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In This Issue

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Smallpox vaccination: Risk is hard for experts to quantify

Side effects are just one of many serious concerns

The White House's smallpox vaccination plan, especially its assertion that health care workers should be among the first immunized, was certainly welcomed by many occupational health professionals.

But the devil is in the details, and some of those details have left observers confused and concerned. Chief among those concerns is the possibility — albeit slight, according to the government — of serious side effects and the potential impact this has on frontline workers. The fact that inoculation will be voluntary, both for individual workers and facilities, raises other issues such as whether to inoculate at all, who should get the vaccine, and what to do if people refuse to be inoculated?

"Clearly, I believe it is positive to be preparing for a bioterror event," says **Robert McLellan**, MD, MPH, chair of the American College of Occupational and Environmental Medicine's (ACOEM) special committee on disaster preparedness and response. "It's pulling together the private health community with the public health community in a way that hasn't happened in over 30 years. I believe quite strongly all these preparations will have a positive spin-off, improving public health and clinical medicine not only for bioterror events, but also for a range of population-based medical events."

Jack Richman, MD, medical director of AssessMed Inc., in Mississauga, Ontario, says the policy is good in terms of prevention for terror attacks as the people who will be looking at sick people will be health care workers "My only concern is that if health care workers, in doing their work, fall ill, the government is not covering them. They need to be covered."

Jean Randolph, RN, COHN-S, a member of the Board of the Atlanta-based American Association of Occupational Health Nurses (AAOHN) thinks the best part is that it's a voluntary immunization of frontline health workers and that the government is providing it. "That means there are some liability protections under the Homeland Security Act. But you also have to look at the risk factors," she adds.

However, says McLellan, the level of risk is difficult to quantify.

"Here we are, spending huge amounts of money we may be diverting from other activities that are important in terms of public health, be it obesity, diabetes, or cardiac disease," he says. "Plus many of us in the field of disaster response believe we need be prepared for an all-hazards response. By preparing so much for smallpox, we could be ignoring something else."

On the other hand, Randolph notes, "the government probably has some information I don't, and maybe they think the threat is bigger than before. From their current position, the direction we're getting from government is that this is a fairly serious threat."

McLellan strongly emphasizes that he approves of the approach being taken as opposed to offering mass vaccinations.

"What is happening here is a phased response," McLellan adds. "We are initially trying to inoculate the people most likely to be involved in caring for individuals with smallpox and asking for volunteers."

This helps address side effects, he explains. "This way, we have the luxury of time. We can screen people so we will have the least likelihood of side effects. Technically, they could be immunized within three days of exposure and have protection. There is some concern that as many as one-third of those immunized will feel sick enough to miss work, which is not a good thing, but we can get the side effects out of the way."

Not a clear-cut decision

The decision as to whether you should inoculate frontline workers is not as cut and dried as it may first appear, says Randolph. "There are several issues involved. First, there can be complications. The world today is different."

A big part of that difference is the large number of immunosuppressed individuals — those most susceptible to side effects. Some observers say there may be as many as 100 times as many immunosuppressed people in the population as there were the last time the vaccine was administered.

"Of all the vaccines available this is probably the one with the nastiest side effects," says Randolph. "It's also the toughest one to give and to get, and we haven't got the most skilled workers to give it. The people who gave it before did it routinely." **(For more on the importance of proper inoculation techniques, see p. 17.)**

"I certainly wouldn't recommend the current plan of treating all hospitals the same," says **Edward P. Richards**, JD, MPH, a professor at the Louisiana State University Law School in Baton Rouge, and director of the program in law, science, and public health. "I would like to see the government be a little more clear on why they are recommending this strategy, if they want to prepare every hospital. So if there is a big outbreak, we'll be greeted by immune personnel. A voluntary system where about half the frontline staff is opting out is not good."

Richards is clear that he is not recommending that hospitals *not* inoculate staff.

"For hospitals that have frontline care, they ought to figure out their own plan for why they are doing it," he advises. "In Louisiana, for example, smallpox cases will only be cared for at regional hospitals. The feds did not involve hospitals in the development of the plan and they do not care for criticism. Therefore, it would be useful to develop

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your own answer as to why you're doing it — why you are only immunizing some people, and how to handle the volunteer situation."

The biggest problem, he says, is that you can't deal with a smallpox outbreak *and* have other patients.

"A lot of hospitals don't have negative-pressure rooms or ways to get people in and out. Once you have smallpox patients and you have staff going in and out, well, this is a dangerous infectious disease. When the government is worried, they place people into level three and four military facilities. Yet the CDC [Centers for Disease Control and Prevention] expects hospitals to do the same thing. Hospitals should be screaming about setting up a regional plan, identifying a smallpox hospital, and evacuating people to that facility."

Screening comes first

If you do decide to inoculate hospital staff screening becomes a critical issue, says Richards. "The occ-med staff would need to decide the right type of screening."

The screening used in the clinical trials for developing the vaccine would be a useful model, he adds.

"They could do an HIV test — a regular blood count would go a long way [toward identifying immunosuppressed staff]," he suggests. "I'm really concerned that not enough attention is being paid to family members at home — something else the clinical trials did."

Does this raise potential privacy issues? The potential is definitely there, says Richards.

"The ideal situation is to have the health department handle both the screening and the immunizations — then it all falls under public health, which helps the hospital," he explains. "But absent that, you could still work out a system for privacy. Occ-med deals with this all the time. It's not really a special issue, but you have to pay attention to it."

McLellan agrees.

"This is confidential medical information, and needs to be treated as a medical document," he asserts. "You have to have a clear policy, so that anyone volunteering knows what they're getting."

Will it impact productivity?

Inoculating frontline staff may for a short time have the opposite of the intended effect. Initially, a certain percentage of them will likely become ill and miss work. There is even the chance of a fatal reaction to the vaccine.

"About 30% of those who have never been inoculated will have some chance of a reaction," says Randolph. "That likelihood is reduced tenfold if they had the vaccine in the past. In other words, if you're under 30, you're not really in the best company."

What about fatalities?

"In a 1947 study done in New York City, more people died from the vaccine than from smallpox," she observes. "If you have two cases of smallpox and you vaccinate 6 million people prophylactically, lo and behold, you will see people die."

But, says McLellan, "the likelihood of serious side effects is very low."

However, he concedes, "reactions can be uncomfortable and disabling. People can have a high temperature for a few days."

This raises a number of issues, including recruitment, for hospitals that are inoculating frontline staff.

"Who really wants to feel sick?" McLellan asks. "If I do get sick and am out of work, who pays for this? And solo practitioners who are sick for three days will also lose revenue. You have to explore whether and when the employee comes back to the work force — it depends on their job and how they feel. Generally, you will see 60%-80% with fever. As an employer, you shouldn't penalize these people by making them use vacation time. Verify the side effects and pay them regular hours for those days. In the long run, they will be the ones working in the hospital and seeing patients should smallpox become weaponized. And how much is *that* work to you?"

Which raises a point that's important to remember: Not all hospital staff will be immunized.

"We're just looking at frontline workers — emergency departments and ICUs," says Randolph. "First responders are second tier — and that's OK. Keep in mind — the vaccine has not even been released yet. We have studies that have been done on vaccines when they were given in the past, but we do not know a lot about what happens in a large population with a component of immune-compromised people that had not been there before."

The progression of those to be vaccinated is very specific, note McLellan.

"This is spelled out clearly on the CDC web site [www.cdc.gov/smallpox]," he notes. "Only very specific categories of people will be immunized.

The first phase will be people on the smallpox response team — those directly involved in the clinical care of an identified smallpox case. In my hospital, as the occ-med physician, I will sit down and list them. It could include infectious disease specialists, support personnel, transport personnel, diagnostic imaging, and so on. But this would be no more than about 100 people per medical center and 500,000 in the country."

When the inoculation process begins, it has to be accomplished in 30 days," says McLellan. "You'll have as many as one-third of those people out of work, so you will need to stagger the inoculations, but there will still be scheduling challenges."

Follow-up is essential

Follow-up is an equally critical element of the process, not only to look for harmful side effects but also to ensure proper site care.

"Once you have been immunized you will get an ugly blister, which is potentially infectious," McLellan explains. "There are ways to cover and clear that."

The American Council of Immunization Practices and HICPAC, says McLellan, recommend site-care checks.

"Before you report back to work you should go to a site care team, have your bandage checked, and see if it needs to be replaced," he says. "So, you have to identify staff to do that for three shifts, seven days a week."

"It should be normal to follow up when pustules start to form, or at about five to seven days, to make sure the inoculation took and to be sure it's being managed appropriately," adds Richman. "You want be sure the bandages were used appropriately and that staff clearly understood they must not touch the pustules because you can self-inoculate."

For staff that is being re-vaccinated, follow-up should take place in three to five days, he adds. A special consideration for health care workers who have been inoculated is that they do not accidentally inoculate sick people.

"They don't have to remove themselves from seeing people, but they must avoid direct contact," says Richman.

The vaccine is a 5:1 dilution compared to what was used before and more people are compromised now that before, Randolph says. "With that in mind, we've got be careful be around those people, make sure the dressing is clean and nothing is leaking. Some places will make the decision to furlough these people for 21 days while going through this inoculation period."

Richards finds it hard to argue with the FDA's stance that inoculated workers should be furloughed unless they are essential.

Still, there are steps than can be taken to lesson such concerns.

"In health care workers we're talking about utilizing a dressing called Tegaderm that's 98% impervious to the virus coming through it," notes Randolph, saying this will help alleviate some of those fears. "This makes the situation better, but we still have a big question mark. After all, where do you find more immune-compromised people than in a hospital?"

With caution, the chances of complications are very minimal, counters Richman. "Proper hygiene and proper technique should allow safe vaccination and remove fear."

Yet it's only natural that some concerns remain among health care workers. "Some people are very nervous about taking care of patients who are immunosuppressed," notes McLellan. "Some institutions are nervous about liability and there's still some fuzziness about the Homeland Security legislation."

No need to hurry

At present, however, there's no rush to go out and vaccinate health care workers, Randolph says.

"There's no cases of smallpox in the world," she notes. "If it is used as a weapon, the vaccine is available and could get to any part of the U.S. that needed it; we'd then have four days from exposure to get immunized."

However, she concedes, should smallpox be weaponized and we need to vaccinate thousands of people, "Everybody can't be off for three weeks. It's a thoughtful decision on the part of the institution as well as the individual. The individual has to consider their family, as well as the job they have to do. That's why it's reasonable to leave it as a voluntary option."

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Proper inoculation: Learn from the past

Improper smallpox inoculation techniques can actually threaten the health of the patient, says one expert. The issue is more pressing than it appears at first, he notes, because so few of today's practitioners have ever administered the vaccine.

"It is most important that you be trained by someone who knows how to do it," says **Jack Richman**, MD, medical director of AssessMed Inc., in Mississauga, Ontario. "It is basically no more than a fine puncture of the skin, but not going t*hrough* the skin — in other words, barely scratching the surface."

If the puncture goes too far you can carry the virus to subcutaneous tissue, from where it can spread to the body and cause what's called a vaccinia reaction. This would then cause lesions all over the body, as well as high fever.

"This can be fatal in an immune-compromised person," says Richman.

Because no one has administered smallpox vaccine for 27 years, it stands to reason you need to be taught the technique by somebody who was practicing 27 years ago. There are other alternatives, however. For example, the Centers for Disease Control and Prevention offers a video on vaccination techniques. "Still, it is better to have it demonstrated in person," says Richman. "Barring that, my second choice would be to see the video."

In the ideal training situation, however, a knowledgeable person would be present to answer questions, and articulate the technique in different ways. "A video will show only one way to vaccinate, but people do not all learn in the same way," Richman explains. "In addition, it is extremely helpful to bring up each individual and, using a needle, show them what it feels like. This doesn't hurt at all, but it's a much more preferable way of demonstrating the technique."

Who should get this training?

"Public health docs, occupational medicine physicians [workers] and all emergency doctors, as well as family doctors," Richman advises. "Beyond that, any doctor who wants to be trained." ■

EOL a work-life issue for occ-med professionals

An act by Last Acts

The often taboo but critical issue of terminally ill employees or family members has received less attention than it merits, say many occupational health professionals. But the issue was brought to the fore again recently with the publication of a workplace end-of-life (EOL) implementation toolkit by Last Acts, a Washington, DC-based national coalition to improve care and caring near the end of life.

"This is a work/life issue, a family issue, a productivity issue, and, I argue, it is also an economic development issue," asserts **Donna L. Wagner**, director of gerontology at Towson (MD) University and a consultant to Last Acts on the toolkit.

Deborah V. DiBenedetto, MBA, RN, COHN-S/CM, ABDA, president of the Atlanta-based American Association of Occupational Health Nurses, agrees.

"I think it's a work/life issue," says DiBenedetto, who once worked as a hospice nurse. "We have dealt with this issue for many years. Going back to the 1980s, we had a lot of employees with HIV or cancer. The main idea was to keep them as healthy as possible in the context of living and doing as many of their normal activities — including work — as they wanted."

This requires flexibility on the part of the employer.

"You've got to look at the workplace and see what the employee can safely do," she explains. "Or it may be as simple as providing carpooling services to help them get to work. Of course, you still need to meet the needs of the organization as well."

In any event, she says, the occupational health professional should serve as an advocate for the affected employee.

While there is much progress to be made, some has already been achieved, says Wagner.

"What we've seen since about the mid-'80s has been a broadening of employer response concerning the interface between the employee and work," she notes. "A number of companies began programs for caregivers — family and friends providing ongoing care for older relatives or those with chronic ailments. There is now a good body of literature in that area, and it shows very clearly the business case for employer involvement." **(See "The Business Case for End-of-Life Programs," p. 19.)**

At same time, she continues, people have been looking more at EOL issues.

"It's important from a health care standpoint and it is also often a natural consequence of caregiving," she observes. "Then we also have an aging population, so you see a lot more people involved."

In fact, she notes, a 1997 study from the National Alliance for Caregiving (www.caregiving.org) noted that one in four families was involved in providing care for a total of 22 million people.

And yet a 1999 survey Wagner cites in the toolkit indicates that only 10% of employer respondents felt they were dealing with the issue "very well."

"I think it's the same today," she says.

Why the reluctance on the part of employers?

"In part, it involves the same reasons we encountered when we tried to introduce corporate eldercare programs — cost," Wagner says. "And frankly, people are uncomfortable with the topic. Plus, many don't feel qualified. But if we don't have a productive workplace, we are all going to suffer."

DiBenedetto agrees.

"In many cases, it's probably because the companies don't have the medical people to serve as gatekeepers," she notes. "Also, people don't like to talk about death and dying; even if it's a case of an employee not being 100% healthy, sometimes people shy away from that. They're not sure what to do or say."

But silence is probably the worst response.

"My attitude is, these people are still alive and kicking," says DiBenedetto. "In the hospice, we had patients who had just stopped working *the day before* — even if only for a couple of hours. They still had meaning in their lives and felt like a valuable person."

In fact, adds Wagner, there are people who are actually choosing to die at work.

"Rather than saying 'I quit' and being home with their families, they say they want to keep living their lives the same way," she explains. "Of course this poses a number of challenges for co-workers."

Seeing both sides

It's also important to remember that there are two sides to the EOL issue: employees who are terminally ill, and/or family members who are being cared for by the employee.

"Both areas absolutely need to be addressed," says DiBenedetto. "If the illness is not directly affecting the employee, then appropriate use of the FMLA [Family Medical Leave Act] is very important. The challenge arises when it's not a direct parent or child, such as in-laws. In today's world, people have extended families and this needs to be recognized. The bottom line is, valuing employees is an important issue, whether it is the individual worker or a family member who is affected."

Across most of Middle America, she adds, you are more likely to face the problem of employee as caregiver.

"In the inner city, younger heads of household are more of an issue," she notes. "And single individuals don't have anyone to advocate for them. Once their benefits run out, it's a real problem if they don't have long-term disability."

Wagner is concerned with both. "The only thing out of the scope of the toolkit is those organizations that routinely deal with EOL issues, such as ambulance drivers, firefighters, and so on. What we're talking about is expanding awareness to other workplaces that have never thought of it, such as nonprofit organizations."

Cost should not be obstacle

You can make effective changes in the workplace for little or no cost, says Wagner. "If your company is wired, you can simply provide workers with links to specific sites and types of information, like living wills," she explains. "Or you can bring together a small group of employees to talk about issues like whether the company benefits make sense to them."

If a company believes that EOL issues need to be addressed, she adds, "Every community has professional death educators or hospice professionals who are happy to come out. Most will do it as a community service."

The business case for workplace EOL programs

The following responses were reported in a survey of companies on end-of-life issues conducted in 1999 by Last Acts, when respondents were asked for input on the benefits of addressing issues:

- employee satisfaction, good will and improved morale;
- being able to care for employees/showing employees the company cares;
- employee loyalty, increased commitment;
- increase in productivity, rapid return to work.

The publication, *Research Findings from Studies with Companies and Caregivers,* reported the following business reasons for starting an end-of-life program:

- Research has shown that work-life programs positively affect the bottom line of an employer's balance sheet by fostering loyalty, morale and productivity of the work force.
- Companies that have started end-of-life programs report a decrease in medical, mental health, and substance abuse claims as well as a decrease in mistakes and an increase in productivity.
- An increased number of workers are actively involved in providing care for a family member — approximately one out of five employees. With an increasing aging population, more workers will be addressing end-of-life issues associated with this care giving.
- Dealing with grief not only affects the worker directly experiencing a loss, but affects his or her co-workers as well.
- Managers and supervisors are better able to support and manage a work team with the enhanced resources of an end-of-life program.
- A workplace end-of-life program demonstrates a company's commitment to the needs of its work force, and therefore is an excellent recruitment tool. ■

It's important to be aware, says Wagner, that there are really two levels of culture at work in every place of employment — formal and underground. "For example, the formal policy may allow two days off for a funeral, but the supervisor may tell you, 'Take as much time as you need,'" she explains. "You can arrange creative responses, and find a way to encourage those managers who do not have a full understanding to realize people are *not* trying to slack off."

Informal support systems can develop within the organization, notes DiBenedetto. "One major company has prayer groups," she says. "Occ-health professionals can encourage things like that. Where people are religious, when they are terminally ill they want to reach out for something. Of course, the occupational health professional has to be comfortable with spirituality issues, so they can be an advocate."

Wagner agrees that occupational health professionals should be the ones to bring the issue into the workplace.

"It's more effective if the champion is the CEO, but they usually won't do it," she concedes.

Occ-med professionals might consider starting a small program on their own, says Wagner. "Or if they see people come in with related concerns and wondering what to do, they might get a copy of the toolkit [at www.lastacts.org], if they don't see themselves in the position of creating a sea change in the company."

If they do see themselves in such a role, she adds, they can certainly take advantage of some of the benefits of the individual programs in the toolkit.

"Whatever they do, they need to know that this is an issue that's not going to go away," says Wagner, "And they will be more effective in supporting and boosting the overall well-being of their patients if they consider this as a factor that may be underlying a lot of reasons why they come to see them in the first place."

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HIPAA deadline looms: Is your facility ready?

If you're not moving, start

On April 14, covered entities under the Health Insurance Portability and Accountability Act (HIPAA) are expected to be in compliance with the new Standards for Privacy of Individually Identifiable Health Information.

"This implies that you have to have trained people in what the policies are," explains **Larri Short**, Esq., of Washington, DC-based Arent Fox, which serves as counsel to the Atlanta-based American Association of Occupational Health Nurses (AAOHN) on HIPAA matters. "Also you have to begin giving all defined [privacy] rights by April. As an example, AHA's [American Hospital Association's] model notice is 12 pages long — and you have to actually say what you as an organization intend to do."

That being the case, by this time, it would have been prudent to have thought through the regulations, taken a good first stab at appropriate new policies and procedures and thought of framing what you need to do to make all of this really happen.

"If not, you need to move forward as fast as you can to assess the situation and develop policies," Short advises.

Not all-encompassing

The new requirements are not entirely as broad as some might fear.

"You only have to apply these requirements to data that can reasonably be linked back to a person," Short explains. "If the information is aggregated, you don't have to worry about it."

In the occ-health context there will be some providers — be they nurses or physicians — who will not be subject to the new regulations, depending on where they work. The three categories of covered entities are health care clearinghouses, health plans, and health care providers. Commercial health insurers, HMOs, and government-funded health care programs such as Medicare, Medicaid, and Tricare are health plans under HIPAA, says Short.

"More occupational health physicians are likely to work in an environment where the rule will apply to them than nurses, but the construct is the same for both," says Short. "Plus, if you don't engage in standard transactions, i.e., filing health claims, coordinating benefits, checking claim status, electronically, the rule doesn't apply to you."

In essence, Short explains, the new regs break down into three major pieces:

1. How providers handle information. Covered entities are required to have permission to use or disclose individual patient information. It can come in the form of written permission from the patient or, in some cases, it can come in the form of regulatory provisions that allow you to use and disclose information for a designated list of pubic policy issues. Examples would be a response to judicial demands, or to law enforcement.

2. Patient privacy rights. The use of information will be restricted to the "minimum necessary" to accomplish the purpose at hand, which maximizes patient privacy. "For the first time at the federal level, we have a set of privacy rights for the patient," says Short. "Every patient has the right to access his or her own medical information. You have the right to have your health care provider give you a notice to explain how they are going to use your information." Some of the rights outlined in the new standards are only a right to *ask;* for example, if an employee is not happy with what the employer says it will do with the information, the provider can say they can't accommodate the request. If the employer agrees, however, it is then bound to do so.

3. Privacy compliance program. Covered organizations must appoint an individual who will be responsible for making sure it deals with the first two pieces of the new standards. There are to be written policies and procedures that can be surveyed and, where feasible, technical safeguards and access controls are to be put in place. (The Centers for Medicare & Medicaid Services sends surveyors for institutional Medicare providers.)

Outside help available

If you do not have the in-house expertise necessary to bring your facility into compliance, there are a wide variety of resources available, says Short.

"You can look to the office of civil rights web site, retain attorneys or consultants, or attend workshops," she suggests. For example, AAOHN's web site (www.aaohn.org) offers a series of workshops on the topic. There are a number of sources on the Internet as well.

"The HHS [Department of Health and Human Services] site [www.hhs.gov/ocr] provides lots of links," Short adds.

The good news is that enforcement will be "kinder and gentler" than it is for some other government regulations, she adds. "The government will 'seek to achieve voluntary compliance,' with punishment as a last resort," Short explains.

In other words, if all of your preparation is not completed by April 14, you should simply attempt to get it done as soon as possible.

"As long as you are cooperative and have made a sincere effort, I don't expect you to get really slammed unless you work in an organization that was certified to participate in Medicare," she adds.

Such organizations are subject to some risk outside of HIPAA through CMS; if they do not meet certain quality standards, reimbursements could be threatened.

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SCI patients at risk for other health woes

Study shows lack of exercise a significant problem

Workers with spinal cord injuries (SCI) face more than just the challenge of successful rehab and recovery — they are often at greater risk than the general worker population for developing diseases related to a sedentary lifestyle due to a lack of exercise.

This higher level of risk and some of its major causes were highlighted in a recent study conducted by researchers at the University of Michigan (UM) Health System, Ann Arbor. Their findings were presented at the annual meeting of the American Academy of Physical Medicine and Rehabilitation in Orlando, FL.

"People with SCI are living a lot longer nowadays," explains **William Scelza**, MD, who led the study while completing his residency in physical medicine and rehabilitation at UM. "A long time ago, when you would get such an injury, a lot of this wasn't addressed because patients were not living very long. Now, we're getting much better with general overall care, but many people are now looking at a greater risk in terms of such things as heart disease and diabetes."

In fact, he adds, it appears that people with SCI seem to have some degree of glucose intolerance that puts them a bit more at risk because they are not using the majority of their muscle mass.

"In addition, a lot of them have not been following an exercise regimen because they were either unable to, or because they were fearful of injuring themselves or having trouble finding accessible places or programs," Scelza notes, hinting at some of the study's findings.

Not an impossible task

While there are specific challenges for SCI patients when it comes to regular exercise, they can be overcome, says Scelza, currently a fellow in spinal cord injury at Kessler Institute for Rehabilitation in West Orange, NJ, and himself a spinal cord injury patient at age 17. An active wheelchair basketball player, he knows that people with SCI can work out but that doctors and fitness centers often don't offer exercise help.

"For example, a lot of people with high-level spinal cord injuries have limited use of their upper extremities and legs, but so many things are being developed now — like electrical stimulation — that we are constantly finding new ways for people to exercise," he observes.

Of course, exercise regimens need to be individualized because each person has different needs and abilities and problems.

"One thing that would really be beneficial would be for therapists familiar with spinal cord injuries, their related limitations and abilities to help coordinate the program," Scelza offers. "In addition, it will take lots of encouragement from the occupational health care team to recommend programs for these people and encourage them to participate. They can also educate them about the risks and benefits of exercise, and how much it is practical for them to endure."

How can occupational health professionals help these employees overcome their lack of motivation?

"If you consider the general population, barriers to exercise most often cited are lack of motivation and time — this is also very high for people with SCIs," he explains. "Not everyone with an SCI is going to be gung ho about going out and exercising. It's good to inform people what the benefits of the exercise program would be. And

the programs should not only be geared to exercise, but to wellness and other activities as well."

A potential model

A potential model for such a program is currently being studied at UM. The program was designed to improve wellness and prevent secondary complications associated with SCI such as carpal tunnel syndrome, pressure sores, spasticity, obesity, and so forth, notes **Denise G. Tate**, PhD, ABPP, professor and director of research in the department of physical medicine and rehabilitation.

"It is well known that persons with SCI have a very sedentary lifestyle, which contributes to these complications after the onset of injury," says Tate. "One way for those with SCI to avoid secondary conditions and take control over their lives and health is through participation in health promotion programs."

The program, funded by the University of Michigan Venture Investment Fund and supported in partial collaboration by the UM Model SCI Care System through a grant from the National Institute on Disability and Rehabilitation Research, U.S. Department of Education, consisted of a series of six four-hour workshops, Well on Wheels, held over a period of three months at University Hospital in Ann Arbor. The program focused on improving physical activity, promoting appropriate nutrition, and teaching stress management skills.

Forty-four adults having spinal lesions participated in the program. They were randomly assigned to either program or control groups.

The results showed no differences on biometric data such as levels of blood cholesterol, body mass index, or blood pressure, but significant gains in health behaviors. Workshop participants also reported fewer secondary conditions by the end of the study, when compared to their baseline data.

"Keep in mind this was a very small sample," says Tate. "I believe if we had a larger sample to compare with, we would have obtained significant differences. And we *did* obtain them on some of the health behaviors; people who went through the program seemed to have made health behavior changes which would have impacted [the biometrics] over time."

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Careful analysis shows DM is money-saver

Start with benchmarking

While disease management (DM) programming intuitively makes sense to many occupational health professionals, it has been difficult to demonstrate that such programs actually save money.

One of the impediments in the past has involved less than ideal benchmarking techniques. What statisticians call *regression to the mean* can result when participants are identified with a condition during a high point of medical utilization, when treatment is most costly. Because of the inherent bias of such a setup, probabilities can favor a return to average utilization even without any DM intervention.

Richmond, VA-based Health Management Corporation (HMC) appears to have overcome some of these obstacles with the use of a control group that was statistically similar to the group receiving the DM intervention, but was not offered the program services. This, HMC statisticians claim, eliminates the effects of selection

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bias because the control group did not opt out of the program.

In a unique position

Since HMC was owned by a managed care organization, namely Anthem Southeast, it was able to obtain data for a control group as well as for the study group. The control group was drawn from Virginia employees who were not eligible for HMC's DM services, because the benefit managers in the self-insured PAR/PPO (Participant/Preferred Provider Organization) did not choose to use those services for their workers. The study group was composed of employees eligible for the DM services.

"We were in a unique position, so it was advantageous for us to do the study this way," notes **Michael Cousins**, PhD, a biostatistician who is HMC's director of informatics.

There were 76,194 members and 2,359 diagnosed participants in the study group. Each group was tracked for the year prior to DM implementation (1999) and the year following implementation (2000).

The study covered most, but not all, of HMC's DM offerings.

"We looked at asthma, coronary artery disease, congestive heart failure and diabetes," Cousins reports. "In this study, we did not analyze congestive heart failure because there were only 24 people who qualified."

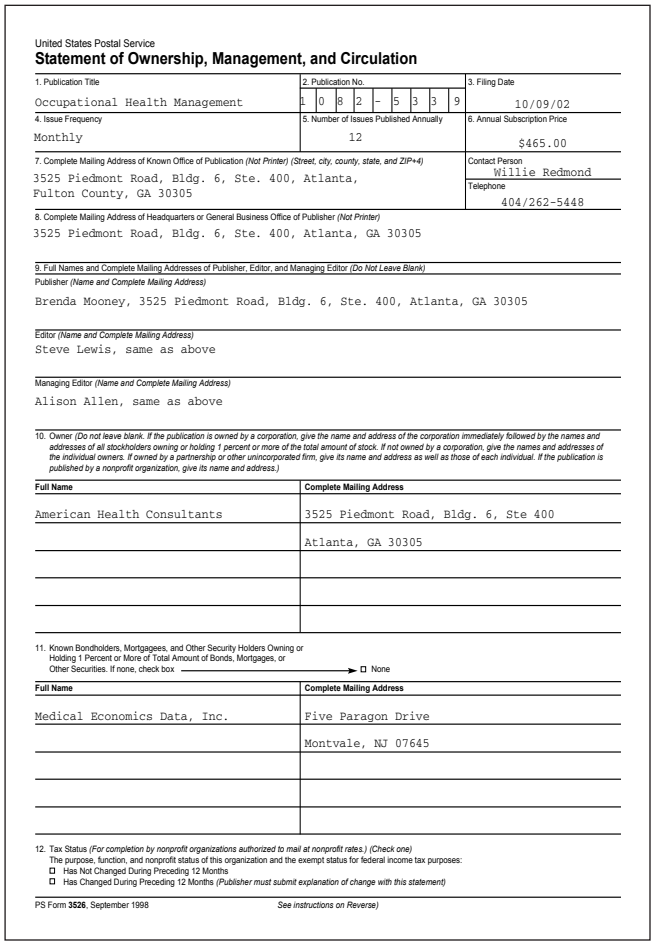
Study yields positive results

The study showed that the DM programs did, in fact, save money. Preliminary analyses showed that they produced net savings of 94 cents, per member per month, for total net savings (after the cost of the program) of $859,471.

The term "net program savings" means the actual costs for all the people in the study group were $859,471 less than what could be expected for the control group. To get the 94 cents the researchers divided that by total member months.

The study group's medical claims costs to the plan were $12,048,275. Gross and net savings as a percent of the study group's claims were 11% and 7.1%, respectively. Claims costs for the 76,194 members studied totaled $124,029,000, and net savings as a percent of claims for the whole population were 0.7%.

"We subtracted the cost of the program [to reach the net figure]," notes Cousins. "So, for the



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people in study, we had total claims costs of just over $12 million. We took the $859,471 and divided it by 12 million to get the 7.1%. That is the proof of the pudding."

In addition, he notes, all dollars were *normalized.* "We had actuaries as well as statisticians working on the study," he explains. "Normalized means we took the costs for procedures in both groups and calculated the average cost for those procedures, and applied it to both groups. This way, we ensured that the hospitals contracts for the control group weren't biased vs. those of the study group."

Furthermore, Cousins and his colleagues employed statistical simulations that showed there is an 82% chance there will always be savings with this program.

Being a biostatistician, he is conservative by nature. Nevertheless, he is comfortable with the conclusion that the program saved money. "Another good thing I can say is the methodology we used avoided selection bias and regression to the mean, so I certainly have greater confidence in the results," he observes. "There are not a whole lot of companies out there in the DM industry who use this rigorous methodology."

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Patient violence one of many ED threats

In spite of heightened awareness of bioterrorism and the recent terrorist threat to hospitals in key U.S. cities, more than 90% of emergency department (ED) managers at VHA member hospitals polled at a recent conference cited patient violence as the greatest threat to ED personnel.

Roughly 66% of the 74 managers recently polled at the VHA Inc. Emergency Department Conference in Chicago saw the risk of contracting hepatitis C as the second-biggest threat. Roughly 70% of respondents indicated their hospitals were not prepared to deal with bioterrorist-related medical emergencies, down from 80% in 2001.

Nearly a third of respondents said a lack of acute and critical care beds to which ED patients can be transferred was the primary factor for overcrowding in EDs. Other primary reasons for overcrowding included work force and staffing issues (24%) and uninsured patients using the ED for primary care (19%). For more information, go to www.vha.com and click on "News Room." ■