5,7,8</sup> Thus, the role of the emergency physician is to avoid delay in recognition and delay in referral to the appropriate specialist.

The use of steroids for acute cord compression also is controversial. It is common practice to initiate high-dose steroids in the ED, particularly if a malignancy is suspected, but there is no significant primary evidence to support the practice.<sup>14</sup> Emergency physicians should make the diagnosis, raise the steroid issue with our consultants, and let them make the decision for each individual patient.

**Transfers.** Whether the patient with suspected SCCS should undergo a diagnostic procedure prior transfer can be a very difficult clinical decision. When in doubt, discuss the question with the accepting specialist and document your interaction and reasoning.

### **Discharge Instructions, Referral, and Follow-up**

Inadequate discharge instructions are only occasionally the source of litigation related to SCCS; usually SCCS lawsuits arise from failure of the emergency physician to diagnose the disease process and/or refer the patient to the proper specialist in a timely manner.<sup>7,8</sup> (See Table 2.)

However, proper discharge instructions may be an invaluable defense tool if litigation stems from a case in which the patient develops SCCS after the initial ED visit. As noted above, most patients develop SCCS over a period of only a few hours. Thus, when discharging a patient with LBP or sciatica, the emergency physician must instruct the patient on what symptoms to look for

**Table 2**

#### **Common Errors Found in "Low Back Pain" — Missed Cord Compression Lawsuits**

- Failure to recognize or address a patient's complaint of urinary difficulties or motor weakness in a timely manner (or failure to notice such complaints in the EMS, triage, or nursing notes).
- Failure to believe the patient who says he/she "can't walk."
- Failure to document the patient actually can walk.
- Failure to adequately examine the patient, particularly lack of an appropriate neurological exam of the lower extremities or perineum.
- Failure to ascertain if the patient has urinary retention; no post-void residual measured if urinary complaints.
- Failure to obtain an MRI on a timely basis.
- Failure to obtain timely consultation with an appropriate specialist or arrange transfer to an appropriate facility/specialist if none available at your facility.
- Failure to explain potential complications, particularly urinary difficulties or motor weakness, and warn of the necessity of immediate medical reevaluation.

**Table 3****Low Back Pain Discharge Instructions**

- Move around as tolerated but avoiding heavy lifting. “Bed rest” is not recommended nor is it the best treatment for low back pain.
- Return to the ED immediately if you develop any of the following problems:
  - Leaking urine or difficulty urinating;
  - Inability to control your bowels;
  - New numbness or weakness in your legs or numbness between your legs;
  - Inability to walk; or
  - Fever.
- Medications will help control your discomfort:
  - Ibuprofen (800 mg every 8 hours for pain).
  - Acetaminophen-hydrocodone (one to two tabs every 4 to 6 hours for pain).
  - Do not drink alcohol, drive a car, operate machinery, or get up on ladders or heights when taking any prescribed pain medications.
  - Do not drive home if you received prescribed pain medications here in the ED.
- Follow up with your primary care doctor in \_\_\_\_\_ days. Return to the ED immediately if you get worse in any way.

and the proper procedure for emergency follow-up. (See Table 3.) Thereafter, a patient’s failure to follow-up as instructed creates a strong defensive position for the emergency physician if the patient suffers an adverse outcome.

Inform all patients with disc disease/LBP that cord compression is a possible complication of their disease and that they should immediately contact their physician or return to the ED if they experience any bowel or bladder problems, numbness or tingling in the perineal area, or weakness in a lower extremity.

The discharge instructions should be given verbally and in writing, and the patient should sign the instructions to document their receipt and understanding. As with all discharge instructions, the goal is to provide the proper instructions, explain the important issues, and set expectations for the patient to avoid surprises or unexpected outcomes.

**Summary**

SCCS must be considered in all patients presenting to the ED with back pain or leg pain. A careful history and neurological examination, as well as rapid consultation and MRI imaging, are the keys to early intervention and liability prevention. Delays in diagnosis and treatment directly correlate to the severity of complications and the likelihood of claims for medical malpractice. ■

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**Could drug rep relationship get your ED sued?**

*Gifts and perks may inflame a jury*

**C**onsider this scenario: During a malpractice trial involving a patient’s adverse outcome in your ED, the jury learns that you’ve been in the habit of accepting expensive dinners and vacations from drug companies.

This fact may have nothing to do with the patient’s care, but if the jury is allowed to hear it, it can still make you appear less trustworthy and help the plaintiff to make his/her case.

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## Resident Physician Interface in Medical Malpractice

*By Rade B. Vukmir, MD, JD, FCCP, FACEP, FACHE, Chairman, Education & Risk Management, Emergency Consultants, Inc./National Guardian Risk Retention Group, Inc., Clinical Professor of Emergency Medicine, University of Pittsburgh Medical Center.*

The scenario of a resident physician who is involved in a medical malpractice case occurs more commonly than you might think in the day-to-day practice of emergency medicine. Some more common examples might include the following:

- A patient disposition decision is made by the emergency department (ED) physician that is then countermanded by a resident physician who discharges the patient, and an untoward outcome results.
- A patient is admitted by the ED physician and cared for by a resident physician; the resident physician performs an alleged error soon after the patient's admission but prior to the next day-service attending physician's evaluation. A resulting allegation of this scenario would involve inadequate "stabilization" of the patient by the ED physician prior to floor transfer, as well as subsequent "supervision" of the admitting resident while they are physically in the ED.
- A radiology resident physician performs an evening preliminary radiology "wet reading" after consulting the ED physician for assistance and an error is made in the consultative interpretation. A poor patient outcome results.

These medical-legal scenarios distill down to the most basic question: who is responsible and to what degree?

### Resident Malpractice

A case analysis for resident malpractice renders the usual morass of factors. Typically, the ED physician gives a patient care judgment that is somehow countermanded by a resident physician without on-site attending physician guidance.

An overtly simplistic analysis would attribute 100% of the liability to the ED physician, while the resident and "supervising" physician are eliminated from any responsibility as they were not independently functioning as credentialed physicians.

However, a more contemporary analysis might find that the resident physician, resident supervising physician, and the ED physician share a proportionate responsibility in a comparative negligence analysis.

The ED physician retains the proportionate share of responsibility in cases in which patient admission is refused by the resident and the patient is discharged to home. However, the resident and supervising physician share more responsibility for alleged medical negligence that occurs in cases in which a specifically credentialed activity, such as radiology interpretation, is performed.

Either analysis often still would note that the ED physician was as involved as the senior consultant and they would share responsibility. There is an additional risk of the ED physician who is insistent on his/her own care plan as opposed to the resident's plan being viewed as "non-collegial" or unable to perform in a teaching environment as they are often labeled "difficult."

### Interventions: Protecting the Patient and Yourself

#### Legal Theory.

*1. Respondeat superior.* This is the "captain of the ship" premise in which

the ED physician would be viewed as responsible for all departmental events whether they occur with or without his/her knowledge. It is not firmly held in all jurisdictions, yet it remains a potential analytic template for assigning negligence responsibility.

If there are differing opinions about a patient's discharge, possible interventions for protection under this premise include:

- a. If the ED physician has a discrepant opinion with the resident, he or she should ask for accommodation and try to educate the housestaff; however, the patient should always be protected. A patient should not be discharged if it is not appropriate.
- b. An antiquated strategy is to challenge the attending physician to come in to perform the discharge him or herself. This approach often is associated with ill will, and it cannot effectively offer complete liability protection.
- c. Involve others in the discussion (e.g., patient, family, and other consultants) to develop a consensus of opinion that may help to diffuse risk.

*2. Chain of administrative command.* The "chain of administrative command" theory requires the ED physician to alert the department chairman if he or she believes a patient's safety is at risk. If the department chairman is unavailable, the medical staff president should be informed of the situation. There is a corollary parallel nursing requirement involved in which the staff nurse is required to notify the nursing supervisor or administrator on duty.

*3. Last chance.* The "last chance" tort premise notes that the ED physician often is felt to be the last person capable of reversing an errant deci-

sion-making process and that he or she can be held legally responsible.

### **Specific Case Law Analysis**

*Can a residency program director be held liable for resident acts?*

It is accepted that a resident faculty “supervisor” who is on call from home and who has not been consulted is not liable for alleged resident negligence. The case of *Vasquez v. Bd of Regents* specifically applied to the vicarious liability of pediatric program coordinator who did not have actual rounding responsibility.<sup>1</sup> Here, the court upheld the premise that the administrative director is responsible for general educational direction, but not patient specific guidance for the rounding resident caring for the ward patient.

However, residency program directors can be charged with having and maintaining programs for adequate resident supervision. Failure to provide a structure and framework to ensure necessary resident and attending contact sustains a negligence action against a departmental chairman. *Maxwell v. Cole* involved a departmental chairman who was found liable for not having appropriate faculty supervision in place when a bladder perforation was presumably caused by the resident physician during an elective tubal ligation on a gynecologic service.<sup>2</sup>

*How do residents share in medical negligence liability?*

Resident physicians, as well as their supervising physicians, can share in the financial liability in a comparative negligence analysis. They are typically assigned less liability, with recovery limits restricted to their insurance portion limited by their proportionate liability.

As residents, this typically results in less recovery due to lower policy limits and the perception of less actual responsibility. Therefore, joint and several liability where the plaintiff may recover all damages from

any defendant regardless of proportional share of liability does not exist for negligence monetary awards above individual policy limits accruing to the excess liability carrier. *Capistrant v. Froedtert Memorial Lutheran Hospital, Inc.*, a case involving a radiology resident, concluded that “all” insurance must be exhausted before the liability fund pays on appeal.<sup>3</sup> This is in contradistinction to the proportional liability approach in which the defendants are limited in damages to their respective causality shares of responsibility.

*Who is responsible for resident-on-away rotation, the program or clinical site?*

The resident rotating physician functions as a “borrowed servant” of the clinical facility, while the residency educational program has not been held liable for alleged negligence of the resident on an away rotation. *Starnes v. USA* references a military resident who was rotating at a pediatric hospital training program.<sup>4</sup> Here, the surgical resident allegedly committed a procedural error during central line placement in a pediatric patient; this case held the supervising community-based surgeon liable rather than the residency program director.

*How accurate is radiology resident interpretation in the ED patient?*

The off-hour radiology reading process appears to occur in a repetitive fashion: a verbal report of “normal” is offered by radiology, acted upon by the ED staff, and then subsequently reported as “abnormal” at some later point.

A recent study found a miniscule error rate when residents were required to interpret neuroradiological studies such as head CT scans.<sup>5</sup> The study reported an error rate of 0.9% of significant CT findings missed when studies were viewed by residents compared to when they were viewed by physicians. The study also reported

an even lower percentage of patients whose outcomes were negatively affected (0.08%).<sup>5</sup>

Additional studies of this kind found an overall disagreement rate between resident and attending physician interpretation of 2% for significant events when reading head CT scans.<sup>6</sup> Subtler analysis reports a clear linear relationship between training experience and reading accuracy, which was manifested as a specified impression and a decrease in discrepant findings.<sup>7</sup> Finally, according to the study the broader array of diagnostic possibilities leading to body (thoracic, abdomen, pelvis) imaging was found to be more difficult to interpret than head CT scans for resident trainees.<sup>8</sup>

*Resident-attending supervisory interface: who is responsible?*

If a resident physician commits an alleged negligent act and does not inform the supervising attending physician of this event, the liability rests predominately with the resident.<sup>9</sup> The finding on appeal in *Joseph Hospital v. Wolff* overruled a previous decision that suggested that “joint enterprise” liability between a training center and clinical rotation site did not exist and that the training program was not responsible for clinical activities that occurred at the resident clinical rotation site. This case references a surgical airway where the attending was not informed of a potential error by the resident during the tracheotomy procedure; a subsequent bleeding complication occurred days later.

However, if a resident commits the alleged negligent act under the supervising physician’s direct observance, as in an operative procedure acting as a “borrowed servant,” the attending physician is primarily responsible as opposed to the resident or facility.<sup>10</sup> *Alswanger v. Smego* addresses the respondeat superior argument, suggesting that the obligation for super-

vision rested with the attending of record and not the hospital of the surgeon's employ and that this trainee remained under the surgeon's and not the hospital's control. This case continued over a delayed neurovascular complication allegedly induced by a first year surgical resident during a routine venous ligation operation.

However, in *Lilly v. Brink*, a different conclusion was arrived at in a different jurisdiction.<sup>11</sup> In this case, it was found that the resident physician truly acted as an independent clinician when discharging a patient from the ED with indigestion who later succumbed to a cardiac event. Here, the resident physician was found to be directly liable. The active clinician role was distinguished from the medical teaching and learning responsibilities of a resident trainee, resulting in liability.

#### Interventions

1. You, the ED physician, are still in charge based on case and statutory phone (EMTALA) provisions. Discuss

the case with the attending, sometimes placing a second or third call and including a "cool off" period. This may modify the admitting physician's decision.

2. A strategy of asking the attending physician for an on-site evaluation that can be viewed as inflammatory, even though proper, should be attempted as a last resort. However, switching to an alternate care resource (e.g., calling another service or physician) may diffuse the situation.

3. The burden to activate the chain of administrative command is sometimes facilitated by the nursing supervisor/charge nurse or by involving the administrator-on-call as a path to the department chairman or medical staff intervention.

4. When in doubt: Do the test; admit to the hospital; and keep in the ED as an observation patient if you are uncertain.

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*continued from page 89*

"Anytime something of value is exchanged, whether it's lunch, cash, or a trip to Cancun, you get into the question of conflicts of interest and fraud and abuse," says **Robert W. Markette, Jr.**, a health care attorney with Gilliland & Markette in Indianapolis, IN. "And appearances can be as bad as anything else."

Unless a medication was inappropriately given that can be linked directly to a patient's adverse outcome, it's unlikely that a lawsuit would be filed purely on the basis of an ED doctor's accepting gifts from drug companies. "I think it's a pretty weak prosecution unless it's flagrant. You may not be able to make a case out of that alone, but you can certainly use it to inflame a jury," says **Frank Peacock, MD**, vice chief of emergency medicine at The Cleveland (OH) Clinic Foundation.

In most jurisdictions, however, the fact that an ED doctor accepted gifts from a drug company would not be allowed to be introduced as evidence simply to inflame the jury during a malpractice trial. "If you show that somebody is a bad person, the jury is more likely to think they have committed a bad act," says Markette. "But as a society, we frown upon trying the person for what they are instead of what they have done."

However, if the plaintiff's theory was that the doctor's judgment was influenced by gifts from the pharmaceutical company, anything received from the company might become relevant — but the evidence would be offered simply to show the gifts were received. "The plaintiff would need to have other evidence to show the effect of the gift — for example, data showing the doctor's prescribing trends," says Markette.

If the plaintiffs do not have the evidence to support that kind of claim, they might try to find another way to make the gifts relevant. For example, if the plaintiff is arguing that the doctor routinely breached compliance, the information could be relevant if the ED physician didn't follow the hospital's policy on drug representatives to the letter.

"They could find a way to offer it as evidence to prove some other point, knowing that when they get that fact in front of the jury, that they will do exactly what the judge will tell them not to do," says Markette. "The jury may think of the doctor as 'bad' simply for doing what is common in the industry, and be more likely to find against the doctor."

If your hospital doesn't have a policy on accepting gifts from pharmaceutical companies, your ED should develop one, advises Markette. "If you develop your own compli-



ance guidelines in advance and apply them consistently to all pharmaceutical reps, it is much easier to argue that one manufacturer was not favored over another,” he says.

Still, there may appear to be a conflict of interest that will be hard for a jury to ignore. “Patients need to be treated for their individual situations, not because the doctor got a free trip,” says Peacock. “You can taint somebody by asking if they got \$50,000 from the company. There is no doubt in my mind that if you were involved in a lawsuit, that would come up.”

### **Concerns are growing**

There is a growing focus on pharmaceutical companies and their marketing practices, which could trickle down into ED malpractice litigation.

“This is an issue that more and more people are looking at,” says Markette. “How come pharmaceutical companies give away all these freebies and gifts?” is a question being asked by legislatures and states. Until now, they have basically gotten a free pass.”

Recently, five states (Minnesota, Vermont, California, Maine, and West Virginia) and the District of Columbia passed laws mandating disclosure of payments made to physicians by pharmaceutical companies, and in Vermont and Minnesota, payment disclosures are publicly available. Other states are likely to follow suit, says Markette, due to concerns that the perks being offered can color the medical judgment of physicians.

Even if a given drug is medically appropriate, if you are steering all of your patients to a particular drug because you are getting a benefit from it, this can raise the question of fraud and abuse. “Any arrangement where a physician is receiving remuneration from a pharmaceutical company can implicate several federal laws and state laws,” says Markette.

Penalties can range from being convicted of a felony and going to prison to steep civil monetary penalties, and exclusion from participation in Medicare or Medicaid.

For example, if a pharmaceutical company has a rewards program for high volume prescribers, there may be a medical reason for giving the drug in a particular circumstance, but the appearance is that all of your patients are getting the same treatment. “You might be prescribing the same drug in every case when others would also be appropriate,” says Markette. “Maybe there are clinical reasons for it, but maybe you are looking to hit a certain volume.”

There is value to meeting with drug reps, as they provide information and free samples that patients can benefit from, says Markette. The question is, how much is too much?

“When you really are looking at the benefit to yourself, that’s when you will get into trouble,” says Markette. “Maybe you see free dinners as a perk, but if the perception is you are out there fishing for them, it

might cause people to question your true motivation.”

To avoid this, Markette suggests:

- Limiting any one physician’s interactions by having a jar out front where drug reps drop cards, and having physicians draw the cards at random.
- Designating an administrative staff person to handle all initial pharmaceutical rep contacts, and allotting each ED physician a set number of lunches to meet with the reps, who would be assigned at random.
- Scheduling lunch meetings with two or three ED physicians and an assigned pharmaceutical rep.

“An added benefit of such a system is it reduces the physician’s need to field the phone calls and contacts,” says Markette. “The physicians only need to appear at the appointed time for lunch.”

### **Disclosure is key**

If you do any kind of research and you have not disclosed a relationship that is perceived as a conflict of interest, your career can be derailed, warns Peacock.

This can start with your own institution saying that the Institutional Review Board will no longer approve your research, and it can go all the way to the federal level, with the Food and Drug Administration barring you from participating in research.

“If either one of those happens, your career as an academic researcher functionally ends,” says Peacock.

There are many ways you can have a relationship with a drug company, says Peacock. “They can give you a pen, well that’s not really much of a relationship, or they can give you to a trip to Hawaii. That’s a problem because it’s excessive and inappropriate,” he says.

Giving talks for money or working as a consultant for drug companies is fine so long as you disclose the fact that you do so, says Peacock. “It is commonly established that accepting anything greater than \$10,000 per year for work done for a drug company is considered a significant relationship,” says Peacock. “If you have done that, you have to engage in conflict mitigation.”

That means taking steps to make sure that the relationship is not affecting your presentations if you are giving talks for a company. For example, if you are doing research for a manufacturer of a certain drug, you shouldn’t be involved in enrolling patients for that study. “If the company gave you \$50,000 last year, you might want to make their product look good,” explains Peacock. “The idea is to establish some boundaries.”

The reality is that the pharmaceutical industry funds about 60% of the research done in the U.S., says Peacock. “If we ignore that, we lose a lot of research. So we have to have rules to do it within an ethical framework to preserve the patient-physician relationship,” he says. “Patients need to feel like doctors are acting in their best interest, not the pharmaceutical

company's best interest."

Peacock recommends adopting a full disclosure strategy. "I have an Excel spreadsheet and anytime I get money from anyone for anything, it goes on that spreadsheet," he says. "When somebody asks me for my disclosures, I whip out the form and say 'Here they are.' If anyone tells me I don't need to disclose \$25, I do anyway."

Lunches and dinners are commonly exchanged in the business world, but they must be within reason. "If these are to be considered a business expense, then business must be performed — you can't be there just for fun," says Peacock. Also, only doctors and relevant staff may attend — no spouses, kids, or dates may come. Furthermore, the total value of the dinner may not exceed \$100 per person.

Peacock says \$10,000 per year for the total amount of work reimbursed for doing research or providing any other consultant service from any single company is the "magic number" generally set by the professional societies without having to declare a conflict. To accept more than that gives patients a valid reason to suspect you might be biased.

"I don't ever cross that number for any reason, and I think that is the best advice," says Peacock. "You have to decide: Are you a doctor working for the patient, or are you a doctor working for a company? If you are going to do projects for industry, where you may be biased to excessively support the person paying your stipend, your personal gain needs to be less than 10 grand if you want to also do research."

When giving talks for a drug company or device manufacturer, choose your words carefully. "You are allowed to do that, and you can make a pile of money doing that. But the downside is, you better be very careful about what you say," says Peacock.

For CME talks, the physician is allowed to say anything they want, as long as it is good science and they have data to support it. Some of the drugs used in the ED every day have off-label uses because there is good

research that shows it works and it's in the best interest of the patient, notes Peacock.

But for a corporate-sponsored, non-CME lecture, you cannot talk about off-label use. "There is a case pending right now involving a doctor making all sorts of specious claims that were beyond the label. The way it looks to a layperson looking in, was that this guy was working with the company," says Peacock. "He could be in serious trouble with fines and prison sentences. This is punishable at the federal level." ■

## What if parents request tests, but child refuses?

**A** 15-year-old girl's mother demands that you give her daughter a pregnancy test, but the child refuses. What do you do?

"A very real dilemma arises when parents insist that some evaluation or procedure be performed when it is not desired by the minor," says **Matthew Rice, MD, JD, FACEP**, an ED physician with Northwest Emergency Physicians of TEAMHealth in Federal Way, WA. "There is no easy answer as to what is right. The details of every circumstance must be carefully analyzed."

Ethically and legally, it is well-established that a physician should not do anything that will harm a patient. "The patient, no matter what their age, is entitled to certain rights, including to prevent known harm," says Rice. "Thus, there is no mandate for a physician to provide evaluations or treatment that could physically or psychologically cause more harm than good."

However, minors may be unaware of the risks of not undergoing evaluation or treatment, notes Rice. He recommends having an open and frank discussion with the patient, the parents, and other appropriate professionals to resolve the situation without involving the legal system.

"Any time a simple medical request escalates to a legal issue with others involved, it can be damaging in itself to a minor," says Rice. "Thus, the experienced emergency medical provider is wise to ponder all options that are viable and best for a patient before invoking complex responses."

Consider the following to reduce legal risks:

**Know state laws on confidentiality.** California law is very clear that a minor's medical records are confidential for all encounters regarding reproductive health and drug and alcohol treatment. The law also stipulates when a physician's knowledge of sexual activity of a minor must be reported to authorities — usually in cases involving age disparity of the patient and their sexual partner.

"Other states' statutes may not be so clear," says **Jonathan D. Lawrence, MD, JD, FACEP**, an ED

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physician and medical staff risk management liaison at St. Mary Medical Center in Long Beach, CA. “To that extent, the directives of the current administration in Washington has made the situation more difficult.”

Under the Clinton administration, a minor’s medical records in areas of reproductive health and substance abuse were confidential nationwide, based on evidence that confidentiality leads to minors seeking care and treatment for problems in these areas. “The Bush administration changed all that, declaring that parents have full access to their minor children’s medical records unless a state law explicitly states otherwise,” he says. “Therefore, ED physicians must know their own state’s laws before promising confidentiality to minors.”

The basic rule to follow is that your patient is the child, not the parent. “Obviously it is a somewhat sticky situation, because if you as the doctor tell the parents, ‘Sorry, I can’t tell you that,’ a lot of parents will assume that their son or daughter has engaged in something they disapprove of,” says **Joseph P. McMenamin**, MD, JD, FCLM, a partner at Richmond, VA-based McGuireWoods.

McMenamin recommends attempting to get the child to voluntarily disclose the nature of the problem, diagnosis, and treatment. The child may well take that advice, and if he does, then from a legal standpoint you are off the hook, because you now have the patient’s consent.

“But none of that obligates the child to listen to you — and if that is the case, you are bound by that in most states,” says McMenamin. “Make your argument as well as you can but if at the end of the day, the kid still says ‘No, keep your mouth shut,’ then that is what you have to do.”

Recently, Lawrence cared for a 13-year-old girl who had run away from home, whose mother brought her to St. Mary’s ED for a virginity test and drug test. The daughter allowed the drug test to be done, but refused the virginity test.

“My experience ended with a confidential conversation, during which she still refused to discuss her sexual history,” says Lawrence. “I still made it a ‘teaching moment’ by touching on important topics to remember ‘when you do become sexually active.’”

In this situation, have a chaperone present and ask the girl if she wants to tell you anything in confidence. “Say ‘You’re my patient, not your mother. Anything you tell me will not be repeated to her,’” says Lawrence. “If she says she’s had sex, it’s the perfect time for a discussion about STDs. If in fact she wants the morning after pill or prophylaxis for STDs, then you can offer it.”

**Consider requirements of EMTALA.** EMTALA requirements for a medical screening examination to determine whether an emergency medical condition exists also come into play, says Lawrence. “Even though finding out whether your patient is a virgin is

not usually an emergency medical condition, it could be considered as a medical emergency,” he says. “If you could prevent a pregnancy in a 15-year-old with one simple pill, or if you could give an injection to prevent a STD that could possibly cause infertility, that sounds like many people might consider that an emergency.”

However, evaluation and treatment of a STD that has already been identified is rarely an emergency, adds Rice. “EMTALA requires a medical screening exam and a stabilization of the medical emergency. EMTALA does not mandate that an evaluation or treatment in a stable patient must be done when alternatives are better medical care,” he notes.

**Don’t force tests on the child.** When determining whether to perform an exam or treatment against a minor’s wishes, balance the risk and benefit. “A virginity exam has little to no merit to a minor,” says Rice. “This, of course, is much different than an evaluation for sexual assault, which brings into purview a very different approach.”

Drug testing is a more “black and white” scenario, since the need for this is based solely on the patient’s clinical presentation. If the child doesn’t appear intoxicated, there is simply no reason to get a drug or blood alcohol level test, says Lawrence.

Unlike preventing pregnancy or an STD, the need to know this information cannot be construed as a medical emergency because all you are looking for is evidence of past drug use, says Lawrence. “If the minor has a normal medical exam, there is no reason to do it,” he says.

“If the kid is intoxicated, they can’t say no to a test, but otherwise, I see no reason whatsoever to justify getting a drug test if [the] kid refuses.”

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## Lawsuits from parents not likely

If you fail to perform STD or pregnancy tests because the child refuses, would the parents have grounds for a lawsuit against you? Not likely, since there is no evidence that you violated the standard of care or did anything to contribute to an adverse outcome, according to Lawrence.

“They would not be able to show that anything you had done would have made a difference, other than giving their child the morning after pill or treating a preventable STD despite her saying she never had sex. Is it the standard of care to not believe a patient?” he asks.

Tell the parents ‘I want to help you, but my understanding of the law is that I need your child’s consent to do this, and if he withholds it, I am not at liberty to do what you want,’” says McMenamin. “This might get them pretty upset, but it’s better to stay within the law.”

Medically, there likely isn’t any great rush to find out a teenager’s blood alcohol level. “It’s not critically important to know that information right this second — so by declining on the basis that the patient refuses, you haven’t done anything terrible,” McMenamin says. “If something happens to justify doing it or there is some legal compulsion to proceed, you probably haven’t lost much.”

On the other hand, there are significant liability risks if you perform tests even though the minor refuses. Examining or treating against a minor’s will could lead to mental and psychological damage, with a claim being filed by parents who suddenly have a change of mind.

“Such litigation could consist of negligence, or assault and battery,” says Rice, adding that the statute of limitations could allow a minor to litigate many years later.

Forcing a child to undergo these tests would technically constitute unconsented touching and battery, says McMenamin.

“If you decide that it’s more important to help mom and dad out and subject the child to some sort of testing or examine him against his wishes, he may have a cause of action against you that might well prevail,” he says. “I can imagine a skilled lawyer portraying this as a massive invasion of civil liberties. The best approach is to honor the child’s wishes.” ■

## CNE/CME Questions

35. Which of the following is true regarding ED physicians accepting gifts from pharmaceutical representatives?
- A. Acceptance of non-monetary gifts would not be admissible in a malpractice lawsuit.
  - B. It is not advisable to disclose gifts under \$1000.
  - C. Discussion of off-label use is permitted when

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giving talks for a drug company or device manufacturer.

- D. Compliance guidelines should be applied consistently to all pharmaceutical representatives.
36. Which of the following is recommended if a child’s parent asks you to perform tests to determine if the child is sexually active, but the child refuses?
- A. Perform the requested tests against the child’s will.
  - B. Avoid speaking to the child without the parents present.
  - C. Attempt to convince the child to disclose the information voluntarily.
  - D. Immediately contact authorities.
37. Which of the following is the most likely cause of action for a lawsuit?
- A. Forcing a minor child to undergo testing for pregnancy, virginity, and sexually transmitted diseases against her will.
  - B. Failing to find out a child’s blood alcohol level because the child refuses the test.
  - C. Refusing to inform a parent what their daughter has told you about her sexual activity to comply with state confidentiality laws.
  - D. Failing to perform a drug test requested by a child’s parents because the patient is not showing any signs of intoxication.

Answers: 35. D; 36. C; 37. A