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Liability waivers can be effective in some cases, but they're no panacea

More useful for elective procedures; enforceability still in question

You're fed up with being dragged into every lawsuit that has even the slightest connection to your institution, so you daydream about having patients just sign a waiver up front promising to never sue you for anything.

Nice fantasy, but those things don't really hold up in court, do they?

Sometimes they do, and sometimes they don't, say the experts. The key is knowing what situations are best for using liability waivers and which ones hardly ever are going to hold up in court, they say. Recent changes in health care practices may have opened up more opportunities for the appropriate use of liability waivers, so you could be missing an opportunity if you hardly ever use them because you still think courts automatically throw them out.

Risk managers interested in using liability waivers should do so with their eyes open. Liability waivers may be gaining popularity among risk managers but they won't be a panacea for all that ails your department, the experts say, and you need to do a lot more than just photocopy a waiver and hand it to patients.

Liability waivers can be very an effective defense in limited situations, says **Jeffrey Driver**, JD, MBA, chief risk officer with Stanford (CA) University Medical Center and president of the American Society for Healthcare Risk Management in Chicago. But don't expect them to protect you from most of the lawsuits filed against hospitals and other providers, he says. State law will vary considerably on how much you can enforce a waiver of liability, Driver says.

He says he understands risk managers' interest in liability waivers as a defense against malpractice costs.

"We're seeing the severity of claims go up, while the frequency of claims holds steady," he says. "So people are doing whatever they can do to mitigate or offset the claims coming in. Waivers can play a role."

Driver advises using liability waivers as another tool in the risk manager's

toolbox, carefully choosing where they are most likely to be enforceable. **(See p. 64 for the situations in which waivers are most appropriate.)**

The problem with waivers is that sometimes they're worthless if a plaintiff actually pushes the issue and takes you to court. In California and many other states, for instance, a waiver of liability for medical negligence is not likely to hold up in court. But a waiver of liability for other matters is more enforceable as long as you have clearly explained the terms to the patient, Driver says. Even waivers for medical negligence might hold up in some courts when they are used for elective cases.

And here's another tip from Driver: Even when the waiver is not enforceable, there still may be reason to ask a patient to sign one.

"You can still use them to set expectations. They're a good tool to mitigate the possibility of a claim," he says. "They actually can keep people from filing claims because they understand that they accepted this risk. It sort of drives home the informed consent process even more, and they realize they knew this outcome could happen."

Informed consent on steroids

A waiver of liability goes far beyond the standard informed consent process, but it depends on the patient clearly understanding what he or she is giving up. **(See p. 63 for more on the importance of a good informed consent process when using a waiver.)** Sort of like informed consent on steroids, a liability waiver not only asks the patient to acknowledge the known risks but also to go ahead and agree not to sue the health care provider. If it is upheld by the court system, you're home free.

A softer alternative is to have the patient agree to arbitration of any claim, which can result in significant savings for the defendant. Driver says there is never any harm in asking for a liability waiver but courts are not likely to uphold them in situations in which the patient needed emergency care or otherwise was under duress and seeking help.

While Driver does not advise trying to get a waiver of liability in the emergency department (ED), he says an agreement for arbitration might pass muster in court. The arbitration agreement can be included in the informed consent process along with the other paperwork necessary for an ED admission, he says.

But no talk of arbitration can occur before the emergency patient has received a medical screening examination, of course. That would be a violation of the Emergency Medical Treatment and Labor Act, Driver notes.

"At Stanford, we're just beginning to look at whether we want to put arbitration clauses in our conditions of admission forms, because we're getting nailed with lawsuits and it's very expensive," he says.

Smith points out that some courts have challenged them on the grounds that arbitration costs

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money and the patient may not be in a position to pursue that path, making the agreement invalid.

Health care changes create options

Another risk manager using liability waivers is **Paul English Smith**, JD, CPHRM, vice president and general counsel at Cabell Huntington (VA) Hospital. He notes that many risk managers have dismissed most use of liability waivers on the assumption that they never hold up in court, but that situation is changing.

"It used to be black-letter law that these waivers never held up in court, so there was no use in trying to use them," Smith recalls. "But a lot of things in health care are changing, and there are a lot more health care services now that are more choice-driven and money-driven. That creates new scenarios in which waivers might be seen as enforceable by the courts."

With that development in mind, Smith says he is "pushing the envelope a little" in choosing when to use them. For general health care in which the patient is not seeking treatment by choice, he agrees with Driver that liability waivers won't be of much use because state courts are unlikely to support them.

Kentucky courts have sent clear signals in recent years that such waivers would not be enforceable because the patient had no real choice in whether to be treated and so did not enter into the agreement willfully.

Waiver covers affirmative acts

But for any other situation in which patients voluntarily seek out treatment and could reasonably go elsewhere if they don't like your requirements, a liability waiver is an option, Smith says. For example, his hospital offers an in vitro fertilization program and requires that participants sign a liability waiver as part of the consent process.

The agreement states that the couple "understand and agree that the parties involved do not assume responsibility for the physical and mental characteristics of any child or children born as a result of artificial insemination." Then later it goes on to say that "We hereby absolve, release, indemnify, protect, and hold harmless from liability for the mental or physical nature of the character of any child, and for any affirmative acts or omissions which may arise during the performance of the agreement."

"We explain thoroughly what we can and can't

Check informed consent before trying waiver

A health care attorney cautions that you should not rush to use liability waivers until you have confirmed that your informed consent processes are the best they can be. All of the questions about whether waivers are valid in certain situations come down to whether the patient had a choice in the matter and truly understood what rights were being waived, notes **Mark Kadzielski**, JD, a health care attorney with Fulbright & Jaworksi in Los Angeles.

"The question will be whether this was a true informed consent process, whether the patient really had an opportunity to consider all the risks and benefits and then thoughtfully waive his rights to a jury trial, or the right to sue," he says. "The more time and the more explanations you gave to the patient, the more likely the court would uphold the waiver. If they just signed a form you shoved in front of them with no real discussion, that's not going to be upheld."

In theory, you can ask the patient to give up as much of his rights as you want — including signing away all the right to sue you in any way for anything, no matter how egregious your actions, Kadzielski says. But when you ask for more, you'd better be prepared to work hard for it, he says.

"The more aggressive you want to be with the patient, the more time and thoughtfulness you have to put into the explanation process," he says. "That's so true that it might even be a good idea to videotape your discussions so that when the patient claims you didn't explain what rights they were giving up, you can prove otherwise. But if it's on tape, you have to be certain it's a process you want to show in court and have critiqued."

Kadzielski also cautions against the tendency to use a generic liability waiver you found elsewhere instead of devising one specifically for the situation in question.

"If you photocopy somebody else's waiver on your letterhead and start handing it out, chances are not good that it actually says what you need it to say," he says. "This needs to be a more thoughtful process than that." ■

do and explain all the risks, and then we ask them to agree to hold us harmless if they have a child that has problems related to an anonymous donor or something like that," Smith says. "We're dealing with couples who have investigated their options and know a lot about what is going on, and we're talking about a contractual agreement for which we don't want to risk any liability."

Smith notes that though the waiver language absolves the provider of any liability for "affirmative acts or omissions" during treatment, he does not expect it to shield the hospital or physicians for claims of gross negligence. But it doesn't hurt to add that line either, he says.

"I do think it would shield you against claims you made a guarantee that the child would be perfect," Smith says. "The rest is something you might have to find out if they try to sue you."

Smith and Driver say none of their liability waivers have been challenged yet in court, but they both think they have used them judiciously so that they would be likely to withstand a court challenge.

"I think it's something that risk managers should look at and see if you have areas where they could be of use," Driver says. "At the very least, they give you the opportunity to point out to people that we had a discussion about this and you even agreed not to sue us. You can argue that this was more than just health care per se, that this was a contractual relationship between the parties." ■

Pony rides definitely need waiver of liability

Liability waivers are best used for voluntary activities or when patients refuse your clinician's advice, says **Jeffrey Driver**, JD, MBA, chief risk officer with Stanford (CA) University Medical Center and president of the American Society for Healthcare Risk Management in Chicago. He suggests these categories:

• Elective procedures.

Liability waivers, or agreements to settle a case in mediation, are most appropriate for elective procedures in which the patient has been well informed of any risks and has the ability to forgo the procedure without any adverse effects, Driver says.

"So they're not going to be of much use in your emergency room," he says. "But for cosmetic procedures, you can tell the patients they have to sign the waiver or they can get their Botox somewhere else. You have the ability to be that aggressive, and the courts probably would hold up the waiver, because that is totally an elective procedure."

• Nonhealth care activities.

Liability waivers also are useful in health care settings for situations other than treating patients, Driver says. Here's an area in which the waivers are much more enforceable, and you're missing a real opportunity to avoid some lawsuits if you don't employ waivers, he says. If the hospital is hosting a fun walk or bike ride, participants should agree not to sue you.

For instance, the auxiliary at Driver's hospital wants to have a pony ride on hospital property as a fundraiser. But, of course, what sounds like a nice idea to most people causes a risk manager to envision children falling off a horse and angry parents suing the hospital.

"I absolutely will get a waiver of liability in that case, and those are upheld in court," he says.

California law, like that in many states, draws a line at liability waivers for any service in the public interest or those that result from unfair bargaining. The idea is that you shouldn't be able to force people to sign away their rights when you have them over a barrel.

"But pony rides are not in the public interest, and there's no unfair bargaining. It's a dollar for

a pony ride, and you have to agree not to sue us," he says. "But when you come to the emergency room, you have to come here for help, and it's a service in the public interest. That's the dividing line on enforceability."

• **Informed refusal.**

Waivers can be useful when a patient refuses the course of treatment or examination that clinicians consider the best option. If a patient refuses a liver biopsy because it would be too painful, Driver suggests that you should ask the patient to sign a liability waiver that acknowledges he or she is refusing the best care.

"That's a great use of a waiver of liability," he says. "If the patient says no, and there's no trouble with it being an emergency situation, you can refuse to treat them and they can go get care somewhere else. I've actually done that." ■

Defamation lawsuits may chill reporting of docs

A closely watched case in Connecticut has some observers worried that health care providers will be discouraged from reporting information about physicians to state boards, other monitoring groups, and even a hospital's internal peer review system. For risk managers, the case also may serve as a reminder of how easily you can be drawn into a major lawsuit when you were simply cooperating with a state investigation.

The case involves a physician who sued several fellow doctors and a hospital that he says defamed his reputation when they provided opinions about his emotional health to the state Department of Health. In a 2-1 ruling last year, the Connecticut Appellate Court gave the physician the go-ahead for the lawsuit, but the defendants are appealing the decision and say the lawsuit could jeopardize patient safety if health professionals are reluctant to give honest opinions about others.

Jeffrey R. Babbin, JD, an attorney with Wiggin & Dana in New Haven, is representing the physicians and Charlotte Hungerford Hospital in Torrington. He tells *Healthcare Risk Management* that the case could have implications reaching far beyond Connecticut.

"There is a lot of risk that physicians will sue in this situation; and without absolute immunity, the liability could be very high," he says. "If this case is any indication of how courts will interpret statutes, health care entities could be in for a shock when a case like this is tested in other states."

Absolute immunity at issue

The question at the heart of the Connecticut case, whether physicians should have absolute immunity for comments made for investigations regarding competency, comes up often in tort reform debates across the country, Babbin says.

"What happens in this issue could be ironed out in some ways by what happens with tort reform," he says. "The argument is that if you're going to have meaningful tort reform, you have to give physicians a way to weed out the bad apples in their profession."

The plaintiff is psychiatrist Mohinder Chadha, MD. The case started with the hospital's referral of Chadha to the Connecticut State Medical Society. The medical society is obligated to report any concerns about a physician's competency to the state Department of Health, which it did with Chadha.

The hospital also terminated Chadha's privileges at the hospital and reported him to the National Practitioner Data Bank. He sued the hospital for both actions, but the lower court threw out those claims as unfounded. That left claims against the individual physicians for their involvement.

Hospital sued for reporting doctor

One of the physicians was employed by the hospital, so Chadha also sued the hospital as his employer. And he sued the state medical society and the licensing board. He failed on all those claims but the physicians remain in jeopardy.

"The physicians and hospital were participating in an investigation by the state Department of Public Health into the competency of a physician," Babbin says. "Those physicians should not have to worry that the disgruntled physician who is the subject of the investigation is going to sue them. If the rule is that they can be sued, with only qualified immunity, and if the plaintiff can make a case for malice or a false statement, he'll be able to get to a trial."

Concerns over false reports

Physicians who participate in hospital peer review or state investigations into physician

conduct usually are granted absolute immunity, but Chadha argued in his lawsuit that doctors who participate in "quasi-judicial" proceedings are not entitled to absolute immunity when they provide information about a colleague. Chadha said he believes that absolute immunity makes it too easy to falsely report a colleague.

But Babbin says anything short of absolute immunity will stifle honesty.

"When you let the process work usually the physician under investigation comes out fine with his license intact, as happened in this case," he says. "That's actually where you have the greatest risk of that physician suing someone for what they said during the investigation, and that's when you need as much protection as you can get."

AMA supports defendants

The American Medical Association (AMA) and Connecticut State Medical Society (CSMS) insist that absolute immunity is absolutely necessary, and so does **Michael D. Neubert**, JD, an attorney with Neubert, Pepe & Monteith in New Haven. He wrote a brief that the AMA and CSMS filed urging the Connecticut Supreme Court to overturn the lower court ruling. Neubert says the groups are concerned that not providing absolute immunity could have a chilling effect on physicians' willingness to independently report another physician.

And the AMA and CSMS argue that physicians will not be willing to cooperate with investigations if they worry that they could open themselves up to litigation and personal liability.

Even if the lawsuit ultimately was dropped or decided in favor of the physician who did the reporting or provided information, the doctor would have to retain a lawyer, would not be covered by traditional medical liability insurance, and would forfeit time that could be spent practicing medicine.

"The unlikely possibility that a health care professional might use the system to professionally harm a competing medical professional is far outweighed by the stifling impact of retaliatory lawsuits on the peer review process and mandatory reporting," says the brief filed by the groups. "While it is unlikely that a physician will attempt to abuse the system to affect competition, it is very likely that a physician who is the subject of an investigation will be angry with the individual, doctor(s) or committee that initiated the proceedings and, therefore, may file a retaliatory lawsuit."

The state's highest court recently heard oral arguments and is expected to rule on whether Chadha's suit will go forward by the end of the year.

Conflicting state laws

Babbin explains that the appellate court and a trial court in Connecticut each have determined that, although common law in Connecticut provides for absolute immunity, it does not trump another law in the state that provides only qualified immunity. Their rulings are based partly on language in the Connecticut statute stating that someone who is making a complaint or providing information to a hospital board, medical board, professional licensing board, medical review committee or the Department of Public Health "as part of an investigation . . . or disciplinary action . . . shall, without showing of malice, be personally liable for damage or injury to a practitioner arising out of any proceeding of such boards . . . or department."

Apparently, the courts concluded that the legislature wanted to ensure that the law protected health professionals who report colleagues even if the protection was not total, Babbin says. The Connecticut Appellate Court said in its ruling in *Chadha v. Hungerford Hospital, et al.* in May 2003 that, "We can presume that the Legislature provided only a qualified immunity to those covered by the statutes for a reason: It wanted to discourage individuals who otherwise would be protected by those statutes from acting out of improper motive."

Review physician comments first

The court added that other courts had recognized a potential for abuse, quoting from a 1992 New Mexico case in which the court said "the members of peer review committees are often in direct competition with those being reviewed and the system has potential for abuse of the person being reviewed. Possession of hospital privileges . . . is crucial to a physician's success, and a negative decision could be tantamount to excluding a doctor from the profession as a whole."

The Appellate Court noted that the Legislature could have provided absolute immunity but chose not to. But Babbin says the physicians and hospital defendants disagree with that interpretation of the law.

So what's a risk manager to do to if you want to stay out of a sticky situation like this? Babbin says exactly what is said when physicians comment on each other's competence can be crucial to whether you get sued and how you defend yourself. For that reason, he suggests that it might be wise to have physicians consult with the risk manager before opening their mouths.

"You don't want to censor them, but it's all in how you say things. You may be able to soften some of their comments," he says. "And you want to make sure that their comments are not just the product of some internal or personal dispute between the physicians."

The risk manager's goal, he says, should be to ensure that the physicians are providing the necessary information in an objective way with no hint of malicious intent. That will not help as much as having absolute immunity, but it will improve your defense if you're dragged into a lawsuit like this, Babbin notes.

"Having an internal procedure in place before the doctor goes running off to the state health department could be a useful thing," he says. ■

Phone advice could be major liability risk

The risk of giving advice to patients by phone should be well known to risk managers, and most have educated staff about what not to say to patients with questions. Add in the automated answering systems that urge patients to call 911 for emergencies, and you should be well covered in this area, right?

Not necessarily. Advice by phone may be a liability risk that is flying low and under your radar.

Try taking a stroll through your labor and delivery unit one night, and you might be shocked by what you hear nurses saying to patients on the phone, says **Monica Berry**, BSN, JD, LLM, DFASHRM, CPHRM, regional director of risk management with SSM Health Care of Wisconsin in Madison, and past president of the American Society for Healthcare Risk Management.

The liability risk comes in two forms, Berry says. In the first concern, a patient calls and asks for information. Most organizations have some type of help or referral line that is staffed by personnel trained to answer these questions and refer the callers on to the appropriate help. But obstetrical (OB) calls often are referred directly to the OB unit.

"Then the OB nurse may attempt to help the patient figure out whether to come in, stay home, or go see their physician," Berry says. "The patient is giving information she thinks is important, but unfortunately the nurse may hear it differently. The patient also might not appreciate the significance of some signs and symptoms."

Documentation always needed

So the nurse is trying to render advice for a patient she doesn't really know and basing that advice on incomplete information. That constitutes a major liability risk but might happen every day in your OB department, Berry warns.

The second question involves documentation. If those phone calls to the OB unit are permitted, or if they make their way to an OB nurse despite hospital policy to the contrary, the nurse should always document the call carefully.

"They should document the caller's concerns, what information was provided to the nurse, and what advice was given," she says. "You can always use that log book if the patient has a bad outcome."

The OB unit is a primary concern for such phone calls, but it is not the only risk, Berry notes. Similar scenarios occur in the emergency department (ED) as well. People call and ask if they should come to the ED, and the nurse taking the call doesn't have the necessary background about the patient to understand the significance of the signs and symptoms relayed.

Many risk managers encourage ED staff to play it safe and tell the patient to come to the ED if there is any doubt whatsoever, which Berry says can be a safe strategy. No matter what advice is given by phone, ED staff always should document it well.

Discharged patients different

Another issue involves the patient who has been discharged but calls back to the unit with a question. Should the nurse answer the question? Berry says yes, but he or she should also refer the patient on to the private physician, especially if the questions persist.

"You want them to avoid being put in an awkward spot because the patient isn't there any more, and the nurse may not know the whole story," she says. "And document it. Always."

Berry suggests that the best policy on phone advice is to have a referral line or a nursing hot line for patients with questions — a controlled situation. But if you choose to allow such calls to go straight to the OB unit or the ED, Berry says you should educate staff about the right and wrong ways to handle such calls.

For starters, she would explain the difference between talking with a patient recently discharged from your unit vs. talking with someone you've never met.

"If you have interfaced with the caller and they're calling back for clarification, it's a good idea to go ahead and clarify their discharge instructions or help them understand when to call their doctor, but I think the policy should limit it to the purpose of clarification," Berry says. "If it is an individual you have never had contact with, the policy should be more restrictive."

Complete ban not required

It may not be necessary to completely ban giving advice to those callers, however. It may be possible to give some advice as long as the nurse emphasizes that the decision regarding coming to the ED, for instance, lies with the patient. The nurse must make clear that he or she is not instructing the patient not to seek care.

"They can tell the caller that, 'If you think this is serious enough, come to the emergency room. If you don't think it's that serious, contact your family physician,'" Berry says. "That may not be what a caller wants to hear if they hoped you would make the decision for them, but you just can't allow that."

Despite the best intentions, nurses can easily let their guard down when they pick up the phone and someone is asking for advice, she says. Nurses, by nature, tend to want to help others and they have substantial knowledge at their disposal, so their inclination is to tell the caller what they think would be helpful. But it is up to the risk manager to educate them about why that is so dangerous, Berry says.

Diplomacy required for rebuke

She recommends including education and the risks of phone advice in annual risk management inservices. And what do you do if you're walking through the ED one day and hear a nurse tell a caller that he doesn't need to come in for treatment, and that the wait would be really long anyway?

First, don't dismiss it as an isolated incident. If you happened to hear one nurse say it, chances are good that more are saying the same thing. Some diplomacy may be necessary, though. Avoid making the nurse feel bad for simply trying to helpful.

"If you know the employee, you could approach him or her directly. But if not, it might look like a slap on the hand, and that's not a good idea," Berry says. "Then I would approach the unit director or manager and tell that person what I heard. I would explain why that's not a good idea and that the person might need to be educated on this risk." ■

Union files OSHA complaint about needlestick safety

Citing serious concerns about needle safety at Connecticut's largest hospital, a union representing hospital service workers has filed a formal complaint with the federal Occupational Safety and Health Administration (OSHA) in Washington, DC.

The complaint against Yale-New Haven (CT) Hospital, submitted by the New England Health Care Employees Union, District 1199 of the Service Employees International Union, cites evidence that the hospital made its selection of safety syringes based on a restrictive buying agreement with Novation, a group purchasing organization that provides hospitals with supplies. The complaint details the union's allegation that "the hospital's potentially dangerous practices may constitute willful violations of OSHA's Bloodborne Pathogens Standard."

That standard requires that hospitals choose safety syringes based on employee feedback and device effectiveness. Instead, the union says, Yale-New Haven based its selection decision on a contractual relationship between Novation and Becton Dickinson, the world's largest needle producer.

According to the complaint, Yale-New Haven Hospital had been using a retractable syringe called VanishPoint, made by Retractable Technologies, which has the highest safety rating from the Emergency Care Research Institute (ECRI) (www.ecri.org). The hospital subsequently switched to Becton Dickinson's Safety Glide syringe, which has an "acceptable-not recommended" rating from ECRI,

and has been cited as presenting a greater risk of a needlestick.

A spokesperson for Yale-New Haven did not respond to *Healthcare Risk Management's* request for comment. According to Centers for Disease Control and Prevention estimates, needlestick injuries affect more than 700,000 health care workers each year, exposing them to HIV/AIDS, hepatitis, and other potentially deadly diseases. ■

Failure to diagnose cancer yields $8 million verdict

A Dallas County, TX, jury has awarded an $8 million verdict to a woman and her husband after a group of doctors and other medical professionals failed to diagnose the woman's breast cancer for more than a year after she discovered a lump in her breast.

Rebecca Stephens and her husband, Tripp, were represented during the three-week trial by attorneys **Charla G. Aldous** and Cary L. McDougal in Dallas.

Aldous explains that in September 2000, Rebecca Stephens went to her primary care physician for her annual medical examination, which showed no signs of breast cancer. The following month, she discovered a lump in her right breast while performing self-examination. That same day, she visited her obstetrician, who ordered a mammogram and sonogram to be conducted the following day.

That examination also came back negative. Six months later, Stephens still had the lump in her breast, and went through another mammogram and sonogram. For the second time since she first discovered the lump, she was told that she did not have breast cancer. Six months after that examination, she informed her doctor that the lump remained, but was told it was benign.

Two months later, Stephens began experiencing back pain, and visited her primary care physician and a breast surgeon. After a series of tests, it was determined that Stephens had cancer in her spine and hip. Another mammogram and sonogram revealed that Stephens also had breast cancer. The Stephens sued, claiming that the doctors and medical professionals who examined Stephens were negligent and failed to uphold the accepted standards of medical care.

On April 8, 2004, a Dallas County jury awarded Stephens and her husband $8 million in the trial heard by 68th District Court Judge Charles Stokes. The jury issued its verdict against Stephens' primary care physician and a breast surgeon who examined her in November 2000. The jury found no negligence on the part of a radiologist who interpreted one of Ms. Stephens' breast studies in July 2001.

Of the $8 million total verdict, Stephens was awarded $3 million for past and future physical pain and mental anguish, and $3 million for past and future physical impairment. Her husband was awarded $2 million for past and future loss of consortium. ■

ISMP warns of critical issue with drug mix-up

The Institute for Safe Medication Practices (ISMP) in Huntington Valley, PA, has issued a special alert about lookalike packaging of two drugs that can lead to serious adverse events. The ISMP urges risk managers to send the alert to the appropriate clinicians.

"A medication error reported last week has highlighted the need for health care practitioners caring for obstetrical patients to take action to avoid serious errors resulting from lookalike commercial labeling and packaging of Methergine [methylergonovine maleate] and Brethine [terbutaline sulfate], which are pharmacological opposites," the alert says.

Despite previous warnings about this potential error, the United States Pharmacopeia-ISMP Medication Errors Reporting Program continues to receive numerous reports of medication errors and patient injuries resulting from Methergine-Brethine mix-ups.

Both agents are frequently used in labor and delivery settings, but for very different clinical reasons, the ISMP reports. Brethine is used to treat pre-term labor, and Methergine is used primarily after delivery of the placenta to treat hemorrhage and failure of the uterus to contract. Since Methergine can contribute to spontaneous abortion, it is absolutely contraindicated in pregnancy and would be especially dangerous to a patient in pre-term labor.

Both products are packaged as 1 mL ampuls within an amber plastic tub, covered by a foil label with the product name in tiny print, making them difficult to tell apart. Both ampuls also have

very similar colored rings around the ampul necks that can be seen through the amber plastic, which further adds to the visual similarity.

In the recent case reported to the ISMP, a 35-year-old woman was experiencing pre-term labor, and was prescribed a Brethine intravenous push. Instead, the nurse accidentally prepared and administered Methergine intravenously. The mother required an emergency cesarean, but the patient and her newborn were able to be discharged on schedule two days later.

To reduce the risk of this type of error, ISMP suggests that health care providers take these steps:

- Keep obstetrical and pharmacy staff informed of the potential for dangerous mix-ups involving these products.
- Store Methergine and Brethine in different areas; Methergine ampuls should be refrigerated, which helps keep the two separated.
- Since errors still are possible even when the products are stored separately, apply label reminders on the ampuls. ■

Reader Question

There are exceptions to EMTALA during disasters

Question: I've heard that the final Emergency Medical Treatment and Labor Act (EMTALA) states that the federal Centers for Medicare & Medicaid Services (CMS) will not sanction hospitals for inappropriate transfers during a national emergency if the hospital is the area affected by the emergency. Does a large-scale disaster in our community, such as an airliner crash, qualify? Should we have a procedure in place to suspend EMTALA during major emergencies?

Answer: It is not true that EMTALA will be overlooked during a national emergency or that you can unilaterally "suspend" EMTALA in your institution because of one, says **M. Steven Lipton**, JD, an attorney specializing in EMTALA interpretation with the law firm of Davis Wright in San Francisco.

There is a grain of truth to this misconception, however. Lipton says the idea is based on a passage in the final EMTALA rule that states that "sanctions under EMTALA for an inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act. In the event of such a national emergency, CMS would issue appropriate guidance to hospitals."

But what exactly does that mean in a practical sense? Lipton says the answer is found partly in the rule's explanation of how that passage came to be. When CMS was collecting comments on EMTALA and considering changes, one commenter referenced the recently issued CMS guidance, in the form of letters to regional administrators and state survey agencies, regarding EMTALA responsibilities in the event of a bioterrorist attack. The commenter believed that the guidance might be viewed as being inconsistent with a hospital's statutory responsibility to provide screening services under EMTALA, and suggested that the regulatory language be revised to reflect the guidance so that hospitals that follow it would not be at risk for a citation of noncompliance with EMTALA.

In the final rule, CMS wrote, "We agree that hospitals should be informed of their EMTALA responsibilities in the event of a bioterrorist attack or other national emergency. We also believe the commenter's suggestion is consistent with the intent of section 143 of the Public Health Security and

Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188, enacted June 12, 2002) . . . ," which allows health care providers to forego some standard obligations in order to respond to a national crisis. Then the rule states that sanctions may not be handed out in some circumstances involving a national emergency.

"So the [Department of Health and Human Services] Secretary has the ability to waive sanctions, but that does not mean EMTALA does not apply," Lipton explains. "And we're only talking about waiving sanctions for inappropriate transfer. That's all that's involved here. They don't say anything about waiving sanctions for any other kind of EMTALA violation."

Lipton says the definition of a "national emergency" is unknown for the purposes of knowing when transfer sanctions might be waived. But he says that the explanation in the final rule implies a significant disaster with national implications, such as the bioterrorism specifically mentioned by CMS. A more typical community disaster is not likely to be included, he says, even if it strains the local hospital's abilities to provide care.

And even in the narrowly defined circumstances in which CMS might not sanction a hospital for EMTALA transfer violations, there is little that risk managers can do to take advantage of this promise. The hospital always is obligated to comply with EMTALA, Lipton says, and this passage in the final rule does not change that.

Even alerting emergency department staff to this provision could be a bad move for the risk manager, he suggests, because the details may be lost in translation and staff may seize on this idea to cut corners with EMTALA during a crisis.

"This is just an acknowledgment from CMS that in these rare circumstances they might understand why you couldn't comply with all the necessary EMTALA paperwork for a transfer. They're saying they know that can happen and they might not penalize you for it, but only in these rare cases," Lipton says.

"It would be a serious mistake to think that you can just tell CMS your ED was swamped and you were in disaster mode so you couldn't comply with EMTALA. They won't go for that, and you shouldn't even hint to your emergency staff that they can use that as an excuse," he adds. ■

Liability crisis threatens health care access

A poll released in March by the Health Coalition on Liability and Access reveals that Americans believe a growing crisis in health care liability is pushing health care costs up and forcing good doctors out of medical practice. Of those polled, 82% said their ability to get the health care they need is threatened by excessive litigation.

Seventy-three percent believe that Congress should enact reforms to limit payments to trial lawyers from medical liability claims. Seventy-one percent favor changes to the law to guarantee full payment for lost wages and medical expenses and place common-sense limits on payments for noneconomic damages. The poll results reveal that most Americans believe:

- **Access to quality health care is at risk:** More than eight in 10 (82%) surveyed believe that doctors are being forced to leave their practices because excessive litigation has put the cost of medical liability insurance out of reach.
- **Cost of health care rising due to excessive lawsuits:** 72% said that health care expenses for all people are being driven up by the rising cost of medical liability lawsuits.
- **Too many frivolous malpractice lawsuits:** 55% said the high number of medical liability lawsuits is unjustified.
- **Common-sense reforms are needed:** 75% want Congress to pass reforms to fix the medical liability crisis; 72% favor a law that guarantees full payment for lost wages and medical expenses but limits noneconomic damages; 73% want to limit the amount of money personal injury trial lawyers can get from the excessive litigation settlements their clients receive.

The full report can be viewed at www.hcla.org. ■

COMING IN FUTURE MONTHS

- Legal fights with medical staff more common
- Improving fire safety in patient areas
- Unlicensed personnel increase patient falls?
- Most common mistakes when talking to family
- Least expensive way to lower workers' compensation claims

CE objectives

After reading this issue of *Healthcare Risk Management,* the CE participant should be able to:

1. Describe legal, clinical, financial, and managerial issues pertinent to risk managers in health care.
2. Explain how these issues affect nurses, doctors, legal counsel, management, and patients.
3. Identify solutions for hospital personnel to use in overcoming challenges they encounter in daily practice. Challenges include HIPAA and EMTALA compliance, medical errors, malpractice suits, sentinel events, and bioterrorism.
4. Employ programs used by government agencies and other hospitals (such as EMTALA, HIPAA, and medical errors reporting systems) for use in solving day-to-day problems. ■

CE Questions

Nurses participate in this continuing education program by reading the issue, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. **After completing this activity this month, you must complete the evaluation form provided and return it in the reply envelope provided in order to receive a certificate of completion.** When your evaluation is received, a certificate will be mailed to you.

21. What does Jeffrey Driver, JD, MBA, advise regarding the use of liability waivers?
A. They are almost always invalidated by courts and therefore are of little use.
B. They are almost always supported by courts and therefore should be used widely.
C. They are unethical and should not be used regardless of enforceability.
D. Courts sometimes invalidate them but they still can be useful in some situations.

22. According to Monica Berry, BSN, JD, LLM, DFASHRM, CPHRM, when should a nurse document a telephone call in which someone asks for advice?
A. Always
B. Only when the nurse provides substantial clinical advice.
C. Only when the caller seems unhappy with the advice offered.
D. Never

23. How does Michael D. Neubert, JD, suggest risk managers get involved when physicians need to comment on a colleague's competence with state regulators or other investigators?
A. Not at all
B. Have the commenting physician sign a statement indicating their comments do not represent the institution.
C. Discuss the comments beforehand to assure that they are objective and not based on a personal dispute.
D. Attend any investigation-related hearings with the physician.

24. According to M. Steven Lipton, JD, which of the following is true concerning EMTALA?
A. EMTALA does not apply during national emergencies.
B. EMTALA violations regarding inappropriate transfers may not result in sanctions during a bioterrorism emergency.
C. EMTALA does not apply during bioterrorism events but it does during other national emergencies.
D. EMTALA is not affected in any way by bioterrorism events or other national emergencies.

Answers: 21-D; 22-A; 23-C; 24-B.

Healthcare Risk Management's
Legal Review & Commentary™
A Monthly Supplement

Failure to treat asthmatic patient results in brain damage: $5 million NY verdict

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News: A woman having an asthma attack presented at the emergency department (ED). After being hospitalized for three days, the patient's daughter came to visit and found her mother nonresponsive and blue. The patient was resuscitated; however, she was left brain damaged. The patient's daughter brought suit against the hospital and attending physician. The jury returned a $5 million verdict in favor of the plaintiff.[1]

Background: On July 29, the 56-year-old, unemployed woman was admitted to the hospital ED with an asthma attack. She was intubated, placed on a respirator, and given asthma medications. The patient was placed under the care of a pulmonologist and critical care specialist.

From the ED, the patient was transferred to the intensive care unit. At the time, she was on a respirator and had been medically paralyzed and sedated because she was fighting the endotracheal tube. At 6 a.m. on July 31, the patient suffered an episode of bradycardia and cyanosis, which was attributed to mucous plugs obstructing her lungs. She responded to suctioning and the administration of 100% oxygen. X-rays revealed atelectasis (which is akin to pulmonary collapse due to the absence of gas from all or part of the lungs), consistent with additional mucous plugs; however, no additional care was administered as a result of this episode.

On Aug. 1 at 8:13 a.m., the patient's heart rate increased to 150 bpm from 100 bpm. Although the nursing staff noted this change, the attending physician was not called to evaluate the patient's changed status. At 8:38 a.m., the patient's daughter came to the ICU to visit her mother and found her purple and not breathing. The patient's daughter called for help, and a code was called for respiratory and cardiac arrest.

The arrest was attributed to mucous plugs obstructing the oxygen flow to the patient's lungs, although oxygen saturation levels via pulse oximeter were not documented during this time. The patient was resuscitated, but she suffered anoxic encephalopathy, resulting in severe brain damage.

The patient's daughter brought suit against the hospital and attending physician for negligence, claiming her mother now was in a persistent vegetative state. The patient exhibited no meaningful level of awareness or consciousness since the cardiac arrest. Her condition is permanent, and she requires constant skilled nursing care, which will be needed for the remainder of her life.

Specifically, the suit claimed that the attending physician departed from accepted medical standards in failing to perform a bronchial lavage through a bronchoscope or catheter as soon as July 31. The suit claimed that this procedure would have loosened and removed the mucous plugs from the patient's lungs and protected her from pulmonary obstruction. The suit further contended that the hospital personnel failed to call for an evaluation of the patient at the first signs of the dramatic change

in her heart rate, which is a known sign of oxygen deprivation, and that the hospital personnel also failed to respond to the patient's respiratory arrest, which was made known through her daughter in a timely fashion. This delay allowed oxygen deprivation for a more prolonged period. In summary, the suit claimed that these departures from the standard of care were substantial factors in causing anoxic encepholopathy, brain damage and the patient's resultant vegetative state.

The defendant hospital argued that the nursing staff acted appropriately in evaluating and suctioning the patient, that the staff responded to the respiratory and cardiac arrest in a medically correct and timely manner, and that the patient's brain damage was an unavoidable complication of her severe asthma.

The attending physician countered that neither bronchoscopy nor bronchial lavage were indicated because the patient's mucous plugs were located in the bronchioles and in the peripheral areas of the lungs and were not amendable to that particular type of treatment. In his defense, the physician further argued that even if the bronchial lavage had been performed, it would not have altered the patient's course.

The jury sided with the patient and awarded $5 million; the breakout between the hospital and physician is not known.

What this means to you: Because many Americans live with asthma every day, the understanding that asthma can be a potentially fatal disease is not always accepted or appreciated. "Deaths still occur in asthmatics of all ages, and the failure to recognize the seriousness of an asthma attack may be due to the presumption that the disorder is one of broncho-constriction rather than mucous plugging,"[2] notes **Melanie Osley**, RN, MBA, CPHRM, risk manager at St. Francis Hospital & Medical Center in Hartford, CT.

"Mucous hyper-secretion is often a significant presenting symptom, particularly in status asthmaticus.[3] In cases of asthmatic exacerbation that is not responsive to aggressive medical management, patients will continue to produce sputum which leads to mucous impaction, exhibited by prominent rhonchi and wheezes on auscultation.[4]

The argument has been made that bronchial lavage is associated with a significant excess of respiratory infections.[5] However, this must be weighed against the importance of opening up the airway system to provide maximum oxygenation.

In one study,[4] clearance of inspissated secretions by fiberoptic bronchoscopy with lavage greatly improved spirometric measurements in refractory asthma with mucous impaction, and did so with no complications," states Osley.

Severe asthmatics who require mechanical ventilation must be observed closely as mechanical ventilation is associated with an increased risk of death in severe asthma attacks.[6] "One potential complication of mechanical ventilation is a sudden drop in blood pressure. Because sedation is often necessary in mechanically ventilated patients, the sedation, combined with the sudden release of histamine due to the asthma exacerbation, may cause vasodilation. On the ventilator, when the work of spontaneous breathing is relieved, there will be a drop in the level of catecholamines, which will stop the vasoconstriction that has helped maintained the blood pressure," adds Osley.[6]

In addition to observing for deteriorating blood pressure, the patient also must be closely observed for accompanying changes in heart rate, as well as changes in oxygenation saturation. An increase in mucus secretions may require frequent suctioning that would cause a temporary decrease in oxygen saturation levels during and shortly after the suctioning. However, oxygen saturation levels that do not return to appropriate levels need to be addressed immediately, and monitoring of oxygen saturation levels at all times in these patients is imperative," observes Osley. "However, in this instance it seems that the hospital staff and physician oversight were woefully inadequate; and the patient was allowed to deteriorate rapidly."

"Accurate assessment of asthma severity is crucial in ensuring a patient's health and well being. The variable nature of asthma, the poor concordance among measures of asthma severity, and patients' tendency to underreport their asthma symptoms can contribute to inaccurate severity assessments, which can lead to inappropriate therapeutic choices, such as undertreatment," she adds.[7]

References

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2. Dornhorst AC. Dangerous asthma. *Aviat Space Environ Med* 1984; 55(5):422.
3. Groneberg DA, Eynott PR, et al. Expression of respiratory mucins in fatal status asthmaticus and mild asthma. *Histopathology* 2002; 40(4):367-73.
4. Lang DM, Simon RA, et al. Safety and possible efficacy of fiberoptic bronchoscopy with lavage in the management of refractory asthma with mucous impaction. *Ann Allergy* 1991; 67(3):324-30.

5. Luksza AR, Smith P, et al. Acute severe asthma treated by mechanical ventilation: 10 years' experience from a district general hospital. *Thorax* 1986; 41(6):459-463.

6. Carrol, P. How to intervene before asthma turns deadly. *RN* 2001; 64(5):52-58, 60.

7. Spahn J, Calhoun WJ, Challenges in assessing asthma severity in clinical practice. *Advanced Studies in Medicine* 2003; 3(5A):S372-8, S388-9. ■

Alleged assault not treated: Patient wins $300K verdict

News: A patient alleged that an equipment technician sexually assaulted her after she found her buttocks exposed and seminal fluid in her groin area. After reporting the situation to several nurses, the patient was given medication to calm her, and she was discharged quickly thereafter. A Texas jury awarded the patient $300,000 based on the hospital's failure to provide treatment.

Background: The patient, a 45-year old single woman, suffered from brittle diabetes, which caused her to be hospitalized several times a year. She alleged that during one of her hospitalizations, she was sexually assaulted by a cardiopulmonary equipment technician. The technician had first starting working at the hospital as a kitchen aide, and four years prior to the alleged event had been transferred to his cardiopulmonary tech position. It was his duty to check the oxygen saturation levels of patients who were on oxygen.

The patient was not on oxygen when in the early morning hours the equipment tech entered her room. She awakened to find that her bed covers had been pulled back, her buttocks were exposed, and the technician was standing behind her. The technician attempted to cover her and then quickly left the room. The patient immediately called for her nurse. The nurse, finding the woman very emotionally upset, left to get some medication to calm her. While the nurse was gone, the patient allegedly found seminal fluid on her groin area, which she reported to the nurse when she returned with the medication.

The patient reported the incident to several other nurses to no avail. She was discharged later that day without her allegations ever being investigated nor was she offered anything other than the medications to ease her emotional distress. No counseling was provided by the hospital, and she was not referred to a therapist following discharge.

The patient brought suit against the hospital alleging negligent hiring, negligent job transfer of the technician, negligent supervision of the tech, and failure to have reasonable policies and procedures in place to protect patients. In addition, she claimed that the hospital failed to treat her condition after she had reported the incident to her nurses and that she was treated more as a problem than a patient. She also maintained that the hospital failed to preserve the evidence of the assault and failed to report the incident in her medical record.

The court granted the hospital summary judgment on the claims of negligent transfer and supervision of the technician and the failure to have adequate policies and procedures in place to protect patients on the basis that the assault was a criminal act outside the course and scope of the technician's employment at the time. However, the case against the hospital on the failure to treat the patient proceeded.

In its defense, the hospital maintained that it was not necessary to document the alleged incident in her medical record because a separate occurrence report had been made, and this in and of itself caused the patient no harm. The hospital also argued that the patient's nurse had to make a difficult judgment call in a difficult and delicate situation and her actions did not rise to the level of a negligent act. The defendant hospital contended that the failure to preserve the evidence and document the alleged event in the medical record did not cause the woman's emotional distress. The jury found in favor of the patient and awarded $300,000, finding the hospital was 32% negligent and the technician 68% at fault.

What this means to you: "Fortunately, it is not every day that health facilities are faced with allegations of rape by patients. Because of the rarity of such events as this taking place in a hospital setting, opportunities exist for improving educational efforts among nursing and medical staff," says **Patti L. Ellis**, RN, BSN, LHRM, risk manager at Pedatrix Medical Group Inc. in Sunrise, FL.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) considers rape a sentinel event. "Therefore, all allegations of rape in a JCAHO-accredited facility must be investigated. In addition, your jurisdiction may have risk management laws requiring that all allegations of abuse and assault be investigated and reporting to the governing agency," adds Ellis.

"In this situation, the nurse had a duty to her patient to further assess the situation and

intervene as the patient's advocate and report the alleged rape to the patient's physician, nursing supervisor, hospital security, risk management, and at a minimum advise the patient that she herself could contact law enforcement and report the alleged rape," notes Ellis. The facts of the case raise red flags that should have triggered a more responsive reaction from nursing staff. "The patient's age and heightened emotional state were signs that the nursing staff should not have discounted," she adds.

With a prompt, appropriate response from staff, "risk management would have been able to interview the patient in a timely fashion. It is critical that the facts — such as time and circumstance of the incident — be obtained as soon as possible and to see if the patient can identify the alleged perpetrator. The staff on duty at the time of the alleged occurrence should also be interviewed by risk management," observes Ellis.

In this instance, the alleged perpetrator was an employee. "Employee background checks at the time of hire are extremely important and should be required as an integral part of the hiring process — particularly if an employee is to have contact with patients. However, pre-screening may not identify a problem employee if there is no prior criminal history. After an employee is accused of wrongdoing, human resources should be involved in the interview and follow-up process of the employee as they may need to place the employee on administrative leave or suspension until further notice," says Ellis.

"Providing the patient with the necessary counseling and medical attention is critical in meeting the needs of the patient both during hospitalization and after discharge. Follow-up with the patient after discharge should have been offered to this patient. Access to rape crisis counselors should be rapidly available and telephone numbers included as a part of the hospital community resource directory if your facility does not have one on site," she notes.

The review and assessment of documentation remains a critical element in risk management's review. "At the time the incident was reported, it was not necessary that the staff document 'rape' in the patient's medical record; however, it was clear error not to document the fact that the patient was emotionally upset and had reported an 'alleged cause' of that condition. Two documents should have been produced — the medical record and the risk management occurrence report — both of which would have provided the hospital with a record of the incident," says Ellis. "Otherwise, it appears that the facility was noncaring and engaged in cover-up.

"The preservation of evidence extends from the record to the patient's hospital room as bed clothing and linens were part of the crime scene. Here, too, it seems that things were swept under the tile. Had law enforcement been summoned, they would have taken custody of any pertinent evidence. Documen-tation of chain of custody is an important part of the risk management record, and here there was nothing left to document," she states.

"While such situations are rare in the hospital setting, staff need to be prepared and know what to do in such situations. Risk management should include education to nursing personnel and medical staff on proper document of such events. Rape counselors are a good resource in this regard," concludes Ellis.

Reference

• Tom Green County (TX) District Court, Case No. A-99-0132-C. ■