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Future looks bleak as malpractice premiums continue upward spiral

Insurers increasing rates to make up for past mistakes, rise in jury awards

Malpractice insurance premiums have dramatically increased in the past year and the future looks just as bad, maybe worse. Insurance industry analysts are warning risk managers to brace for sharply increased insurance premiums in the next year as insurers try to adjust to a decade of underpricing their products.

Rates are soaring higher than anyone has seen since the mid-1980s, with many insurers raising rates more than 30%. The sharp increases began in 2000, when insurers began to feel the effects of years of price competition that left many insurers unprepared for the cost of claims. The trend picked up speed in 2001, and observers say they see worse days ahead.

"It looks pretty grim," says **R. Stephen Trosty**, JD, MA, director of risk management at American Physicians Assurance Corp. in East Lansing,

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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. ■

MI. "I don't think we've seen the crest yet. It can still get worse before it starts getting better."

Trosty agrees with most other observers that the health care industry will see at least another year of increasing malpractice insurance premiums before costs level out. Similar concerns come from **Larry Smarr**, president of the Physician Insurers Association of America, a national association of 53 physician- and dentist-owned or directed medical liability insurance companies that collectively insure more than 235,000 physicians and dentists. "Things will get worse," he says. "It's not good news. It's bad and it's going to get worse, I'm afraid."

Increases across the board

Thirty-percent increases are the norm in some states and for some insurers, but financial analyst A.M. Best reports that even the insurers considered most conservative with rates — those owned by doctors and hospitals — are increasing premiums by 10% to 18%. With the recent increases, doctors in New York and Florida commonly pay more than $100,000 for $1 million in coverage.

Many insurers also are reducing coverage amounts and raising deductibles, another way to raise the overall cost of insurance. Insurers blame the increases on the recent trend toward larger jury awards, saying they are only passing on the cost of doing business. The number of malpractice cases has held steady for years, but Jury Verdict Research in Horsham, PA, reports that the average jury award was $3.49 million in 1999, up an astounding 79% from $1.95 million in 1993.

Malpractice cases are costing more these days, but analysts say that is not the only reason for the huge increase in rates. Perhaps even more influential is the fact that insurers grossly miscalculated insurance premiums in the 1990s. The result was that health care providers were getting a sweet deal for years and now the premiums are being raised to rates that more accurately reflect the insurers' costs.

Smarr explains that the chain of events started in 1983, when "claim frequency was headed up like a rocket." The insurers raised rates, but then claim frequency peaked a few years later. Since medical malpractice claims are paid about 54 months after they happen, it takes a while for the industry to recognize a change in direction. That meant rates were too high in the late 1980s and companies had a lot of excess profits.

Those profits and the too-high rates allowed companies to get very competitive. Too competitive, it turned out. "We had it good for a while and never realized it," Trosty says. "Unfortunately, sometimes in the desire to increase business a company doesn't always remain true to solid underwriting procedures. They take on more risk for less money because they want the business. After a while, that's going to catch up to you."

And it did in the mid- to late 1990s, Trosty says. Insurers were hit with a double whammy when they realized they had underpriced their coverage, and then claims severity shot through the roof as well. The 1990s were really a buyer's market for malpractice insurance — though anyone paying the bills for an OB/GYN practice would find that hard to believe — and reinsurance was easy to get. (Reinsurance is like insurance for the insurance company; it pays when the insurance company has a big claim to cover.) Since reinsurance is a key hurdle in entering the insurance market, many new insurance companies flooded the market and offered very competitive rates.

"They came in with low prices to entice customers, sometimes known as buying business," Trosty says. "The result was that a lot of carriers were pricing premiums below where they needed to be, let alone enough to make a profit. That's why you saw a lot of carriers go in to bankruptcy or other dire financial straits."

When insurers started paying more for claims, reinsurers started paying more than they expected to cover the insurers' losses so they started going out of business. Suddenly, reinsurance wasn't so easy to find and wasn't so cheap. In some parts of the market, such as long-term care, claims frequency and severity increased even more and forced many insurers out of the market.

COMING IN FUTURE MONTHS

- Reporting another provider's adverse event?
- Finding the best consultants for Joint Commission surveys
- CDC's smallpox plan — what you need to know
- Surgeon sues hospital for suspending medical privileges
- Criminalization of medical errors

All of those factors came together at the same time, and malpractice insurers suddenly woke up from their 1990s stupor and started raising rates as fast as they could print the notification letters. Trosty points to another factor that may have increased claims frequency and severity in the past couple of years. The 1999 Institute of Medicine (IOM) report on medical errors, *To Err is Human,* greatly increased awareness among the general public of medical errors, and Trosty hypothesizes that it could have prompted lawsuits.

"The IOM report had gone a long way toward educating the medical community and patients, but sometimes it makes people look harder at things they might have dismissed," he says. "And it drew attention to the fact that the medical community is not always forthright about medical errors and injuries, and that has caused some anger. With the anger comes the desire to get the answers or to get even."

Position yourself for best rates

Ongoing developments in the health care system could aggravate the situation and spur even higher rates in the next few years, Smarr predicts. Efforts to make it easier for patients to sue health plans could affect insurance rates, for instance, because plaintiffs will find a way to include providers in those cases.

"And if we don't get tort reform, I only see rates going higher," he says. "A million-dollar payment is not a big deal anymore, and until we get a hold on the trial attorneys and how they are milking the system, I see no end in sight."

The future looks expensive, so Trosty says risk managers should react by positioning themselves for the very best rates available. If you want to lessen the pain of the increases, show the insurer that you're a good risk. **(See article, right, for more on how to get the best rate.)**

Smarr says there also is a lesson to be learned from the experience. Even though the health care industry as a whole benefited for years from low insurance rates, some providers were burned when those insurers went out of business or suffered other financial problems that compromised their coverage. And many others are having to deal with the sudden budget crisis of insurance premium increases in the double digits. Watch for deals that sound too good to be true.

"Everyone should be aware that there really is no free lunch in this business," he says. "When you see one carrier offering a product at a greatly discounted price, you need to take a long hard look at that company. You may end up with no insurance." ■

Blow your own horn to prove you're the best risk

Risk managers can't stop the insurance industry from raising insurance premiums, but you can make sure you get the very lowest rates available. **R. Stephen Trosty**, JD, MA, director of risk management at American Physicians Assurance Corporation in East Lansing, MI, says this is no time to be shy.

Premiums are going up, but they're not going up at the same rate for every hospital. If you deserve the better rate, now is the time to say so.

"You have to blow your own horn," he says. "Don't be content to let the insurer just look at claims and severity, especially if they're not all that great. You must take the initiative and make your case for a lower rate, because if you don't, you'll just be one more provider getting hit with a huge increase." Trosty suggests these moves to get the lowest available premium:

- **Review your policies and procedures (P&P), then show them off.** Review your P&P to make sure you're handling potential litigants in the most proactive way possible. Analyze the approach your staff take when there is an adverse event. Do you have mechanisms in place for talking honestly to the patient without necessarily indicating that malpractice has occurred? Do you trace problems to their origin and learn how to prevent them?

"Show the insurer that these are more than just policies in a big book on the shelf," Trosty says. "Show that you actually use them. Show the corrective action you take after an incident and how you use your policies and procedures to respond and learn from them."

- **Avoid admitting fault too soon.** There has been a lot of emphasis lately on communicating with patients after adverse events and honestly conveying the facts. That's a fine attitude, but Trosty cautions that you must not be too eager to admit fault. Your insurer will be reassured to hear that you don't jump the gun.

"Sometimes when the pendulum has been too far on one side, it goes far in the other direction when we try to correct the situation," he says.

"Take the time to investigate."

• **Investigate near misses.** Risk managers should do a better job of collecting data, especially on events that never result in a lawsuit. The near misses deserve serious investigation and can offer major lessons. Make sure your insurer knows that you investigate those near misses and try to learn from them.

• **Show your works in progress.** Many significant improvements are long-term projects, so you may not be able to point to them yet as a completed effort with proven results. But you still should point them out to your insurer. Moving to electronic records, for instance, can take years to implement. While you're working on it, show the insurer what you're doing and why. "Some things can't be done overnight, but show that you're working toward them and have a timetable for implementing them," he says. "That matters." ■

High premiums for docs to cut back on purchases

High malpractice insurance premiums are having a chilling effect on health care, forcing doctors to cut back on necessary supplies and services, according to a survey of Pennsylvania physician practices.

Spurred by skyrocketing malpractice awards, physicians are closing smaller branch offices and cutting back on office staff, says **Howard A. Richter**, MD, president of the Pennsylvania Medical Society. Patients are feeling the effect in the form of fewer available health care services.

"The soaring cost of liability insurance may be dragging down the availability of health care," Richter says. "Our primary concern is the effect of the malpractice climate on patients' access to medical care. The quality of our medical resources should not be compromised by unnecessary economic factors and, sadly, that's what's beginning to happen."

A recent survey of Pennsylvania Medical Society members backs him up. The response shows that 72% of the doctors said they have deferred buying new equipment or hiring new staff due to sudden increases in their liability costs. To prevent the siphoning of dollars from health care improvements, the Pennsylvania Medical Society made the reform of medical liability laws its top legislative priority for 2001-02.

"We're working to reform — not abolish — medical liability laws," Richter says. "We support the existence of reasonable laws that protect patients. But abuse of the system with frivolous lawsuits and unreasonable jury verdicts has financially strained the majority of Pennsylvania physicians struggling with outlandish insurance premiums."

High costs in Pennsylvania

Medical liability insurance costs more in Pennsylvania than almost anywhere else in the nation, according to statistics supplied by the medical society. Doctors there pay higher rates by far than their peers in every medical specialty in seven surrounding states. And the rates keep going up. On the heels of a 21% to 60% rate hike for 2001, insurance carriers have requested increases as high as 70% for 2002. Driving premiums through the roof are excessive sums awarded in malpractice suits. Pennsylvania ranks second among states in terms of total payouts for medical litigation. "The numbers are off the charts," Richter says.

Combined judgments and settlements for fiscal year 2000 amounted to $352 million — roughly $30 per state resident and nearly 10% of the U.S. total. To fend off litigation and cope with steep premiums, Richter says doctors are being forced to take these defensive measures:

• They feel pressured to order extra tests that could be expensive or unnecessary.

• Medical practices are discontinuing high-risk services, such as delivering babies. Richter tells of an OB/GYN group where insurance premiums nearly tripled in 2001 to almost $1 million. When two of their seven physicians stopped delivering babies, the rates were cut in half.

• Many medical school graduates are shying away from specialties, like OB/GYN, that are magnets for malpractice suits. The result: fears of a shortage in several specialties and a harder time for patients trying to find needed treatment.

• Some older doctors are throwing up their hands and calling it quits altogether, taking valuable years of medical experience with them.

"It doesn't take a rocket scientist to see that the malpractice quagmire is bogging down the entire health care system and shortchanging patients," Richter says. "Reforming the liability laws to eliminate frivolous malpractice suits and reduce unrealistic damages will free up funds needed to enhance the healing environment and improve our health care system." ■

Threats create a need to coordinate with providers

As the nation's health care system continues to prepare for terrorist attacks, risk managers are finding new tasks that may pose unforeseen challenges. Risk management leaders caution, however, that you should not focus so much on those difficulties that you put up roadblocks when your health care provider is trying to take necessary steps.

Risk managers will find a number of new tasks to tackle in the coming months, most of them related to improving the hospital's disaster plans. Though you should take those tasks seriously, you shouldn't be overwhelmed by the risk management implications of the changes, advises **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 cautions that risk managers could become the naysayers at a time when they should focus on being part of the team.

"The nation is at war, so let's not throw up roadblocks where none are needed," she says. "We're trying to get away from the image of risk managers as the people who always point out the negative and get in the way of progress. That's not what we are and this is a good opportunity to show that."

Don't cry wolf

But risk managers have a fine line to walk, she admits. There are some legitimate risk management concerns arising from the health care industry's response to terrorism — confidentiality concerns, for example — and Porto says she has no doubt that risk managers will be on top of those issues. She's more worried that they will go overboard.

"This should be a team effort among everyone in the organization, and the risk manager should work hard to be a constructive part of the team," she says. "We don't want to start crying wolf now."

Risk managers likely will be concerned about a recent directive from the Joint Commission on Accreditation of Healthcare Organizations that calls for more explicit, in-depth coordination between health care providers in a local community. That could lead to some dicey confidentiality problems.

The Joint Commission recently added a new requirement to E.C.1.4, the standard requiring each organization to have an emergency management plan. Noting that "the experiences of health care organizations responding to the September 2001 terrorist attacks in New York City and Washington, DC, "showed gaps in the way hospitals cooperate during a community disaster, the Joint Commission added a clause requiring "cooperative planning." The goal of that planning should be to facilitate the timely sharing of information about:

- essential elements of their command structures and control centers for emergency response;
- names, roles, and telephone numbers of individuals in their command structures;
- resources and assets that could potentially be shared or pooled in an emergency response;
- names of patients and deceased individuals brought to the organizations to facilitate identification and location of victims of the emergency.

Robert Wise, MD, vice president in the division of research at the Joint Commission, says the commission realized that in a communitywide disaster, "it's not going to work to have each organization trying to decide what to do on their own." Wise notes that though the new language has only been added to the intent section of the standard, meaning it is technically not a new part of the standard, surveyors will check for compliance with this new clause.

"We will want to see evidence of this later on," he says. "This is a change in a requirement; it's not important whether it's in the intent or the standard."

Porto says the new requirement will force most providers into relationships they've never had with competitors across town. Current community disaster coordination usually focuses on triage and making sure there are enough health services for a mass-casualty incident, but the New York attacks revealed a major weakness: there was no central system for listing patients treated at a number of hospitals. Family and friends were forced to wander the streets, visiting every hospital to look for a missing loved one.

"We hope not to see that again," Wise says.

The Joint Commission indicates that the best way for a hospital or other provider to coordinate with others in the community would be through the existing structures such as local hospital councils or state hospital associations. That is where some risk management issues may crop up because the new focus is on *information* exchange.

One expert on health care confidentiality says there are some issues to work out, but that the real risk may not be as bad as it first sounds.

George Schroeder, BSN, Med, JD, is a principal with RiskNet Consulting in Westminster, CA. He says state privacy laws may pose the biggest challenge for risk managers.

"It is easier said than done to share this information," he says. "What is confidential will vary from state to state. The problem with the Joint Commission is that they are a great advisory body but they have no authority to supercede state law. They are basically encouraging you to maximize what is appropriate to share."

Schroeder points out that the Joint Commission requirement applies only to a disaster situation. It does not require a central database that is available all the time so a person can walk into any hospital and find out where a patient is being treated. In that context, risk managers might find little to balk at when the hospitals set up a plan for sharing patient names. But he has one important caution for risk managers.

"Remember that the intent here is really only to share a list of names, not much else," he says. "If you see that the plan is spiraling and you're getting into sharing more than that, then you could have a problem and you might have to put a stop to that. The people in New York just wanted a name and a hospital so they could find people. That's all."

Share your privacy concerns

Keeping to that minimum amount of information should make it easy to comply with state laws, Schroeder says. A patient list is not necessarily confidential, but any further information about the patient usually is.

The Chicago-based American Hospital Association (AHA) has released new guidelines for releasing information on the condition of patients, in response to the concern about improved information flow after a terrorist attack or other disaster. The recent advisory updates the AHA's 1997 *Guide for the Release of Information on the Condition of Patients.* As part of your disaster plan revamping, the AHA suggests you share the guidelines with public relations and human resources staff, legal counsel, chief privacy officer, and the heads of your compliance and risk management departments, among others. The guidelines also should be incorporated into the overall disaster readiness plans, and the AHA suggests that your public relations staff share the guidelines with local reporters so they will know what to expect when looking for information. It also might be a good idea for the public relations director to hold a joint media briefing with area hospitals during an emergency. **(See article, p. 7 for more on the AHA guidelines.)**

EMTALA and pathogens

Porto points out that one worry among risk managers has been effectively dealt with by federal regulators. With all the concern about a biological terrorist attack, some risk managers worried that it would be practically impossible not to violate the Emergency Medical Treatment and Active Labor Act (EMTALA) without exposing hospital staff to the pathogen. (EMTALA requires that patients be evaluated and stabilized before transferring to another facility.) But the Health and Human Services' Office of the Inspector General recently issued a statement clarifying that EMTALA is not violated if the facility is incapable of treating the victim of a biological attack.

The statement says hospitals must meet EMTALA obligations during a terrorist attack "within the hospital's capability and capacity, and/or within the provisions of a community response plan developed by a state or local government." It goes on to say that there may be situations "where referral of a potentially exposed patient prior to the actual examination is appropriate." When a communitywide program for responding to such an event has been put in place, examination at the first hospital where the patient presents may not be required.

"There may be cases in which state or local governments have developed community response plans that designate specific entities [hospitals, public health facilities, etc.] with responsibility for handling certain categories of patient in bioterrorism situations," the statement says. "The transfer or referral of these patients in accordance with such a community plan would not violate the hospital's EMTALA obligations."

(Editor's note: For more information on preparing for terrorism and other disasters, see the Joint Commission's publication, "Perspectives." The December 2001 issue is a special report on emergency management and contains a wealth of useful information. The issue is available online for free at www.jcrinc.com/subscribers/perspectives.asp?durki=187.) ■

AHA guidelines urge protection of privacy

Much of the new American Hospital Association (AHA) guidelines on patient privacy are driven by the Health Insurance Portability and Accountability Act (HIPAA) of 1996, which specifies the purposes for which information may and may not be released without authorization from the patient. The new guidelines make these major points:

- Inquiries must contain the patient's name, unless the inquiry comes from clergy.
- You may release the patient's one-word condition and location without obtaining prior patient authorization.
- The terms to describe a patient's condition are undetermined, good, fair, serious, and critical.
- The patient's location within the hospital (such as room number) can be included in the hospital directory to facilitate visits by friends and family and delivery of flowers and gifts, but the location within the hospital should not be given to the media.
- The patient must provide written authorization before the hospital can release a detailed statement or allow photographs or interviews with the patient.
- Patients can opt out of providing any information at all. This includes confirming or denying the patient's presence in the facility.
- The health care provider should not release any information that could embarrass or endanger patients. This includes confirming that the patient has an infectious disease.
- The risk manager should exercise good judgment when the patient is unable to express a preference regarding the release of information.
- Celebrities, public officials, and any patient involved in a case that is a matter of public record are entitled to the same protection as any other patient. Even if a patient is involved in a crime, for instance, and information is available from the police as a public record, that does not change the hospital's obligations to protect confidentiality.
- When feasible, notify the next-of-kin first.
- Don't hesitate to cooperate with other hospitals or relief agencies.
- When appropriate, release general information to help dispel public anxiety. For example, you may say that the hospital is treating four adults injured in the explosion, and they are all adult males.
- Work effectively with the media and cooperate within the limits of these guidelines.

(For the entire text of the AHA guidelines, see the web site at www.aha.org/Emergency/Readiness/MaGuideInfoPatientB1108.asp.) ■

$11 million settlement in brain damage case

A Dallas court has approved an $11 million settlement between an Oklahoma woman and her son and the hospital and physician she accused of causing her son's severe brain damage during his birth.

Baylor Medical Center at Garland paid $10.8 million of the settlement, with Erik Gunderson, MD, paying the remaining $200,000, according to Dallas attorney **Jeffrey Rasansky**, JD, who represented the plaintiff. Kristi Hamilton claims that Baylor and Gunderson failed to recognize signs of fetal distress while she was in labor, and that she was allowed to continue to labor when she should have had an emergency cesarean section. When it was apparent she could not deliver her son vaginally, she then was given one.

Kevin Hamilton, who had no heart rate when he was born, suffers from profound brain injuries that require a feeding tube. He will require intense medical supervision his entire life. "This settlement will merely help Kristi Hamilton pay for the care her son will require for as long as he lives," Rasansky says. "She would gladly exchange every dime in return for her son's health." ■

Sentinel Event Alerts still useful, but not for scoring

Risk managers can breathe a sigh of relief now that a much-criticized plan to use the Joint Commission's *Sentinel Event Alerts* for scoring is being abandoned, for now at least. But don't let down your guard entirely: the plan could be revived at a later date and the Joint Commission still expects you to put the *Alert* information to use.

For months, the Joint Commission planned to use the *Sentinel Event Alerts* for calculating a hospital's patient safety management score. Published periodically by the Joint Commission, the *Sentinel*

Event Alerts focus on a particular type of sentinel event and provide advice on how to avoid them. Under the original plan, the *Alerts* were to be used as criteria for determining how well a hospital has addressed patient safety. Surveyors would consider each *Alert* as a lesson on that particular hazard and then accredited hospitals would have to put those lessons to use.

The Joint Commission makes clear that risk managers still should pay close attention to the *Alerts* and incorporate its lessons whenever possible.

Risk managers and other hospital leaders were highly skeptical of the plan, according to **Ken Shull**, FACHE, president of the South Carolina Hospital Association in West Columbia. Shull chairs the Joint Commission's Accreditation Process Improvement Implementation Task Force. He says many risk managers feared the plan was just unrealistic, that the Joint Commission was expecting hospitals to move too quickly in response to the *Sentinel Event Alerts.*

Recently, in response to that criticism, the Joint Commission announced "a moratorium on the scoring of health care organization with *Sentinel Event Alert* recommendations." Surveyors will not score hospitals on compliance with the alerts and figure that into the facility's patient safety management score, but that's not necessarily the end of the story. The Joint Commission makes clear that risk managers still should pay close attention to the *Alerts* and incorporate its lessons whenever possible. Spokeswoman **Janet McIntyre** also notes that the plan was not killed off entirely. The moratorium could be lifted at a later date, she says.

"Current standards require organizations to review all *Sentinel Event Alert* recommendations, determine their applicability to their organization's services and, where applicable implement the recommendations or reasonable alternatives within 90 days of publication in Joint Commission Perspectives," according to the Joint Commission statement. "Although the implementation of recommendations will not be scored during the moratorium, surveyors will assess, for consultative purposes, the organization's knowledge of *Sentinel Event Alert* recommendations and how the organization plans to implement these recommendations."

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With the assistance of the state hospital association-based Accreditation Process Improvement (API) Implementation Task Force, the Joint Commission is developing a revised approach to the publication and survey of *Sentinel Event Alert* recommendations. The revised approach will address concerns regarding the frequency and content of *Sentinel Event Alerts* and the number of *Alert* recommendations subject to survey each year. At a recent meeting, the API Task Force recommended decreasing the frequency of publication of *Sentinel Event Alert*; establishing a standing *Sentinel Event Alert* advisory expert panel to assess the validity and practicality of recommendations; and identifying a limited number of *Sentinel Event Alert* evidence-based recommendations that would be the focus of on-site surveys for one year. ■

Joint Commission say some standards are ambiguous

This may come as no surprise to risk managers, but the Joint Commission's Standard Review Task Force is reporting that its first assessments show some leadership standards are ambiguous and result in "overpreparation by organizations because of uncertainty of what is required to meet the standards."

The task force is charged with reviewing nearly all Joint Commission standards to look for those that are overly burdensome, unrealistic, or ambiguous. The team will take about a year to review each chapter of accreditation standards, one by one, but the first suggestions for change already have been released.

The Leadership chapter was reviewed first, and then the task force began work on these other chapters: Improving Organization Performance, Management, and Nursing. In its initial assessment, the task force reported that "leadership standards are ambiguous, resulting in over preparation by organizations because of uncertainty of what is required to meet the standards. Currently, surveyors conduct

a leadership interview and then look for evidence of clinical integration between various departments. Task force members suggest a better approach is to reverse this process — surveyors should first look for evidence of integration during visits to patient care units and staff interviews, then proceed to the leadership interview to seek an organizational response to pertinent observations."

In addition, the task force reports that many of the standards in the Improving Organization Performance chapter are related to the collection and use of data. For that reason, the task force suggests that the chapter could be condensed after pertinent unduplicated standards are integrated into the Information Management chapter. The task force also found that the material in the Management and Nursing chapters are consistent with the Leadership chapter, so relevant concepts should be integrated into the Leadership chapter and these chapters should be eliminated.

Mark Crafton, MPA, CPHU, director of state relations for the Joint Commission, says the task force is releasing its findings as soon as they finish each chapter instead of waiting for all the work to be completed. "The task force is asked to rate the standard on whether it's relevant, how it contributes to good patient outcomes, how it contributes to patient safety and quality, the clarity, and how compliance can be consistently and effectively evaluated," he says. "We ask them to rate those issues on a one to five scale, and there also are some open ended questions like 'How could you best demonstrate compliance with the standard and how does that compare to what you're currently doing?'"

Crafton says the task force probably will take about eight weeks to review each chapter. All the evaluations are expected to be completed by June. ■

Medication errors related to poor communications

The Joint Commission is warning that one of the major causes of medication errors is the ongoing use of potentially dangerous abbreviations and dose expressions. Risk managers should take action immediately to counter this pervasive problem, the Joint Commission advises.

In its latest issue of *Sentinel Event Alert*, the Joint Commission warns that patients can be harmed by illegible or confusing handwriting by clinicians and the failure of health care providers to communicate clearly with one another.

"Despite repeated warnings for more than 25 years by the Institute for Safe Medication Practices (ISMP) — and other organizations — about the dangers associated with using certain abbreviations when communicating medication information, the practice of using these dangerous abbreviations continues, increasing the potential for patient harm," according to the *Sentinel Event Alert*.

Symbols and abbreviations are frequently used to save time and effort when writing prescriptions and documenting in patient charts, says **Darryl S. Rich**, PharmD, MBA, FASHP, associate director of surveyor development and management with the Joint Commission. Rich lists these examples of Examples of especially problematic abbreviations:

- **"U" for "units" and "µg" for "micrograms."** When "U" is handwritten, it can often look like a zero. The root cause of many sentinel events related to insulin dosage has been the interpretation of a "U" as a zero. Using the abbreviation "µg" is dangerous because when handwritten, the symbol "µ" can look like an "m."
- **The use of trailing zeros such as 2.0 vs. 2,** or the use of a leading decimal point without a leading zero such as .2 instead of 0.2.

The Joint Commission points out that the decimal point is sometimes not seen when orders are handwritten using trailing zeros or no leading zeros. Misinterpretation of such orders could lead to a tenfold dosing error.

To combat these errors, the Joint Commission says electronic prescribing is one of the best solutions. But such systems can be costly, so the Joint Commission makes these other recommendations that can be implemented with little or no budget:

- **Develop a list of unacceptable abbreviations and symbols that is shared with all prescribers.**
- **Develop a policy to ensure that medical staff refer to the list, and take steps to ensure compliance.**
- **Establish a policy that if an unacceptable abbreviation is used, the prescription order is verified with the prescriber prior to being filled.**

Those improvements are more than just a suggestion from the Joint Commission. Accreditation can depend on such changes, because the Joint Commission requires that medication orders have "the degree of accuracy, completeness, and discrimination necessary for their intended use," as found in Standard IM.3 in all manuals.

Standard IM.3 also requires the use of standardized abbreviations, acronyms and symbols.

"Use of confusing and dangerous abbreviations is not consistent with the intent of this standard," the *Sentinel Event Alert* reports. Hospitals also are required to assess orders in the medical record for "presence, timeliness, legibility, and authentication," and see that "action is taken to improve the quality and timeliness of documentation that impacts patient care, " as found in IM.7.10 in the *Comprehensive Accreditation Manual for Hospitals.*

The Joint Commission reminds risk managers that the assessment should be done as part of the quarterly medical record review that hospitals undertake for record completeness and authentication. "As part of the review, Standard IM.7.10 clearly requires that legibility be addressed as well as completeness and authentication," the *Sentinel Event Alert* says. ■

Joint Commission tip: Live up to your job description

The standard requiring staff members to "fulfill expectations of their job descriptions" is most likely to result in an ambulatory care provider receiving a Type I recommendation during an accreditation survey, according to a recent report from the Joint Commission.

Larry Poniatowski, RN, associate director of the Standards Interpretation Group, recently released the list after analyzing Type I recommendations issued for ambulatory care in 2001. These are the most common issues:

• Management of Human Resources / Competence Assessment — H.R.5 — Staff members' abilities to fulfill expectations of their job descriptions are assessed.

• Management of Human Resources / Credentialing — HR.7.1 — Credentialing criteria are uniformly applied to licensed independent practitioners applying to provide patient care services for the organization.

• Management of Human Resources / Credentialing — HR.7.2.1 — Clinical privileges are granted based on the practitioner's qualifications and the care provided by the organization.

• Surveillance, Prevention, and Control of Infection — IC.4 — The organization takes action to prevent or reduce the risk of nosocomial infections in patients, employees and visitors.

• Leadership — LD 1.10.3 — Leaders evaluate the outcomes related to use of clinical practice guidelines and determine indicated refinements to improve pertinent processes.

• Management of Human Resources / Competence Assessment — HR.4.2 — Ongoing data collection about staff competence patterns and trends is used to respond to staff learning needs.

• Care of Patients / Medication Use — TX.3.4 — Preparing and dispensing medication(s) adhere to law, regulation, licensure, and professional standards of practice.

• Leadership — LD 1.9 — The leaders are responsible for making initial appointments and reappointments, and granting or curtailing the delineated clinical privileges of licensed independent practitioners.

• Patient Rights and Organization Ethics — RI.1.2.6 — Patients receive assistance in formulating advance directives.

• Care of Patients / Medication Use — TX.3.9 — The organization has emergency medication systems. ■

OIG may ease integrity agreement reviews

The head of the Health and Human Services Office of the Inspector General (OIG) is offering to ease up on some previously established provisions of the corporate integrity agreements (CIA) that hospitals may have abide by after being caught with their hands in the cookie jar.

Inspector General **Janet Rehnquist** recently issued an open letter to health care providers in which she explained that her review of previous OIG policies indicated that there had been substantial dissatisfaction in the health care community. "I am pleased to announce modifications to OIG policies and practices that are responsive to concerns that we have heard from the provider and enforcement community regarding the civil settlement process," she says.

"The OIG and the Department of Justice will continue to seek to resolve a provider's permissive exclusion liability concurrently with its False Claim Act liability. However, we recognize there may be a limited number of cases where it would be appropriate to resolve a provider's permissive exclusion liability separately or subsequent to resolution of the False Claims Act

case," Rehnquist writes. "We also recognize that in certain cases it may be appropriate to release the OIG's administrative exclusion authorities without a corporate integrity agreement."

Rehnquist says she has directed her staff to consider the following criteria when determining whether to require a CIA, and, if so, the substance of that agreement: 1) whether the provider self-disclosed the alleged misconduct; 2) the monetary damage to the Federal health care programs; 3) whether the case involves successor liability; 4) whether the provider is still participating in the Federal health care programs or in the line of business that gave rise to the fraudulent conduct; 5) whether the alleged conduct is capable of repetition; 6) the age of the conduct; 7) whether the provider has an effective compliance program and would agree to limited compliance or integrity measures and would annually certify

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such compliance to the OIG; and 8) other circumstances, as appropriate.

Rehnquist also says she is concerned about the financial impact of CIAs on providers. To address this concern, the OIG is modifying the provisions of CIAs that address billing reviews and the use of independent review organizations to reduce their financial impact without weakening the integrity of a provider's compliance program. Specifically, the CIA billing review requirements will, in the future, require the use of a full statistically valid random sample only in instances where the initial claims review (which we will call a discovery sample) identifies an unacceptably high error rate.

The OIG will be reviewing each provider's CIA to determine whether it is appropriate to incorporate the new claims review procedures into the provider's existing CIA. ■

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

Failure to diagnose, treat endocarditis in a timely manner: Confidential Florida settlement

By **Jan J. Gorrie**, Esq., and **Mark K. Delegal**, Esq.
Pennington, Moore, Wilkinson, Bell & Dunbar, PA
Tallahassee, FL

News: A primary care physician referred a young woman to a cardiologist for an echocardiogram. A follow-up transesophageal echocardiogram was canceled when the patient found she was pregnant. She was admitted to a hospital three times during her pregnancy. Blood was detected in her urine the first time, and her physicians suspected kidney stones. The second time, she was diagnosed with a splenic artery aneurysm, which was successfully operated on with no harm to the unborn child. The third time, she was admitted with a high fever. An emergency cesarean section was performed and the child was born without complications. However, the mother died several days later as the result of an embolic cerebral infarct and resulting hemorrhage.

Background: In January 1994, the young woman was diagnosed with a heart murmur. She also had a history of fatigue and severe chills following workouts and would often develop a rash on her face following intense physical activity. Her primary care physician, an internist, ordered a complete blood count and echocardiogram. The cardiologist who performed her echocardiogram interpreted the results as a mitral valve prolapse with regurgitation and a possible vegetative lesion on the mitral valve.

To affirm these findings, the cardiologist suggested to the internist that his partner perform a transesophageal echocardiogram. The follow-up was canceled when the patient became pregnant.

When the woman entered her second trimester of pregnancy in May of 1994, she had a follow-up with the cardiologist. Again, the cardiologist diagnosed her as having a mitral valve prolapse with regurgitation and probable myxomatous degeneration. The cardiologist recommended the patient be placed on subacute bacterial endocarditis prophylaxis if she were to undergo any dental treatments during the pregnancy and at the time of delivery. He also instructed her to follow-up with him four to five months prior to her delivery.

In early June, blood was found in her urine and she was admitted to a hospital. Kidney stones were suspected as the cause, but diagnostic testing ruled them out. She did, however, have pneumonia. She was discharged after three days.

In late June, 22 weeks pregnant, she was readmitted, this time with severe abdominal pain. Based on a pathology work-up showing evidence of a splenic infarction, she was diagnosed with a splenic artery aneurysm. A vascular surgeon performed an emergency spleenectomy on her without complications.

The hospital's contract neonatologist was consulted to watch over the unborn child. The neonatologist, who never examined the mother, merely reviewed her medical records relative to the pregnancy and present admission. She was discharged and returned to work.

In late August, during a follow-up with the

Correction

A story in the October 2001 *Legal Review and Commentary* about complications during the birth of twins stated that ABC Hospital of Union County, OH, was part of a $4.9 million settlement in the case. The hospital actually did not participate in the settlement eventually reached by plaintiffs. In a jury trial, a verdict was rendered for the defense. ■

cardiologist, she said she had been hospitalized for pneumonia and a splenic artery aneurysm, but she failed to mention the blood in her urine or the splenic artery infract. Based on the recent medical history provided and his physical examination, the cardiologist believed that the patient was stable and had no signs of symptoms consistent with subacute bacterial endocarditis. The specialist discharged her to follow up with him if she displayed any symptoms.

In early October, 36 weeks pregnant and with a high fever, she was admitted to a hospital. An emergency cesarean section was performed without complications. The newborn was discharged. The mother remained, however, and died several days later from an embolic cerebral infarct and hemorrhage. The medical examiner attributed her death to subacute bacterial endocarditis and an embolus from her heart valve vegetation that had traveled to her brain.

The plaintiff, the patient's husband, brought suit against all the physicians who provided care to his wife prior to and during her pregnancy as well as the hospital and the insurer who claimed that she suffered from undiagnosed bacterial endocarditis as early as February 1994. The plaintiff maintained that all providers deviated from the standard of care by not making the appropriate diagnosis.

The case against the internist was based on a claim that the patient's history of fatigue and severe chills after strenuous physical activity were signs and symptoms consistent with subacute bacterial endocarditis and that the internist should have arrived at that conclusion. The plaintiff also alleged that the internist failed to provide the various referral physicians with the patient's full medical history, that she had more knowledge than anyone else concerning the patient's condition and should have made the proper diagnosis or at least accumulated all the information so that someone else could.

The plaintiff alleged that the first cardiologist underdiagnosed the patient's condition by underreading the echocardiogram results. The plaintiff maintained that the second cardiologist failed to obtain and review the pertinent medical and hospital records that would have revealed blood in the patient's urine, suggesting embolic showering in the kidneys from vegetation on the heart valve and that the diagnosis of endocarditis could have then been made.

The claim against the vascular surgeon alleged that he failed to interpret the splenic infarct as a sign of endocarditis.

The plaintiff also sued the hospital and its staff neonatologist under theories of possible apparent agency and failure to recognize the circumstances. The plaintiff also indicated that all members of the obstetrical group failed to diagnose and treat the situation. The plaintiff argued that his wife would have lived if the correct diagnosis been made and appropriate antibiotic therapy initiated.

Each defendant denied negligence. The internist said she referred the decedent to cardiologists and appropriately relied upon their expertise and advice regarding any underlying cardiac conditions or complications. The cardiologists maintained that their care had been interrupted and delayed by the pregnancy and incomplete medical information. The vascular surgeon said he adequately read the splenic infarct as being caused by the rupture of an aneurysm or by an occlusion caused by the aneurysm. The hospital's neonatologist said his care was restricted to the fetus. The obstetricians maintained that they, like the internist, appropriately relied upon the cardiologists' opinions.

Prior to trial the plaintiff settled for confidential amounts with his wife's HMO, vascular surgeon, neonatologist, and hospital. While the settlement amounts are unknown, the hospital considered it a nuisance claim and the amount was minimal.

During jury selection, the plaintiff settled with the cardiologists for confidential amounts. The case proceeded to trial against the only remaining defendants, the internist, and they prevailed.

What this means to you: This is an unfortunate situation that emphasizes the need for complete communication between patient and physician(s) and, in particular, between physicians. This case highlights the pitfalls of physicians relying on what the patient tells them, forgetting that what is important to a patient is not all that a physician

needs or wants to know. There was a critical communication lapse when the patient failed to tell the cardiologist of her splenic infarct or that she had been hospitalized with blood in her urine. That lapse was coupled with the physician's failure to obtain and review her records. The information may have been very important to the cardiologist, but the patient may have disregarded them. She may have overlooked the infarct thinking that the aneurysm and resultant surgery was the important medical fact. She may have disregarded the fact that blood was found in her urine because it is a frequent condition that usually does not require hospitalization.

Many physicians rely on the patient, forgetting that they come to the physician for their expertise. Doctors should always request copies of the medical records — at least the discharge summaries from any hospitalizations — to be sure they have all pertinent information regarding diagnosis, treatment, and all other information that could be important.

Risk managers should educate physicians about why asking for records is good practice and tell the medical records (health information management) department about the importance of timely faxing or sending copies to physicians' offices when requested, says **Leilani Kicklighter**, RN, ARM, MBA, CPHRM, CHt, of The Kicklighter Group in Fort Lauderdale, FL.

"That being said, it is very common in such situations that a plaintiff's attorney uses the scattergun technique to name any and everyone who had anything to do with the plaintiff when filing suit. Oftentimes it is the hospital or other facility that is the deep pocket, especially in jurisdictions like Florida, where there is no requirement that a doctor carry professional liability insurance coverage [however, they must prove financial responsibility upon licensure by the state.]

"This theory is further supported by this case as it is one that appears, on the facts as presented, to be totally related to diagnosis and treatment from the physician/medical view. There are no facts in this scenario that would lead one to believe that the hospital or its staff were negligent in any way. It is this type of claim that frustrates hospital risk managers and insurance carriers," states Kicklighter.

"This is the type of claim in which the hospital and other claimants are kept in the case for unknown reasons, during which time the hospital must continue to pay [its] defense counsel until [it] reach[es] a point where the claimant's attorney will entertain an offer to settle. It is in these types of nuisance claims that I have seen claim expenses reach five to six times more than the actual settlement payout," notes Kicklighter.

"When to settle a claim is always a tricky decision for the risk manager and claims manager, and sometimes the principals get involved, especially when there is a strong conviction that the defense can prevail in convincing the jury. Emotional cases, those with exceptionally sympathetic plaintiffs, are other situations that are often difficult to address, particularly when it does not appear that the defendants were negligent but the outcome was devastating.

"The risk manager is always cognizant that all monies paid out against a claim — even those that are minimal — are taken into consideration by the carrier or actuary at the time of renewals or developing funding levels. In this case, each group of the defendants had to weigh their options and select the route best suited to them — the calls had to be made on when to settle [and for how much] and when to fight," she concludes.

Reference

• Dean Fresonke as personal representative of the estate of *Nancy Fresonke vs. Prudential Health Care Plan Inc. d/b/a Prudential Health Care System of Orlando; Orlando Regional Health Care Systems Inc., et.al.,* Orange County (FL) Circuit Court, Case No. CI 95-6456. ■

Thumb injury ends in settlement for $7,500

News: A hairdresser caught her thumb in a sliding glass door and drove herself to the emergency room. X-rays were taken, and no fracture was revealed. But when she returned to the hospital 16 days later, it was agreed that she had a displaced fracture of the proximal phalanx of the left thumb. The hairdresser claimed that this resulted in a need for surgery and that she was left with permanent pain and disfigurement, impacting her ability to perform her professional duties and everyday activities. She brought suit against the hospital, radiologist, and emergency room physician. On the first day of trial, the hospital settled for $7,500 and the jury found in favor of the physicians.

Background: On the morning of Dec. 14, the

woman, a hairdresser, inadvertently slammed her thumb in a sliding glass door. At the emergency department, X-rays were read as negative by the emergency room physician and radiologist. She was discharged, but returned later that afternoon saying she was still in pain. Repeat X-rays were not ordered. Nor were repeat X-rays ordered when she returned to the emergency department on Dec. 17. It was not until she went back to the emergency department on Dec. 30 that additional X-rays were ordered. Those X-rays revealed that she had sustained a fracture, which was now displaced.

Because the fracture was untreated for 16 days, the injury necessitated corrective surgery and resulted in the plaintiff having permanent pain, disfigurement, and disability, including a restricted range of motion that impacted her ability to perform her professional duties and everyday activities. The defendants denied that the plaintiff was injured in the manner or to the extent alleged. After the hospital settled for $7,500 on the first day of trial, the jury returned a verdict in favor of the defense for the physicians.

What this means to you: There are many factors to consider before determining whether a particular claim merits pursuit, says **Stephen Trosty**, risk management director at Physicians Assurance Corp., of East Lansing, MI. "Initially, one must assess the legitimacy of a claim so that it can be determined if the claim has substance and represents medical malpractice or is a claim that really does not have a malpractice basis. And, if malpractice is a potential, then the amount of potential damages must be reasonably assessed. These potential costs must be weighted against the cost of trial and potential cost of an adverse verdict. Many factors go into the decision of whether or not to fight or settle any given claim.

"Once the potential for damages is determined, the costs of taking the matter to trial must be evaluated vis-à-vis that estimated potential. This assessment must include the cost of obtaining expert opinions and other requisite witnesses as well as the depositions, interrogatories, witness fees, and attorneys' fees associated with the procurement of such. This may also entail the assessment of interaction with the media [if necessary] and the potential impact on the physicians on one's medical staff [including the time, and mental and emotional impact]. For instance, if the belief is that there is no liability but you must admit some liability and guilt to settle the nuisance claim, one should determine the potential impact on malpractice insurance rates and the potential need to report to the National Practitioner Data Bank those persons who should be reported. These are not easy decisions for risk managers to make," adds Trosty.

"Furthermore, if too many nuisance claims are settled, then the facility and/or associated physicians run the risk of gaining a reputation for being too willing to settle claims and be deemed unwilling to go trial and fight the good fight before a jury. The risk in settling is that additional nuisance suits may be brought against you and the case material becomes weaker over time in the hopes of easy money for the plaintiff," notes Trosty.

"In addition, the risk manager must determine the strength of their legal counsel and their reputation in the local legal community. One does not want to seem too willing to settle because their team is not able to win at trial or seemingly afraid to take legitimate issues before a jury. Settling a nuisance claim should be considered in the context of the whole matter, including counsel," adds Trosty.

"The status and demeanor of the plaintiff as well as defendants must also be considered. There are some plaintiffs more sympathetic to juries than other. They may compel stories that are more likely than not to appeal to any jurist sensitivities and these too must be taken into account. On a related note, the jurisdiction in which the matter is to be considered must be taken into consideration. For instance, if the economy is in a downturn and jobs are tight, the potential loss of employment for the plaintiff might become a factor underlying the juror's mind. Further, the strength or weakness of your defendant might also play a pivotal role in the determination to go forward or to settle. If you clearly are going to have difficulties with the defendants, then settlement may be an option," he states.

"Bottom line: The decision to stay and fight or settle a claim involves evaluation of the many facets and nuances of the case. No two claim situations are alike, and each factor must be weighed individually before a final decision can be reached. In this particular instance, the factors lead to settlement, and even in light of the favorable defense decision for the physicians, one must assume that settling for $7,500 was the best decision for the hospital," concludes Trosty.

Reference

• *Carmela Lisa Freedman vs. Emergency Physicians Group Ltd., Dr. William Graffeo, Dr. Robert Broadhead, Dr. Reza Parsavand, and Highland Park Hospital,* Lake County (IL) Circuit Court, Case No. 98L-814. ■

BIOTERRORISM WATCH
Preparing for and responding to biological, chemical and nuclear disasters

Ring of Fire: CDC plan to immunize around first smallpox cases has the devil in the details

Used successfully to eradicate smallpox in 1980

Should a bioterrorist strike with smallpox, the Centers for Disease Control and Prevention's (CDC's) recently released response plan calls for investigators to rapidly immunize a "ring" around the first cases. The ring concept calls for isolation of confirmed and suspected smallpox cases followed by contact tracing, vaccination, and close surveillance of contacts.

"Ring vaccination — sometimes called search and containment —- is identifying individuals with confirmed smallpox and then identifying and locating those people who came in contact with that person, and vaccinating those people in outward rings of contact," says **Harold Margolis**, MD, CDC senior adviser for smallpox preparedness. "This produces a buffer of immune individuals and was shown to prevent smallpox and to ultimately eradicate this disease."

Indeed, the ring approach was used to successfully eradicate smallpox from the world in 1980. The only officially acknowledged stocks of live virus remaining are in the United States and Russia, but bioterrorism experts have long feared that smallpox may have fallen into other hands.

But the ring concept was effective when the demographics of smallpox were very different, when few were infected and the vast majority of people were already immune. The CDC plan acknowledges as much, noting that several current factors could contribute to a more rapid spread of smallpox than was routinely seen before this disease was eradicated.

These factors include virtually nonexistent immunity to smallpox, increased mobility of the population, and delayed recognition of smallpox by health personnel who are unfamiliar with the disease, the plan states. Concerning the latter — similar to the fine line between initial symptoms of anthrax and influenza — one of the most confounding differential diagnoses for smallpox is chickenpox. **(See related story, p. 3.)**

Preemptive strike

While the ring strategy is a classic public health approach, some favor a more aggressive preemptive action in this new age of bioterrorism: Immunize response teams of health care workers throughout the nation.

"I would be in favor of a plan to prospectively immunize not only the strike force at the federal level, but [also] a cadre of people in each state," says **William Schaffner**, MD, chairman of preventive medicine at Vanderbilt University in Nashville.

Having groups of health care workers immunized in advance could also be critical if the "ring" is difficult to perceive, he notes.

"We think of it conceptually as a ring, but clearly people are not all in one geographic area," he says. "The people who may or may not have contact with this first case will be scattered all over the community. They went shopping

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there, had a church group here, and then they played bridge. The first thing we will be looking for is information from public health authorities about who is within the ring and who is outside the ring. If that is not articulated with great clarity everybody is going to be in deep trouble."

The CDC is certainly aware of such issues and concerns, and discussions are still ongoing within the agency about preemptively immunizing some health care workers. "We have to weigh the risks and benefits of vaccination for any group, and that would include health care workers. We are kind of working through those issues right now," **Lisa Rotz**, MD, medical epidemiologist in the CDC bioterrorism response program, tells *Bioterrorism Watch*.

The overriding factor in holding back immunization of health care workers is the hazards and side effects of the vaccine.

"In 1972 we actually discontinued routine vaccination [in the United States] because the risks of adverse events from the vaccine outweighed the risk of any one person coming down with smallpox, even though it was still occurring in other parts of the world," Rotz says. "I think that still holds true here. We are dealing with a vaccine that presents problems in and of itself."

Indeed, death occurs in about one per million primary vaccinations, usually as a result of progressive vaccinia, post-vaccinal encephalitis, or severe eczema vaccinatum. Other adverse events include inadvertent inoculation from the vaccinated site (e.g., to the eyes).

CDC will bring vaccine within 'hours'

In addition, the CDC has immunized approximately 100 of its personnel, who could be dispatched immediately to a stricken area and begin investigating and administering vaccine.

"We have people trained to respond to smallpox who can go rapidly to an area to evaluate a case, and then help the local and state officials begin implementing control measures," Rotz says. "That would include helping them implement surveillance, making sure we have identified people who need to be vaccinated right away and to start setting that up. We would get things started there until they get their own response up and running."

But instead of immunizing health care workers in advance, the CDC plan is to administer the vaccine after a case occurs. The CDC could deliver personnel and vaccine within "hours" to any area in the country, Rotz says. Moreover, the vaccine can be effective up to four days after infection sets in, and may prevent death in the patient.

Among the top priority for immunizations after smallpox is reported are "those involved in the direct medical care, public health evaluation, or transportation of confirmed or suspected smallpox patients," the CDC plan states. **(See story on priority immunization groups, p. 3.)** In addition, smallpox patients would be placed under airborne precautions similar to that used for tuberculosis patients, who are placed in negative pressure rooms (vented outside) and treated by workers with respirators.

Another important factor in favor of the CDC approach is that smallpox is not communicable in its incubation period, says **D.A. Henderson**, MD, director of the office of public health preparedness at the Department of Health and Human Services in Washington, DC.

"You have an incubation period of 10 to 12 days when the individual feels perfectly well and is not able to transmit infection," he says. "Then he gets a fever for a couple of days and then the rash. It's only when the rash begins that the individual transmits the disease. So, in fact, [those are] the people we're really concerned about isolating so that they don't transmit the disease. But just because somebody's infected does not mean that they're going to transmit infection during that incubation period. They won't do that."

Into the thousands very quickly

Still, while emphasizing that the CDC plan is a good starting point, Schaffner argues that it would make sense — and allay subsequent chaos — to immunize groups of health care workers before an event occurs.

"The immediate [CDC] public health strike team is like being out on the beach and walking in up to your ankles, but the next step you take gets you into water over your head," he says. "Because if you start thinking about [immunizing health care workers], you're talking about emergency personnel, ambulance drivers, infectious disease doctors, [and] nurses in hospitals who would be designated to care for such patients. It could get into the many thousands very quickly."

In addition, with the exception of the recently trained CDC personnel, few clinicians in the country know how to administer the smallpox vaccine using the "little pitchfork" bifurcated needle.

"That is one potential benefit of vaccinating a group of first responders around the country,"

Schaffner says. "You train these people how to administer the vaccine and all of sudden you have a bunch of trained people out there that we haven't had before. I think that would be a substantial additional benefit." ■

Health workers, contacts priority for vaccination

Others include lab personnel and waste disposal

According to the Centers for Disease Control and Prevention (CDC), the following groups should be a high priority for smallpox vaccination should a bioterrorism release of the pathogen occur:

1. Face-to-face close contacts (less than or equal to 6.5 feet or 3 meters), or household contacts to smallpox patients after the onset of the smallpox patient's fever. Although individuals with smallpox are not infectious until the onset of rash, vaccinating contacts from the time of the onset of fever helps provide a buffer and assures that contacts who may have been exposed at the early onset of rash, when the rash may have been faint and unrecognized, have been vaccinated.

2. People exposed to the initial release of the virus (if the release was discovered during the first generation of cases and vaccination may still provide benefit).

3. Household members (without contraindications to vaccination) of contacts to smallpox patients' (to protect household contacts should smallpox case contacts develop disease while under fever surveillance at home).

Household members of contacts who have contraindications to vaccination should be housed eparately from the other vaccinated household members until the vaccination site scab has separated (approximately two weeks) to prevent inadvertent transmission of vaccinia virus. They should also be housed separately from the contact until the incubation period for smallpox has passed and the contact is released from surveillance.

4. People involved in the direct medical care, public health evaluation, or transportation of confirmed or suspected smallpox patients (this includes personnel whose public health activities involve direct patient contact such as case interviewing).

5. Laboratory personnel involved in the collection and/or processing of clinical specimens from suspected or confirmed smallpox patients.

6. Other people who have a high likelihood of exposure to infectious materials (e.g., personnel responsible for hospital waste disposal and disinfection).

7. Personnel involved in contact tracing and vaccination, or quarantine/isolation or enforcement, or law-enforcement interviews of suspected smallpox patients.

8. People permitted to enter any facilities designated for the evaluation, treatment, or isolation of confirmed or suspected smallpox patients. (Only essential personnel should be allowed to enter such facilities.) Only personnel without contraindications to vaccination should be chosen for activities that would require vaccination for their protection. Personnel with contraindications should not perform duties that would place them at risk for smallpox exposure and should otherwise only be vaccinated if an exposure already has occurred.

9. People present in a facility or conveyance with a smallpox case if fine-particle aerosol transmission was likely during the time the case was present (e.g. hemorrhagic smallpox case and/or case with active coughing). Evaluation of the potential risk for aerosol transmission and initiation of vaccination for non-direct contacts will be done by CDC, state, and local public health personnel. The decision to offer vaccination to non-direct contacts of smallpox cases will be made jointly by federal and the state health officials. ■

Smallpox or chickenpox? How to make the diagnosis

Rash progression, location, will be different

Smallpox or chickenpox? That clinical question has been long confined to the academic dustbin in the United States, where the last case of smallpox (variola) was diagnosed in 1949 in Texas.

Smallpox has been vanquished yet is still feared; chickenpox (varicella) remains a fairly common pediatric infection. Continuing use of the varicella vaccine (recommended for use in the United States in 1996) should continue to reduce cases of chickenpox in the years to come. With

Smallpox vs. Chickenpox

	Variola	Varicella
Incubation	7-17 days	14-21 days
Fever prodrome	2-4 days	minimal/none
Distribution	face/extremities	trunk/clusters
Progression	synchronous	synchronous
Scab formation	10-14 d p* rash	4-7 d p* rash
Scab separation	14-28 d p* rash	<14 d p* rash
Lesions soles/palms	yes	no

** d p = days after rash onset*

Source: Centers for Disease Control and Prevention, Atlanta.

bioterrorism a reality and a whole generation of medical students having never seen a case of smallpox, the Centers for Disease Control and Prevention (CDC) is again emphasizing the classic distinctions between the two poxes.

Though similar at onset, the two rash diseases take distinctly different progressions that provide more than a few telltale signs, says **Lisa Rotz**, MD, medical epidemiologist in the CDC bioterrorism response program. **(See chart, above.)**

"The incubation period for both diseases spans similar time periods, but we do see a longer incubation period in the development of chickenpox as opposed to smallpox," she says.

Usually symptoms such as high fever, malaise, and backache will proceed development of rash in smallpox cases. On the contrary, fever associated with chickenpox generally appears in conjunction with the first signs of rash.

"You will also see a different distribution of lesions of the rash between the two diseases," Rotz says. "In general, smallpox lesions are much more numerous on the face and extremities."

In contrast, chickenpox lesions are more numerous on the trunk, and occur in clots or clusters. Moreover, as rash progresses in smallpox, the lesions in a particular area of the body progress along the same lines and appear similar.

"Whereas in varicella in any one area of the body you may see lesions in different levels of progression," she says. "You might see a vesicle next to a scab. Also the rash of varicella progresses much more quickly and resolves more quickly than the rash of smallpox. So the overall illness has a much shorter course for chickenpox vs. smallpox."

As opposed to chickenpox, smallpox also will reveal itself through lesions on the soles and palms of those infected. Despite the disease names, chickenpox lesions are usually smaller than those created by smallpox.

"It is difficult to distinguish early on between the two diseases, but they quickly diverge in their rash progression," Rotz says. "By day five a child with smallpox is showing increasing numbers of lesions still occurring on the face, while the child with chickenpox has about the same number of lesions on the face as appeared on day three. By day seven the rash is still progressing in the patient with smallpox but seems to be resolving in the child with chickenpox."

Though smallpox patient isolation measures are understandably more stringent, the patient isolation guidelines for the two diseases are actually very similar. The CDC recommends contact isolation for both (until scabs are gone) and airborne isolation measures for patients infected with either chickenpox or smallpox. Contact precautions include wearing gloves and a gown to enter the patient's room; removing gloves and washing hands with an antimicrobial soap prior to leaving room; dedicating noncritical care items to individual patients; and taking extra care to clean the patient environment.

Airborne precautions call for placing the patient in a private room that has monitored negative air pressure in relation to the surrounding areas; six to 12 air changes per hour; and discharge of air outdoors or monitored high-efficiency filtration of room air before the air is circulated to other areas in the hospital. Keep the room door closed and the patient in the room, the CDC advises. Health care workers immune to chickenpox need not wear respiratory protection, but the CDC is calling for workers to wear N95 respirators — typically used for tuberculosis patients — when caring for smallpox patients. ■