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FDA adds to momentum to limit use of powdered latex gloves in hospitals

New labeling will give hospitals greater choice

Concerns over latex allergy are causing a rapid shift in glove use at hospitals, as state and federal regulators move to limit the use of powdered latex gloves.

The Food and Drug Administration (FDA) will release a final regulation later this spring that sets recommended maximum levels of protein and powder content of latex gloves and requires labeling of those ingredients. For the first time, hospitals will be able to purchase gloves based on their protein or powder content.

Some state legislatures are considering bills to address latex allergy, and New Jersey's Department of Health is considering guidelines that would urge hospitals to eliminate powdered gloves.

The FDA and many latex experts contend that a switch to powder-free gloves can greatly reduce the incidence of latex allergy among health care workers. The U.S. Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health have both recommended the use of powder-free gloves.

"The research has clearly shown what the problem is," says **Gordon Sussman**, MD, associate professor of medicine at the University of Toronto and a leading researcher of latex allergy. "I don't think there's much doubt. It's the proteins in the latex, [and] the powder acts as a carrier."

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Workers' comp trust mandates safer needles

The Palmetto Hospital Trust in Columbia, SC, adopted new underwriting guidelines that require member facilities to implement a sharps injury prevention program that includes safer devices. Trust directors realized that even a single claim triggered by a needlestick could be extremely costly for the self-insurance pool 32

NJ becomes the fifth state with a safe needle law

State-by-state activity on safer needles continues as New Jersey passes a law mandating that sharps devices have 'integrated safety features.' New Jersey is the fifth state to pass legislation on needle safety. The New Jersey law allows for waivers if the safer devices would harm patient care or aren't available, or in the case of emergencies. 32

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Even without required limits, hospitals are rapidly moving away from the more allergenic powdered gloves. The FDA estimates that powdered glove use will decline from 65% of the market to 20% within four years, lowering the annual number of allergic reactions to about 4,800. Based on reports to the Adverse Experience Reporting System, the FDA estimates that there are currently 43,500 allergic reactions to latex medical gloves each year.¹

Lower protein and powder content would further reduce allergic reactions to about 1,000 cases a year, the FDA asserts.

By deciding not to ban powdered gloves, some latex allergy

experts say the FDA did not go far enough in its proposed rule, which doesn't become effective until two years after it is finalized and doesn't remove even the most allergenic gloves from the market.

"I believe the data are strong enough to say that the powdered natural rubber latex glove is . . . the primary factor that elicits occupational exposure to health care workers," says **Robert Hamilton, PhD**, associate professor of medicine at Johns Hopkins University School of Medicine in Baltimore. "I think [the FDA rule] is a positive move, but I don't think it's going to be sufficient."

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Hospitals increasingly are powder-free

The risk of latex allergy and what should be done to prevent it have stirred controversy and provoked hundreds of lawsuits against glove manufacturers. (See *Hospital Employee Health*, **November 1999**, p. 126.) Some consumer and union groups have called for a federal ban on powdered gloves, while latex backers have cautioned against a backlash that could lead to the use of gloves with less durability.

"Inconsistent federal and state initiatives to ban the use of powdered natural rubber latex gloves, lacking a sound scientific basis, have potentially ominous and costly implications for physicians, hospitals, and other health care providers," stated **F. Samuel Eberts III**, assistant general counsel for Allegiance Healthcare Corp. of McGaw Park, IL, in a response to federal and state measures that was released on a latex Web site (www.ppdnet.com/latex_gloves.htm).

Allegiance, a leading manufacturer of latex and synthetic medical gloves, supports the FDA

rule but believes customers should have the option of using powdered varieties, says spokeswoman **Donna Gaidamak**.

“We’ve got clinical educators who work with our customers and try to help them set up protocols and identify latex-sensitive individuals,” says Gaidamak. “If one of our hospital customers wants to go in that direction [of powder-free gloves], we’re happy to support them.”

Powder-free gloves cost, on average, \$5.80 per 100, compared to \$3.90 for powdered gloves, according to an FDA analysis. That amounts to about two cents more per pair.

Yet some medical organizations have endorsed a switch to powder-free gloves, including the American College of Surgeons in Washington, DC, and the American College of Allergy, Asthma and Immunology in Arlington Heights, IL.

While it is rare for hospitals to ban latex gloves altogether, the switch to powder-free gloves is becoming more commonplace as a relatively painless way to protect sensitized workers, who can be exposed through particles on airborne powder.

For example, the two hospitals in the Heritage Valley Health System in Sewickley, PA, switched to a powder-free environment on the advice of a hospital task force. Powder makes it easier to don and remove gloves, but the powder-free gloves haven’t led to any problems, says **Mary Ann Gruden**, MSN, CRNP, NP-C, COHN-S/CM, an employee health nurse practitioner at Sewickley (PA) Valley Hospital.

“I have not heard any complaints from the staff with regard to using a powderless glove,” she says. A task force of surgeons and operating room staff is considering alternatives to latex, as well, she says.

With the proposed FDA rule that would require labeling, Gruden says the hospital could consider purchasing only low-protein gloves to further reduce exposure. “It would also encourage manufacturers to provide the best gloves as their product, realizing that lower levels of powder and protein decrease the risk to

employees but provide the same level of protection,” she says.

A multidisciplinary task force at Dartmouth Hitchcock Medical Center in Lebanon, NH, conducted trials in which various health care workers tested different brands and types of gloves for tensile strength, comfort, and dexterity. “We phased out any powdered latex exam gloves in the institution and replaced them with nothing but powder-free latex,” says **Kathleen Golden McAndrew**, MSN, ARNP, COHN-S, CCM, department director and nurse practitioner in the hospital’s section of Occupational Medicine.

Dartmouth-Hitchcock has increased its stock of vinyl and nitrile gloves and created an algorithm to help employees determine which glove would be most appropriate for different tasks.

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Estimated Allergic Reactions from Powdered Latex Gloves

	Year	Gloves in use (in billions)	Powder content (in billion grams)	Estimated number of reactions
With FDA- proposed rule	Current	12.87	3.35	43,500
	Year 1 (of final rule)	10.06	2.62	26,900
	Year 2	6.98	.84	2,800
	Year 3	3.95	.47	900
	Year 4	4.10	.49	1,000
	Year 5	4.26	.51	1,200
Without FDA- proposed rule	Current	12.87	3.35	43,500
	Year 1	10.06	2.62	26,900
	Year 2	6.98	2.13	17,900
	Year 3	3.95	1.62	10,400
	Year 4	4.10	1.09	4,800
	Year 5	4.26	1.11	5,000

Source: Food and Drug Administration, 1999. Based on a current average powder content of 260 mg per glove and a recommended powder content of 120 mg per glove.

“We’re encouraging everyone to use latex-free wherever possible,” McAndrew says.

Educational programs also have prompted employees to seek treatment of dermatitis as soon as symptoms appear. That skin reaction is not always due to latex and may occur in response to chemicals in the glove or in response to other factors, such as trapped moisture, she notes.

McAndrew acknowledges that the changes have increased the cost of medical gloves. “However, as more and more demand is made for natural rubber latex substitutes, we’re seeing the prices go down,” she says. “We hope that’s a continual process.”

Latex allergy linked to exposure

Just what *is* the risk of latex allergy to health care workers? That question is still the subject of some debate.

Various studies show that 8% to 12% of health care workers are allergic to latex, compared to 1% to 6% in the general population.^{2,3} In fact, some studies have found much higher rates among workers with high levels of exposure.⁴ Yet efforts to determine more precise information on prevalence have been hampered by limitations of blood tests, which can show false positives or negatives.

Studies also often don’t provide information on actual exposure to latex, making comparisons less useful. For example, some health care workers may have duties that rarely require them to wear gloves, while others, such as operating room nurses, have extraordinarily high exposure. Conversely, some non-health care occupations may require workers to use latex gloves or other latex materials. **(For a related article on prevalence of latex allergy, see p. 30.)**

Sussman tried to determine the risk of latex allergy among health care workers at a hospital in Hamilton, Ontario, by following them for a year between 1994 and 1995 to record new cases of sensitization. At baseline, 12% of the employees had a positive skin-prick test for latex allergy.

Of those who tested negative (indicating no allergy), 227 used powder-free gloves and 208 used powdered gloves. A year later, only four conversions had occurred — two in the powdered glove group and two in the powder-free group. Only the employees using powdered gloves were symptomatic for latex allergy.⁵

The study doesn’t indicate that powdered and powder-free gloves are equivalent, says Sussman, who is head of allergy and the section of immunology at St. Michael’s Hospital in Toronto. “If you have a resistant group of people you’re looking at, you may not see many conversions,” he says, noting the high level of sensitization found at baseline. With few conversions to evaluate, the study’s conclusions are limited, he says.

In fact, the protein levels in the powdered gloves declined during the study period, Sussman reported. Protein levels in different batches of gloves may vary greatly, complicating clinical studies, he says.

“These results should not be interpreted to suggest that low-protein, powder-free gloves have no effect on reducing latex sensitization,” Sussman states. “Additional studies involving larger populations for longer periods of follow-up are required.” Despite the inconclusive results, Sussman says he recommends the use of powder-free gloves.

FDA sets recommended limits

The FDA’s proposed rule would define the term “powder-free” and would require manufacturers to measure and label the amount of powder and protein in all latex medical gloves.

The FDA found that powder levels currently range from 70 mg to 375 mg per glove in surgical gloves and from 50 mg to 426 mg per glove in patient examination gloves. The proposed rule would set a recommended limit of no more than 120 mg of powder and 1,200 µg of water-extractable protein per glove.

“One of the biggest issues is reducing the sensitization rate,” says **Mel Stratmeyer**, PhD, chief of the health sciences branch in the office of science and technology at the FDA’s Center for Devices and Radiological Health. He notes that cornstarch powder “provides a route of exposure we’d like to see reduced.”

But Stratmeyer acknowledges that the FDA rule isn’t likely to please those who want to see a complete elimination of powdered gloves. “The limit is not going to assure absolute safety at all for somebody who is sensitized,” he says. “It’s based on what’s technologically feasible without causing a shortage in the market and all kinds of other considerations.”

The FDA also is conducting its own research to determine the possible need for tougher regulations. An analysis of medical glove adverse event

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Proposed FDA Labeling Requirement

Under a proposed rule by the Food and Drug Administration, latex gloves would carry the following label:

CAUTION: This product contains natural rubber latex which may cause allergic reactions. FDA recommends that this product contain no more than 120 mg powder and 1,200 µg extractable protein per glove. This glove contains no more than ___ mg powder and no more than ___ µg extractable protein.

reports covered 2,396 reports between 1985 and March 1999.

Nurses working in an inpatient facility represented the largest group. Rash was the most common dermatologic symptom, and anaphylaxis and asthma were among the non-dermatologic symptoms.

The number of reports were “enough for us to take notice that there appears to be some problem that warrants investigation,” says **Brockton Hefflin**, MD, MPH, medical officer in FDA’s division of postmarket surveillance.

To Hamilton, the solution is clear. “The most effective and possibly the least expensive [way to eliminate latex allergy] is avoidance,” says Hamilton, noting that Johns Hopkins University has decided to convert to synthetic gloves, using vinyl for nonsterile examination gloves and nitrile for surgeon’s gloves. (See **HEH**, **September 1999**, p. 99.) Surgeons also may have to retain the option of using powder-free latex gloves. Hamilton also led a multicenter investigation of a new latex skin test reagent; its use is pending approval by the FDA.

“If you take the allergen out of the environment, you are improving that environment for the patient and for the worker in that environment,” says Hamilton.

(Editor’s note: A copy of the proposed rule is available on the FDA Web site at www.fda.gov/ohrms/dockets/98fr/073099a.txt.)

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Latex allergy cases are costly to workers’ comp

Allergic workers awarded total disability

Latex allergy may be emerging as one of the higher-cost employee health risks in hospitals. A New Jersey plaintiff’s lawyer analyzed workers’ compensation adjudications for the past four years and found a trend of increasing disability awards.

“The financial cost is beginning to soar,” says **Jon L. Gelman**, an attorney in Wayne, NJ, and author of the text *Workers’ Compensation Law*.

“The trend lines are dramatic in the last four

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years. All these cases are starting to be adjudicated. That alone will be a wake-up call for hospitals to have a safer environment,” Gelman predicts.

Gelman found 30 latex-related workers’ compensation cases in 13 states. In 21 (70%) of the cases, workers were granted compensation, at times including total and permanent disability.¹

“The compensation benefits, remarkably, were extensive,” says Gelman. “The benefits awarded to plaintiffs were the same type of benefits you would see awarded in catastrophic disease claims.”

Gelman reported that cases seemed to be clustered in certain states, such as Wisconsin, New York, Texas, Virginia, and South Dakota.

“Both Wisconsin and New York have dramatically demonstrated that a claim for latex sensitivity is extremely serious in nature and is indeed compensable,” he wrote in *Update on the Law* newsletter. “A significant percentage of the claims

resulted in the awarding of total and permanent disability benefits to the claimant.”

In a 1996 Wisconsin case, a nurse who wore latex surgical gloves and made frequent glove changes developed respiratory symptoms related to latex allergy. She asserted that she couldn't obtain regular, continuous employment anywhere, and an administrative law judge agreed that she was permanently and totally disabled (*McMillan v. County Milwaukee*, 1996 WL 98882).

In Montana, a hospital nurse's aide was hospitalized due to a severe allergic reaction to latex gloves. A workers' compensation court declared her to be totally and permanently disabled and indicated the need for some housing adaptations to accommodate her allergy (*Daniels v. Kalispell Regional Hospital*, WL 109850). Many household products, including some types of carpeting, contain latex.

“Home modifications cost thousands and thousands of dollars,” says Gelman. “You either modify a house or you have to find a new house for them.”

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National survey sparks dispute about latex risk

NHANES can't gauge HCW problem, official says

Can the survey used to track the nation's most serious health problems also reveal the risk of latex allergy to health care workers?

Leading researchers say the data collected in the National Health and Nutrition Examination Survey (NHANES) by the National Center for Health Statistics aren't complete enough to compare the risk between health care workers and the general public. But in an independent analysis, Allegiance Healthcare Corp. of McGaw Park, IL, a leading manufacturer of latex and synthetic medical gloves, asserts that health care workers are not at greater risk of latex allergy.

Out of 20,050 adult respondents to the survey, 5,524 were tested for latex sensitivity using the

AlaStat immunoassay produced by Diagnostic Products Corp. of Los Angeles. According to the Allegiance analysis, 1,026 respondents tested positive, including 21% of health care workers and 19% of non-health care workers. (The Centers for Disease Control and Prevention has not yet released its own analysis of the data.)

“The results of NHANES III are consistent with several studies published over the past few years which show that there is little difference in latex sensitization rates among health care workers and the general population,” concluded Neil Roth, MD, an epidemiologist and consultant to Allegiance.

Michele Pearson, MD, a medical epidemiologist with the hospital infections program at the Centers for Disease Control and Prevention in Atlanta, notes that there are potential problems with any analysis of the NHANES data that attempts to gauge risk and exposure. For example, the occupation codes used to identify health care workers could include workers who don't wear latex gloves. While the survey asked about glove use, it didn't specify type of glove and doesn't include any detailed information about exposure.

Furthermore, the “health care worker” category would exclude workers who develop allergic symptoms and change jobs, she notes.

When NHANES is repeated in about three years, it may reveal a clearer picture of latex allergy, says Pearson. Yet it can't carry the scientific weight of a controlled study, she adds.

“We were trying to find out how many people might have evidence of sensitization and were there any patterns. Did [sensitization rate] differ from one group to another?” says Pearson. “We hoped this might be a baseline to look at trends over time.

“Neither the NHANES study or virtually any study out today can tell you what the risk is [of latex allergy],” says Pearson, who is analyzing the NHANES data.

“These studies can tell you the prevalence, not the incidence,” explains Pearson, noting that only by following exposed workers over time can researchers determine the risk. “I think that question is still to be answered.”

(Editor's note: The Allegiance Healthcare Corp. analysis of NHANES data is available on the company's Web site at www.allegiance.net.) ■

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Experts offer advice on reducing latex risk

A hospital hires a worker who reports no known latex allergy. Yet within a year, that employee complains of rash and other symptoms that grow progressively worse. Could anything have been done to prevent that occurrence?

While some health care workers will undoubtedly develop allergic reactions as long as any latex products remain in the hospital, many cases of sensitization can be avoided, latex experts say. Here are some steps employee health professionals can take to reduce the risk of latex allergy:

- **Establish a latex allergy task force to set hospitalwide policy on the use of latex products.** Consider the needs of latex-allergic patients as well as health care workers.

- **Educate health care workers about the symptoms of latex allergy and how to minimize exposure.** This is particularly important because worker preference influences the choice of glove type.

- **Limit latex gloves to activities that require protection against bloodborne pathogens.**

- **Eliminate powdered gloves in favor of low-protein, powder-free versions.**

- **Develop a latex-free crash cart in case of severe reactions to latex.**

- **Provide a latex-safe environment for employees with sensitization.** This means they should have access to nonlatex gloves, and powdered gloves should not be used by co-workers.

- **Evaluate cases of possible dermatitis as early as possible to provide treatment and corrective action.**

- **Test workers who are at high risk for developing latex allergy.** This would include people who have multiple allergic conditions; those with existing allergies to banana, kiwi, avocado, chestnut, tomato, and papaya; and those who have a history of hand dermatitis.

[Editor's note: For guidelines on reducing the risk of latex allergy among health care workers, see OSHA Technical Information Bulletin: Potential for Allergy to Natural Rubber Latex Gloves and Other Natural Rubber Products (April 12, 1999) and NIOSH Alert: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace (Publication 97-135). They are available on-line at www.osha.gov and www.cdc.gov/niosh/latexalt.html.] ■

Going latex-free: Hospital takes it step by step

Eliminating latex gloves from a hospital may seem daunting. They may be used by housekeepers, food handlers, physicians conducting physical exams, surgeons in the operating room, or obstetricians in the delivery room.

The University of Maryland Medical System in Baltimore decided to phase in less allergenic products, with the goal of having a completely latex-free environment in three to five years, says **Mary Beth Bollinger**, DO, director of allergy and assistant professor of pediatrics at the University of Maryland.

At each step, doctors, nurses, and other employees were involved in evaluating alternative gloves.

The hospital began using only powder-free exam gloves in the fall of 1999, and switched

to powder-free sur-

geon's gloves in January. Next will come latex-free versions, Bollinger says. "It's a gradual transition to a latex-restricted hospital," she says.

The University of Maryland's latex allergy task force analyzed the cost implications of the phase-in, expecting to spend an extra \$100,000 a year on the powder-free and latex-free gloves. But by reducing the number of glove types and focusing business on one manufacturer, the hospital actually saved \$80,000, says Bollinger.

Meanwhile, the hospital discovered that six cases of latex allergy in 1997 involved an average of 50 lost work days per case. "It was very easy [to justify a switch] from a financial point of view, if you look at all the issues," says Bollinger.

An important aspect of the university's program has been a system of screening for latex allergy. All new employees — from accountants and clerks to nurses and technicians — are screened for latex allergy using serologic tests. Current employees who exhibit possible symptoms or who transfer from one clinical area to another also are screened.

Skin tests are used to confirm a serologic test or to follow up if an employee has symptoms but a negative test result.

Baseline data show that 5.6% of employees entering or engaged in non-patient care services are sensitized, compared with 8% to 10% in patient care services. The hospital will track sensitization data that may reveal more about the rates of allergy and the impact of the hospital's latex program. ■

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Worker's comp insurer mandates sharps program

SC trust helps hospitals with injury prevention

Hospitals in South Carolina have an imperative to adopt safer needle technology that is even stronger than federal regulation: Their workers' compensation insurer demands it.

The board of directors of the Palmetto Hospital Trust in Columbia, a self-insurance pool that covers 65 acute care hospitals and other health care facilities, voted unanimously to adopt new underwriting guidelines that require members to implement a "sharps injury prevention program."

While the trust hasn't suffered a significant liability from needlestick injuries, the potential exists for high costs from just one claim, says **Chip Wise**, MHA, assistant vice president for business development of PHT Services Ltd., the administrative arm of the trust.

"There is definitely a great deal of concern about the future," says Wise. "The potential is there for a claim to be very devastating."

A single seroconversion of hepatitis C in an injured worker could lead to workers' compensation costs of \$500,000 to \$1 million, he says.

Money isn't the only motivation. The trust also recognizes a moral obligation to promote the well-being of health care workers, says Wise. The trust created a Health Care Workers Safety Center to provide education and information, support research, and conduct surveillance.

"We would like to be a resource of clinical data," says Wise. "If a client wants to implement a safety syringe, what are some of the success stories [in other facilities]?"

The Palmetto Hospital Trust didn't set a time line for implementing a sharps injury prevention program. Rather, the trust administrators plan to work with the hospitals collaboratively. They are also developing criteria to define an "effective" program.

An initial survey showed wide variation in the use of safer technologies. Some hospitals already have a sophisticated program for evaluating and implementing new devices, while others have just taken initial steps toward safer technology.

"We expect within two years that we should see a substantial change in South Carolina with [safer technology in our client facilities]," he says.

"I think we'll see dramatic progress in the use of safer processes and equipment."

PHT hospitals already had been working on needlestick prevention. In 1992, 40 PHT hospitals joined EPINet and worked with the International Health Care Worker Safety Center at the University of Virginia to incorporate safer devices. From 1993 to 1997, sharp object injuries declined by 37%.

Now, the trust is emphasizing better reporting of injuries by all members through the EPINet system, which provides a "Uniform Needlestick and Sharp-Object Injury Report" and "Uniform Blood and Body Fluid Exposure Report." All hospitals will have a Windows-based version of the EPINet software, allowing better in-house tracking and reporting to the national database.

That puts South Carolina hospitals just ahead of the curve, as more complete reporting of sharps injuries is likely to become mandatory for hospitals nationwide. The California safe needle device legislation, passed in 1998, included reporting requirements, as does recent New Jersey legislation. (See related article below.) The U.S. Occupational Safety and Health Administration has indicated that its pending recordkeeping standard will include stricter reporting requirements.

"Good records — effective tracking — is the first step before you can address the problem," says Wise. "You have to know where your exposures are occurring." ■

New Jersey adopts tougher needlestick law

Push continues to require safer devices

New Jersey became the fifth state to mandate use of safer needle devices, as tougher state laws on needle safety increase pressure on hospitals to evaluate and update their sharps devices. The law gives hospitals in New Jersey one year to switch to devices with "integrated safety features" that have been approved by the Food and Drug Administration.

If a suitable device doesn't exist or if a health professional believes the safer device would compromise patient care, the hospital may file for a waiver.

The law was lauded by needle safety experts, who say such legislation creates swift improvements in the use of safer devices.

"We can see very clearly in California [the first state to pass a needle safety law] that there has been a very rapid and significant increase in the use of safety devices," says **Janine Jagger**, PhD, MPH, director of the International Health Care Worker Safety Center at the University of Virginia in Charlottesville. "That is directly related to the law.

"We can see that there are increases in other states where there are no laws, but not to the extent that there is in California," she says. "A law is simply stronger than the OSHA compliance directive."

The U.S. Occupational Safety and Health Administration issued an updated directive in November, calling for hospitals to review their exposure control plans annually and implement the most effective "engineering controls" to reduce needlestick injuries. The OSHA directive guides inspectors, but OSHA generally conducts inspections in response to complaints.

OSHA also is reviewing its bloodborne pathogens standard. Incorporation of device safety requirements in the standard would represent a stronger regulatory mandate.

Nationwide, the use of safer devices varies widely. For example, 63% of IV infusion sets in use incorporate safety features, compared to less than 10% of vacuum tube phlebotomy needles and disposable syringes.¹ About 600,000 to 800,000 needlesticks occur each year, about half of them unreported. Safety devices have been shown to reduce needlesticks by about 80%.

Bill Borwegen, MPH, occupational health and safety director of the Service Employees International Union in Washington, DC, called the New Jersey law the "most significant" since California passed its needlestick law in 1998.

Hawaii, Texas, and Tennessee also mandated the use of safer needle devices, but with different provisions. In Texas, the mandate covers only state and local hospitals, although the bill has spurred use of safer devices statewide, says Borwegen.

"The private sector in hospitals are buying the needles too, even though the law only covers the public sector," he says.

Legislatures in about a dozen other states are considering needle safety bills. The Health Care Worker Needlestick Prevention Act also is currently pending in the U.S. House of Representatives with 162 co-sponsors.

The new laws often cover reporting requirements in addition to the implementation of safety devices.

New Jersey hospitals must report any needlestick injuries, including type and brand names of devices, on a Sharps Injury Log or OSHA 200 log. The state Department of Health and Senior Services will compile needlestick information and report to the Legislature.

The law also requires hospitals to establish sharps device evaluation committees in which at least half the members are "direct-care health care workers."

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Wellness program pays for itself with lower claims

Employees earn bonuses by meeting healthy criteria

Exercise. Healthy diet. Relaxation. This is the Rx that doctors and nurses routinely give their patients. But how can you influence them and other hospital employees to follow that advice as well?

Providence Everett Medical Center in Everett, WA, found the answer with a bonus program for employees to meet the "Wellness Challenge." If employees meet eight out of 10 wellness goals, they receive a bonus of \$250. That rises to \$275 for their second year of meeting the goal and \$325 for subsequent years. Even employees who meet just four out of 10 of the goals receive a modest reward of \$50.

More than half of Providence Everett's 1,800 eligible employees participate in the program. That may sound like an expensive proposition, but **Ron Burt**, MEd, manager of prevention services, notes that the costs of sick days and injuries far exceed the payout.

"Over the past seven years, we've seen a three-to-one return on our investment," says Burt. "People aren't sick as often. They're not using health care and they're not as likely to have injuries."

Alliance (OH) Community Hospital adapted the Wellness Challenge program and found a similar benefit. The average health care benefits cost per employee dropped from \$2,326 in 1996 before the program began to \$1,993 in 1998.

“When you multiply that by 800 employees, that’s a hunk of change you’re saving,” says **Ann Walker**, director of wellness services at Alliance. “We figured in the two years we’ve had the program running, we’ve saved almost \$338,000 in [lower] absenteeism, workers’ compensation, and health care dollars.” That total is a net savings, after deducting the \$132,650 cost of the program, she says.

The Wellness Challenge begins with a health risk assessment. In 1998, Providence Everett offered \$25 bonuses to employees just for signing up and completing the health risk assessment. About 75% of the employees responded.

Participants motivated by outreach

But those small incentive bonuses may not even be necessary to spur participation. When Burt’s department surveyed employees, they found that outreach to the workers was a more powerful motivator than the money. “It was more of an incentive that someone came to them and asked them personally to sign up [for the Wellness Challenge],” he says.

This year, the hospital isn’t offering the sign-up bonus. But Burt will still try to encourage nonparticipants to join the program. “We wanted to get not only the healthy, health-conscious people, but also those people who were really in need of some help and tended to be higher users of health care.”

Wellness Challenge criteria may change from year to year, depending on employee health patterns or response to the program. For example, Burt found that some employees decided not to participate in the program because they didn’t want a body composition test or they had trouble scheduling the lengthy assessments. Now, the hospital offers quarterly screenings that include body composition, lipid profile, and blood pressure, but the testing is optional. **(For a list of criteria, see box at right.)**

The definition of wellness is broader than physical functioning or even fitness. Providence Everett encourages employees to get some TLC from massage, hobbies, or other relaxing activities — and gives them credit for it.

“People haven’t taken time for themselves. We felt that it was an important part of stress management and mental health wellness,” Burt says.

Each institution adapts the Wellness Challenge to meet that hospital’s needs. Ann Walker at Alliance Community Hospital reviews the criteria annually for possible changes.

“Last year, our infection control committee came to me and said, ‘We’re having a huge increase in needlestick and sharps injuries. Is that something we can add to the Wellness Challenge?’”

Walker added an item that gave employees credit if they had no needlestick or sharps occurrence. Alliance employees must meet nine of 13 possible criteria to receive a \$350 bonus.

“From last year to this year, we had a 17% decrease in needlesticks and sharps occurrences. That doesn’t mean the Wellness Challenge can take all the credit for that. But it certainly contributed to that,” she says.

This year, Alliance is adding flu shots to the list. “[Wellness] is not just fitness and eating right. There’s so much more involved with wellness and reducing the costs of employee benefits,” says Walker.

Employees who don’t attain a bonus receive a certificate for participating. Meanwhile, Walker

Wellness Challenge: Could you meet these criteria?

To get a Wellness Challenge bonus payment at Providence Everett Medical Center in Everett, WA, employees must meet at least eight of these criteria:

- No lost work time during the past year due to pain or injury that occurred on the job.
- No sick time in three of four quarters of the year.
- Less than \$250 in health care claims or use during the benefit year, excluding dependents, deductibles, and preventive medical services.
- Earn at least nine or more points in a self-directed learning program, including reading articles, watching videos, or taking classes.
- Sign an agreement to wear a safety belt every time they ride in a motor vehicle.
- View a 30-minute presentation on personal self-care and meeting the Wellness Challenge.
- Be a nonsmoker or show verification of participation in a smoking cessation program.
- Blood pressure measured and recorded by an employee health nurse or wellness staff person at least twice a year.
- Earn at least 75 points for physical fitness activities.
- Earn at least 90 TLC points for “mental wellness” activities, including such things as gardening, reading a book, and getting a massage.

continually tries to boost enrollment. "People who smoke, who are under a lot of stress, who have health problems, who are overweight, think, 'I would never be able to do that [meet the criteria]," she says. "But we're chipping away at it. Every year, we see a few more people."

The program can have an impact on employees' lives. At Providence Everett, Burt recalls a nurse who told him that before she began participating in the Wellness Challenge, she never wore a safety belt when she drove. But because safety belt use is one of the program's wellness criteria, the nurse started wearing her safety belt more often.

Now, she's glad she made the change, and not just because she wants the bonus. "She was in a head-on collision and would have died if she hadn't been wearing her seat belt," Burt says.

[Editor's note: Providence Everett Medical Center licenses the use of the Wellness Challenge program and provides materials, training, and consulting services. For more information, contact Ron Burt at (425) 258-7881.] ■

Literature Review

HCWs seroconvert to HIV despite drug therapy

Jochimsen EM, Luo CC, Beltrami JF, et al.

Investigations of possible failures of postexposure prophylaxis following occupational exposures to Human Immunodeficiency Virus. *Arch Intern Med* 1999; 159:2,361-2,363.

Why does postexposure prophylaxis fail in some cases to prevent seroconversion after occupational exposure to HIV? Researchers at the Centers for Disease Control and Prevention in Atlanta are exploring that question through case studies. This article discusses two such case studies, in which health care workers seroconverted to HIV after needlestick injuries despite PEP with combination drug therapy.

The researchers begin by noting that guidelines call for the use of combination drug therapy, including zidovudine, as chemoprophylaxis after

certain occupational exposures to HIV. "Since little is known about the effectiveness of PEP for occupational HIV exposures, investigation of cases of possible failure can provide important information about factors that may influence PEP efficacy and occupational HIV transmission," the authors state.

In the first case, a health care worker received three cuts to the thumb from a broken blood collection tube containing the blood of an HIV-infected patient. The exposure involved a deep injury and a large volume of source blood, leading to a high risk of HIV transmission. The source patient was being treated with antiviral agents, raising the possibility that the patient had drug-resistant HIV.

The health care worker received PEP with zidovudine, lamivudine, and indinavir within 30 minutes. A baseline HIV test the next day was

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negative. However, within eight days, the health care worker had an “acute, viral-like illness,” and within 17 days, tested positive for HIV.

However, further investigation showed that the health care worker had another possible risk factor for HIV infection and took no more than one dose of the PEP regimen. The two “alleged” HCW virus samples didn’t match each other (that is, they came from different individuals) and also did not match the source patient. Researchers concluded that this did not represent a failure of PEP.

In the second case, a health care worker was splashed in the face with serum from an HIV-infected patient. The HCW had had a facial dermabrasion procedure the day before, and the source was being treated with combination therapy.

The HCW began PEP with zidovudine, lamivudine, and indinavir within six and a half hours of exposure. Although tests at baseline and at six weeks were negative, tests at one month were positive. A follow-up at 12 weeks produced positive test results, despite six weeks of PEP. Analysis showed the one-month and three-month samples did not match each other. The CDC obtained a blood specimen directly from the HCW and compared it to blood from the source patient and found they were not genetically related.

“We have concluded that the HCW did not seroconvert to HIV from the reported occupational exposure but that the seroconversion occurred sometime between six and 12 weeks after that exposure,” the authors state. “The source of the HCW’s HIV infection remains unclear, although a follow-up interview with the HCW revealed a possible nonoccupational exposure to HIV.”

The authors stress the importance of epidemiologic and laboratory investigations following reports of possible PEP failure. In both cases, blood samples thought to come from one person actually were from different individuals, a situation that could occur due to lab error or deliberate substitution.

“The outcome of a PEP failure investigation should not affect the management of the infected HCW or change the institution’s infection control policies for managing occupational exposures to HIV,” the authors state. Hospital employee health practitioners can receive assistance with such investigations from the CDC by calling (404) 639-6425. ■

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- 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. ■