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Federal needle safety mandate appears likely; will OSHA finally act?

Experts advise providers to begin implementation

The same day that federal legislators introduced bills to require hospitals to replace conventional needle devices with safer technology, the U.S. Occupational Safety and Health Administration (OSHA) quickly announced plans that would accomplish essentially the same goal, drawing criticism from observers who charge the agency's move is a smoke screen for years of foot-dragging on the issue. Regardless, the growing consensus is that hospitals should begin preparing now for federal requirements to implement the use of needleless systems and other safety mechanisms designed to prevent sharps injuries.

In fact, some critics point out that OSHA can enforce the present bloodborne pathogens standard to require hospitals to evaluate and use safer devices right now. However, they're concerned that OSHA's plans may never materialize into action.

Federal legislation modeled after California law

The Health Care Worker Needlestick Prevention Act of 1999 (HR 1899), a bill to reduce the risk of transmission of bloodborne diseases via needlestick injuries, is modeled after a California law set to be enacted this summer. **(See *Hospital Employee Health*, December 1998, pp. 144-146.)** The federal legislation was introduced in the House by Rep. **Pete Stark** (D-CA) and Rep. Marge Roukema (R-NJ). At press time, 47 other Democrats and eight more Republicans had signed on as co-sponsors.

A companion bill is sponsored in the Senate (SB 1140) by Barbara Boxer (D-CA), who last year successfully introduced a directive aimed at pushing OSHA and other federal agencies to accelerate the use of safer needle devices nationwide and to mandate more accurate needlestick injury reporting. **(See *HEH*, March 1999, pp. 25-28.)**

The current bills not only require the use of needleless systems and other safety mechanisms to prevent injuries, but also would enhance current needlestick reporting requirements and establish a clearinghouse for data collection on safer technologies within the National

Institute for Occupational Safety and Health (NIOSH). In addition, the clearinghouse would serve as a resource for hospitals by designing a training curriculum for selecting and using safer devices.

OSHA's plans include three elements:

- bolstering contaminated sharps injury reporting by requiring all those injuries to be recorded on OSHA logs;
- revising the bloodborne pathogens compliance directive later this year to reflect the newer, safer technologies now available;
- taking steps to amend the bloodborne pathogens standard by placing needlestick injuries on its regulatory agenda this fall.

In a prepared statement, Secretary of Labor **Alexis M. Herman** said OSHA's plans resulted in part from comments received from nearly 400 hospitals and other interested parties in response to the agency's request for information on minimizing needlesticks. **(See related story, p. 88.)**

"We can and must reduce the estimated 590,000 needlesticks that occur each year among our 5.6 million health care workers. It's time to make sure that health care workers have up-to-date devices that limit the risk of needlesticks and the potential for contracting deadly diseases such as AIDS and hepatitis," Herman's statement reads.

Union pursues grass-roots campaign

However, some critics assert that the time is long overdue.

"Talk is cheap," states **William K. Borwegen**, MPH, occupational safety and health director of the Washington, DC-based Service Employees International Union (SEIU), which led the fight for the California law. The 650,000-member union recently launched a state-by-state grass-roots campaign to implement needle safety legislation similar to that in California, while continuing to lobby for a national law and urging OSHA to act. At present, 20 states are considering bills designed to help protect health care workers from accidental injuries.

"This is an agency that can't get out of its own way. This agency seems incapable of doing anything, but I wish they'd prove me wrong," says Borwegen. "I would love for them to get this thing done, and then I'll be glad to be embarrassed and eat crow, but they've been talking about it for years and haven't actually done anything yet."

OSHA announced its plans simply "for cover," he states. "There's a difference between actually doing something and trying to make it look as though you're doing something."

Borwegen charges that OSHA finished revising the compliance directive seven months ago, but has lagged on the internal review and issuance. He says the agency also has failed to obey the congressional directive handed down last fall to revise its record-keeping requirements for contaminated sharps exposures.

Why isn't OSHA citing hospitals now?

Additionally, he notes that OSHA cited a Denver hospital recently for failing to evaluate and implement safer needle devices **(see *Hospital Employee Health*, April 1999, pp. 37-40)**, a move that proves the agency can enforce present versions of the bloodborne pathogens standard and compliance directive.

"Health care workers are risking their lives using unsafe needles today while OSHA is talking about putting out a [new] compliance directive," Borwegen says. "The current wording allows hospitals to be cited, so why are they not citing hospitals all over the place right now?"

Although contacted repeatedly for a response, OSHA officials declined to comment on criticism or its own announced plans.

The legislation would in effect force OSHA to require safer needle devices, with some exceptions, such as when the devices are unavailable for certain procedures or if they would compromise patient safety. However, Stark points out that provisions of the bill exceed OSHA's authority and scope. For example, OSHA cannot establish the NIOSH clearinghouse. In addition, OSHA does not cover public employees. He thinks legislation is needed for another reason as well.

"OSHA testified on this issue in 1992, and we still haven't seen anything. I intend for health care workers to be protected from needlestick injury by whatever means is the quickest way to do it," Stark tells *Hospital Employee Health*. "If the fact that there's a bill in Congress with a lot of support makes OSHA do something on its own, that's fine with me. There needs to be a symbiosis of Congress and an agency wanting to accomplish the same thing."

Stark says the legislation is important because technology exists to prevent many needlesticks, and "it's wrong that it's not being used." Health care facilities will save money in the long run by

not having to pay health care costs of workers who are injured and require treatment, he adds.

Two previous versions of the bill were defeated due to controversial provisions. Stark's 1993 version included an excise tax penalty for the sale of unsafe devices, and a bill introduced last year threatened hospitals with expulsion from the Medicare program for not using safer devices.

"That's a very heavy hammer," he says. "It raised strong opposition from the hospital industry. This year we chose an approach that has been tried at the state level and worked. Changing the way we're doing it to a successful model makes it more palatable to a broader array of members of Congress."

AHA still opposes legislation

However, the hospital industry still is against any legislative action, although officials say they support its intent.

Richard Wade, a senior vice president of the Chicago-based American Hospital Association, says the organization fears that a law will be too rigid, and has "made it clear to OSHA that we think they have all the power they need" to accomplish most of what's in Stark's bill.

"We think they should move ahead and develop guidelines for the field very quickly. Passing a law is a long and arduous process to get to something we have a regulatory process in place to do," Wade states.

Others support the legislation, especially in light of OSHA inaction.

Janine Jagger, PhD, MPH, director of the International Health Care Worker Safety Center at the University of Virginia in Charlottesville and a world-renowned needle safety expert, says if OSHA fails to voluntarily enforce the bloodborne pathogens standard using the criteria of safety devices as engineering controls, legislation forcing the agency to do so is the answer.

"It appears [OSHA is] not going to move any farther than they're forced to," Jagger says. "The only kind of action I would recognize as definite is something that has actually been done, as opposed to what an agency says it's going to do. To say they're going to do it could go on forever. Until they actually take a step, I would not regard statements as actions."

Becton Dickinson (BD), the largest worldwide manufacturer of both conventional and safety devices, also backs the bill, but officials of the Franklin Lakes, NJ-based company say they would prefer regulation to legislation.

"It makes more sense to let federal OSHA take care of it," says **Kevin Seifert**, director of business development and policy. "We support the legislative action in the form of the Stark bill because it's a mechanism to make OSHA react."

BD introduced the first safety-engineered device — a safety syringe — 11 years ago, but "in the past 11 years, conversion to safety devices just didn't happen in most product areas," Seifert notes.

Supplier says costs are overstated

He cites end-user resistance as the cause, due both to lack of training in how to use safer devices and concerns over cost. However, Seifert says company estimates show that for an average 300-bed hospital converting to safer products in the categories of syringes and needles, blood collection devices, and IV catheters, the increased cost would be about $71,000 per year.

"For the budget size of a 300-bed institution, I wouldn't think that would be viewed as crippling or even substantial," he says. "It's not the millions that many people sometimes automatically think it is."

While costs of different product categories vary widely, Seifert notes that conventional needles cost 6 cents to 8 cents each, while safer versions cost 22 cents to 25 cents each. He expects that as demand volume increases, as it would if all hospitals were required to purchase safer devices, prices for those devices would decrease.

In fiscal year 1998, 29% of the company's revenues from its needle-based medical device businesses came from safety-engineered products. A variety of conventional devices still would be in use after legislation or regulation, either due to patient safety considerations or because safer technology is not available or necessary, so Seifert cannot presently predict how that percentage might change after widespread device conversion.

"We're in favor of good legislation that allows for good patient care, end-user selection of technology they want to use, and no prevention of advancement to future technologies," he states. "If the law says the customer chooses what product they think is the most appropriate, and if it's effective and protects the worker, why wouldn't we want to support that? We're assuming this is coming and we're preparing for it." ■

OSHA needlestick RFI reveals pertinent data

Safer devices work, but are underutilized

Safer needle devices are an effective means of injury reduction for health care workers, but are used infrequently in all applications except for intravenous line access, according to results of the Occupational Safety and Health Administration's (OSHA) recent request for information (RFI) on preventing needlesticks.

OSHA got 396 responses to its RFI, published late last year. It asked for information on engineering and work practice controls used to eliminate or minimize the risk of occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.[1] **(See *Hospital Employee Health*, November 1998, pp. 129-132.)**

More than 300 individual health care facilities responded. Several health care organizations submitted combined responses on behalf of members. Comments also were sent by individual HCWs, researchers, unions, educational institutions, professional and industry associations, and medical device manufacturers.

Respondents' answers to questions posed in the RFI apparently helped convince OSHA officials to formulate specific plans to help reduce the risk of occupational exposure to bloodborne diseases due to needlestick injuries. **(See cover story.)**

Based on responses, OSHA officials observed:

• Safer medical devices are an effective and feasible method of hazard control in many instances. Nearly every responding health care facility noted injury reductions after safer medical devices were introduced.

• Most IV line access is now accomplished using safer devices. However, safer devices are used much less frequently in other applications.

• The rate of percutaneous exposure incidents is declining. The best and most current national estimate available was submitted by the International Health Care Worker Safety Center in Charlottesville, VA, based on surveillance system data. It estimates that approximately 590,000 percutaneous exposure incidents occur annually.

• Training and education in using safer needle devices and work practices are an effective means of preventing needlesticks. Staff involvement in device selection and evaluation plays an important part in achieving injury reduction.

• The OSHA 200 log does not accurately reflect injuries involving bloodborne pathogen exposures. Criteria for recording those exposures (loss of consciousness, transfer to another job, work or motion restriction, medical treatment beyond first aid, or seroconversion) do not require recording all injuries with the potential for disease transmission. Also, many facilities do not correctly interpret established recording criteria.

• Responding health care facilities have almost all adopted surveillance systems in addition to the OSHA 200 log. They commonly record all reported percutaneous injuries involving exposures to blood and other potentially infectious materials.

• Increased costs and staff resistance to change were the most frequently reported obstacles to adopting safer needle devices. Other barriers included equipment compatibility problems, facility purchasing agreement limitations, and unavailability of effective safer devices for certain applications.

• Use of safer devices did not substantially affect patient care delivery.

• Safer devices generally are more expensive than conventional devices. However, total additional cost per facility appears to be a small fraction of total health care costs, and reductions in number of injuries may result in substantial financial benefits from reduced postexposure testing and treatment costs, as well as health benefits from decreased disease transmission.

• Many respondents consider a comprehensive safety and health program to be the most effective means of reducing bloodborne disease transmission risks.

• Some respondents support OSHA's interest in making safer devices more available to employees. Others expressed reservations about any broad mandate requiring safer device use, citing that needs of particular areas of practice must be considered and that device efficacy and effects on patient care should be established prior to device adoption.

(Editor's note: To see the entire RFI report, go to OSHA's Internet Web site at: http://www.osha-slc.gov/html/ndlreport052099.html.)

Reference

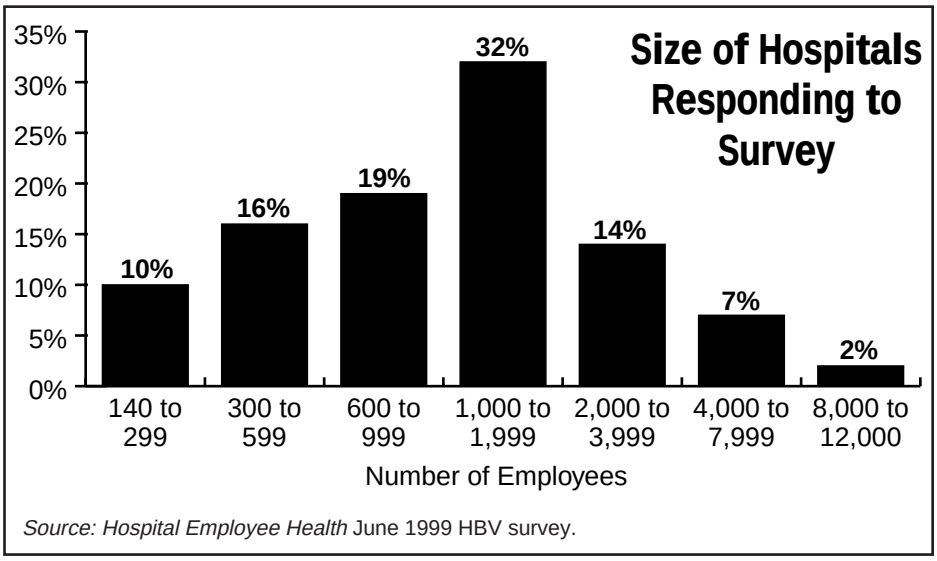
1. Department of Labor, Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens: Request for information. 63 *Fed Reg* 48,250-48,252 (Sept. 9, 1998). ■

Survey reveals controversy concerning titer testing

Hepatitis B vaccination policies vary

The issue of postvaccination titers — when to test, why, and what to do if they're low or negative — emerges as the most controversial aspect of hepatitis B vaccination programs for health care workers, according to the exclusive *Hospital Employee Health* survey of readers' policies and procedures.

A fax-back survey included in the June 1999 newsletter drew 135 responses from employee health professionals who work across the country in facilities with between 140 and 12,000 workers. **(See chart, at right.)** Respondents answered 12 questions ranging from the number of employees considered eligible for HBV vaccination to whether they test for prevaccination and postvaccination titers and why. Other questions asked about policies regarding low postvaccination titers, who pays for titer tests and revaccinations, and whether the vaccine produced any adverse reactions.



Source: Hospital Employee Health June 1999 HBV survey.

Of the total number of employees — 148,249 — employed at the hospitals of respondents who provided complete sets of figures, 79% were considered eligible to be offered HBV vaccine. While the Occupational Safety and Health Administration (OSHA) requires health care facilities to offer vaccine to workers with the potential for blood and body fluid exposures,[1] nearly one in four facilities responding to the survey (24%) offer vaccine to all employees.

"We push HBV vaccine for all direct caregivers and ancillary staff, such as housekeeping and laundry," says **Nancy B. Childs**, RN, BSN, CIC, director of infection control and employee health at 1,000-employee Holzer Medical Center in Gallipolis, OH. "We offer it to every employee."

At Johnston Memorial Hospital in Abingdon, VA, industrial/employee health nurse **Darla Barrow**, RN, also classifies all employees as eligible for HBV vaccine. She presently has vaccinated 98.3% of the facility's 654 employees with all three doses. Only two workers signed declinations, and nine presented physicians' letters stating the vaccine was contraindicated due to allergies and other health conditions.

Barrow has a two-pronged strategy for obtaining compliance. First, she speaks to new employees at orientation, after which she offers vaccine on the spot. Second, she follows up with a personal work site visit.

"After three months, if we have some who have not taken it, I go talk to them individually and see what their reasons are," she says. "I explain to them the importance of being vaccinated. If they say they don't like needles, I tell them, 'This is three [injections] over a six-month period when you get the vaccine, but can you imagine how many times you're going to be stuck if you get hepatitis?'"

Overall, the survey shows that an average of 80% of employees classified as eligible have completed the three-vaccine series. Eleven percent of those eligible declined to be vaccinated. **(See chart, p. 90, top.)**

Asked if they test for prevaccination titers, most respondents (84%) answered that they do not. For the 16% who indicated that they do prevaccination testing, the main reasons were if employees began the series at another facility or in school, if they never had a titer drawn, as part of the preplacement physical assessment, or to establish a preplacement baseline for liability purposes.

Several respondents said they test before vaccinating based on occupational risks or on history

Vaccination Totals

Total number of employees	148,249
Total number of classified eligible	117,132
Total number completing series	93,936
Total number declining vaccination	13,053
Percentage of total employees classified as eligible	79%
Percentage of those classified as eligible completing series	80%
Percentage of those eligible declining vaccine	11%

* Data based only on surveys providing complete sets of figures

Source: Hospital Employee Health June 1999 HBV survey.

of hepatitis or birthplace. **Steven R. Weiner**, FNP, MS, MPA, clinical manager of employee health at New York University Medical Center, says testing for prevaccination titers at the 8,348-employee facility has "demonstrated cost-effectiveness" due to high HBV seroprevalence in New York City, with its "international population."

Other reasons given for testing included: only for renal dialysis staff, if employees have no medical records, to rule out active HBV, or upon employee request.

Cost-effectiveness is the only rationale for prevaccination titering, says **William Bower**, MD, a senior research associate with the hepatitis branch of the federal Centers for Disease Control and Prevention (CDC). Otherwise, the practice is not recommended.

Answers to questions related to testing for postvaccination titers and the need for booster doses generated the biggest differences and the most comments in the survey results.

The CDC now recommends postvaccination titering one to two months after completion of the three-vaccine series for HCWs who have contact with patients or blood and are at risk for sharps injuries. Workers who do not respond to the primary vaccine series should complete a second three-dose series or be evaluated to determine if they are HBsAg-positive. Revaccinated workers should be retested following completion of the second vaccine series. Primary nonresponders who are HBsAg-negative should be counseled about the need for hepatitis B immune globulin (HBIG) after high-risk exposures.[2] **(For more information about postexposure treatment, see chart, below.)**

Most (94%) survey respondents indicated that they test for postvaccination titers. Of those, 85% said they test within six months, with most indicating they test between four and eight weeks postvaccination completion. Three percent said they test after five years, 1% after 10 years, and 48% after a needlestick injury/occupational exposure. Four percent said they test postvaccination titers at other times, such as every year, one year later, six years later, or at an employee's request. **(See chart, p. 91, top.)**

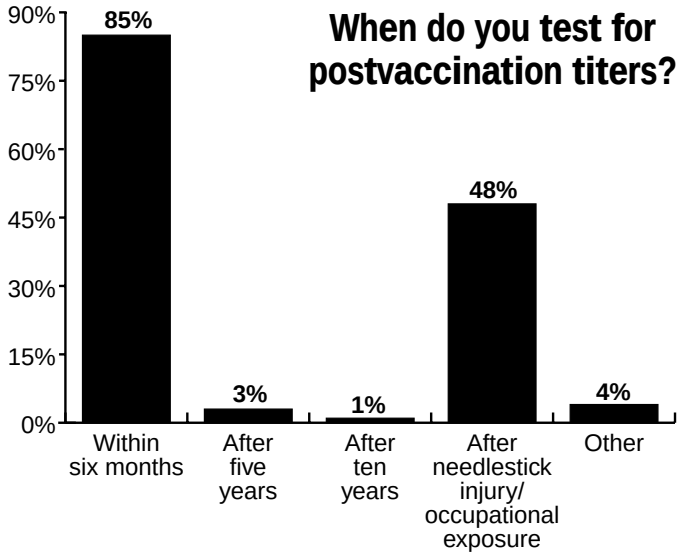
If postvaccination testing reveals a low titer, 50% of respondents said their policy is to administer one booster dose and retest. Thirty-four percent reported they repeat the entire three-vaccine series and retest. Fourteen percent said they give HBIG after a high-risk needlestick, and 17% gave

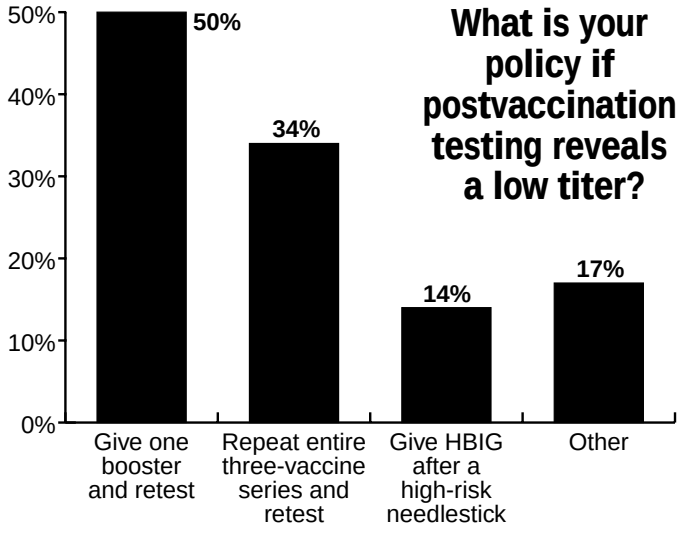
Recommended postexposure prophylaxis for percutaneous or permucosal exposure to hepatitis B virus, United States

Vaccination and antibody response status of exposed person	Treatment when source is: HBsAG* positive	HBsAg negative	Source not tested or status unknown
Unvaccinated	HBIG† x 1; initiate HB vaccine series§	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated:			
Known responder¶	No treatment	No treatment	No treatment
Known non-responder	HBIG x 2 or HBIG x 1 and initiate revaccination	No treatment	If known high-risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs** 1. If adequate¶, no treatment 2. If inadequate¶, HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate¶, no treatment 2. If inadequate¶, initiate revaccination

*Hepatitis B surface antigen.
†Hepatitis B immune globulin; dose 0.06 mL/kg intramuscularly.
§Hepatitis B vaccine.
¶Responder is defined as a person with adequate levels of serum antibody to hepatitis B surface antigen (i.e., anti-HBs ≥ 10 mIU/mL); inadequate response to vaccination defined as serum anti-HBs < 10 mIU/mL.
**Antibody to hepatitis B surface antigen.

Source: Centers for Disease Control and Prevention, Atlanta.





Source: Hospital Employee Health June 1999 HBV survey.

a variety of answers in the "other" category. Those answers included: repeating the vaccine series but not retesting; giving a booster dose but not retesting; giving two boosters and retesting; giving up to three boosters and retesting after each; giving a booster, retesting, giving two more boosters if titers remain low, then retesting; and giving up to six booster doses. **(See chart, above.)**

Bower says the chance of developing adequate titers is 95% following the three-vaccine series. CDC guidelines note that while vaccine-induced antibodies decline gradually over time, vaccine-induced immunity continues to prevent clinical disease or detectable viremic HBV infection. An anamnestic immune response after HBV exposure is the proposed mechanism for continued protection against HBV infection despite antibody titers that have declined below detectable levels. Therefore, the CDC considers booster doses unnecessary for HCWs who have responded to vaccination and have a normal immune status; nor does the agency recommend testing titers except for one to two months post-vaccination.[2,3]

The bloodborne pathogens standard states only that hospitals are to follow current CDC recommendations for postvaccination titer testing, but an OSHA spokesman says a new compliance directive being finalized will specify that titers are to be tested only one to two months after completion of the vaccine series.

Nevertheless, some employee health professionals responding to the survey take a more cautious view.

The infection control committee at Olean (NY) General Hospital decided to test hepatitis B surface antibody for all vaccinated employees after needlestick follow-ups indicated that three out of four exposed workers were nonimmune, says **Cindy Rodd**, RN, employee health manager. They discovered that overall, 40% of employees were not immune to HBV.

"We boosted them, took another titer, and if they were still nonimmune, we gave another booster, then another titer. If they were still not immune at that point, we stopped there," she explains. "We gave them special instructions to double-glove and to report needlesticks immediately."

Between six and eight of the facility's 900 employees still lack immunity after five injections, she says.

Vaccinated employees are tested for immunity at preplacement, and postvaccination titers are tested six to eight weeks after completion of the vaccine series.

"We don't mind the cost because we want people to know if they're immune or not," Rodd states. "The anamnestic response is one school of thought, but our infection control committee still wants to go ahead with our policy."

Vaccinated workers at 1,600-employee Trinity Health System in Steubenville, OH, are offered the option of having their titers checked six years after the third or last vaccine they've received, says employee health coordinator **Karen Russell**, RN, BSN, COHN-S. The practice was begun six years ago.

"At first, we didn't know how long the antibody titer would be good for. Since that time, there's been some other information published by the vaccine manufacturer, stating [that titers remain positive] 10 to 12 years, but we wanted to see if employees still had titers six years after the vaccine," she relates.

Results of the titer testing showed that nearly one out of three employees tested six to eight years postvaccination had negative antibodies. Between 85% and 89% of vaccinated workers now take advantage of the titer-testing opportunity, notes Russell, who adds that she still sees "quite a few" negative titer reports, but not as many as at first. Employees with negative titers six years postvaccination are offered a booster dose.

"Research [into postvaccination immunity] is still going on," she says. "That's what makes it so hazy."

Annette Cort, RN, employee health coordinator at The Cornwall (NY) Hospital, says the policy at her 560-employee facility is to test all workers every year for postvaccination titers. She finds workers are remaining positive for five to seven years postvaccination, with 10% to 15% showing negative titers after that.

"We want to make sure they're staying positive," she states. "If not, we give them a booster."

Adverse reactions noted

Ninety-nine percent of survey respondents indicated that the employer pays for titer tests and revaccinations. One respondent said her employer pays for vaccine, but employees pick up the tab for titer testing.

Responses to the survey question asking whether employees have had or claimed to have had an adverse reaction to HBV vaccine were split down the middle. Fifty percent answered yes, with the most common reactions listed being rash, itching, local reactions at the injection site, upper arm soreness and swelling, arthralgia, fever, nausea/vomiting/diarrhea, malaise/fatigue, allergic reactions, and flu-like symptoms.

Other adverse reactions noted include anaphylaxis/shock (two employees), elevated liver enzymes, hives, hair loss, visual disturbance/eye pain, chest pain, headache, abdominal pain, welts, and Guillain-Barré syndrome.

The most common side effects from hepatitis B vaccination are pain at the injection site and mild to moderate fever, Bower notes. He adds that carefully controlled studies are under way to examine whether vaccination is associated with serious neurological disease in a small number of people.

However, presently there is no confirmed scientific evidence that hepatitis B vaccine causes chronic illnesses, including multiple sclerosis, chronic fatigue syndrome, rheumatoid arthritis, optic neuritis, or other autoimmune disorders.

"Serious adverse events reported after receiving hepatitis B vaccine are very uncommon and may represent coincidence rather than causation," he says. "Given the frequency and severity of hepatitis B infection, the benefit of vaccination far outweighs the known and potential risks."

References

1. U.S. Department of Labor, Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens: Final rule. 56 *Fed Reg* 64,004-64,182 (Dec. 6, 1991).

2. Centers for Disease Control and Prevention. Immunization of health-care workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR* 1997; 46(No. RR-18):1-42.

3. Mahoney FJ, Stewart K, Hu H, et al. Progress toward the elimination of hepatitis B virus transmission among health care workers in the United States. *Arch Intern Med* 1997; 157:2,601-2,605. ■

HBV vaccination programs: Your questions answered

Survey respondents express common concerns

[Editor's note: Those who responded to the recent Hospital Employee Health *hepatitis B vaccination program survey posed a number of questions about policies and procedures. We asked* ***William Bower****, MD, a senior research associate with the Centers for Disease Control and Prevention's (CDC) hepatitis branch, for the answers. Most of the information provided can be found in one of the three documents listed in the first answer.]*

Q: Where can current CDC recommendations regarding hepatitis B vaccination programs for health care workers be found?

A: Updated guidelines are now in the approval process and will be issued possibly later this year. Meanwhile, current recommendations are published in several documents:

Bolyard EA, Tablan OC, Williams WW, et al. Guideline for infection control in health care personnel. *Am J Infect Control* 1998; 26:289-354.

Centers for Disease Control and Prevention. Immunization of health-care workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *MMWR* 1997; 46 (RR-18):1-42.

Centers for Disease Control. Hepatitis B virus: A comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR* 1991; 40 (RR-13):119.

Q: To whom should hepatitis B vaccine be offered? For example, do unit secretaries who may be touching specimen containers need it?

A: Any employees who have the potential to come into contact with blood or body fluids should be encouraged to receive vaccine.

Q: What is the recommendation on testing for prevaccination titers?

A: We don't recommend it. Pre-vaccination serology screening for previous infection is not indicated for persons being vaccinated because of occupational risk unless the hospital considers screening cost-effective.

Q: What do you recommend when employees don't return for the second or third vaccine dose according to the recommended 0-1-6 vaccination schedule?

A: It depends on the schedule, but it shouldn't be a problem. For maximum effectiveness, the second dose should be received one month after the first. Employees can get the second vaccine greater than a month later and the third vaccine greater than five months after that, but the maximum interval has not been established. Anecdotally, in vaccine trials it did not appear to affect efficacy as long as there was one month between the first two doses and at least four months between the second and third doses.

The recommendation for an interrupted schedule is to give the second dose as soon as the person presents, as long as at least one month has passed since the first dose. If the employee gets the second dose on time, then is lost to follow-up and doesn't get the third dose five months later, give the third dose whenever possible after that, even if it is two years later. We consider them protected. If the vaccine schedule is interrupted, never re-initiate it.

Q: For how long does vaccination confer immunity? Any update on length of effectiveness? What about the need for booster doses?

A. We feel in 1999 that the vaccination series is good for at least 17 years because that's what the data show so far. Of the people who were vaccinated in 1982 when the vaccine first became available, those who showed a response have not developed symptomatic disease. We recommend booster doses only when a health care worker tested after a documented exposure has low titers and you don't know if they were ever a responder. If they were a vaccine responder, you don't have to give any postexposure treatment. **(For more postexposure recommendations, see chart, p. 90.)**

The 1991 *MMWR* (see reference above) reports that long-term studies of healthy adults and children indicate that immunologic memory remains intact for at least nine years after vaccination and confers protection against chronic hepatitis B infection even though anti-hepatitis B surface antibody (anti-HBs) levels may become low or decline below detectability levels. That information hasn't changed in the last eight years since the report was issued.

Q: What about postvaccination testing for titers? And what do you consider an adequate titer?

A: Greater than or equal to 10 mIU/ml is what we recommend. Postvaccination screening for anti-HBs is advised for personnel at ongoing risk for blood exposure to determine whether response to vaccinations has occurred and to aid in determining the appropriate postexposure prophylaxis or the need for revaccination. Personnel who do not respond to or do not complete the primary vaccination series should be revaccinated with a second three-dose vaccine series or evaluated to determine whether they are HBsAg-seropositive.

Revaccinated persons should be tested for anti-HBs at the completion of the second vaccine series. If they do not respond, no further vaccination series should be given, and they should be

evaluated for the presence of HBsAg (possible chronic HBV infection).

Vaccine-induced antibodies decline gradually with time, but vaccine booster doses are not routinely recommended. People who respond to the initial vaccine series remain protected against clinical hepatitis and chronic infection even when their anti-HBs levels become low or undetectable. We don't recommend that you test except one to two months and no more than six months after the last dose. That is the only time you can determine if someone is a responder.

Q: Why do schools for health care workers not require students to start and complete the vaccination series?

A: Health care workers' risk for percutaneous or permucosal exposure to blood varies but is often highest during their professional training period. Therefore, vaccination should be completed during training in schools of medicine, nursing, dentistry, laboratory technology, and other allied health professions.

Q: A recent television program broadcast a segment claiming a connection between hepatitis B vaccine and development of multiple sclerosis. Is there any truth to this?

A: We believe that the hepatitis B vaccine is very safe. There is no scientific evidence to show any correlation between the vaccine and multiple sclerosis. Anyone who is concerned should read the articles on this Web site: www.cdc.gov/nip/vacsafe/vaccinesafety/hottopics/hepb.htm. ■

OSHA ergonomics rule will hit hospitals in September

Patient-lifting injuries targeted in second category

After seven years in development, the U.S. Occupational Safety and Health Administration's (OSHA) proposed ergonomics standard is scheduled for release in September, effectively requiring hospitals to implement ergonomics programs to prevent patient-lifting and other musculoskeletal injuries.

The public has had an unusual chance to view a draft proposal of the standard, which was placed on OSHA's Internet's Web site (www.osha-slc.gov/SLTC/ergonomics/ergoreg.html) earlier this year. Under the recent Small Business Regulatory Enforcement and Fairness Act, proposed regulations must first be reviewed for economic impact on small businesses before being published in the *Federal Register* for public review and comment.

OSHA crafted the proposal — written in plain language in a question-and-answer format — around six basic elements: management leadership and employee participation, hazard identification and information, job hazard analysis and control, employee training, medical management, and program evaluation.

The proposed standard will cover workplaces where work-related musculoskeletal disorders (WMSDs) are most severe. Coverage will focus on three main categories: manufacturing operations, manual-handling operations, and other jobs causing demonstrated WMSDs.

Gary Orr, CPE, PE, an OSHA ergonomist and leader of the ergonomics standard development team, tells *Hospital Employee Health* that hospital employees definitely will be covered by the proposed standard, mainly in the second category.

"One area we're clearly trying to get at is movement of patients in the manual-handling category," he says. "Some workers in dietary or accounts payable departments, where they're using their hands a lot and might develop carpal tunnel syndrome, will be covered in [the third category], but the data show quite a bit of risk among workers who do a lot of patient-handling."

Under the draft proposal, hospitals will have to create ergonomics programs if they have reported

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an OSHA-recordable musculoskeletal injury. Orr says this provision has drawn the most criticism from small business panel reviewers, who object to only one incident precipitating development of an ergonomics program.

"They think there should be a combination of more incidents or a pattern of incidents, because one incident might be a rare event, so we'll probably ask some questions about that in the formal proposal," he states.

However, Orr admits that other commenters have taken an opposing view.

"Their issue is, 'Wait a minute! You're hurting people before you'll start an ergonomics program,'" he relates. "We're trying to address that in a couple of ways. We believe that if workers are encouraged to report early, we can intervene with OSHA-recordables at a very early stage. OSHA's responsibility is to address serious injuries in the workplace; for example, a first-degree burn would not even show up as an OSHA-recordable. So we're hoping that when something like tendinitis is at a very early stage, employees will report it, and the employer will start to react by restricting their duty, which automatically makes it an OSHA-recordable."

Also, once a report is filed, it launches a "proactive stage" in that the same work activities implicated in the reported injury would be covered for other workers, Orr adds. Therefore, if one worker reports an injury related to patient-handling, other workers who do patient-handling would automatically be covered in the ergonomics program that the employer must develop, even though they did not report an injury.

OSHA further defends its use of an incident trigger by stating that many employers already use one in their ergonomics programs. The trigger helps ensure that employers take action when real problems occur, allows employers to limit the number of jobs they must address at one time, and minimizes costs for employers who have only limited or isolated problems. At the same time, the working draft leaves employers free to develop ergonomics programs that use more sensitive triggers. Many employers already initiate action early — before WMSD symptoms progress to recordable injuries — which OSHA encourages. The use of a trigger incident establishes a "minimum threshold" for employer action, OSHA officials state.

Hospitals are among the top five work sites where WMSDs occur most frequently, Orr says. One reason why patient-lifting-related WMSDs are so prevalent in health care is the "caring till it hurts" philosophy of many health care workers and facilities, he notes.

The concern for patient safety has long taken precedence over the safety and even the lives of workers, a consideration not faced by other types of industries subject to OSHA regulation. Orr says a more balanced approach is necessary.

"The life of the worker is as important as the life of the patient," he asserts. "We don't want to put the health care worker at great risk to save the life of a patient, and people are starting to understand now that worker safety and patient safety go hand-in-hand. If a worker tries to lift a patient and gets back strain in the process, probably both of them will hit the floor, and we'll have an injured worker and an injured patient."

Through other regulations such as the bloodborne pathogens standard **(see related cover story, p. 85)**, health care employers have developed more awareness in recent years of the need to protect workers. "The health care industry has

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been very keen on providing good health care for the public, but when it came to their own people, they probably weren't as good as many other industries were," Orr says.

In terms of lifting injuries, other industries generally are more aware of the need to eliminate manual lifts to protect workers. However, many health care employers still insist that if workers "would just do the lift correctly," they wouldn't get injured, he notes. "Industry has said there's really no right way to lift 100 pounds, so it's probably better to get [mechanical] assistance. Industry has probably recognized the problem more and what can be done about it."

Still, the final standard won't be prescriptive, Orr says. Instead, it will motivate employers to explore options for preventing injuries.

Development of an ergonomics standard, which was first announced in 1992 by a notice of proposed rulemaking, has been delayed largely by political opposition from Republicans in Congress representing the interests of big business. Attempts to issue a standard were further derailed after a 1995 draft proposal was released, when Congress prohibited OSHA from promulgating a proposed standard before Sept. 30, 1998. Nevertheless, the agency held stakeholder meetings throughout much of last year in preparation for a final rule.

Orr says political opposition remains active, "but, for the time being, we're going to see it move ahead."

Presently, the biggest "question mark" will be the results of a new National Academy of Sciences (NAS) study that will review the medical literature in search of data linking musculoskeletal injuries to occupational hazards, he predicts. The new study, commissioned by Congress, will be a longer version of an NAS report released last year, which verified the existence of substantial scientific evidence connecting musculoskeletal disorders to biomechanical stress on the job.[1] **(See *Hospital Employee Health*, January 1999, pp. 1-3.)**

Bills in the House and Senate require OSHA to wait for the results of the larger study before issuing a final standard. The study is not expected to be complete until spring 2001.

Reference

1. Steering Committee for the Workshop on Work-Related Musculoskeletal Injuries: The Research Base, Committee on Human Factors, National Research Council. *Work-Related Musculoskeletal Disorders: A Review of the Evidence.* Washington, DC: National Academy Press; 1998. ■

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. ■