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JCAHO Update for Infection Control — a new, free supplement — in this issue of HEH

IN THIS ISSUE

FEBRUARY 2003

VOL. 22, NO. 2 (pages 13-28)

Employee health takes charge of smallpox vaccination plans

Phased-in approach gains favor as vaccines begin

As hospitals prepare to vaccinate hundreds of health care workers, they face a host of opposing pressures: Some health care workers may request the smallpox vaccine, but those designated for smallpox response may not want it. Vaccinations may lead to increased absenteeism in the midst of a nursing shortage and the flu season. And concerns about serious adverse events may spur some hospitals to restrict or even opt out of vaccination.

The burden of the logistics for vaccinating those workers falls largely on the shoulders of hospital employee health professionals.

Meanwhile, different approaches by state health departments create disparities in who will be vaccinated and how the vaccinations will occur. For example, Georgia announced a phased-in plan to limit vaccination to emergency department (ED) staff in the state's 15 trauma centers and regional response teams in 19 public health districts — for a total of about 500 vaccinees. Then the state amended its plan to accelerate vaccination of health care workers at other acute-care hospitals. New York City announced plans to vaccinate about 15,000, with response teams at each hospital, and California's plan would lead to about 50,000 vaccinations of health care workers.

The vaccination patterns will vary based on population and the nature of the health care delivery system. "We anticipated that states would have very variable plans for many good reasons, and whatever immunization occurs, we are certainly going to be more prepared than we are right now," **Julie Gerberding**, MD, MPH, director of the Centers for Disease Control and Prevention (CDC), said in a recent teleconference.

In fact, the estimates are likely to change many times as the plans evolve. "The big question mark is how many people are going to want it and be eligible for it," says **James Garb**, MD, director of occupational health and safety at Baystate Health System in Springfield, MA, who

plans to conduct his vaccinations over a 10- to 12-week period. "We might not reach our quota."

The vaccinations were scheduled to begin late in January, after the provisions of the Homeland Security Act providing immunity from liability became effective Jan. 24. While the CDC recommends vaccination in centralized public health clinics for the most effective use of the 100-dose vials, many hospitals are planning to create vaccination clinics within their employee health service. Where the vaccination occurs may have an impact on the hospital's potential legal liability for adverse events. **(See related article on legal liability, p. 17.)**

The CDC asked for vaccination to occur within a 30-day time frame, but acknowledged that more time would be needed. The agency approved state plans that allowed for a longer time span. "We want people to do it as safely as they need to — to gear up and get the job done right," Gerberding said.

Hospitals also must plan for mild reactions. Many employees will feel ill seven to 10 days after vaccination with symptoms that include fever, malaise, and swelling at the injection site or a lymph node.

One study found that about one-third of vaccinees felt ill enough to miss school, work, recreational activities, or to have trouble sleeping.[1] Hospitals are factoring that into their planning, while union leaders are advising health care workers to obtain assurances about sick leave, medical costs, and workers' compensation before receiving the vaccine.

"We need to make sure that safeguards are in place for the public and workers before this [vaccination] plan is released," says **Bill Borwegen**, MPH, occupational safety and health director for the Service Employees International Union (SEIU) in Washington, DC. "These are incredibly important issues that have not been addressed. [Congress and the administration] go out of their way to protect vaccine manufacturers. We need to do what we can to protect frontline health care workers."

The SEIU is advising health care workers to gain protections for possible lost work time and medical costs for themselves and family members who may be affected before agreeing to the vaccine. "There are very serious gaps in this program," he says. "We're advising our members, if they want to be vaccinated, make sure these serious gaps are dealt with first."

Only eligible HCWs to receive first vaccines

In selecting the health care workers who receive the first vaccinations, hospitals consider the positions of highest need to treat a case of smallpox 24/7 for a period of seven to 10 days. Anyone who receives the vaccine must be willing to treat smallpox patients. Those who are not designated as high need will not be entitled to the vaccine in this first round of vaccinations.

But hospitals and public health departments may make their own assessment of the benefits and risks of the vaccine in deciding who receives it. "It's clear that individual hospitals and public health departments may modify the [CDC] recommendations in order to meet their needs," said **Jane D. Siegel**, MD, professor of pediatrics at Southwestern Medical School of the University of Texas in Dallas and chair of the bioterrorism working group for the CDC's Healthcare Infection

Hospital Employee Health® (ISSN 0744-6470) 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 **Hospital Employee Health**®, P.O. Box 740059, Atlanta, GA 30374.

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Subscription rates: U.S.A., one year (12 issues), $429. Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $343 per year; 10 to 20 additional copies, $257 per year. For more than 20 copies, contact customer service for special handling. Missing issues will be fulfilled by customer service free of charge when contacted within 1 month of the missing issue date. **Back issues**, when available, are $72 each. (GST registration number R128870672.)

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THOMSON
AMERICAN HEALTH CONSULTANTS

Control Practices Advisory Committee (HICPAC). "The goal is not to vaccinate the entire emergency department staff."

That assessment of "need" may vary dramatically. Hospitals may set stricter screening guidelines for contraindications, or may choose to initially vaccinate only those who had been previously vaccinated as children. Those who were previously vaccinated are expected to have milder effects.

Patrick O'Neal, MD, EMS medical director for the Georgia division of public health, says hospitals are reluctant to participate without strong protections from liability.

Hospitals that treat a large number of AIDS patients are particularly concerned about the risk of transmission of vaccinia to vulnerable patients. Restricting employees from contact with such patients may be impossible, O'Neal says.

"We've got major staffing issues in hospitals across the state of Georgia. To furlough active employees is just almost unthinkable," he says.

Concerns about the risk of the vaccine prompted the state's largest hospital, Grady Memorial Hospital in Atlanta, to opt out of the vaccination plan.

Children's Hospital of Philadelphia likewise chose not to vaccination health care workers at this time. **Paul Offit**, MD, chief of the division of infectious diseases, says he would identify the smallpox response team, screen and educate the employees — and then wait. He would activate the plan only if a case of smallpox is reported somewhere in the world.

Offit, who was the only member of the Advisory Committee on Immunization Practices (ACIP) to vote against the recommendation for vaccinating health care workers at most acute care hospitals, says not enough is known about the likelihood of a smallpox case.

In announcing the smallpox vaccination program, President Bush said, "Our government has no information that a smallpox attack is imminent." While the potential for a bioterrorism event

Maybe the vaccine won't be as bad as we think

No serious reactions at biotech firm

Smallpox vaccination of selected health care workers may actually occur smoothly with relatively few severe adverse events, if recent experiences are a guide.

At Acambis, a Cambridge, MA-based company that won a Centers for Disease Control and Pre-vention contract to restock the nation's supply of smallpox vaccine, occupational health physician **Reid Boswell**, MD, MPH, has vaccinated about 300 to 400 employees, after conducting careful screening for contraindications. "I've had very few complications with the vaccine and nothing that has required hospitalization or Vaccinia Immune Globulin (VIG)," says Boswell, who is medical director of the Mount Auburn Hospital Occupational Medicine Clinic in Cambridge, MA. "If you carefully screen people, we're probably not going to have a lot of major problems."

One woman had a whole body urticarial rash, probably as an allergic reaction to trace amounts of antibiotics in the vaccine, Boswell says. She was treated with Benadryl. "I have no case where anyone has had an accidental inoculation of another person," he says. Boswell uses a six-page consent form, and employees are well-informed before they get the vaccine, he says.

He notes the common, mild effects of fever, pain, headaches, and malaise. But even those are not as bad among people who were previously vaccinated, he says. "It turns out that people vaccinated as children have fewer minor side effects. They still have a major take response, which shows they don't have a lot of circulating antibodies, but they seem to have fewer of the side effects," he says.

What if emergency vaccination suddenly became necessary? The federal government is not recommending vaccination of the general public at this time. But if a smallpox case occurred, those exposed could still gain protection from vaccines administered within four days of exposure.

Public health officials in Tucson, AZ, recently tested the distribution of National Pharmaceutical Stockpile medicines to the general public as part of a bioterrorism drill. Although the scenario didn't involve vaccination, the logistics would be similar, says **Bryn Bailer**, spokesman for the Bioterrorism Preparedness Program of the Pima County Health Department in Tucson.

"The public health department's goal was to process 1,000 people during the six-hour clinic," Bailer says. "That includes registration, where people would fill out [forms listing] their health conditions. We had different scenarios set up for them. You might be a 12-year-old boy with asthma and epilepsy."

Public health staff and volunteer pharmacists determined what would be the best response for people with various medical conditions. In the drill, the ad hoc clinic was able to process 1,854 people and could easily have processed more, Bailer says. ■

involving smallpox is undetermined, the risks of the vaccine are well-documented.

"The question is, 'Is it right to use that vaccine now?' No one knows the answer to that question," Offit says. "Right now we don't have all the information we need to make the decision. We have to make the best decision we can."

Offit concedes that some employees may want the vaccine even if he recommends waiting. He had not decided how to handle those requests.

Ironically, Offit actually is one of the few infectious disease specialists who has experience with the vaccine, which he administered to about 100 employees at the Wistar Institute, a research facility in Philadelphia. Moderate effects caused many employees to miss a day or more of work, he says.

"It's not at all uncommon for one to have fever, malaise, aching, significant swelling at the site, swelling of the lymph gland under the armpit. That's all part of the vaccine," he says.

If he eventually administers the vaccine, Offit says he would consider a post-vaccination furlough for employees who work with immunosuppressed patients.

EH depts become smallpox vaccine clinics

Many hospitals are planning to conduct the vaccination in phases to minimize the impact. Employee health must offer confidential HIV and pregnancy testing, and make sure health care workers understand the contraindications. Employee health professionals also may need to recruit other nurses to help with the daily injection site monitoring.

At Baystate Health System, senior leaders are appealing to designated employees for cooperation with the vaccination program. Garb and the chief of infectious diseases will be among the first vaccinated.

Garb says he plans to transform the employee health clinic into a smallpox vaccination clinic one morning per week until the hospital vaccinates staff who are willing and eligible.

He adapted the CDC screening and consent form, including questions about whether the health care workers have itchy or inflamed eyes, whether they have received the varicella vaccine within the last four weeks, and whether child care takes place in their home. **(See form, inserted in this issue.)** Infants 1 year or younger should not be in contact with vaccinated individuals.

"I'm hoping most of the people who aren't eligible or don't want it will screen themselves out," he says. Skin conditions may cause the greatest concern. The contraindication relates to eczema and atopic dermatitis, but even contact dermatitis — a common condition during New England winters — could eliminate some employees from the vaccination list.

Garb says he plans to ask any health care workers with raw, chapped hands to consult a dermatologist or wait until spring for the vaccination.

At Pitt County Memorial Hospital in Greenville, NC, **Patricia Dalton**, RN, COHN-S, occupational health administrator, also plans to phase in the vaccinations.

"I remember when this was not a big deal. In 1966, I was administering smallpox vaccine all day long for school kids," she says.

Out of 6,000 employees, Dalton says she expects to immunize 80 to 100. "I don't even know if we're going to get that much [vaccine]," she says. "One of the physicians had heard we might get 40 to 50 doses. We are strategizing about who would get it first."

Dalton expects that occupational health nurses will provide the vaccinations at the hospital, so they will be the first immunized.

The hospital's response plan calls for suspected smallpox cases to be triaged at an urgent care center, and for suspected smallpox patients to be treated in a care center set up in a surgicenter facility. "As much as possible, we would like to keep any potential for a smallpox case from coming into the hospital," she says.

For employee health departments with minimal staffing for even routine duties, the new responsibilities of monitoring smallpox vaccination can be overwhelming. **MaryAnn Gruden**, MSN, CRNP, NP-C, COHN-S/CM, executive president of the Association of Occupational Health Professionals in Healthcare in Reston, VA, an employee health nurse practitioner at Western Pennsylvania Hospital in Pittsburgh, notes that her hospital conducts annual TB skin testing every January.

"In some offices that have good staffing, it may not be as much of an impact. For those of us working on a shoestring," she says, it will be a challenging process.

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Smallpox vaccine leaves hospitals open to claims

HHS promises compensation for vaccine costs

Despite legal protections included in the Homeland Security Act, hospitals still face workers' compensation liability and possibly other legal exposure from the smallpox vaccination of health care workers, according to lawyers who specialize in the health care field. The uncertainty of the legal and financial risk may prompt some hospitals to limit or even decline vaccination of their employees.

In a telebriefing after President Bush formally announced the smallpox vaccination program, **Tommy Thompson**, the secretary of the Department of Health and Human Services, reassured hospitals that they may receive funding and possibly even additional legislation to address their concerns about the costs and liability.

"We anticipate when Congress passes the next appropriate bills for the Department of Health and Human Services, there will be included in there, almost $1.5 billion, of which about $535 million will be for hospitals, and we will be working with the states in the implementation of their plans . . . to be able to take into consideration any further costs that may result as a result of this vaccination program," he said. "And we are also looking at the potential of introducing some further legislation."

The protections of the Homeland Security Act were scheduled to become effective Jan. 24 and are triggered by a declaration from Thompson that vaccination is a necessary countermeasure against a smallpox bioterrorism threat. He said workers will be covered by workers' compensation plans. Funding for hospitals could offset some of the costs related to those claims.

Thompson also said doctors, hospitals, "and other licensed individuals" would be considered "agents of the federal government," and therefore, covered by the Homeland Security Act immunity protections. "I want to point out here that we will be interpreting the statute very generously to cover as many of these people as possible."

However, previously, a fact sheet issued by the Centers for Disease Control and Prevention (CDC) in Atlanta indicated that hospitals might not be covered if the vaccines were administered by public health officials in another location.

Unless Congress further clarifies the liability issue, hospitals may be reluctant to participate — particularly if their employees would receive the vaccine from a public health clinic, says **Edward Richards**, JD, MPH, director of the program in law, science, and public health at the Louisiana State University School of Law in Baton Rouge.

"A hospital would have to be pretty gutsy to participate in this program at all if that [liability] is not clear," Richards says.

Shortly after President Bush announced the administration's smallpox vaccination plan, the legal implications remained unclear. In interviews with *Hospital Employee Health*, several lawyers who specialize in workers' compensation and health care law offered this assessment:

- **Workers' compensation likely will cover employees who are injured by the vaccinia vaccine.**

"They're on the line on workers' compensation," says **Jon Gelman**, an attorney based in Wayne, NJ, who specializes in work-related injuries. Gelman is the national media advisor on workers' compensation for the West Group legal publishers.

"There are no insulation factors against paying for workers' compensation, and there has been no removal of liability by Congress," he says. "So workers' compensation is going to be the primary source of benefits should anybody have an adverse response to any of the vaccine programs, including smallpox."

For the few who have severe reactions, which could include progressive vaccinia, encephalitis and death, workers' compensation medical benefits would include all future medical treatment, accommodations, and dependency benefits, Gelman notes.

The voluntary nature of the vaccinations apparently will not affect the workers' compensation status. Workers may suffer from lost work time due to milder reactions, without workers' compensation benefits.

Workers' compensation programs may not cover employees with milder reactions, and those employees may fail to get any compensation for their sick time, says **Dominick Tuminaro**, JD, a New York City-based attorney who specializes in workers' compensation. "Typically, most workers' comp systems have a waiting period. If you're out for seven days or less, you're not eligible for compensation," he says.

Many employees may simply use their own medical insurance, and they may fail to establish

the causal link necessary to trigger workers' compensation, he says. Hospitals should ensure that workers don't need to use their own sick time for symptoms related to the vaccine, he says.

"The appropriate thing would be for institutions to recognize that you're asking people to volunteer," he says. "If they do have an adverse reaction, you ought to hold them harmless."

In fact, some hospitals are taking that approach. For example, Baystate Health System in Springfield, MA, will cover employees for any vaccine-related symptoms, so they will not have to use their sick time. The three-hospital health system also will cover medical costs for employee's household contacts who are inadvertently inoculated, says **James Garb**, MD, director of occupational health and safety.

"There are certainly enough barriers to vaccination that I didn't want to create any unnecessarily," he says. "At least they won't have the financial concerns to worry about."

- **No clear mechanism of compensation has been established for those who suffer from secondary transmission of vaccinia.**

Although the Homeland Security Act protects those producing and administering the vaccine from lawsuits, it does not spell out any mechanism for compensation for those who are injured by the vaccine. The compensation issue will need to be addressed, Thompson said in a briefing.

But until it is, uncertainty prevails. Suing the federal government over vaccine effects would be very difficult, Richards says. "This is not a claim like the vaccine compensation fund. You have to prove negligence in order to collect. That Federal Tort Claims Act provides very significant defenses."

But if victims have no clear path to compensation, a judge may scrutinize the Homeland Security Act. "They're going to be looking for reasons to narrow the immunity protections of the act," he says.

The act states, "[A] covered person [is] a manufacturer or distributor of such countermeasure, a health care entity under whose auspices such countermeasure was administered, a qualified person who administered such countermeasure, or an official, agent, or employee of a person" in the other groups.

- **Extra precautions taken in screening or in limiting employee contact with the most vulnerable patients could reduce liability.**

Hospitals face yet another dilemma. Careful screening for contraindications will greatly reduce the danger of serious adverse effects. But when more restrictions are placed on who can receive the vaccine, the hospitals may have difficulty finding enough eligible volunteers.

Richards advises taking a conservative approach, even if it means vaccinating fewer workers.

The risk of nosocomial transmission of vaccine to vulnerable, immunosuppressed patients also worries hospitals. The CDC does not recommend furlough of employees and says semipermeable dressings, good hand hygiene, and monitoring of the injection site can greatly reduce the risk.

Yet the Food and Drug Administration- (FDA) approved label for Dryvax, the current stock of vaccinia vaccine, states: "Recently vaccinated health care workers should avoid contact with patients, particularly those with immunodeficiencies, until the scab has separated from the skin at the vaccination site.

"However, if continued contact with patients is essential and unavoidable, they may continue to have contact with patients, including those with immunodeficiencies, as long as the vaccination site is well covered and good hand-washing technique is maintained by the vaccinee."

"This label sets a pretty strong legal standard," Richards says. "The FDA, through their official label, says you do have to keep [vaccinated health care workers] away from patients. If the hospital doesn't have Homeland Security Act immunity and they get sued, the plaintiffs' lawyer exhibit one is going to be this label. 'Could no one else take care of these patients? Was this essential and unavoidable?'" ■

OSHA pushes TB standard into long-term action plan

Move spells end to rules on fit-testing

A tuberculosis standard requiring annual respirator fit-testing and skin testing is all but dead as the U.S. Occupational Safety and Health Administration (OSHA) removed it from the "proposed-rule" stage.

In its semiannual unified regulatory agenda, OSHA placed the TB rule in its "long-term action" category, and called future activities "undetermined."

(Continued on page 23)

JCAHO Update for Infection Control

News you can use to stay in compliance

'Flip-flop' flap: Joint Commission urges ICPs to report fatal, impairing nosocomial infections as 'sentinel events'

ICPs 'back on their heels' as JCAHO reinvents itself

In an unusual direct appeal to health care facilities, the chairman of the Joint Commission on Accreditation of Healthcare Organizations is asking for reports of nosocomial infections that result in patient deaths or permanent loss of function.

"We have until recently believed that the [Joint Commission] database is representative of the broad universe of sentinel events," **Dennis O'Leary**, MD, said in an open letter to all accredited institutions.

"Now, in retrospect, it appears that we are receiving a disproportionately low volume of reports on [deaths and impairment due to infections]. In view of the importance and high visibility of such occurrences, we urge you to share this information with the Joint Commission, just as you might share information about other types of sentinel events with us," he wrote. "Given the nature of these events, we believe it likely that you will have already conducted the related in-depth analyses anticipated by Joint Commission standards."

However, reporting to the JCAHO Sentinel Event Database continues to be voluntary, he said. O'Leary acknowledged that such events are often already being reported to various government agencies and confidentiality is no small concern. "While the Joint Commission has thus far been able to maintain the confidentiality of all sentinel event information reported to it to date, we do understand that confidentiality concerns limit the number of cases actually brought to our attention," he explained.

The request comes as the Joint Commission continues a dramatic process to reinvent itself in an age of patient safety. Scalded by criticisms in the press that it is lax on infection control, the Joint Commission recently warned that it was going to become more aggressive in the area.

"If a patient dies in a hospital or has a permanent disability as a result of a nosocomial infection, the hospital really should think about that as a sentinel event and treat it and evaluate as such," says **Paul Schyve**, MD, Joint Commission senior vice president.

In addition, the Joint Commission is scheduled to convene the first meeting of a special task force on infection control in late January or early February. The agency decided to form the panel after ICPs protested a proposal to consolidate and reduce the number of infection control standards in 2004, when the commission plans to implement its ambitious Shared Vision/New Pathways accreditation program. The whole series of events is befuddling to some ICPs.

"First of all, they tell us they are going to cut infection control regs — [making us] a less important part of the survey process," explains **Susan**

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Kraska, RN, CIC, an ICP at Memorial Hospital of South Bend, IN. "All of the ICPs ask, 'What are you guys thinking?' Now, we have the opposite end of the spectrum, wanting us to report fatal or life-impairing infections. Wait a minute, either they are important or they are not," she continues. "It just doesn't seem to be very well thought out on the Joint Commission's part. I think they really have ICPs back on their heels right now because of this flip-flop."

That said, ICPs certainly view such serious nosocomial infections with deep concern, she emphasizes. "I am working every day to prevent those things from happening," she says. "To add additional reporting, I guess I want to know to what end? Is this going to improve patient outcomes by reporting it? What are they looking for — are they just looking for data so they can tell folks their survey process is [thorough]?"

William Scheckler, MD, one of the recently appointed members to the Joint Commission's infection control task force, says in informal discussions with JCAHO officials, he has strongly disagreed with interpreting nosocomial infections as sentinel events. Traditionally, nosocomial infections have been regarded as "complications" rather than sentinel events, he explains.

"[Sentinel events] are supposed to be limited to "unexpected serious injury or disability," says Scheckler, hospital epidemiologist at St. Mary's Hospital in Madison, WI. "Hospitals do not have to report these directly to the JCAHO as long as they keep track of them and do the proper analysis of such events and demonstrate they are doing so when their accreditation visits occur. I hope this new advisory panel can discuss this issue at some length."

Such infections are probably not reported to the Joint Commission as sentinel events very frequently because it is actually quite rare that a nosocomial infection is the obvious sole reason for a patient death, adds **Patti Grant**, RN, BSN, MS, CIC, director of infection control at RHD Memorial Medical Center in Dallas. Patients frequently have multiple underlying diagnoses across the broad spectrum of disease, from diabetes to pulmonary hypertension, she stresses. In contrast, a wrong site surgery or medication error is 100% external to the patient.

"A nosocomial event is rarely 100% external, and involves the patient's internal ability to fight infection, their colonization with endogenous pathogens, the invasive procedures required to save their life," Grant says. "Calling a wrong-site surgery a catastrophic sentinel event is obvious, and correct, and must be reported if patient safety is ever to improve. But in my 12 years of infection control, I can honestly say that I have seen very few black-and-white [cause/effect] deaths from a nosocomial infection."

Even with morbidity associated with a nosocomial infection, there are often many extraneous variables that confuse the issue, she notes. "Which came first, the chicken or the egg? The patient's intrinsic risk factors for infections are fluid and complicated — making such a 'call' for a sentinel event reckless. We must be responsible to our professionalism, JCAHO included, and not be cavalier about requesting, or supplying, such potentially misguided information."

Pushing for such data could cause a chill factor on open discussions in the medical literature, she adds. "My overall fear of this type of reporting, and for that matter most 'external' benchmarking of nosocomial infection surveillance, is that it will stifle our openness with publication in peer-review journals of outbreaks and [hinder our] success with process improvement." ■

ICPs won't push JCAHO for new staffing formula

Study shows ratio of 1 ICP to 250 beds outdated

Though recent research supports the need for more infection control staffing than traditionally allotted, ICPs are not expected to press for a specific staffing requirement from the Joint Commission on Accreditation of Healthcare Organizations.

The guideline for staffing infection control programs has traditionally been one ICP for every 250 licensed beds, but a recently published study indicates the ratio should be approximately one ICP per 100 licensed beds under current conditions in health care.[1] The longstanding benchmark of one ICP per 250 occupied beds was recommended by the Centers for Disease Control and Prevention's Study on the Efficacy of Nosocomial Infection Control (SENIC) project[1] The SENIC data were gathered in the 1970s.[2]

"That study was what was appropriate for that time in history," says **Carol O'Boyle**, PhD, RN, assistant professor at the University of Minnesota School of Nursing in Minneapolis. "I think we

need to question the appropriateness of the guidelines that people derived from that in today's contemporary health care."

O'Boyle is lead author of the new staffing study, which involves the Delphi method — time and task surveys and re-surveys of 32 participating ICPs. It is well known that ICPs are stretched thin over an increasing array of responsibilities. Infection control has expanded into a variety of different health care settings, including physicians' offices, affiliated clinics, and long-term care. All the while, additional functions, including bioterrorism, patient safety, employee health, and management of central services have been added to the traditional ICP program.

Data were obtained from the ICPs in 20 states through a series of 10 surveys. Competing responsibilities and lack of adequate resources were the most frequently cited reasons for nonperformance of essential infection control tasks. A ratio of 0.8 to 1.0 ICP for every 100 occupied acute care beds was suggested as adequate staffing by the Delphi panel. However, the findings need to be confirmed through subsequent research, O'Boyle says.

"One needs to be careful in looking at these recommendations, in that these were made by a panel of 32 [people]," she says. "The advantages of using this Delphi method are that they did not meet each other and did not see what others were writing to me. So the value of a Delphi is that you are able to get recommendations without having panel members influence each other."

The Joint Commission has emphasized in its standards that infection control programs should be adequately staffed, but has never required a specific ratio or formula, "One of the issues that we always have to take into account is the differences in organizations and patient mix," says **Paul Schyve,** MD, Joint Commission senior vice president. "That's one reason why we have concluded that hard-and-fast staffing ratios — say for nurses — are not the best way to approach staffing effectiveness."

Indeed, ICPs would be asking the Joint Commission to codify a ratio or formula that is not drawn out for any other medical profession.

"I can't think of any other standard that says thou shalt have this number of people to do anything," says **Candace Friedman**, MT (ASCP), MPH, CIC, manager of infection control and epidemiology at the University of Michigan Hospitals and Health Centers in Ann Arbor.

"The staffing standards of the Joint Commission imply that an institution needs to evaluate all of its staffing and be staffed appropriately. If there are data that support a particular type of staffing, then that is what should be brought forward if there are issues within a particular institution. I don't think it should be a specific number because there may be instances where an institution may need to be better staffed than that for other reasons. I wouldn't want to be held to any specific requirement."

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JCAHO looking at timing of surgical drug prophylaxis

Research may lead to new quality indicators

The Joint Commission on Accreditation of Healthcare Organizations is partnering with the University of Tennessee, the Centers for Disease Control and Prevention, and the Society for Healthcare Epidemiology of America to conduct a four-year study under an Agency for Healthcare Quality and Research-funded grant project entitled "Trial to Reduce Antibiotic Prophylaxis Errors" (TRAPE). The study will examine hospitals' timely use of antibiotics before and after cardiovascular, joint replacement, and hysterectomy surgeries to effectively reduce post-surgical infection.

It is estimated from one-third to one-half of surgical patients do not receive antibiotics or receive them in such a way as to leave them relatively unprotected from infection, says principal investigator **Stephen B. Kritchevsky**, PhD, professor of the department of preventive medicine at the University of Tennessee in Knoxville.

"If you split the difference, about 35% or 40% of patients are getting suboptimal prophylaxis," he says. "It is quite widespread. Most antibiotics should be given about an hour before surgery. If they are given before that or after the incision, it is really not optimal. So [this study] is really a 'process' focus — here's a target, that if people could hit, patient care quality would be improved. What is stopping people from hitting this target and

what can they do to do a better job?"

As ICPs are well aware, post-surgical infections can lead to readmission, extended hospital stays and even death. "Patients who don't get prophylaxis or get it very late are somewhere on the order of four to six times more likely to get infections," Kritchevsky says.

The study will start early this year, as 40 hospitals will enroll in the randomized trial for six months. Half of the hospitals will receive feedback on their error rates. The other half will receive feedback plus intensive assistance in identifying and implementing solutions to improve the appropriateness and timeliness of preventive antibiotics. While 20 hospitals will only get baseline and summary information, another 20 selected at random will receive much more detailed feedback.

"We have a few interventions — innovations, we hope — that we are trying to validate," says Kritchevsky. "We will be doing a process assessment of how each of the hospitals in our study provide antibiotic prophylaxis. We'll relate that to the timing problems and hopefully identify a list of best practices."

The Joint Commission is serving as coordinator of the study, but is participating through its research — as opposed to regulatory — branch. That means, essentially, that the study is not being done with an eye on changing Joint Commission requirements, though that could be the result somewhere down the road. ■

Surveyors checking for new patient safety goals

Be advised that accreditation surveyors now are looking for signs of implementation of the six patient safety goals established for 2003.

Effective Jan. 1, 2003, all Joint Commission Accreditation of Healthcare Organization organizations will be surveyed for implementation of the recommendations or of an acceptable alternative. Alternatives must be at least as effective as the published recommendations in achieving the goals. Failure to implement any of the applicable recommendations or an acceptable alternative will result in a single special Type I recommendation (citation).

Surveyors will look for evidence of consistent implementation of the recommendations, but you don't need to do any special documentation for the Joint Commission that you wouldn't be doing already to implement the recommendations.

"The surveyors will look at whatever documentation you have that is relevant and will interview the organization's leaders and direct caregivers to determine whether the recommendations have been implemented and how consistently they are being done," the Joint Commission stated in a patient safety advisory. "It's the actual performance we are interested in, not the paperwork."

The 2003 patient safety goals are:

1. **Improve the accuracy of patient identification.** Use at least two patient identifiers (neither to be the patient's room number) whenever taking blood samples or administering medications or blood products. Prior to the start of any surgical or invasive procedure, conduct a final verification process, such as a "time-out," to confirm the correct patient, procedure and site, using active — not passive — communication techniques.
2. **Improve the effectiveness of communication among caregivers.** Implement a process for taking verbal or telephone orders that requires a verification "read back" of the complete order by the person receiving the order. Standardize the abbreviations, acronyms, and symbols used throughout the organization, including a list of abbreviations, acronyms, and symbols not to use.
3. **Improve the safety of using high-alert medications.** Remove concentrated electrolytes (including, but not limited to, potassium chloride, potassium phosphate, sodium chloride >0.9%) from patient care units. Standardize and limit the number of drug concentrations available in the organization.
4. **Eliminate wrong-site, wrong-patient, wrong-procedure surgery.** Create and use a preoperative verification process, such as a checklist, to confirm that appropriate documents (e.g., medical records, imaging studies) are available. Implement a process to mark the surgical site, and involve the patient in the marking process.
5. **Improve the safety of using infusion pumps.** Ensure free-flow protection on all general-use and patient-controlled analgesia intravenous infusion pumps used in the organization.
6. **Improve the effectiveness of clinical alarm systems.** Implement regular preventive maintenance and testing of alarm systems. Assure that alarms are activated with appropriate settings and are sufficiently audible with respect to distances and competing noise within the unit. ■

(Continued from page 18)

"'Long-term action' is a euphemism for 'dead,'" says **Bill Borwegen**, MPH, occupational safety and health director for the Service Employees International Union (SEIU) in Washington, DC.

"Like when you say somebody 'passed away' instead of 'died.' Well, this is dead. Dead as a doornail," he explained.

The timing is particularly ironic, Borwegen says, in the wake of a smallpox vaccination plan.

"It's a clear indication that we do not have a comprehensive approach to the bioterrorism threat," he says.

"Everybody's working on the smallpox vaccination program but nobody's looking at these larger infection control issues posed by bioterrorism agents. Nobody's looking at how many negative pressure rooms hospitals have," he adds.

"Nobody's requiring hospitals to set up rudimentary respiratory protection programs." A TB rule would have provided protections against other airborne diseases, Borwegen contends.

Were TB provisions outdated?

But others have argued strongly that the provisions of the TB rule became outdated even before the final draft was completed. The Association for Professionals in Infection Control and Epidemiology (APIC) worked actively against the standard and hailed OSHA for backing down.

Even some TB experts found the news heartening. The work on the OSHA standard was one of several influences on hospitals and others as they improved their TB protections in the 1990s, notes **Lee Reichman**, MD, MPH, executive director of the National Tuberculosis Center at the University of Medicine and Dentistry of New Jersey in Newark and author of *Time Bomb: The Global Epidemic of Multi-Drug Resistant TB* (New York City: McGraw Hill; 2001).

But as TB prevention practices improved, a standard was no longer necessary, he says.

"More power to them," Reichman remarks. "There are not many government agencies that can admit they're wasting a lot of time and effort."

The provisions of the rule would have added burdens to hospitals without preventing TB transmission, he contends.

"The underlying issue of all of this is the dangerous case of tuberculosis as the undiagnosed case. As soon as it is diagnosed, it's not dangerous anymore." ■

Simple, accurate test now available for latent TB

A new blood test for tuberculosis infection could revolutionize the method for screening health care workers and lead to a reduction in false positive results.

"It's tremendous. It's a 100-year upgrade of the tuberculin skin test," says **Gerald Mazurek**, MD, medical epidemiologist with the Division of Tuberculosis Elimination at the Centers for Disease Control and Prevention (CDC) and the principal investigator for CDC's Phase III trials of the test.

"Diagnosing tuberculosis infections is difficult, especially when the infections are asymptomatic. We have relied on the tuberculin skin test for years despite its limitations," he says.

While the Food and Drug Administration approved QuantiFERON-TB in November 2001, hospitals and other facilities with high-risk populations are just beginning to conduct pilot programs with the new test, says **Mark Boyle**, senior vice president, sales and marketing at Cellestis of Valencia, CA, which is manufacturing and marketing the test in the United States.

In guidelines published in December, the CDC recommends confirming some positive QuantiFERON-TB test results with a skin test.[1]

But Mazurek and other researchers say the blood test improves upon and eventually could replace the skin test. QuantiFERON-TB is produced by the Australian medical diagnostic firm Cellestis Limited. It costs $10 per patient for the diagnostic kit.

"I think it's the future of testing for latent tuberculosis infection," says **Lee Reichman**, MD, MPH, executive director of the National Tuberculosis Center at the University of Medicine and Dentistry of New Jersey in Newark and author of *Time Bomb: The Global Epidemic of Multi-Drug Resistant TB* (McGraw Hill, 2001).

The current TB skin test presents a host of potential problems for hospital employee health. Health care workers must return for follow-up within 48 to 72 hours for an evaluation of the reaction, and redness or erythema is sometimes mistaken for a positive reaction. Infection with other mycobacteria or previous BCG vaccination also can produce false positive results.

The blood test works by measuring a component of the cell mediated immune response to tuberculin purified protein derivative (PPD). It

identifies gamma interferon, a protein produced by white blood cells as a reaction to TB infection. Mazurek and colleagues compared the two tests in 1,226 subjects and found that the QuantiFERON was comparable to the skin test in its ability to detect latent TB but was less affected by previous vaccination with BCG or by other nontuberculous mycobacteria.[2] And while the PPD skin test sometimes provokes an immune response that can impact future test results, the blood test can be repeated as often as needed.

How much will the convenience of a TB blood test be worth to hospitals?

The skin test is currently less expensive (about $2 per test for the reagent) than QuantiFERON. But Boyle contends that the extra staff time used to track down employees, read their reactions, and follow up on questionable reactions makes the two tests roughly comparable in cost. The blood test requires some additional lab time, but it is still much more efficient, he says. "Just by having only a single contact with the employee, you cut down on a lot of money."

The objectivity of QuantiFERON also is appealing. For those with a known risk of exposure to tuberculosis, which includes hospital and nursing home workers, the response to a PPD antigen must be at least 15% of the response to a positive control antigen. In subjects judged to be at low risk for TB exposure, the response must be at least 30% that of the control. The blood test also can compare the reaction to *Mycobacterium tuberculosis* with other mycobacteria antigens to rule out false positives.

"The results can be available the next day," Mazurek notes. "There's much more versatility in its ability to give you a result."

If the QuantiFERON test is negative, CDC does not recommend any further evaluation. But people with positive results should have a chest X-ray and possibly a TB skin test to confirm the QuantiFERON test results. People with no identified risk for TB infection should have a positive QuantiFERON result confirmed with a skin test before therapy is advised, Mazurek says.

For people at increased risk of infection, including health care workers, the confirmatory skin test is optional. In contrast, TB skin tests should not be confirmed with the QuantiFERON-TB because the injected PPD could affect the blood test results, he adds.

"We think this will increase the accuracy of detecting latent tuberculosis infection," he says. "We think this methodology will probably be more accurate than just getting the TB skin test alone."

Further research is under way, but currently QuantiFERON is not recommended for people with active TB, contacts of people with active TB, children under the age of 17, pregnant women, and immunosuppressed individuals.

Eventually, the blood test itself will offer an even greater ability to detect latent TB. "We can improve the specificity or sensitivity of the test by looking at multiple antigens," Mazurek says. The CDC is collaborating with the manufacturer and others to identify more sensitive and specific antigens for the test. "We need to develop collaborations and encourage others to evaluate the assay," he says. "The tuberculin skin test has been evaluated and improved over the last 100 years. The QuantiFERON also needs [more] evaluation."

[Editor's note: More information on QuantiFERON-TB is available from mark_boyle@cellestis.com. Telephone: (800) 519-4627.]

References

1. Mazurek GH, Villarino ME. Guidelines for using the QuantiFERON-TB test for diagnosing latent *Mycobacterium tuberculosis* infection. *MMWR Dispatch* 2002; 51:1-5.
2. Mazurek GH, LoBue PA, Daley CL, et al. Comparison of whole-blood interferon assay with tuberculin skin testing for detecting latent *Mycobacterium tuberculosis* infection. *JAMA* 2001; 286:1,740-1,747. ■

Lift teamwork: MSD injuries drop from 34 to 0

When patients need a lift, CNAs page colleagues

It's a common paradox: Employees become injured during patient transfers, while lift equipment sits idle down the hall.

El Camino Hospital in Mountainview, CA, enlisted the health care workers to create a better ergonomic climate. They did it — not with lift teams, but with teamwork. The Sixth Floor medical unit once had the highest injury rate in the hospital. Since January 2002, there hasn't been a single injury.

"There's a certain amount of pride now on that floor relative to their performance," says **John Deex**, RN, MS, OHNP, COHN-S, director of employee health and safety. "It's really cool to tell people, 'We don't have any injuries.'"

Other units, such as the critical care unit, are now launching the same improvement process.

Although the action plan may differ, the basic strategy is the same: involving frontline workers in the solution.

Deex also maintains the importance of regular feedback and recognition. The hospital CEO even singled out the Sixth Floor project as an example of excellence. "The whole idea of prevention is to keep it on the forefront of people's minds," he says. "They can't take care of other people until they take care of themselves."

The patient lift/transfer program began with an evaluation of the current ergonomic compliance. The results were bleak.

On admission, nurses were supposed to assess patients for their risk of falling, their level of dependency, and need for lift assistance on a computerized patient care plan. But most plans made no mention of lift needs. Patients on this medical floor suffer from chronic conditions, including Alzheimer's Disease, and are among the weakest and sickest in the hospital.

Employee health nurse practitioner **Beverly Nuchols**, RN, OHNP, PhD, asked certified nurse assistants (CNAs), who were responsible for many lifts and transfers, about the ergonomic equipment. "Even though they had it there and they had been trained on it five years ago, they didn't have the culture to support that. They didn't have the time to use it," she says. "They didn't feel comfortable using it because they hadn't used it a lot. Some of them felt the patients would be afraid of it."

The registered nurses knew even less about the lift equipment than the CNAs and didn't encourage its use, Nuchols discovered.

"What we have found is that it really requires an ongoing motivated program to educate and support people on the floors to use the equipment," Deex says.

Nuchols arranged meetings with workers and managers from each shift. "We would talk about the high-risk scenarios for patients," she says.

For example, the CNAs talked about a common scenario in which a family member wanted the patient moved up in bed or transferred to a chair. They didn't want the CNA to wait for assistance. They wanted to move the patient right away, and they offered to help.

"They end up not doing their part. They pull at a different time," Nuchols says. "People got hurt that way by not having the other person they're working with work as a team." How could the Sixth Floor staff get quick and safe transfers? They used the pagers carried by all employees on the floor to create a "transfer team page."

"When a CNA wants to move someone up in bed or get someone up in a chair or they're going to transfer someone to a bed or a gurney, they would go to the front desk and say, 'Please get a transfer team to this room,'" Nuchols says. "The people responding to the page know they're only going to be in that room for 30 seconds. The person sending the page has already gotten the room ready." Sometimes, five people might show up to respond to a page. The person leading the lift can pick the helpers, and the rest go back to their tasks, she explains.

The Sixth Floor has 10 transfer teams of about eight or nine members each, with an equal number of RNs and CNAs. A CNA is the transfer team leader, who trains the other on the use of the equipment.

At the launch of the new program, the teams entered a friendly competition to see who could be the most successful at reducing injuries. For six weeks leading up to the Oscar Awards, the teams vied to win Blockbuster gift cards. The team with no injuries would get the cards.

"Because the program was so successful, everybody was a winner. We had no injuries. Not one," Deex says.

Positive feedback and reinforcement from Nuchols helps keeps the teams on track. So does another imperative: Team lift support is now one of the employees' job competencies. Being able to use the lift equipment and responding to the transfer team page will be addressed at annual performance reviews.

Call out the 'Bod Squad'

She continues to audit care plans and monitor use of the equipment and transfer team pages. But she also has moved on to other departments.

The Critical Care Unit calls their teamwork system the "Bod Squad." The unit is small, so employees just call out, "Code Bod Squad," and co-workers come to help them.

She's also working with the transporters to track and prioritize calls, and with nurses to help them understand the importance of waiting a few minutes for a safe lift. Nuchols also is evaluating equipment needs and the purchase of new items.

El Camino expects to save money due to a lower rate of injuries. But that main message of the program involves a safety mindset — and the value of the workers to the hospital, Deex says. "It's a culture you generate within your institution about

how you feel about your employees and what it is you're trying to do," he says. "If you start bringing in the issues of dollars and how much injuries cost, people perceive it's all about money. It's not all about money. It's about preventing people from getting hurt." ■

Needle safety tops citation for hospitals

OSHA reports increase in inspections

Inspections by the U.S. Occupational Safety and Health Administration (OSHA) rose this year, exceeding the agency's goals for enforcement action. Of the 37,493 inspections in FY 2002, 159 occurred at hospitals, resulting in 277 citations. The bloodborne pathogen standard continued to be a major source of enforcement action at hospitals, accounting for the greatest number of citations.

"Since the incorporation of the Needlestick Safety and Prevention Act into OSHA's bloodborne pathogens standard in 2000, heightened awareness among health care professionals regarding the requirement to use safer medical devices to protect against needlesticks has increased the number of complaints that OSHA has received from hospitals," says OSHA spokesman **Bill Wright**.

"That, along with the agency's National Emphasis Program in Nursing and Personal Care Facilities, has resulted in a steady increase in the number of violations issued under the bloodborne pathogens standard since 2000," he says.

Other frequently cited areas at hospitals include lockout/tagout, electrical/wiring methods, hazard communications, and electrical systems design. Although ergonomics has yet to lead to a single citation, OSHA reported that it investigated the hazard in 63 inspections overall, which included some health care facilities. The fiscal year ended Sept. 30.

Most of the ergonomic-related inspections are related to the Site-Specific Targeting Program, which included nursing homes. Others resulted from complaints, OSHA administrator **John L. Henshaw**, said at the National Ergonomic Conference in Las Vegas.

"OSHA has issued 16 ergonomic hazard letters advising employers that they needed to make changes in their workplace to reduce hazards that could lead to injuries," he said. Other inspections are still ongoing.

Henshaw also named the 15 members of the national advisory committee on ergonomics, part of the agency's four-pronged "comprehensive approach" to ergonomics. The committee will meet two to four times a year and will evaluate ergonomic research and make recommendations on possible interventions, he said. "Each committee member brings skills and expertise that, collectively, will help the agency accelerate the decline of ergonomic-related injuries."

However, the Service Employees International Union (SEIU) lambasted Henshaw's choices. "This is the first time that OSHA has put together an advisory committee that wasn't balanced [between labor and management]," says **Bill Borwegen**, MPH, SEIU, occupational safety and health director. "I don't know how they expect to get balanced advice when these committees are so unbalanced. It's a prescription for an ineffective committee." ■

CE *questions*

5. According to a study in the *New England Journal of Medicine*, what portion of adult vaccinees are likely to miss work, school, recreational activities or have trouble sleeping after smallpox vaccination?
   A. about one-fourth
   B. about one-third
   C. everyone vaccinated
   D. only those with severe reactions
6. According to **Tommy Thompson**, the secretary of the U.S. Department of Health and Human Services, how will health care workers be compensated for adverse effects of smallpox vaccination?
   A. workers' compensation
   B. federal vaccine fund
   C. special act of Congress
   D. private medical insurance only
7. Quantiferon-TB, a new TB blood test, measures what marker for latent TB infection?
   A. antibodies
   B. RNA
   C. DNA
   D. gamma interferon
8. When a CNA on the Sixth Floor at El Camino Hospital in Mountainview, CA, issues a transfer team page, who responds?
   A. special hospitalwide lift team
   B. hospital transporters
   C. nurses and CNAs on the floor
   D. employee health

Answers: 5. B; 6. A; 7. D; 8. C

NEWS BRIEFS

Check the box for hearing loss cases on OSHA 300

Provision to record MSDs delayed again

Employers will need to record hearing-loss cases in a separate column on the OSHA log beginning Jan. 1, 2004, the U.S. Occupational Health and Safety Administration (OSHA) announced.

The agency again delayed the new definition of musculoskeletal disorders (MSDs) contained in its record-keeping standard and the use of a separate column to collect data on MSDs. They will continue to be reported with other occupational injuries. "While the agency has not yet decided on the correct approach for dealing with the Part 1904 MSD definition, OSHA plans to publish a final rule in 2003 to resolve the MSD definition issue for the year 2004 and beyond," the agency said in a *Federal Register* notice.[1]

The hearing-loss and MSD recording provisions had been delayed since the record-keeping standard became effective Jan. 1, 2002. Hearing-loss is recordable if there is a 10-dB shift from baseline, and the overall hearing loss represents a shift of at least 25 dB.

"Data from the new column will improve the nation's statistical information on occupational hearing loss, improve the agency's ability to determine where the injuries occur, and help prioritize hearing loss prevention efforts," OSHA administrator **John L. Henshaw** said in a statement.

OSHA also acknowledged that the new hearing-loss criteria will lead to an increase in the number of hearing-loss cases reported. The new criteria became effective Jan. 1, 2003.

"Caution must be used when comparing the 2003 and future data to prior years, when the 25 dB criteria for record keeping was used," the agency said. "OSHA recognizes this increase, and will take the changes in the record-keeping rule into account when evaluating an employer's injury and illness experience."

OSHA also clarified the use of a baseline to determine the standard threshold shift. "An annual audiogram may be substituted for the baseline audiogram when, in the judgment of the audiologist, otolaryngologist, or physician who is evaluating the audiogram: The standard threshold shift revealed by the audiogram is persistent, or the hearing threshold shown in the annual audiogram indicates significant improvement over the baseline audiogram."

Reference

1. Occupational Safety and Health Administration. Occupational injury and illness recording and reporting requirements. 67 *Fed Reg* 77,167 (Dec. 17, 2002). ▼

New HIV test is as easy as a pregnancy test

The Food and Drug Administration approved a quick HIV test that only requires a fingerstick of blood and takes 20 minutes.

The OraQuick Rapid HIV-1 Antibody Test, manufactured by OraSure Technologies of Bethlehem, PA, uses simple technology similar to that of a pregnancy test.

In the test, a small blood sample is placed in a vial, where it is mixed with a developing solution. If HIV-1 antibodies are present in the solution, a dipstick-style device will display two reddish-purple lines in a small window.

In clinical tests, OraQuick had a sensitivity of 99.6%. Positive results must be confirmed by additional testing.

The test can be stored at room temperature and requires no specialized equipment.

More information on the test is available at www.orasure.com. ■

COMING IN FUTURE MONTHS

- What's the best way to monitor smallpox vaccine injection sites?
- Will all HCWs have a chance to get the smallpox vaccine?
- How to counteract myths about blood-borne pathogens
- Detecting TB is the key to protection
- New research targets violence prevention in hospitals

United States Postal Service

Statement of Ownership, Management, and Circulation

1. Publication Title	2. Publication No.	3. Filing Date
Hospital Employee Health	0 7 4 4 - 6 4 7 0	9/25/02
4. Issue Frequency	5. Number of Issues Published Annually	6. Annual Subscription Price
Monthly	12	$429.00

7. Complete Mailing Address of Known Office of Publication *(Not Printer) (Street, city, county, state, and ZIP+4)*
3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta,
Fulton County, GA 30305

Contact Person: Willie Redmond
Telephone: 404/262-5448

8. Complete Mailing Address of Headquarters or General Business Office of Publisher *(Not Printer)*
3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

9. Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor *(Do Not Leave Blank)*

Publisher *(Name and Complete Mailing Address)*
Brenda Mooney, 3525 Piedmont Road, Bldg. 6, Ste. 400, Atlanta, GA 30305

Editor *(Name and Complete Mailing Address)*
Coles McKagen, same as above

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10. Owner *(Do not leave blank. If the publication is owned by a corporation, give the name and address of the corporation immediately followed by the names and addresses of all stockholders owning or holding 1 percent or more of the total amount of stock. If not owned by a corporation, give the names and addresses of the individual owners. If owned by a partnership or other unincorporated firm, give its name and address as well as those of each individual. If the publication is published by a nonprofit organization, give its name and address.)*

Full Name	Complete Mailing Address
American Health Consultants	3525 Piedmont Road, Bldg. 6, Ste 400 Atlanta, GA 30305

11. Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1 Percent or More of Total Amount of Bonds, Mortgages, or Other Securities. If none, check box → ☐ None

Full Name	Complete Mailing Address
Medical Economics Data, Inc.	Five Paragon Drive Montvale, NJ 07645

12. Tax Status *(For completion by nonprofit organizations authorized to mail at nonprofit rates.) (Check one)*
The purpose, function, and nonprofit status of this organization and the exempt status for federal income tax purposes:
☐ Has Not Changed During Preceding 12 Months
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PS Form **3526**, September 1998 *See instructions on Reverse)*

13. Publication Name: Hospital Employee Health

14. Issue Date for Circulation Data Below: October 2002

15. Extent and Nature of Circulation			Average No. of Copies Each Issue During Preceding 12 Months	Actual No. Copies of Single Issue Published Nearest to Filing Date
a. Total No. Copies *(Net Press Run)*			1983	2102
b. Paid and/or Requested Circulation	(1)	Paid/Requested Outside-County Mail Subscriptions Stated on Form 3541. *(Include advertiser's proof and exchange copies)*	1528	1593
	(2)	Paid In-County Subscriptions *(Include advertiser's proof and exchange copies)*	11	7
	(3)	Sales Through Dealers and Carriers, Street Vendors, Counter Sales, and Other Non-USPS Paid Distribution	6	59
	(4)	Other Classes Mailed Through the USPS	44	2
c. Total Paid and/or Requested Circulation *(Sum of 15b(1) and 15b(2)*			1589	1661
d. Free Distribution by Mail *(Samples, Complimentary and Other Free)*	(1)	Outside-County as Stated on Form 3541	20	24
	(2)	In-County as Stated on Form 3541	2	2
	(3)	Other Classes Mailed Through the USPS	0	0
e. Free Distribution Outside the Mail *(Carriers or Other Means)*			4	0
f. Total Free Distribution *(Sum of 15d and 15e)*			26	26
g. Total Distribution *(Sum of 15c and 15f)*			1615	1687
h. Copies Not Distributed			368	415
i. Total *(Sum of 15g, and h.*			1983	2102
Percent Paid and/or Requested Circulation *(15c divided by 15g times 100)*			98	98

16. Publication of Statement ofOwnership
Publication required. Will be printed in the February issue of this publication. ☐ Publication not required.

17. Signature and Title of Editor, Publisher, Business Manager, or Owner: Publisher — Date: 9/25/02

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