# Health Officials Reacting to Infection Mishaps

**Following a trio of HIV-related incidents, authorities in California and New York have identified infection-control problems in nuclear medicine departments, and New York has imposed new regulatory requirements for nuclear physicians and nuclear pharmacists when labeling and reinfusing blood cells.**

HEALTH DEPARTMENTS IN at least two states are taking a close look at infection control practices in nuclear medicine settings in the U.S. following a trio of HIV-related accidents in 1990. In each case, a patient was misidentified and injected with labeled blood cells, or in one instance a used syringe, from a patient with HIV, the AIDS virus.

The three mistaken injections occurred within a period of six months in 1990, according to a report by the U.S. Centers for Disease Control in Atlanta, Georgia, which investigated the incidents with the stated intent of assessing the need for revision of nuclear medicine infection control practices. So far, health officials in California and New York, both states where mistaken injections were made, have stated that problems exist in nuclear medicine departments, and New York has imposed new regulatory requirements for nuclear physicians and nuclear pharmacists when labeling and reinfusing blood cells.

Physicians from The Netherlands reported an HIV infection in a nuclear medicine department in the *New England Journal of Medicine* in 1990 ("Failure of Zidovudine Prophylaxis After Accidental Exposure to HIV-1," 322: 1375-7). In the U.S., only one of the three hospitals where an HIV-related mishap took place has been publicized. On July 11, 1991, a 23-year-old California woman filed a civil suit against Mercy Hospital and Medical Center in San Diego, the hospital's parent corporation Catholic Health Care West, and two nuclear medicine technologists (see *Newsline*, March 1992, p. 32N).

The patient was scheduled to receive a bone scan for a back injury, according to the CDC account of the incident, but a technologist, worried about time, mistakenly picked up a contaminated syringe and injected a residual amount of technetium-99m macroaggregated albumen. The syringe had earlier been used on an HIV-positive male patient. (Neither the lawsuit nor the official reports of the incident reveal whether the woman was infected by the virus, although CDC investigators noted in their report that the HIV-positive patient was injected through a peripheral intravenous line, which hospital officials say may have prevented blood to blood contact.)

### Lack of Awareness?

The CDC attributed the mishap to "a breach of standard infection control procedures." Officials of California's Department of Health Services went on to survey 14 nuclear medicine departments across the state and found widespread "oversights" and "a lack of awareness" of infection control requirements.

The surveyors focused on 15 criteria including the adequacy of the hospital-wide infection control plan, the departmental infection control plan for nuclear medicine, policies for intravenous injections of radionuclides, handling of needles and infectious waste, and whether the departmental infection control plan had been developed with the institutional infection control committee.

"We found no regulatory changes were needed from our point of view," says Patricia Edgerton, an associate health physicist with the radiological health branch. "All of the nuclear medicine departments were up to snuff as far as radiation control. Almost all of the departments had sufficient hospital-wide infection control plans, but they had no plan of their own." Where departmental infection control plans existed, they were often at odds with radiation control plans. For example, she says, rules for disposal of radioactive waste often conflicted with rules for disposing of infectious waste, and many departments lacked specific procedures for reconciling the differences.

The surveyors concluded that only 3 out of 14 nuclear medicine departments complied fully with the infection control requirements of the licensing and certification unit of Health Services. One department violated 11 of the 15 criteria in the survey.

"Of particular concern," says Ms. Edgerton, "was the fact that we found only one-half of the infection control departments conducted surveillance of nuclear medicine departments as required by Title 22." Title 22 refers to regulations under the licensing and certification unit that apply to all hospital departments. But the licensing and certification unit does not conduct inspections of Title 22 compliance in nuclear medicine departments and that caused California regulators to question the adequacy of current infection control

monitoring of hospitals.

Don Lee, health programs specialist in the licensing and certification branch, called the results "disturbing." Nuclear medicine physicians say that the results of the survey of only 14 departments may misrepresent the majority of nuclear medicine departments. Physicians are quick to point out that nuclear medicine maintains one of the lowest misadministration rates in all of health care. The diagnostic misadministration rate in nuclear medicine is about 1 per 10,000 procedures. The error rate for non-radioactive drugs in hospitals is about 2000 per 10,000 administrations.

"There were three cases [of HIV-related misadministrations] in the United States—compare that to the nearly 9 million procedures performed involving injections," says Carol Marcus, MD, PhD, director of the nuclear medicine outpatient clinic at Harbor-UCLA Medical Center. "Year after year, the misadministration rate in nuclear medicine is a constant, low level," says Robert J. Lull, MD, chief of nuclear medicine at San Francisco General Hospital Medical Center and president of the American College of Nuclear Physicians.

The Department of Health Services has abandoned plans to write new regulatory requirements, contrary to earlier stated intentions to revise regulations and institute new inspections. "That flurry has died down," says Mr. Lee, after the department decided that existing rules were adequate and that adopting new rules would only pile more work on a staff already strapped for funding and pressed for time.

Instead of drafting new rules, the regulators mailed a letter in January to hospital administrators, and chiefs of radiology and nuclear medicine advising them of the survey results and the need to comply with existing rules. "We're placing our trust in the nuclear medicine departments to make sure that they are in compliance," says Mr. Lee.

Dr. Lull says most departments are well aware of JCAHO standards mandating that departmental infection control procedures be approved by the institution's infection control committee. Dr. Lull says that from his experience, nuclear medicine departments have long since scrutinized their infection control practices in the wake of the three HIV-related incidents in 1990. "About a year ago we instituted a policy where the injection of blood products must be checked by two people."

### New York Enacts Rules

In New York, that requirement and other preventive measures are law as of February 19. The state regulators adopted the changes, they say in a state register announcement, because of the "risk of disease transmission" as evidenced by a report in New York of a patient infected with HIV during a nuclear medicine procedure. The patient was mistakenly injected with labeled blood cells taken from another patient, the notice says, without identifying the institution or individuals involved.

The rule changes require nuclear medicine physicians, technologists, and pharmacists in New York to label all syringes and containers used in handling blood with two forms of identification. And nuclear medicine personnel must obtain approvals from the hospital's director of transfusion services and the transfusion committee for written protocols for blood "reinfusion procedures," a general phrase meant to include not only labeled leukocytes for detecting infections, labeled red blood cells for performing gated heart studies and detecting gastrointestinal bleeding, but also any conceivable reinfusion of altered blood cells, such as for gene therapy.

### Reactions Mixed

Private practices and clinics that perform any of these blood reinfusion procedures are required to obtain a permit for "blood services—transfusion." The final rule goes on to note that such facilities "shall be open for inspection" by the Department of Health. "We do not anticipate regular inspections, that just covers the right to go in and inspect nuclear pharmacies and physicians' offices if there is a problem," says Jeanne Linden, MD, the state health department's director of blood and tissue resources.

Physicians in New York have mixed reactions to the new rules. Many told *Newsline* that the added measures were probably a good idea, but a few had yet to carefully review the recently adopted changes. Although all physicians agreed that taking steps to reduce the risks of infection is important, some doctors strongly disagreed with aspects of the rule, maintaining that it was drafted without the input of nuclear medicine physicians.

Says David V. Becker, MD, director of nuclear medicine at New York Hospital-Cornell Medical Center: "It sets a bad precedent—a bureaucracy in a regulatory agency has decided that a procedure should be done differently and without consulting with the professionals has made major changes." Letty Lutzker, MD, chief of nuclear medicine at St. Barnabas Medical Center in Livingston, New Jersey, agrees. "The way the rule was dictated is objectionable—we're going to make that clear to the state," says Dr. Lutzker, who is active in the Greater New York Chapter of The Society of Nuclear Medicine.

Dr. Becker says the requirements for confirming the identity of the donor and recipient is a procedure that, if not already practiced, should be followed by all nuclear medicine departments, but he asks, "Why must the blood bank approve the details of how this is accomplished?"

"To suddenly decide by fiat, apparently without consultation with representatives of the specialty, that board certified nuclear medicine specialists cannot follow new and simple regulations but must have that responsibility put in the hands of other specialists does not seem logical nor in the best interest of patients," Dr. Becker wrote in a letter to the Department of Health.

Dr. Linden replies that nuclear medicine specialists "very much were consulted." She says that the physician members of the New York Council on Blood and Transfusion Services made

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committee targeted about 4585 hospital and outpatient facilities where nuclear medicine is practiced in the U.S. SNM obtained the list from Technology Marketing Group, a marketing research company in Des Plaines, Illinois that compiled the information from the Society's membership rolls and rosters of licensees with the Nuclear Regulatory Commission and state radiation health agencies.

A previous manpower survey, conducted by mail-in questionnaire in 1986, generated a 29% response rate. By far the majority of the respondents were full-time practitioners of nuclear medicine. That survey thus inadvertently missed many radiologists, cardiologists and others who practice nuclear medicine procedures and as a result did not fully represent the specialty of nuclear medicine.

The current census effort achieved a 35% response rate after an initial round of calls by SNM members to chiefs of nuclear medicine or chief technologists, but the data remained biased by limited responses from small-volume departments. By April 1992, part-time telephone operators overseen by SNM Associate Executive Director Virginia Pappas brought the response rate to 50% for nearly every state. At press time, surveyors had reached over 70%.

The manpower committee's goal was to reach at least 70% of the identified nuclear medicine facilities in each state, the minimum acceptable response rate recommended by statistician Jerry Katzoff, who is advising on the census. Schuyler V. Hilts, MD, manpower committee chairman, obtained $950 in additional funding for the survey at the SNM Mid-Winter Meeting, bringing the total cost of the project to about $25,000. ■

### *Infection Mishaps*

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their recommendations for the new rule after discussing the issue with the nuclear medicine physicians at their institutions. The department sent copies of the proposed rule to every hospital in the state and the six nuclear pharmacies, she says. During the month-long comment period after the proposal was posted in the state register, Dr. Linden says the department received no written responses. The regulatory burden of the revisions, she says, "really is trivial," since the department isn't adding new fees or scheduling regular inspections.

The revised rules don't pose problems for Syncor nuclear pharmacies, according to Joe Fery, senior pharmacist at the company's operation in Long Island, New York. "I think it's relatively easy for Syncor to comply. We have always worked with each nuclear medicine department to draft a protocol that complies with their specifications," he says. "Now may be the time to devise a uniform standard."

What is more important than regulatory actions, some nuclear physicians say, is gaining approvals for alternatives to in vitro autologous blood cell labeling. By far the most prominent infection control problem in nuclear medicine is preventing the mistake of giving the wrong person a prepared blood product, Dr. Lull and other nuclear physicians say.

For imaging infections, at least, the problem is obviated by techniques such as labeled monoclonal antibodies, and human nonspecific immunoglobulin G (IgG). The alternative approaches enable physicians to detect infections without drawing blood for labeling. "What we need," says Dr. Lull, "is rapid approval of these technetium-labeled monoclonal antibodies that are widely available in Europe."

Investigators who have pointed to indium-111-labeled leukocyte scintigraphy as the method of choice for detecting some types of infections say that some physicians nevertheless avoid the technique. "I think indium [leukocyte imaging] is under-utilized," says Christopher J. Palestro, MD, a physician at Mt. Sinai Medical Center in New York. A "big negative factor" he says, is that some physicians choose to avoid working with blood if possible. Perhaps equally intimidating is the lengthy and labor-intensive nature of the procedure. If physicians are avoiding leukocyte imaging, for whatever reasons, development of effective alternatives might not only reduce infection risks but also directly improve management of subacute infections and opportunistic infections.

"We just don't label blood in known AIDS patients," says Dr. Marcus of UCLA. She says that her department lacks adequate facilities to work safely when labeling blood samples. Dr. Marcus has secured an Investigational New Drug (IND) approval for clinical trials of a technetium-99m labeled antibody that binds to neutrophils, chemotactic leukocytes that adhere to immune complexes, to image infections. The labeled antibody was developed by Matthew Thakur, PhD, of Thomas Jefferson University, in Philadelphia, Pennsylvania. So far the UCLA investigators have used the agent in 15 patients, including one patient with AIDS, and are enthusiastic about the results. "We think it's one of the most promising ways to solve the problem," says Dr. Marcus.

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