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OSHA directive requires hospitals to implement safer needle technology

Mandate puts focus on device evaluation, training

The move toward safer needle devices has become a national mandate as the U.S. Occupational Safety and Health Administration (OSHA) has issued a directive requiring the use of "effective engineering controls" to prevent needlestick injuries.

While OSHA previously cited hospitals that failed to evaluate and use safer devices, this updated compliance directive makes clear what actions hospitals should be taking concerning occupational exposure to bloodborne pathogens. "There are a lot of commercially available products, and you should be using them to [prevent injuries]," says **Melody Sands**, director of OSHA's office of health compliance assistance.

OSHA Update: Bloodborne Pathogens Compliance Directive

Experts in needle safety hailed the directive as a milestone in the long effort to protect health care workers from needlesticks. "This is the recommendation I've been making for years, [to adopt safer devices]," says **Janine Jagger**, PhD, MPH, director of the International Health Care Worker Safety Center at the University of Virginia in Charlottesville. "There was no regulatory clout behind it. Now, we have that clout."

Safer devices could reduce sharps injuries by more than 70%, Jagger says. It is estimated that health care workers suffer more than half a million needlestick injuries annually.

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COMING IN FUTURE ISSUES

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■ **HIV exposure:** Getting patient consent on testing before surgery

■ **Clearing the air:** OR nurses push for rules on surgical smoke

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Some union leaders say they will monitor hospital compliance with the new OSHA directive and file complaints against those facilities that don't show a good-faith effort. In fact, complaints in California and Ohio have used existing state laws and federal regulations to force a move toward safer devices. **(See related article on p. 4.)**

"Now that the compliance directive is out, there will be a very organized effort to involve front-line workers in reporting to OSHA when safer devices have not been utilized," says **Susan Wilburn**, RN, MPH, senior specialist for occupational safety and health with the American Nurses Association in Washington, DC.

Meanwhile, the directive, which updates one published eight years ago, isn't the final word on safer needle devices. Legislation is still pending in Congress to require the use of needleless systems and safety mechanisms, enhance reporting of needlestick injuries, and create a national clearinghouse on safer technologies.

OSHA Update: Bloodborne Pathogens Compliance Directive

"This is a great development. This is tremendous progress, but the job isn't done yet," says Wilburn, whose organization wants a national injury record system and new wording in the OSHA standard itself.

OSHA has announced plans to revise the bloodborne pathogens standard by next fall. And the upcoming record-keeping rule, due out next year, will require hospitals to report all needlestick injuries, not just those that result in seroconversion, Sands says.

To find out what is currently expected of them, hospitals need only look as far as the appendices of the updated directive. OSHA provides sample device evaluation forms, committee structures, and a sample exposure control plan, as well as Internet links and copies of the Centers for Disease Control and Prevention (CDC) guidelines. The directive does not mention any specific needle devices, but lists of devices can be found on the Web sites of the Sharps Injury Control Program in San Francisco (www.ohb.org/sharps. htm) and the International Health Care Worker Safety Center (www.med.virginia.edu/medcntr/centers/epinet/links.html).

For example, in an exposure control plan that must be updated at least annually, employee health clinicians must consider all potentially

hazardous situations and how they could be avoided through the use of "engineering controls" (or safer devices). Hospitals must consider how the devices would function in the working environment, and they will be expected to rely on the ample literature on device safety, says Sands.

Act like it's your family you're protecting

"Hundreds of thousands of needlestick injuries occur each year, and the prevalence of bloodborne pathogens is growing, particularly hepatitis C," says Sands. "You should implement these controls wherever feasible. Look at your exposure control plan as if your family was out there. What would you do to keep them from getting stuck?"

Just choosing a device won't be enough. As newer and better products become available, employee health clinicians will need a mechanism for re-evaluating the devices. **(See related article on p. 6.)**

"If a compliance officer sees someone using an engineering control but believes another one would be more effective, they would not immediately issue a citation," says Sands. "They would coordinate with the bloodborne pathogens coordinator [in that region]. That's going to be a judgment call. We'll deal with that on a case-by-case basis. It would have to clearly be more effective."

The new directive doesn't mean *every* conventional sharp device must be eliminated from hospitals. For example, if a needle is used only to draw medication, such as in a pharmacy, and there is no potential for employee exposure to bloodborne pathogens, then a conventional needle can be used, says Sands.

"Exposure is always key for OSHA to find a hazard," says Sands.

The directive also clarifies actions employers must take if an employee is exposed, explicitly requiring hospitals to follow appropriate guidelines of the CDC. Postexposure evaluation and follow-up must occur "as soon as possible after exposure," the directive states.

The CDC guidelines were previously voluntary, but most employee health offices followed them, says **Mary Ann Gruden**, MSN, CRNP, NP-C, COHN-S/CM, executive president of the Association of Occupational Health Professionals in Healthcare in Reston, VA, and employee health nurse practitioner at Sewickley (PA) Valley Hospital.

Sharps rule stresses evaluation and training

For years, the U.S. Occupational Safety and Health Administration has faced growing pressure to strengthen its requirements on needle safety. Much of the new needle safety technology wasn't available when OSHA released its first bloodborne pathogens directive in 1992.

An updated directive, published in November, makes it clear that employers need to evaluate, implement, and provide training on new needle safety devices. Here are some highlights of the directive:

OSHA Update: Bloodborne Pathogens Compliance Directive

- Employers must use effective engineering controls, including safer medical devices, to eliminate or minimize exposure to bloodborne pathogens.
- Exposure control plans must be reviewed and updated at least annually, and must reflect changes in technology and new scientific information on bloodborne pathogens.
- Employers are encouraged but not required to include front-line health care workers in the evaluation of products. Evaluation of products should take into account the "large body of research and data" on safer devices, as well as Food and Drug Administration approval.
- Employers must follow the guidelines of the Centers for Disease Control and Prevention in Atlanta on vaccinations against hepatitis B and postexposure evaluation and follow-up for HIV and hepatitis C.
- Training must be interactive, including "direct access to a qualified trainer" and the opportunity for employees to ask questions. ■

"It reinforces employee health practices that are already occurring," says Gruden. "If an employee health office is not following these standards, this is an opportune time to implement them."

The directive exacerbates the demand for safer devices, which surged after the passage of a needle safety law in California last year. In fact, hospitals are reporting delays in obtaining products and demonstrations or training from vendors.

"Right now, the issue is going to be the availability of devices," says **June Fisher**, MD, director of the Training for Development of Innovative Control Technology (TDICT) project, which is based at the Trauma Foundation of San Francisco General Hospital.

Catholic Healthcare West, a 48-hospital system based in San Francisco, faced delays in trying to get ready by the July 1 deadline set by the California needle safety law, says **Cynthia Fine**, RN, MSN, CIC, infection control and employee health program consultant.

"It was really difficult to be able to get enough product to do that pilot [testing] and then to get enough to stock the hospitals," she says. "There are shortages all over."

However, the new demand may have positive effects, as prices decline and companies develop devices that are even safer and simpler to use.

Training is another concern for employee health practitioners. The OSHA directive specifies that training sessions should be "interactive," giving employees an opportunity to ask questions.

A device isn't really safer unless the employees know how to use it properly, notes Wilburn. The American Nurses Association is teaming with TDICT to offer workshops around the country on preventing needlesticks and evaluating safer needle devices.

"With any new device, the proof [of effectiveness] is not really in the implementation of the device. The proof is in preventing needlestick injuries," she says. "Even with the best device, you still have to train the health care worker so it's implemented successfully."

Health care workers may initially feel frustrated with new devices, particularly if their use takes a little more time and care, says Fine.

"It is a big change in technique. Even though they knew staff was involved in the assessment, I think it's still hard for them," she says. "Anything that takes a little bit more of their time is difficult."

(Editor's note: A copy of the compliance directive is available on OSHA's Web site at www.osha.gov.) ■

Unions press complaints to enforce needle rules

Inspectors look at logs, exposure control plan

Union-backed employee complaints have led to citations of hospitals in Ohio and California for failing to fully implement safer needle devices.

Those hospitals may be just the first to face fines and remedial action as unions vow to use the complaint process to ensure compliance with the California needlestick prevention law and the new bloodborne pathogens directive issued by the U.S. Occupational Safety and Health Administration (OSHA).

The University Hospital in Cincinnati reached an amicable settlement with OSHA, including $7,500 in fines and an agreement to implement additional safeguards, after an anonymous complaint by nurses. In California, Seton Medical Center in Daly City faced fines of $5,100 for failure to implement an adequate exposure control plan, sharps injury log, and transition to safer devices by July 1, 1999, as required by law. The hospital has appealed the citation.

In California, more complaints are pending. The Washington, DC-based Service Employees International Union (SEIU) is targeting hospitals that fail to have a "constructive dialogue" with the union about implementing safer devices or to include front-line health care workers in the evaluation process, as required by California's law, says **John Borsos**, director of SEIU Local 250's hospital division in Oakland.

"There are a million needlesticks that take place each year across health care settings in the United States," he says. "It's our folks who are getting stuck, it's our folks who are getting HIV, it's our folks who are dying because of this. We need to create a sense of urgency in the industry."

While communication about safety device implementation is important, the effort to protect health care workers should not become politicized, says **Cynthia Fine**, RN, MSN, CIC, infection control and employee health program consultant for Catholic Healthcare West (CHW) in San Francisco, the corporate parent of Seton and 47 other hospitals.

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Fine says while Seton moved more slowly than some hospitals in its implementation, the hospital is now in compliance. The corporate-based selection process included "very broad front-line health care worker input," but not necessarily union representatives, she says.

"The unions are using the safe sharps issue as a campaign issue to try to unionize hospitals," Fine laments. "They tend to be more interested in that than they are in actually working with us, which is our concern."

In the case of University Hospital, the complaint actually led to positive feelings on all sides about the creation of a safer environment.

The teaching hospital had relied on an accident and injury log to target high-risk areas for safer devices and practices, says **Michael Grodi**, MBA, vice president of hospital services. That approach led to a successful reduction in needlestick injuries, he says.

But OSHA wants hospitals to review, evaluate, and, if necessary, implement safer devices every year — a requirement that is spelled out in the updated bloodborne pathogens directive that was issued in November. **(See cover story, p. 1.)** "They required a very specific time-cycled review," says Grodi. "We fell short of the letter of the regulation. We were trying to meet the intent. So they cited us for that. Now we're engaged in a comprehensive review of what we have and what's on the market."

By conducting a yearly review, the hospital may be able to further reduce needlestick injuries, he says. "I think this change in focus is going to be beneficial," he says.

Grodi says he found OSHA inspectors were willing to listen to the hospital's point of view, and citations were withdrawn in a couple of cases when he corrected a misunderstanding. "They recognized we weren't sitting around doing absolutely nothing. We just hadn't gone all the way. We appreciated the attitude," he says.

Throwing used sharps on the floor

In another case, an OSHA citation prompted the hospital to discover a product that could help make the environment safer. In the emergency department, rather than reaching toward a sharps container and possibly endangering co-workers, employees were accustomed to dropping sharps on the floor beneath a gurney during a trauma case. Someone would later collect the sharps and dispose of them properly.

"OSHA prompted us to go out on the market and look for a better idea," says Grodi. "We did find some needle disposal boxes that attached to the gurney. We didn't know they existed."

For their part, OSHA officials lauded the positive attitude at University Hospital. "It was a situation where we felt they were very open and honest with us and they were willing to go to state-of-the-art," says **Richard Gilgrist**, CIH, assistant area director of OSHA in the southwest Ohio area. "We were pleased with their attitude toward compliance."

Other situations may not be resolved quite so amicably, particularly if relations between a union and a hospital are strained. In northern California, SEIU Local 250 sought to meet with hospitals to discuss compliance with the new law. In some cases, union representatives became members of committees that conducted the device evaluation process. **(For more information on selection processes, see related article on p. 6.)**

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"Kaiser Permanente agreed to meet with us and set up a process to begin to select the devices that collectively we think are the best to be used. That was a model of how it should be done," says Borsos.

Other hospitals and hospital corporations were not as responsive. In some cases, the union request went unanswered, says Borsos. "Technical compliance with the law doesn't mean the safest needles are being used," he says. "We wanted to have a constructive dialogue with them about what are the safest needles that people were comfortable with."

Catholic Healthcare West was one corporation that failed to respond and didn't invite union representatives to sit on its main committee, says Borsos. "You have to be inclusive of all viewpoints," he says. "The fact that they excluded labor representatives from the discussion is problematic."

Meanwhile, CHW's evaluation process gained recognition as a model by the California Healthcare Association, notes Fine. In the centralized process, 10 of the 48 hospitals volunteered to conduct pilot projects of safer devices.

After an initial screening, employees used and evaluated devices. A small corporate committee then made final selections, in most cases providing at least two choices to hospitals. "We always had front-line health care workers involved in our process," she says.

Only one hospital from the Bay Area volunteered to conduct a pilot, and that hospital isn't unionized, notes Fine. Of CHW's 48 hospitals, only four are unionized, she says.

"I did make offers to make every effort to make sure we included more SEIU representatives in the future," she says. SEIU has requested representation on the CHW corporate committee, and Fine says the corporation felt that would not be appropriate.

Borsos notes that the union has experts on safe needle devices and has offered to assist with training. At the least, the union should receive information about how hospitals plan to comply with the law, and their voice should be heard in the evaluation of safer devices, he says.

"The best place to start would be a dialogue to include the diversity of viewpoints at CHW when they evaluate products," he says.

Responds Fine: "Certainly there was no attempt to close them out of the process. . . . We're doing our best to involve them even more in the future. We care just as much about the safety of our employees as they do." ■

Needle devices require frequent re-evaluation

Process starts again after just six months

As hospitals move to safer needle devices, they enter a period of intense evaluation. Is it the safest? Is it easy to use? How will it impact patient care?

But those questions don't end with product selection. As new and better products reach the market, employee health practitioners must launch a re-evaluation.

In its new bloodborne pathogens directive, the U.S. Occupational Health and Safety Administration is requiring annual reviews of the exposure control plan. But some hospitals will look at new devices at even more frequent intervals.

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"Because there are so many new devices coming out now, we thought for the next year we would do [the evaluation process] every six months," says **Cynthia Fine**, RN, MSN, CIC, infection control and employee health program consultant at Catholic Healthcare West in San Francisco. "As things start to slow down on products, we would go to once a year."

That re-evaluation is important, because some of the newest products may represent real advancements in safer technology, she notes. "Within the next year, I think we'll start to see many more devices that are passive devices and easier to use," she says.

The evaluation needs to occur in all areas that will use the product, advises **June Fisher**, MD, director of the Training for Development of Innovative Control Technology (TDICT) project, which is based at the Trauma Foundation of San Francisco General Hospital.

"There's no one device. The needs are different in different areas," Fisher says. "An emergency room in San Francisco has more in common with an emergency room in Baltimore than [with] its own pediatric service. I strongly advocate that each unit determine what its needs are in a very systematic way."

Set criteria, simulated and real testing

Units should use a systematic process with clear guidelines in the evaluation process, Fisher says. Many hospitals base their process on one developed by TDICT, which is available at the organization's Web site (www.tdict.org). OSHA's newly updated bloodborne pathogens directive also includes evaluation forms developed by TDICT.

Using basic criteria, a device committee can first rule out products that don't seem to provide adequate safety or quality patient care. TDICT publishes criteria-based evaluation sheets with items on the technique and time required to use the devices, training, reprocessing, reliability, and other issues. **(For more information on the TDICT evaluation process, see *Hospital Employee Health*, April 1999, p. 40, and safety evaluation forms inserted in the issue.)**

"Scenarios" allow health care workers to test products in a setting that closely resembles the actual working environment, with similar lighting, noise, crowding, and patient states. Finally, health care workers conduct pilot tests and respond to detailed evaluation forms.

Meanwhile, someone at the hospital should continually monitor the release of new products that may be superior to those currently in use. While OSHA doesn't specify safe products, the bloodborne pathogens directive makes it clear that hospitals should stay current with safe device technology.

At Catholic Healthcare West, health care workers receive a re-evaluation form, asking them

Primary Criteria for Sharps Safety Product Selection

Catholic Healthcare West in San Francisco developed the following list of criteria to assist in evaluating new safer needle devices:

☐ The product must meet all Catholic Healthcare West (CHW) infection control standards and other regulatory requirements.
☐ Use of the safety device should significantly reduce sharps injuries.
☐ Minimal changes in technique/use are required.
☐ The device has a minimal failure rate and consistently functions as intended.
☐ The device is easy to use.
☐ Patient discomfort is not increased.
☐ Users feel safe handling the device.
☐ A minimal number of parts/pieces are required to use the system/device.
☐ Method of disposal is similar to current product and enhances safety.
☐ The safety device must not interfere with the product's intended use.
☐ The manufacturer must be willing to work with and contract through Shared Business Services.
☐ Manufacturer must have adequate product and supply capability to service CHW system without delays or shortages.
☐ Devices that reduce high-risk exposures will be given priority.
☐ Product representatives must be available to educate and demonstrate devices at all CHW facilities.

whether the new device made them feel safer and how it affected patient care. **(See sample re-evaluation form, inserted in this issue.)**

"Re-evaluation forms will be sent out to all hospitals and all front-line practitioners," says Fine. "It lists all the devices we approved and has check boxes: 'It makes me feel safer, it doesn't make me feel safer.' We'll be reconvening our team and looking at our input again. It may be that we'll be replacing our devices."

The safe device evaluation teams have a task that is daunting, at best. "Our goal is to try to find the best device, but in some ways I don't think that is practical," says **Phil Numoto**, CIH, director of environmental health and safety at San Francisco General Hospital. "There may not be a single best device."

To accommodate union concerns, Numoto's evaluation team has equal representation from management and labor. He worried that the committee would become bogged down with conflict between those groups. Instead, the differences of opinion occur among those who use the devices.

Still, Numoto wants to hear those strong feelings about the use of new devices. "This committee was founded on the premise that user input is very, very important."

Staff may initially feel uncomfortable with new devices because, even with training, the new technique may seem awkward, notes Fine.

"There's a learning curve and it's going to take time. I'm still hearing complaints about things," she says. "As we get better devices, more of the passive devices, that will make it easier for them. They'll feel safer and they won't be frustrated. That's my hope. Within the next year, I think we'll start to see many more devices that are passive devices and easier to use."

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The ultimate goal, of course, is to prevent needlestick injuries. Good record-keeping will allow employee health practitioners to determine the effectiveness of the new technology.

While it's too early for data comparisons, the devices seem to be working so far, says Fine.

"No one has called me and said we have needlesticks caused by the devices, and I've had e-mail saying we seem to be reducing them, so we seem to be on the right track," she says. ■

CDC registry finds that PEP is safe for HCWs

But half drop off regimen due to side effects

Postexposure prophylaxis (PEP) for health care workers who experienced potential occupational exposures to HIV was generally safe, although discomforting side effects caused about one-quarter of the employees to quit the regimen, the Centers for Disease Control and Prevention in Atlanta recently reported.

The CDC collected data from 492 health care workers in an HIV Postexposure Prophylaxis Registry from October 1996 through March 1999 in an effort to determine whether the regimen led to any serious adverse effects. The absence of serious lasting effects among registry participants was good news for health care workers who take

the powerful drugs to reduce their odds of HIV seroconversion after exposure.

While scientific evidence suggested that PEP would be effective in preventing HIV infection after occupational exposure, the CDC previously had few data to demonstrate the safety of these potent drugs, says **Adelisa Panlilio**, MD, MPH, a medical epidemiologist in the HIV Infections Branch of the CDC's Hospital Infections Program.

"We were going out on a limb and recommending these drugs for healthy, uninfected workers. We were concerned about the thousands of workers who would take these drugs and wanted to find out if they had unexpected events or serious and unexpected adverse consequences," says Panlilio, adding that most of the CDC's toxicity data had been collected from HIV-infected people.

Data don't support conclusions about toxicity

The registry results confirmed the CDC's belief that PEP was a safe preventive measure after an occupational exposure to bloodborne pathogens and that the drugs caused no unexpected serious side effects, says Panlilio. However, the CDC stated that the registry did not contain adequate power to support any definitive conclusions on the rates of occurrence of toxicity or to correlate toxicity with any particular drug.

The registry included data on 492 health care workers; 71% were female, and the overall median age was 37 years. The median time for exposure treatment was 1.75 hours. The majority (63%) of PEP regimens administered consisted of three or more drugs.

The data showed:

• Of the 449 HCWs for whom four to six weeks of follow-up data were available, the median therapy duration for at least one of the PEP drugs was 28 days.

• Overall, 195 workers completed all of the drugs in the PEP regimens as initially prescribed. In contrast, 197 discontinued all PEP drugs and did not complete the regimen. Also, 39 workers discontinued one or more drugs and/or modified drug dosage and/or added a drug but did complete a course of PEP. The remaining 16 workers completed modified regimens, which did not involve discontinuation of any of the drugs in the original regimen.

• Of the 197 workers who discontinued PEP drugs, 95 did so because the source patient tested HIV-negative. Half of the HCWs who discontinued all PEP drugs prematurely cited symptoms or adverse events as the reason.

• Seventy-six percent of the subjects with adequate follow-up data reported some symptoms or adverse events. The most frequently reported side effects were nausea (57%), fatigue/malaise (38%), headache (18%), vomiting (16%), and diarrhea (14%). Laboratory abnormalities were reported by only 8% of subjects. The median time from the start of PEP to the onset of the five most frequently reported side effects was three to four days.

• Serious adverse events were reported to the registry for six HCWs. All but one experienced resolution of symptoms by the six-month follow-up visit.

Effective dose and duration remain unknown

Failing to complete the postexposure regimen can alter its effectiveness, but researchers don't know exactly what dose or duration is required to prevent HIV transmission, says **David K. Henderson**, MD, deputy director for clinical care at the Warren G. Magnuson Clinical Center of the National Institutes of Health in Bethesda, MD.

"Both the timing of the first dose and duration of therapy are important variables," he says. In animal studies, all animals treated within 24 hours were protected. Those given drugs for a duration shorter than one month had a higher rate of infection.

Changes in drugs or dosage or the use of other medications can reduce the severity of side effects, says Henderson. "We try hard to manage those symptoms, and I think we're doing a better job of that than we did 10 years ago," he says.

Though patients who receive PEP may "feel very sick and experience lots of nausea, vomiting, and diarrhea," the registry data should reassure them that the drug regimens are safe over the four- to six-week period that most will take these drugs, said Panlilio.

The registry report mirrors findings from previous studies. Panlilio notes that the registry may contain some bias because many of the HCWs enrolled after three days following their exposures and had probably already begun a PEP regimen. "Maybe many of the health care workers who enrolled in the registry did so because they started having symptoms," she adds. No comparison registry exists to enable comparison with employees who did not receive PEP.

(Editor's note: The CDC report is available on the Internet at www.cdc.gov/ncidod/hip/default.htm.) ■

Budget debate threatens to delay TB standard

Yet OSHA remains on track for spring release

Opponents of a proposed federal tuberculosis standard gained ground as congressional battles continued late into the fall over the budget of the U.S. Occupational Safety and Health Administration (OSHA).

The U.S. House Appropriations Subcommittee on Labor, Education, and Human Services voted to approve legislation that includes a $450,000 independent review of the need for a TB standard. The subcommittee also voted to slash OSHA's budget by 5%, or $17 million. The president has requested $388.1 million in FY2000, which includes a $12.1 million increase for federal compliance assistance and $8.3 million for federal enforcement.

The provision requiring an independent review by the Institute of Medicine represented a victory for opponents of the proposed TB standard, which is due out this spring. But OSHA officials say they will move forward unless they are expressly prohibited from implementing a standard.

"We're working toward having a spring publication, barring any unforeseen decisions," says **Amanda Edens**, team leader for the TB standard at OSHA.

The Washington, DC-based Association for Professionals in Infection Control and Epidemiology (APIC) has strongly opposed the proposed TB standard, calling it unnecessary, burdensome, and a misdirection of resources. They want OSHA to delay the TB standard until the completion of a study.

"It's not that we don't think TB disease is an issue. It's a public health care issue," says **Jennifer Thomas**, APIC's director of governmental and public affairs. "These precious dollars need to go in the public health arena. Everything in the rule is geared toward adding protections for health care workers, and they're not the ones at risk."

Thomas notes that as the incidence of TB declined in the 1990s, most of the hospital-based exposure occurred with patients who hadn't previously been diagnosed. However, worker safety rules govern precautions that must be taken with patients who are known to have TB.

"TB is largely a problem because of the undiagnosed patients, those who are asymptomatic," says Thomas. "You can't control for TB any more than we already are with this rule."

OSHA has responded to concerns about the TB standard by making changes to conform to existing guidelines of the Centers for Disease Control and Prevention in Atlanta. For example, the frequency of skin testing was changed from every six months to every 12 months to reflect the CDC recommendation, says Edens.

"We're trying to be as much like CDC guidelines as possible so that people currently following CDC guidelines would continue to do what they would normally be doing," she says.

Provisions for annual fit-testing of respirators will reflect recommendations of the National Institute for Occupational Safety and Health and OSHA's more general respiratory protection standard, says Edens.

Thomas contends that the measures should be risk-based, taking into account that some regions of the country very rarely see even a single patient with tuberculosis, while urban areas with a high immigrant population may have occasional outbreaks. APIC also asserts that an OSHA rule that codifies existing CDC guidelines is unnecessary.

Voluntary guidelines give no recourse

"CDC guidelines are voluntary. We recognize that some people are voluntarily using them, and that's great," responds Edens. "But we want to see that those employees in settings where they're not voluntarily following the guidelines have the same protection. If there are employers who elect not to follow the recommendations and they put employees at risk, the employee has no recourse [with voluntary guidelines]. With an OSHA rule, there's a mechanism so the employee can file a complaint and get the appropriate protection put in place."

Meanwhile, even if OSHA's budget is cut, federal enforcement of worker safety rules isn't likely to suffer. A review of OSHA's budget history for the past eight years shows that while budgets have declined in some years and increased in others, federal enforcement and compliance assistance did not always take the reduction.

If increased funds are allotted this year, OSHA plans to expand outreach and training for employees and employers and boost the targeted inspection of workplaces that have "serious safety and health problems," assistant secretary of labor for occupational safety and health **Charles N. Jeffress** said in a published statement. ■

WEB ALERT

How to create your own on-line medical library

By **Geoff Kelafant**, MD, MSPH, FACOEM

Many hospital occupational health practitioners face budgetary or geographic challenges when it comes to obtaining reference materials. Fortunately, there are a number of free references available on-line that cover both occupational and nonoccupational medical problems. Many of these materials are copyrighted, so copy and distribute them with care.

- The *University of Iowa Family Practice Handbook*, third edition (www.vh.org/Providers/ClinRef/FPHandbook/FPContents.html) is a comprehensive primary care text.
- The *Merck Manual of Diagnosis and Therapy*, 17th edition (www.merck.com/pubs/mmanual/sections.htm) is a comprehensive manual of medicine.
- The *Medical Management Guidelines for Acute Chemical Exposures* (aepo-xdv-www.epo.cdc.gov/wonder/prevguid/p0000016/p0000016.htm) Web site covers a number of exposures that may occur in the health care setting.
- Another valuable resource is *emedicine* (www. emedicine.com/), an on-line text of emergency medicine. Also, the *Electronic Textbook of Dermatology* is available on-line (telemedicine.org/stamfor1.htm).
- *Physician Internet References — Clinical Materials* (www.medoccur.com/links/clinical/index.html) is a large collection of links to various guidelines and primary source materials.

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Literature Review

Miscarriages are tied to antineoplastic drugs

Valanis B, Vollmer WM, Steele P. **Occupational exposure to antineoplastic agents: Self-reported miscarriages and stillbirths among nurses and pharmacists.** *JOEM* 1999; 41:632-638.

In this study of the pregnancy outcomes of health care workers exposed to antineoplastic drugs (chemotherapy agents), researchers for the first time included wives of exposed men as well as female health care workers. The findings for both groups were similar, although the risk among wives of exposed men did not reach statistical significance.

As part of the National Surgical Adjuvant Breast and Bowel Project, 4,659 nurses, nurse's aides, pharmacists, and pharmacy technicians at 200 different health care facilities responded to a survey during the fall of 1988 and the spring of 1989.

After ruling out respondents who had never been pregnant, had been treated with antineoplastic drugs, or provided incomplete information, researchers looked more closely at 7,392 pregnancies among 2,976 health care workers or their wives. Barbara Valanis, DrPH, of the Kaiser Permanente Center for Health Research in Portland, OR, was the lead investigator.

For each "handling activity" — mixing the drugs, administering them, or handling bodily waste of cancer patients — researchers collected information on dose, duration, use of protection, and skin contact. They also controlled for maternal smoking during pregnancy, age, gravidity during pregnancy, and prior poor pregnancy outcomes such as miscarriage or still birth.

Overall, miscarriage occurred in 11% of pregnancies and stillbirth in 1%. Eighty-three percent of the pregnancies resulted in a live birth, and 5% of the pregnancies ended due to an elective abortion.

Researchers distinguished between exposures that occurred two years before a pregnancy and those during a pregnancy. Men reported handling antineoplastic drugs during 35.6% of their wives' pregnancies, while women reported drug handling during 20.1% of their pregnancies.

The only statistically significant variable related to exposure was "any reported exposure

to antineoplastics"; dose, duration, and patterns of skin contact were not significant.

The data showed:

• Women who handled antineoplastics had a significantly higher risk of miscarriage (with an odds ratio of 1.5) or of any loss (1.4 times more likely) but not of stillbirths alone.

• Women with a prior miscarriage or stillbirth had even higher risks of poor outcomes (with odds ratios of 2.3 and 2.9, respectively).

• Wives of men with exposure to antineoplastics in the two or three years prior to or during pregnancy showed a similar pattern of increased risk, but the odds ratios were not statistically significant. There were not enough stillbirths in this sample to allow for analysis.

"This analysis suggests the women who have been occupationally exposed to antineoplastic agents during or shortly prior to pregnancy are at an increased risk to have a miscarriage compared with those who were not exposed," the researchers concluded.

That finding is consistent with an earlier study on occupational exposure.[1] As exposures decline with the use of protective equipment, the risk of poor pregnancy outcomes may be lower, the researchers noted. (OSHA guidelines, published in 1986, call for protection against exposure.)

Still, the researchers noted, "The presence of any increased risk should concern workers who are planning a pregnancy. They need to weigh the risks of handling antineoplastic agents during the time of conception and during the pregnancy and whether they should continue in the work setting. If they decide to continue handling these drugs, careful adherence to recommendations for protection will be essential."

Reference

1. Selevan S, Lindbohm M, Hornung K, et al. A study of occupational exposure to antineoplastic drugs and fetal loss in nurses. *N Engl J Med* 1985; 313:1,173-1,177. ■

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Latex glove controversy clouds Koop testimony

Ex-surgeon general consulted with glove maker

Debate over the hazards of latex gloves developed a new twist of controversy when *The New York Times* reported that former U.S. surgeon general **C. Everett Koop**, MD, failed to disclose a lucrative financial arrangement with a latex glove maker when he testified in Congress about glove safety.

Koop told the oversight and investigations subcommittee of the Committee on Education and the Work Force that hazards of latex gloves among health care workers had been exaggerated, provoking a "borderline hysteria."

In its Oct. 29 edition, *The New York Times* reported that Koop had signed a four-year, $1 million contract with glove manufacturer WRP Corp. of Itasca, IL, in 1994 to deliver speeches on health and nutrition and to serve as a company adviser. The company briefly considered entering the nutrition market, then decided not to pursue that line of business. Koop ultimately received $656,250 in consulting fees, the newspaper reported, citing

Securities and Exchange Commission documents and an unnamed source at WRP.

At a press conference a day after the article was published, Koop remarked that his contract was actually with a company called NBF that was later acquired by WRP. "I never consulted with them about latex gloves. I never consulted with them about anything," Koop told reporters. "As a matter of fact, I began to feel very guilty that I was taking a consulting fee for not doing anything at all."

Koop stressed the protection that latex gloves have provided in the wake of the AIDS epidemic. "I'm very sorry for the people who are allergic to latex, but inasmuch as I spent four years of my life trying to put a thin layer of latex between the whole world and the AIDS virus, I guard that very carefully," he said.

Powdered latex gloves in particular have come under scrutiny because the protein mixes with the powder and can become airborne, leading to potentially serious reactions among those who are allergic to the protein — even if they are not wearing the gloves.

The National Institute for Occupational Safety and Health issued a safety alert in 1997 advising that if latex gloves are used, they should be powder-free and low-protein. The Occupational Safety and Health Administration released a technical bulletin recommending that hospitals use powder-free, low-protein latex gloves and provide non-latex alternatives for health care workers and patients who are allergic to natural rubber latex.

Meanwhile, hundreds of lawsuits are pending against latex glove manufacturers from health care workers and others who say they were harmed by severe allergic reactions. **(See *Hospital Employee Health*, November 1999, p. 126.)**

Still, those who represent health care workers worry that Koop's comments carried great influence in support of latex gloves.

"Dr. Koop has been a leader in communicating about health issues in this country, a very effective communicator," says **Susan Wilburn**, RN, MPH, senior specialist for occupational safety and health with the American Nurses Association in Washington, DC.

"When Dr. Koop says, as he did in Congress, that latex allergy is not a serious problem and nurses are hysterical and it's been blown out of proportion, it confers some weight," she says. "Some people are at the very least confused about what they're hearing from various experts." ■

CE objectives

After reading each issue of *Hospital Employee Health*, the nurse will be able to do the following:

- identify particular clinical, administrative, or regulatory issues related to the care of hospital employees;
- describe how those issues affect health care workers, hospitals, or the health care industry in general;
- cite practical solutions to problems associated with the issue, based on overall expert guidelines from the Centers for Disease Control and Prevention, the National Institute for Occupational Safety and Health, the U.S. Occupational Safety and Health Administration, or other authorities, or based on independent recommendations from clinicians at individual institutions. ■