



Healthcare Risk Management™



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— *Legal Review & Commentary*

SEPTEMBER 2002
VOL. 24, NO. 9
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Risk managers at the crossroads: Take advantage of opportunities

Be careful: The job description changes rapidly

Risk managers have seen their jobs change in myriad ways in recent years, but nothing like what will happen in the next few years, say many leaders in health care risk management.

They believe risk managers are at a crossroads and how you react now will determine the course of your career.

Some risk managers worry that risk managers are becoming extinct, systematically replaced by patient safety officers and other people with titles bearing little resemblance to the risk manager of five or 10 years ago. There may be some truth to it, but some say risk managers are not being pushed out — just pushed to change.

But you might have to change in a big way, says **Barbara Youngberg** BSN, MSW, JD, FASHRM, vice president of insurance, risk, quality, and legal services with the University HealthSystem Consortium in Oakbrook, IL. Youngberg worries that many risk managers underestimate how much the

Audio conferences tackle critical compliance issues

Health care organizations today are challenged by more than just providing quality patient care. Compliance issues can create headaches for facilities that aren't prepared. How well does your facility meet certain regulations? Are your staff properly armed with the most up-to-date information? To help you prepare, American Health Consultants (AHC) offers two upcoming audio conferences dealing with current, hot-topic compliance issues: pain management and needle safety.

The first hurdle to overcome in developing a pain management strategy is the misconception that effective pain management is not a problem within your facility

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A big leap forward is in offing for risk managers

Health care risk management has been evolving since its inception, so the current changes in the job description are nothing new, says **Grena Porto**, RN, ARM, DFASHRM, senior director of clinical operations at VHA Inc. in Berwyn, PA, and past president of the American Society for Healthcare Risk Management. She offers this summary of the profession's evolution:

• 1970s — The Birth of Risk Management

At this point, risk management was closely tied to insurance companies, with an emphasis on professional liability and general liability losses. There was little integration with quality initiatives. Quality measurement consisted mainly of counting incident reports.

• 1980s — The Good Old Days

Risk management has evolved so that it is seen as an independent and important function in the health care system. The risk manager's role is broadening to include managed care, directors & officers liability, and similar issues. A move toward integrating risk management and quality improvement (QI) initiatives begins. Measurement now includes the trending of incident reports.

• 1990s — Risk Management Under Fire

The distinction between risk management and QI becomes blurred, and QI starts to take on more prominence. Risk managers focus more on regulatory compliance and still don't focus much on prevention. There is an overemphasis on risk avoidance without any real proof of effectiveness. A soft insurance market encourages complacency. Measurement still consists of trending incident reports.

• 2000 — Risk Management Eclipsed by Patient Safety

The Institute of Medicine's report *To Err is Human* focuses attention on medical errors but barely mentions risk management. Some see the report as proof that risk management has failed. Patient safety is not seen as synonymous with risk management, and many "risk managers" are replaced by "patient safety officers." ■

health care industry is changing and how much they may need to reinvent themselves to remain valuable. The increasing focus on patient safety, plus the continuing insurance crisis, changed the way health care institutions look at risk managers, she says.

"There is a much greater public awareness of the need for creating safe systems in health care," she says. "Risk managers, historically, have been in more of a reactive discipline, trying to understand what happened and fix it. The whole focus now is to look at what might give rise to failure and prevent it. You've got to be able to do that."

And that is not an easy change to make, she says. It is much more than changing your attitude and saying you will focus on prevention and be more proactive. To really change the way you do your job, many risk managers will have to develop new skills, Youngberg says.

"Everything is going to be more data-oriented," she says. "Risk managers have to be able to collect more data and know what they mean. A lot of people collect data but don't know what to do with it. That won't be enough in the future."

Some risk managers worry their profession is on the path to extinction, says **Grena Porto**, RN, ARM, DFASHRM, senior director of clinical operations at VHA Inc. in Berwyn, PA, and past president of the American Society for Healthcare Risk Management. She says she wouldn't go that far in assessing the problem, but she still worries that risk managers could see themselves pushed out of the picture if they don't make some changes. **(See a summary of the risk-management profession's evolution, left.)**

"It's because of all of the focus on safety," she says. "Many of the fundamental concepts of a high-reliability organization, which is what defines a safety-driven focus these days, are totally the opposite of what we do in risk management."

Risk managers must abandon the old-style type of risk management in favor of the more proactive, open type of management that is driving the health care industry now, she says. In the past, risk managers have focused on preventing the dissemination of information, which she says is antithetical to a

COMING IN FUTURE MONTHS

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high-reliability organization. That term, “high-reliability organization,” defines what health care organizations strive for. It is most commonly defined as “one that functions consistently and reliably over long periods of time without error.” (For more on high-reliability organizations, see p. 100.)

Under that approach, old-style risk management can be a serious hurdle because it focuses on keeping a tight lid on information that might be damaging. As the health care industry continues to evolve, organizations will not have use for risk managers standing at the hospital door to bar anyone who wants information.

“We already don’t have effective risk-auditing systems because we have created burdensome behemoths to protect information,” she says. “We’re so scared of something being discoverable that we stifle discussion of risk auditing. We’re so scared about information getting out in the wrong hands that we stifle the learning that should happen.”

The emphasis on defending legal claims can be a major cause of the risk manager’s efforts to protect information and avoid liability at all costs, Porto says. The effect, of course, is that a risk manager may successfully defend one claim while missing the opportunity to fully investigate the incident and stop it from happening again.

“Risk managers can’t even agree on what quality is, when the rest of the industry is saying quality is the most important thing. I was speaking one time and used the example of a retained foreign body, and there were risk managers in the audience who said they could defend that case, that it wasn’t necessarily proof of a quality problem,” she says. “Why would you defend that? Why would you spend resources trying to explain that a retained foreign body isn’t really a problem? This ultimately will be our undoing if we don’t change our way of thinking.”

Risk managers need to evolve, but they will always be around, says **Monica Berry**, BSN, JD, LL.M., DFASHRM, CPHRM, vice president of risk management and loss control for the Rockford (IL) Health System. She also is president of the American Society for Healthcare Risk Management (ASHRM). The role of the risk manager has always varied tremendously from one organization to another, she says, with some taking on more responsibilities than others. So in that way, the next few years shouldn’t be a shock. But the trend is definitely for risk managers to take on more.

“In some organizations, the risk manager is directly involved with the purchase of insurance; and in others, the risk manager gets nowhere

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There also are links to every article published in *Healthcare Risk Management’s Patient Safety Quarterly* and *Patient Safety Alert* supplements from January 1999 to present.

HRM’s 2001 salary survey also is available in its entirety.

Find links to other web sites that are essential references for risk managers. There also is a guide to upcoming conferences and events of interest to risk managers. Click on the User Login icon for instructions on accessing this site. ■

near that and the CFO [chief financial officer] does that part of the job,” Berry says. “At one point, we saw evolution of the chief risk officer. That role still exists, but it’s not yet embraced in health care. Things have always been changing, and now we’re seeing a trend toward more responsibility and patient safety.”

But Berry points out that risk managers have been involved in patient safety since the beginning. The important point now is that different methodology is preferred for protecting patients, visitors, and employees. That means you need to acquire those skills, but the fundamental role of the risk manager will remain.

“I see the role of the risk manager as always being at the table. We’re never going to get away from those fundamentals, but it’s a matter of what’s the soup du jour. What’s the name we’re giving it this year?” Berry says. “I don’t see risk managers or their function morphing into nonexistence. That just won’t happen. We play too much of a key role in the organization.”

On to senior leadership

Youngberg agrees that the fundamentals of risk management always will have a place in health care, but she says they won’t be enough for your career to thrive. The driving forces behind the changes are the focus on medical errors and the hard insurance market, but she says the profession

must take some responsibility for the failure — in some areas — of traditional risk management approaches. Health care organizations have seen the way risk managers addressed issues in the past, and most of them are saying that approach won't be sufficient in the future.

That's not to say, however, that the health care community is pushing risk managers aside or easing them out of the system. To the contrary, health care providers are looking to risk managers to take on more responsibility and more leadership roles within the institution, Youngberg says. But you have to seize that opportunity now or watch your position wither away.

"Risk managers are not usually seen as senior leaders. They're seen more as middle managers," she says. "Organizations are looking for the risk managers now to rise to a higher level of leadership because that's what the new focus requires. In organizations that have embraced a safety paradigm, risk managers are being given safety departments to manage and are rising to meet the added challenge. I'm afraid your choice is to either do that or be phased out and marginalized."

In essence, the risk manager's field is becoming a larger expense and a more important focus for health care organizations. That means employers will hold the risk manager to a higher standard and elevate the risk manager's role.

"But it could elevate the risk manager's role to a point where the current risk manager is not seen as capable of the job. That's a real concern," Youngberg says. "The ones that have positioned themselves well, becoming more data-savvy and business-oriented, might be viewed as the right person to manage this. But I suspect that some risk managers may not."

The good news, Youngberg says, is that risk managers can reap tremendous benefits if they seize the opportunity now to improve their skills. The role of the risk manager may be quite different five years from now, but that doesn't mean it has to be worse, she says. Risk managers who acquire the right skills can find they are taking on leadership roles previously unattainable, she says.

"You have to be more strategic and get a place at the table where the important decisions take place," she says. "But you don't get invited to that table with the senior leaders unless you develop some additional skills. You have to have something to offer."

Berry and Youngberg's advice might sound dismaying, but they say risk managers should just accept that their careers are evolving and take

advantage of the opportunities to excel. There is no need to change to a different career — even if your title changes. Rather, they just advise keeping up with the changes in your chosen career.

"I don't want people to worry about career opportunities. In fact, this is going to open the door for us," Berry says. "The shift to patient safety gives us the opportunity to tout that this is what risk management has always been about. Here's an opportunity to showcase what the profession of risk management is all about. We're not going anywhere."

Youngberg advises health care risk managers to pursue educational opportunities with the goal of enhancing their skills in ways that will satisfy the changing needs of health care institutions. That means studying data collection, statistics, quality improvement, insurance, finance, and other "top-tier" business skills. And she offers this specific advice: Don't shy away from the financial topics. Many risk managers have had only cursory involvement with risk financing and insurance purchasing, for instance, but Youngberg says that is likely to change. Any manager who has financial skills is more likely to become a leader in the organization, she says.

Educational opportunities can be found through many professional organizations and universities, Youngberg says. Don't waste time getting started, she advises.

"I don't think the risk manager will be doing the same work in five years," she says. "If they are, they're going to be in a marginal position in the organization." ■

High-reliability orgs thrive on info, proactivity

Information and analysis are the keys to becoming a high-reliability organization, says **Grena Porto**, RN, ARM, DFASHRM, senior director of clinical operations at VHA Inc. in Berwyn, PA, and past president of the American Society for Healthcare Risk Management. She lists these main components of a high-reliability organization:

- **Acknowledgment of risk:** Errors always will happen, and they are not shameful, so we can talk about them. Errors are opportunities for learning. Those who make errors can help us to learn from them. The focus must be on detection and recovery.
- **Auditing of risk:** Effective risk-auditing

systems use simple standardized forms, multiple formats for reporting, no confusing or restrictive definitions, no complex terminology, minimal duplication, and anonymity. The auditing program also should focus on information, not data, so that it allows narratives, doesn't require the reporter to analyze the information, and provides feedback in a "lessons-learned" format. There also should be immediate response to serious hazards.

- **Appropriate reward system:** Everyone must understand what safety is, and frontline operators must be empowered to act. Rewards must be timely and appropriate, and they must be publicized.

- **System quality standards:** All participants must know what quality is and everyone must be expected to maintain quality. The quality standards must be based on evidence.

- **Flexible management models:** Frontline workers are trained and empowered, and the one with the most expertise is in charge. Anyone can make a safety-motivated decision. The goal is management, not micromanagement. ■

Increased deductible use prompts strategy change

More insurers require health care organizations to carry a deductible or a larger one than they used to carry, and many providers seize the deductible as an option for controlling the current huge increase in insurance costs. But risk managers warn that the emphasis on deductibles will require a significant change in the way you handle claims.

The increasing use of deductibles is an offshoot of the insurance crisis that has left some providers with premium increases of several hundred percent. Many risk managers will be caught unaware by the deductible, says **Monica Berry**, BSN, JD, LLM, DFASHRM, CPHRM, vice president of risk management and loss control for the Rockford (IL) Health System. Berry also is president of the American Society for Healthcare Risk Management (ASHRM). Risk managers who are not directly responsible for the purchase of insurance may be unfamiliar with how deductibles have been changed recently, she says.

"If the CFO [chief financial officer] is responsible for buying insurance, they may go for the lowest price. And, to get a lower price, the CFO may embrace the use of a deductible, for instance,"

Berry says. "Some health care organizations have never had a deductible for liability claims, but now we're seeing a whole lot more. Now we're seeing a mandate for deductibles in some organizations."

Increased emphasis on deductibles — or self-insured retentions, the equivalent for providers who self-insure — is a common result of a hard insurance market, says **R. Stephen Trosty**, JD, MA, director of risk management at APAssurance Corp. in East Lansing, MI. The spiraling insurance premiums of the past few years have created one of the hardest insurance markets, where it is difficult for even the best health care providers to afford insurance.

"And if you've had bad claims experience, very often the only insurance you can get in a hard market will be with a high deductible," he says.

Much more involvement

If you have dealt with deductibles before, the greater emphasis on deductibles may require only a shift in strategy, Berry says. In general, the effect tends to be that the provider must be stricter about when to settle a claim. When the deductible is larger, you may have to change your approach to settling claims so that you don't pay out of pocket too quickly. The greatest impact will be on those who have never had a deductible before, Berry says, and that includes a great many risk managers.

"If a deductible is a new thing to you, you'll need to seek out education on how to negotiate a settlement, how to handle claims, what your settlement authority is. You just plain have to get comfortable with a whole new process," she says. "That means risk managers need to go back for education and training for how to deal with general professional and liability claims that come with a deductible layer. This can radically change how you negotiate claims."

Berry says ASHRM takes the issue so seriously that it is putting a special emphasis on providing continuing education on claims management and deductibles.

"This problem is hitting, and it's hitting big time," she says.

Trosty explains that, with the deductibles, insurers are telling health care providers that they must take on more responsibility for managing claims themselves — and to carry more of the risk. That will mean a tremendous increase in the amount of work that risk managers spend on an individual claim or potential claim, he says.

"One of the effects is that it encourages better risk

management, better quality improvement, better peer review,” he says. “There’s a chunk of your own money on the line for every single claim, and that’s money from the bottom line. It causes you to look at negotiations differently, no matter how much we like to think that we treat the insurance company’s money just as carefully as our own.”

One of the biggest effects of having a larger deductible is that you will have to hang on to claims much longer, and therefore do much more work on claims in general. An insurer usually takes over the primary management of a claim once it is submitted, but with a large deductible, the insurer doesn’t get involved until you cross the deductible line. Claims that previously might have been paid by the insurer may be settled for an amount below the deductible threshold, which means that the entire case will remain on your desk instead being passed on to the insurer to handle. And even for larger claims, it will take longer for you to reach the deductible cutoff and hand it over to the insurer. Depending on how your insurance policy is written, the deductible may include expenses as well as actual payouts to the plaintiffs.

“You’re going to be doing much more of the claims management and legal component of your cases,” Trosty says. “You’re going to do more of everything before the insurance company steps in and takes the lead.”

Seize opportunity or risk extinction

Working with a deductible requires closer coordination with the insurer than some risk managers may be used to. As you handle the initial claims management, you may have to estimate the expenses that are accruing, including legal counsel, and then notify the insurer when you approach the deductible cutoff, Trosty says. Crossing that line will be a mixed blessing.

One the one hand, you can hand over much of the workload to the insurer and you can stop paying the expenses of the claim. But on the other hand, you may have to do considerable work to educate the insurer about the claim and hand over the reins. Then you get to see what the insurer does with all the work you’ve put into the claim so far. Without a deductible, many claims are turned over to the insurer before the risk manager does enough work to feel real ownership. It’s different once you’re put a lot of work into the case.

“You’ve gotten the ball rolling, and now you’ve met the deductible so the insurance company

comes in and may or may not agree with what you’ve done,” Trosty says. “They have a lot of control to say we’re not paying the claim if we don’t think it’s being handled in the best way.”

The major task for risk managers faced with a higher deductible is to improve the claims management process, he says. For many, that will require more education. He recommends the continuing education offered by ASHRM, the Risk and Insurance Management Society, state risk-management associations, and universities offering risk-management degrees. But unlike their approach to many topics, most insurers won’t be eager to help educate you on claims management and working with deductibles. They’ve put the ball in your court.

One option, Trosty says, is to hire a third-party administrator to manage claims. This can be a good option if your risk-management system would need a major revamping to adequately handle claims with a deductible. But even then, he warns that the risk manager should be directly involved in selecting a third-party administrator and managing that person’s work. No matter how you meet your needs in the organization, the risk manager must take charge and not be pushed aside, Trosty says.

The insurance crisis presents a crossroads for risk managers, he says. You can seize the opportunity and play a much larger role in claims management, thereby building a closer relationship in the organization and with the CFO because you’re responsible for more money. But if you are unable to do that, you risk being seen as superfluous.

“You can improve your status or see yourself pushed aside,” he says. “The advantage is that you can end up managing claims better and actually cut costs. The risk manager has the opportunity to be a hero if you wind up saving money.” ■

E-mail, other computer use may increase liability risk

As physician-patient e-mail and other medical communications move on-line, so does the medical liability risk, according to the eRisk Working Group for Healthcare, a consortium of national medical societies and liability carriers representing more than 70% of insured physicians.

The eRisk Working Group for Healthcare has published an updated list of guidelines for physician office on-line communications with patients,

other health care providers, and industry. Driving the creation of these guidelines is the continued growth of physician-patient e-mail, which is being motivated by strong patient demand and already involves roughly 25% of practicing physicians according to recent studies published by Boston Consulting Group, Jupiter Media Metrix, and Medem Inc. The new guidelines were developed by the carriers and medical societies at the second annual eRisk Working Group for Healthcare conference recently held in San Francisco.

The new guidelines address both routine on-line interaction with physician offices as well as on-line consultations, in which providers are reimbursed for providing care on-line, says **Mark Gorney**, MD, medical director for the Doctors Company, one of the largest national malpractice carriers. They emphasize the need for secure on-line messaging, with authentication and encryption, he says, as opposed to the use of standard e-mail for physician-office communications. A second set of guidelines for reimbursed on-line consultations was created in response to the growing interest among both patients and physicians for this service and an increased number of payers who reimburse physicians or are considering reimbursement for on-line consultations.

National survey data presented by Medem at the conference detailed substantial growth in the use of web sites and e-mail for physician-patient and physician-physician communications with tens of thousands of physicians now routinely using e-mail in their offices. Participating liability carriers focused on the use of standard e-mail systems by physicians and the inherent potential liability in these unsecure environments that often involve employer-provided patient e-mail.

"The new eRisk guidelines make it clear to physicians that there are risks in using standard e-mail to communicate with patients or to transmit patient information to third parties using standard e-mail," Gorney says. "Charging patients or payers for an on-line consultation likely increases those risks. Given these risks and the HIPAA [Health Insurance Portability and Accountability Act] guidelines, it makes good sense to use a network that includes both encryption and authentication for transmitting messages."

The liability carriers and the societies agreed that technology adoption among physicians is rapidly advancing and challenging the health care industry to keep up with appropriate guidelines and advice. **Ed Gottlieb**, MD, a pediatrician and representative from the American Academy of Pediatrics, whose

board has formally endorsed the eRisk guidelines, says the frequency of on-line doctor-patient and doctor-doctor communications is rapidly growing.

"This is especially true among younger physicians. Pediatric residents use e-mail routinely," he says.

Gottlieb points out that many physicians may assume e-mail communication is acceptable to patients, but the guidelines specifically say that informed consent is necessary before beginning any e-mail communication with a patient. That means the doctor must explain to the patient e-mail communication may not be as private as other methods, and the patient must consent to communicating that way despite the shortcomings.

In particular, risk managers should warn physicians against routinely collecting e-mail addresses as part of data collection with patients and then using that address without informed consent. The new guidelines have this to say about getting informed consent for e-mail communication:

"Prior to the initiation of on-line communication between health care provider and patient, informed consent should be obtained from the patient regarding the appropriate use and limitations of this form of communication. Providers should consider developing and publishing specific guidelines for on-line communications with patients, such as avoiding emergency use, appropriate expectations for response times, etc. These guidelines should become part of the legal documentation and medical record when appropriate. Providers should consider developing patient selection criteria to identify those patients suitable for e-mail correspondence, thus eliminating persons who would not be compliant." **(See story below for excerpts from the guidelines.)**

The summary guidelines for on-line communications and reimbursed on-line consultations are posted on the liability carrier web sites and also are available at www.medem.com/erisk. ■

Guidelines urge physicians to respect patients' privacy

These are excerpts from the eRisk Working Group for Healthcare's guidelines for physician office on-line communications with patients, other health care providers, and industry:

- **Authentication** — The health care provider has a responsibility to take reasonable steps to

authenticate the identity of correspondent(s) in an electronic communication and to ensure that recipients of information are authorized to receive it.

- **Confidentiality** — The health care provider is responsible for taking reasonable steps to protect patient privacy and to guard against unauthorized use of patient information.

- **Unauthorized Access** — The use of on-line communications may increase the risk of unauthorized distribution of patient information and create a clear record of this distribution. Health care providers should establish and follow procedures that help to mitigate this risk.

- **Informed Consent** — Prior to the initiation of on-line communication between health care provider and patient, informed consent should be obtained from the patient regarding the appropriate use and limitations of this form of communication. Providers should consider developing and publishing specific guidelines for on-line communications with patients, such as avoiding emergency use, appropriate expectations for response times, etc. These guidelines should become part of the legal documentation and medical record when appropriate. Providers should consider developing patient selection criteria to identify those patients suitable for e-mail correspondence, thus eliminating persons who would not be compliant.

- **Doctor-Patient Relationship** — It may be possible to initiate a doctor-patient relationship solely through on-line interaction. The creation of such a relationship can increase the health care provider's liability exposure. Payment for on-line services may further increase that exposure.

- **Medical Records** — A record of on-line communications pertinent to the ongoing medical care of the patient must be maintained as part of, and integrated into, the patient's medical record, whether that record is paper or electronic.

- **Licensing Jurisdiction** — On-line interactions between a health care provider and a patient is subject to requirements of state licensure. Communications on-line with a patient outside of the state in which the provider holds a license may subject the provider to increased risk.

- **Authoritative Information** — Health care providers are responsible for the information that they provide or make available to their patients on-line. Information that is provided by e-mail or on a medical practice web site should come either directly from the health care provider or from a recognized and credible source after review by the provider.

- **Commercial Information** — Web sites and

on-line communications of an advertising, promotional, or marketing nature may subject providers to increased liability, including implicit guarantees or implied warranty. Misleading or deceptive claims increase this liability.

- **Fee-Based On-Line Consultation** — This is defined as a clinical consultation provided by a medical provider to a patient using the Internet or other similar electronic communications network in which the provider expects payment for the service. An on-line consultation that is given in exchange for payment introduces additional risks. In a fee-based on-line consultation, the health care provider has the same obligations for patient care and follow-up as in face-to-face, written, and telephone consultations. For example, an on-line consultation should include an explicit follow-up plan that is clearly communicated to the patient.

In addition to the 10 guidelines stated above, there are additional considerations for fee-based on-line consultations. For instance, on-line consultations should occur only within the context of a previously established doctor-patient relationship that includes a face-to-face encounter when clinically appropriate. Records pertinent to the on-line consultation must be maintained as part of, and integrated into, the patient's medical record. Also, the patient must be clearly informed about charges that will be incurred, and that the charges may not be reimbursed by the patient's health insurance. If the patient chooses not to participate in the fee-based consultation, the patient should be encouraged to contact the provider's office by phone or other means. ■

E-mail system can triage, allay communications fears

An e-mail system that triages messages from patients to their doctors can help overcome many of the concerns that doctors have about electronic communication, and increase the amount and quality of communication between providers and patients, according to a recent study.

But it doesn't cut the number of phone calls or office visits patients make, or the number who miss their appointments.

These results, from the first large randomized, controlled study of e-mail communication between physicians and patients, were presented recently by researchers from the Ann Arbor-based University of

Clinical trials harmed by lack of informed consent

The mention of clinical trials often triggers a silence between physician and patient, usually because neither one knows much about the subject. Nearly 80% of physicians admit they would like to know more about clinical trials so they can help their patients make an informed decision before volunteering to participate.

"Most subjects enrolled in clinical studies have a meager understanding of what they have gotten into," says **Alan Sugar**, MD, chairman, New England Institutional Review Board and professor of medicine at Boston University School of Medicine. "Informed consent has largely focused around the signed form and has not practically become the continuous process that it needs to be. As a result, a subject's misunderstandings largely go unchallenged."

Properly informing patients is not only ethically necessary, say clinical trials experts, but it also ensures better trials and data. Last year, more than 17 million people thought seriously about participating, but only a few million actually completed their trials. And even among them, many gave their consent without a thorough knowledge of the facts. Indeed, patients can be so daunted by questions and lack of information that they simply decide not to volunteer.

"There's a simple ethical mandate that you don't ordinarily do dangerous things to people without their knowledge and consent," says **Dale E. Hamerschmidt**, MD, FACP, associate professor of medicine and director of Education in Human Subjects' Protection for the University of Minnesota Medical School in Minneapolis. "From a more pragmatic perspective, a well-informed subject is likely to cooperate better with the trial and is more likely to report potential problems. The quality of the data and the safety of the trial are both enhanced when the subjects really know what's going on."

A new resource, written for doctors and clinical trial participants, can help answer some of these tough questions. Boston-based CenterWatch, the leading publisher of clinical trial news and information, now offers *Informed Consent*, a guide to the risks and benefits of volunteering for clinical trials.

Informed Consent is a step-by-step guide that begins with a history of the clinical trials industry, explores the drug development process, and shows how a new drug makes its way to the marketplace. It also details why people decide to participate, how to find clinical trials, how to research clinical trials and evaluate their risks, how to ensure proper informed consent, what the vulnerable populations are, and what to do when things go wrong. Cost is \$16.95, and can be ordered from CenterWatch at (800) 765-9647, or by faxing (617) 856-5901. It also can be ordered through www.centerwatch.com, www.amazon.com, and www.barnesandnoble.com. ■

Michigan Health System (UMHS) at the annual meeting of the Society for General Internal Medicine. The e-mail study was funded by Intel Corp. and performed by members of the UMHS Consortium for Health Outcomes, Innovation, and Cost-Effectiveness Studies (CHOICES). Among other findings, it showed that the messages from patients that got through the system to the doctors were appropriate ones that the doctors needed to see or answer, such as patients' updates on their condition, questions about their health, and prescription and referral requests, says **Steven Katz**, MD, MPH, director of the study and an associate professor of internal medicine and health management & policy at UM.

"Medicine has lagged behind the rest of the world in using e-mail and the web to communicate important, time-sensitive information and conduct transactions, but the concerns that have held us back seem to decrease when we provide a framework for this kind of interaction," Katz says.

David Stern, MD, PhD, an assistant professor of internal medicine, a fellow researcher in the study,

says the results should reassure physicians and risk managers who are reluctant to use e-mail for communicating with patients.

"We hope our studies will help guide the evolution of the kind of electronic communication and access that many of our patients and peers tell us they want," Stern says. "Further research is needed on other issues and concerns, but this is a good first step toward establishing a model for Internet-based physician-patient links."

Surveys by UMHS researchers and others have found that the public and physicians want to communicate with one another by e-mail and the web, but concerns about cost, time, convenience and privacy have slowed the use of these new technologies in health care. The UMHS e-mail study being presented at SGIM pitted conventional, uncontrolled e-mail against a system in which patients were asked to send e-mails to a single e-mail address where they could be sorted and triaged by clinic staff and nurses, then sent to the patient's physician if appropriate. The system is called the Electronic Messaging and Information Link, or E-MAIL.

The researchers randomized 98 UMHS primary care physicians and residents in two clinics to either the E-MAIL system or the conventional system. The patients of the 50 doctors randomized to the E-MAIL system received information on how the system worked and encouragement to use it.

Those patients whose doctors were randomized to no intervention could still connect with their doctor through the usual ways — mostly phone and office visits, but occasionally by e-mail.

The study recorded how many patient e-mails, calls, and appointment no-shows occurred

Audio conference

(Continued from cover)

or does not need to be a high priority. The audio conference **Complying with JCAHO Pain Management Standards: Is Your Facility at Risk?** is scheduled for Oct. 8, from 2:30-3:30 p.m., ET. Conference speakers **Patrice L. Spath**, RHIT, and **Michelle H. Pelling**, MBA, RN, will teach participants how to:

- **Comply** with the new Joint Commission on Accreditation of Healthcare Organization standards relating to pain medication range orders and titration.
- **Integrate** the Joint Commission's "Speak Up" campaign into your patient education initiatives. The groundbreaking program encourages patients to become active, involved, and informed participants on the health care team.
- **Develop** a performance measurement system to evaluate the effectiveness of pain management and continually monitor and improve outcomes.
- **Avoid** documentation deficiencies and staff complacency that can derail your pain management program.

"Hospitals must have a systemwide standard of care for pain management that will reduce patient suffering from preventable pain," says Spath. "Failure to meet this standard of care can result in a Type I recommendation from JCAHO. But more important, inadequate pain management will undermine patients' confidence in the quality of care provided by your health care facility."

A Type I recommendation would require your health care organization to resolve insufficient or unsatisfactory pain management standards compliance in a specified amount of time to maintain your accreditation.

This audio conference is a must for hospital nursing directors and staff nurses, pharmacists, pain management team members, quality directors, risk managers, accreditation/compliance directors, patient educators, case managers, ED managers/nurses, same-day surgery managers, and home health managers.

Federal regulators are turning up the heat on needle safety compliance, increasing inspections and issuing more than a million dollars in fines in less than a year.

Emboldened by new federal laws, the Occupational Safety and Health Administration (OSHA) dramatically has stepped up enforcement of needle safety

provisions. In a flurry of activity between July 2001 and May 2002, OSHA issued a staggering 1,876 citations for those who still haven't gotten the message that needle safety now is the law of the land. These unfortunate facilities were slapped with \$1.3 million in fines, and contrary to popular belief, only about 20% of the expensive inspections were prompted by an employee complaint.

With random visits a possibility, you need to know the latest regulatory information to ensure you can pass muster with OSHA while protecting your employees and patients. **Sharps Safety Compliance: How to Avoid OSHA Citations and Costly Fines** is slated for Wednesday, Oct. 23, 2002, from 2:30-3:30 p.m., eastern time, our program will feature practical handouts and guidance along with the answers to some of your most pressing questions. OSHA expert **Katherine West**, BSN, MEd, CIC, veteran infection control consultant at Infection Control/Emerging Concepts in Manassas, VA, will review the latest OSHA requirements and give you the inside tips necessary to pass any future inspection with flying colors.

Bruce E. Cunha, RN, MS, COHN, manager of health and safety at Marshfield (WI) Clinic, has 24 years working experience on the front lines of occupational health and safety. He will provide vital insight on what practitioners can do to ensure safety for clinical procedures for which there are currently no safety needles available.

This conference is critical information for infection control professionals, employee health professionals, ED managers, physicians, nurses, risk managers, compliance directors, case managers, home health professionals, and same-day surgery managers.

Educational programs for hospital staff at all levels can ensure that sound pain management and sharps safety standards are understood and put into practice throughout your facility. To sign up for either conference, call AHC at (800) 688-2421 and mention effort code **62751** for pain management and **62761** for sharps safety. The facility fee for each program is \$299, which includes free CE for pain management and free CE or CME for sharps safety. Also included with each conference package are program handouts and additional reading, a convenient 48-hour replay, and a conference CD. If you sign up for both audio conferences, your cost is only \$500. That's a *\$100 discount*. Don't miss out! Educate your entire facility for one low fee. ■

between both groups over a nine-month period. The researchers also surveyed all the study physicians and a random sample of their patients, to assess attitudes toward electronic patient-provider communication and satisfaction with care. With patients' consent, they also analyzed the content of patient messages that the E-MAIL system sent to physicians.

In all, patients in the E-MAIL system group sent messages to their doctors at up to five times the rate of patients in the control group, reaching 49 messages per 100 scheduled visits midway through the study.

A chief concern among those resisting the routine use of e-mail between doctors and patients has been the issue of appropriateness — the fear that patients will send messages to their physicians that are irrelevant, frequent, complex, or could be handled by others.

The E-MAIL triage system used in the study was designed to allay that fear. It passed all patient e-mails through nurses and other staff first, allowing them to process requests and questions like those they would normally handle if they came in through the clinic's phone triage system. Patients were asked to keep their e-mails focused on one question or piece of information.

The largest percentage of these messages — 27% — turned out to be from patients who wanted to provide their physicians with an update on their condition or events such as emergency room visits or medication side effects, says researcher **Casey White**, assistant dean for medical education at UM Medical School. White analyzed the content of a random sample of 359 of the 1,629 messages received by the E-MAIL account. "This kind of use highlights the need to ensure that electronic communication between patients and providers is appropriately documented in medical records."

White and her colleagues also found that 18% of the messages were about prescriptions, 10% asked the physician to refer the patient to a service or specialist, and 5% asked for the results of laboratory tests. Only 9% asked the physician a health question. Importantly, just a few messages were judged inappropriate, irrelevant, or too complicated for physicians and staff to handle.

Patients and especially physicians who took part in the E-MAIL system were much more likely than those in the control group to see e-mail as a good way to communicate. There was no difference between the study groups in general satisfaction with clinical care. ■

Deaths, injuries often come from multiple failures

Ventilator-related deaths and injuries often are caused by multiple system failures, especially in the intensive care unit (ICU), according to a recent report from the Joint Commission on Accreditation of Healthcare Organizations.

As of January 2002, the Joint Commission had reviewed 23 sentinel events that involved deaths or injuries related to long-term ventilation. Nineteen resulted in death and four in coma. Of the 23 cases, the Joint Commission says 65% were related to the malfunction or misuse of an alarm or an inadequate alarm; 52% were related to a tubing disconnect; and 26% were related to a dislodged airway tube.

Healthcare Risk Management® (ISSN 0199-6312), including **HRM Legal Review & Commentary™**, is published monthly by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to Healthcare Risk Management®, P.O. Box 740059, Atlanta, GA 30374.

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Editorial Questions

For questions or comments, call Greg Freeman, (770) 998-8455.

“A small percentage of the cases were related to an incorrect tubing connection or wrong ventilator setting,” the Joint Commission reports. “None of the cases were related to ventilator malfunctions. As the percentages indicate, ventilator-related deaths and injuries are often related to multiple failures that lead to negative outcomes. The majority of the cases occurred in hospital ICUs, followed by long-term care facilities and hospital chronic ventilator units.”

When the root causes were analyzed, 87% of the incidents involved inadequate orientation or training processes and 35% included insufficient staffing levels. Seventy percent of the cases involved a communication breakdown among staff members; 30% were related to improper room design that limited the observation of the patient; and staff did not respond immediately to ventilator alarms in 22%.

“In addition, several organizations found that during the use of low airway pressure alarms only, some ventilators did not always respond to tubing disconnects at all levels of the airflow circuit,” the report states. “For example, the disconnected airway tube may fall into the bedding or against the patient’s body, ventilation cycling continues, and the ventilator continues to receive indications of correct air pressure.”

The Joint Commission advises risk managers to ensure that their organizations adhere to guidelines from the Food and Drug Administration and the American Association of Respiratory Care (AARC) for testing and evaluating ventilators. The AARC Clinical Practice Guideline for patient ventilator systems recommends that:

- Professionals responsible for application, adjustment, and monitoring of ventilators, alarm systems and airways, possess relevant education, and have undergone validated competency testing.
- Systems are in place to check ventilator and monitoring system performance before and during clinical use.
- All devices and systems are maintained according to manufacturers’ specification. This includes medical gas systems.
- A tracking system is in place to identify, analyze, and remedy all ventilator-related incidents that lead to serious injury or death.
- Protocols for the application and discontinuance of mechanical ventilation are in place.
- A mechanism is in place to track outcomes of all ventilator patients.
- Organized, periodic, ventilator-related continuing education is accessible to those professionals

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responsible for the many components of care directed to ventilator patients.

In addition, the Joint Commission makes these recommendations:

- Review orientation and training programs for job-specific, ventilator safety-related content and include in competency assessment process.
- Review staffing process to ensure effective staffing for ventilator patients at all times.
- Implement regular preventive maintenance and testing of alarm systems.
- Ensure that alarms are sufficiently audible with respect to distances and competing noise within the unit.
- Initiate interdisciplinary team training for staff caring for ventilator patients.
- Direct observation of ventilator-dependent patients is preferred in order to avoid overdependence on alarms. ■



A failure to communicate leads to an \$880,000 verdict

By **Jan J. Gorrie, Esq.**, and **Seema Patel**
Buchanan Ingersoll Professional Corp.
Tampa, FL

News: The victim of an armed robbery was taken to a emergency department (ED) after receiving two gunshot wounds — one to the thigh and one to the chest. The chest wound resulted in a left hemothorax, which was treated by the on-call trauma surgeon. Damage to the patient's lung required vascular surgery. The surgery became increasingly complex, so the patient was referred to a neurosurgeon for additional treatment. After surgery, and an unremarkable stay in the recovery room, the patient was placed in the intensive care unit (ICU), where he quickly deteriorated and died. The patient's wife brought suit against several, but not all of the treating physicians, as well as the hospital. The jury found that the attending trauma surgeon and anesthesiologist met the standard of care, but held the hospital responsible for inadequate monitoring of the patient and awarded the plaintiff \$880,000 in damages.

Background: The patient was shot twice, in the upper left chest and upper left thigh, during an armed robbery assault at his business. He was transported by ambulance to a hospital. The on-call trauma surgeon determined that his leg wound was not serious and focused on the chest wound. Decreased breath sounds and a chest X-ray revealed a lung injury and a left hemothorax. The trauma surgeon treated the hemothorax by inserting a chest tube. A moderate amount of blood was drained initially, but there was no subsequent bleeding. A follow-up chest X-ray showed resolution of the hemothorax and

re-inflation of the patient's lung. The patient remained stable, alert, and oriented in the ED.

Further examination revealed possible vascular damage, so the trauma surgeon consulted with a vascular surgeon, who determined that the subclavian artery had been damaged and required immediate repair. The vascular surgeon took the patient into surgery, and the trauma surgeon continued to treat other patients in the ED.

During surgery, the vascular surgeon and his assistant took a vein from the patient's leg to graft into the damaged subclavian artery. The repair was initially successful and there were no complications. However, during the procedure, the vascular surgeon discovered an injury to the brachial plexus nerve complex, which is close to the subclavian artery. Without consulting the trauma surgeon, the vascular surgeon called in a neurosurgeon to repair the damaged nerve.

The nerve repair extended the surgery for another hour or more, after which the vascular surgeon discovered that his vascular graft had clotted off. This required the reopening of the vessel, removal of the clot, and administration of a second dose of heparin, an anticoagulant, which was left unreversed. In addition, the vascular surgeon used a suction device to clear the surgical field during the operation. While suctioning blood, the vascular surgeon entered the pleural cavity, which negated the therapeutic effects of the chest tube that had been placed by the trauma surgeon. A large but underestimated amount of blood was removed.

The patient was then transferred to the recovery

room with the heparin in full effect, meaning the patient's blood could not clot. Before leaving for home, the vascular surgeon then instructed recovery room nurses to contact the trauma surgeon for any problems with the chest tube. Postoperatively, the trauma surgeon was to resume the primary care of the patient. The trauma surgeon did stop by the recovery room to examine the patient. At the time of the visit the patient was stable, with good vital signs, no significant drainage into the chest tube, and a new chest X-ray showed no further bleeding from his lung.

By all outward appearances, the patient was doing well. With no reports from the vascular surgeon, neurosurgeon or anesthesiologist regarding the extension of the original or subsequent surgeries, as well as the complications encountered in both procedures, the trauma surgeon felt that the patient's condition was stable.

After the patient was transferred from the recovery room to the ICU, the trauma surgeon was called by the ICU nurse and told the patient's blood pressure had fallen. The attending trauma surgeon ordered lab work and blood for a possible transfusion. Shortly thereafter, a second phone call informed the trauma surgeon that the patient was in cardiopulmonary arrest. The trauma surgeon ordered that the blood be hung for infusion STAT. In surgery he opened the patient's chest to resuscitate him, but the patient remained unresponsive and died shortly thereafter. The trauma surgeon later learned that the patient had been fully anticoagulated in recovery and in the ICU, and he probably had lost more blood in surgery than the vascular surgeon had estimated. Those combined factors probably caused the patient's condition to deteriorate until he was unable to compensate for the total blood loss.

The plaintiff, the patient's wife, brought a wrongful-death action against the hospital, trauma surgeon, and anesthesiologist. Neither the vascular surgeon nor neurosurgeon were named in the suit. The plaintiff claimed the trauma surgeon failed to recognize the continuous bleeding from the patient's lung injury and failed to perform surgery to repair his lung. The wife also claimed that the trauma surgeon should have taken the initiative to find out what happened in the surgeries rather than relying on the vascular surgeon, neurosurgeon, or anesthesiologist to approach him.

The plaintiff also claimed the hospital's nurses failed to monitor the patient closely enough in the recovery room.

Conversely, the trauma surgeon and the hospital

criticized the treating anesthesiologist for not informing anyone of the serious complications encountered during surgery. The trauma surgeon claimed that had he known about the nerve repair, the anticoagulant, and the large volume of blood suctioned from the patient's chest, then his suspension for bleeding would have been higher and more blood would have been provided in the recovery room.

In his defense, the anesthesiologist testified that the standard of care requires discussion about the specifics of surgery take place surgeon-to-surgeon, not surgeon-to-anesthesiologist. The anesthesiologist countered that he had no direct duty to communicate any details to the trauma surgeon.

The court called the vascular surgeon as a witness, and both sides cross-examined him. He admitted seeing the trauma surgeon in the recovery room and that he failed to communicate the intraoperative events.

The jury found in favor of the two physicians, saying they had met the standard of care and were not liable. However, the jury held the hospital responsible for inadequate monitoring of the patient in the recovery room, and awarded the plaintiff damages for the value of the decedent's life, which was set at \$880,000.

What this means to you: Wrongful-death actions are rising due to an aggressive plaintiffs' bar and generally litigious tendencies. Health care providers cry for tort reform at the national and state levels.

That makes this a very unusual case — a moderately high jury verdict against a hospital and no findings of fault for the physicians.

"Based upon the given facts of the case, I am first surprised that the jury did not find against the physicians but found that they had adhered to the standard of practice. Second, it is unclear why the plaintiff chose not to name the vascular surgeon given his admitted failure to communicate with the attending physician. And third, I am surprised that the jury only found against hospital on issue of inadequate monitoring of the patient in the recovery room," observes **Stephen Trosty**, JD, MA, director, risk management consulting, APAssurance, of East Lansing, MI. "Procedurally, the plaintiff's attorney appears to have made a major error in not naming the vascular surgeon as a defendant. Given the vascular surgeon's active involvement in the treatment of the patient and his testimony admitting his failure to confer with trauma surgeon or inform him of major occurrences/problems/treatment issues related to patient, it is remarkable

that he was not a party to this action. The vascular surgeon was directly involved in performing the graft to repair the damaged subclavian artery, removal of the clot from the vascular graft, administering second dose of heparin and leaving it unreversed, entering the pleural cavity while suctioning a large amount of blood, and negating the therapeutic effects of the chest tube inserted by the trauma surgeon.

“None of this information was shared with the trauma surgeon by the vascular surgeon. The large amount of blood loss experienced by the patient can be directly related to the actions of vascular surgeon and the fact that the patient’s blood would not clot. These events were directly related to the patient’s cause of death and the fact that this physician was not named is a mystery to me,” he adds.

Communication among caregivers is critical to the delivery of quality care. Even if the physicians had chosen to not communicate directly with one another, the patient’s medical record should have been available and should have contained contemporaneous postoperative by all of the surgeons and the anesthesiologist.

“However, in this case there was a total lack of communication between the three surgeons and the anesthesiologist involved in the care of the patient. Important facts that should have been shared with the trauma surgeon as the patient’s attending physician, and should have very clearly conveyed to the recovery room and ICU staff. These facts include: 1) The patient was in surgery a long and extended period of time; 2) A second dose of heparin was given; 3) The patient’s blood would not be able to clot due to the fact that the second dose of heparin was left unreversed; 4) A large amount of blood was suctioned from patient during removal of the clot; and 5) The pleural cavity was entered, thereby negating the positive effects of the chest tube. This was all critical information for the trauma surgeon, as well as the recovery room and ICU hospital staff to have. This case required extremely close and constant monitoring of the patient, beyond what would normally occur if these ‘problems’ had not occurred and the additional surgeries had not been required,” adds Trosty.

“Finally, as for the finding against the hospital for inadequate monitoring, it seems that patient was monitored but that the actions of the physicians were not. In defending such actions, one can never underestimate the power of the jury and its tendency to go with the person, a/k/a physician, as opposed to the institution, a/k/a hospital. The outcome of this case exemplifies this phenomenon. At

trial, facilities should always have a personal representative from the hospital and, when possible, have hospital personnel testify so that a face can be associated with the institution,” concludes Trosty.

Reference

• *Blanch Lee, et. al. v. Michael J. O’Reilly, MD, Christopher W. Stowell, MD, and Kennestone Hospital, Cobb County (GA) State Court, Case No. 96A-7013-2.* ■

Pierced ear is amputated: \$2 million verdict in PA

News: A 21-year-old woman visited an emergency department (ED) complaining of tenderness and swelling in her right pinna, the outer structure of her ear. She was given antibiotics and sent home. In the next nine days, she returned to the ED three times for the same problem. During her last visit, she was admitted and tests revealed an infection that was not treated by the prescribed antibiotics. Because of the advanced stage of the infection, the only option was to remove portions her pinna, resulting in a structural deformity.

A jury awarded her \$2 million.

Background: On May 19, 1997, the young woman, who had recently had her ears pierced, went to an ED complaining of tenderness and swelling in her right ear. She was examined by an ED physician, who noted the infection and prescribed the antibiotic Keflex.

Because her condition worsened, she returned to the ED on May 25 and was seen by a different physician, who consulted with a plastic surgeon who recommended an incision and drainage of the ear.

Despite making the consult, the ED physician ignored these recommendations and discharged plaintiff, instructing her to use warm soaks and continue the Keflex.

The next day, the young woman returned to the hospital and was seen by a third ED doctor, who aspirated the ear with a needle and sent the fluid to the hospital lab for culture and sensitivity tests. Results were to be returned after 48 hours. He did not ask for a gram-stain test, which may have given relevant information about the infection within an hour. This ED physician changed the patient’s antibiotics, as it seems the Keflex

was ineffective. The young woman was told to see a plastic surgeon.

On May 28 the plastic surgeon made an incision in the ear, drained the fluid, and admitted her to a hospital. The culture and sensitivity test results were then available and showed an infection caused by *Pseudomonas aeruginosa*, a bacteria that the two previous antibiotics did not treat.

The following day, the plastic surgeon removed a substantial portion of the plaintiff's pinna to treat the infection. After surgery, plaintiff's ear was structurally deformed. She was given new antibiotics and discharged June 2.

The patient claimed that the second and third ED physicians delayed the correct diagnosis by failing to follow the advice of the consulting plastic surgeon. She also argued that another alternative would have been a gram-stain test, which would have shown the infection earlier and allowed treatment as early as May 25 or 26. She claimed damages of pain and suffering, emotional distress, embarrassment, and humiliation, disfigurement, loss of life pleasures, and possible future medical expenses. Plaintiff also presented evidence showing that later surgery could worsen her condition and was unlikely to improve her structural deformity. While a trial was pending, the plaintiff suffered from a psychiatric disorder due to her deformity.

The charges against the first ED doctor, the consulting plastic surgeon, and the treating plastic surgeon were dismissed. The parties stipulated that any charges against the second and third ED physicians would be molded to be a verdict against the hospital because both doctors were hospital employees.

The jury, upon finding the second ED attending physician to be 70% negligent and third ED doctor to be 30% negligent, awarded the plaintiff \$2 million.

What this means to you: What may have been a minor infection became an ordeal resulting in disfigurement. The problems may have been prevented with proper communication between physicians, the ordering of proper tests, and adherence to the recommendations of consultants.

"As we begin review of this scenario, we must keep in mind that it is usual practice for the medical record to be pulled and available to the ER physicians for review so that the medical history and previous visits are known to the treating physician. Risk managers should investigate the process for pulling old records for each patient's visit to the ER," states **Leilani Kicklighter**, RN,

ARM, MBA, CPHRM, CHt, director, risk management services, of the Miami Jewish Home and Hospital for the Aged, Miami.

"Keflex, a broad spectrum antibiotic, is often proscribed for infections on an outpatient basis. Although discharge instructions are unknown, when six days later the patient returned to the ER and the tenderness and swelling has gotten worse, the consult was an appropriate step. However, ignoring the suggestions that were requested is troublesome. At this point, even though the signs and symptoms had gotten worse, and a surgical [plastic] consultant recommended definitive treatment, the ED physician chose not to follow the consultant's recommendations, and at this point we do not know if there is any documented support for this decision. In addition, even though the ear was worse than at the visit six days earlier, the antibiotics were not changed, and there is no evidence that the Keflex was continued. A gram stain may have indicated a change in antibiotics but would not have reflected the sensitivity to the antibiotic. Although, it is possible a gram stain may have provoked the doctor to make a change in the antibiotic prescribed," adds Kicklighter.

"The risk manager should refer this case to the peer review. A consultation with a pathologist to review the current standards for indications for gram stains, and the location and set up of the gram-stain area in case there is some aspect that deters the use of the area. It might be worthwhile to refer this case to infection control and the physician director of infection control to determine if there is an opportunity to conduct educational programs to revisit antibiotic use in general and how gram stains can guide use of antibiotics. It is interesting to see that the culture when eventually taken, grew *Pseudomonas aeruginosa*, which is often associated with moisture. This raises the question of whether this was a contamination at the time of the initial piercing, or contamination later from hair washing or other water use in the area. Which in turn raises the question, should this infection be reported to the area health department if the piercing were done in a business setting? In addition the risk manager should review the medical records from each of this claimant's visits to the ED to ascertain if there is appropriate documentation and justification for medical decisions," concludes Kicklighter.

Reference

• *Jeanine Saunders v. Crozer Chester Medical Center, et al.*, Philadelphia City (PA) Court of Common Pleas, Case No. 3933. ■