Baxa Corp. and PhaSeal® references are highlighted – see page 3

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What if the Cure is Also a Cause?

The Same Chemo Drugs That Save Some Cancer Patients' Lives Put Health Workers at Risk

By Jim Morris
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Last March, the federal government issued an unusually detailed alert to the nation's 5.5 million health care workers: The powerful drugs used in chemotherapy can themselves cause cancer and pose a risk to nurses, pharmacists and others who handle them.

Four years in the making, the alert was issued by the National Institute for Occupational Safety and Health (NIOSH). Officials with the institute -- part of the Centers for Disease Control and Prevention (CDC) -- and members of a hazardous-drug advisory panel saw the document as a long-overdue first step toward addressing what could be a serious workplace health problem.

The next step was to be a study of actual exposures at three hospitals, operated by the universities of Maryland, North Carolina and Texas. The plan was to take blood and urine samples from about 50 pharmacists, nurses and pharmacy technicians at the hospitals and look for signs of drugs such as cyclophosphamide (usually administered intravenously to treat lymphoma, leukemia or breast cancer) and ifosfamide (also an IV drug, often used on lung, cervical and ovarian cancers).

But the study, formally proposed in July 2002, is on hold. Twice the CDC submitted the proposal to the Office of Management and Budget (OMB). Twice it was withdrawn, after the OMB raised questions. It has yet to be resubmitted.

OMB spokesman Chad Kolton would say only that the CDC withdrew the paperwork "to address ongoing technical concerns relating to the scope of the proposed study design." CDC spokesman Fred Blosser said, "Traditionally, we don't go into detail on pending discussions or reviews with OMB."

Study proponents, meanwhile, say that precious time is being lost.

"The study is very important," said Marty Polovich, an oncology nurse in Riverdale, Ga., and a member of the NIOSH Hazardous Drug Workgroup. "A lot of the information we have about employee exposures is fairly old."

NIOSH issued the alert on chemotherapy drugs because human and animal studies have shown they have the potential to cause cancer or reproductive problems, said Thomas Connor, a research biologist with the institute. Some studies have found higher-than-expected prevalence of these ailments among health care workers, he said.

Exposures can occur in a number of ways: The drugs can become airborne and be inhaled. They can collect on work surfaces and be absorbed through the skin. Traces of them also can be found on medical equipment, clothing and in patient excreta.

"People have exposures every day," said Bill Borwegen, occupational health and safety director for the Washington-based Service Employees International Union, which represents about 875,000 health care workers. "If you're piercing an IV bag and get a drop [of a drug] on your finger, you could be over the safe level."

And a housekeeper who dumps the contents of a bedpan into a toilet might not realize that the waste is toxic. "Sometimes, 80 percent of the active ingredient [in a drug] goes right through the patient's system," said Borwegen, who also served on the NIOSH work group.

An Emerging Risk

Chemotherapy -- the use of potent drugs to kill cancerous cells -- is more than 60 years old. The first such drugs were nitrogen mustards, originally developed as chemical warfare agents. Modern chemotherapy drugs are so strong, by necessity, that they can cause secondary cancers in patients; to a healthy person, they're poison.

For decades, experts say, most health care workers were oblivious to the risks posed to them by these and other drugs, which attack good cells as well as bad.

By the 1970s, NIOSH says in its alert, "the carcinogenicity of several [chemotherapy] drugs in animals was well established. Likewise, a number of researchers during this period linked the therapeutic use of [certain drugs] in humans to subsequent leukemia and other cancers. Many in health care began to question whether occupational exposure to these agents was hazardous."

Little was done, however, to control exposures. Eleven of 12 studies in the 1980s and '90s, for example, detected cyclophosphamide in the urine of health care workers.

"Even at the big institutions we've looked at, there's contamination," said Connor, who was involved in about 20 exposure studies during the two decades he spent at the University of Texas School of Public Health in Houston. "We think some of the clinics might be worse because they don't take good precautions."

As a rule, European countries have moved more aggressively than the United States, requiring hospitals to monitor employees and keep even minuscule amounts of the drugs from being spilled or aerosolized.

"In Holland, we've seen a decline in contamination. Most workers don't have [drugs] in their urine anymore," Paul Sessink, a chemist in the Netherlands who runs a consulting firm called Exposure Control, said in a telephone interview.

The International Agency for Research on Cancer -- part of the World Health Organization -- lists nine chemotherapy drugs and two "combinational therapies" as known human carcinogens. Another nine drugs are listed as "probable" and 10 as "possible" carcinogens.

U.S. authorities have no way to accurately estimate how much harm has been caused by the careless handling of these drugs. Cancer often takes decades to emerge. A case of leukemia diagnosed in a nurse or pharmacist today might be the product of workplace exposures in the 1970s or '80s. But in many instances, the connection between work and disease is never made.

The closest thing to a landmark legal case involved Sally Giles, an oncology nurse in rural British Columbia who died of bile duct cancer in 1992. Giles's husband filed a claim with the province's Workers' Compensation Board, alleging that the disease was work-related. He lost, but the well-publicized case led to stricter provincial regulation.

"What struck me was what dangerous places hospitals were," said John Steeves, a Vancouver lawyer who represented Giles's husband. "It's sort of counterintuitive. We assume the opposite."

For health care workers who come in contact with chemotherapy drugs, cancer isn't the only worry. According to the NIOSH alert, the drugs also can trigger adverse reproductive effects, including miscarriage, low birth weight, infertility and birth defects.

Measuring Exposures

Beginning in the 1980s, researchers in the United States and Europe found that nurses, pharmacists, veterinarians, housekeepers and others took few precautions when preparing, administering or cleaning up the drugs. As a result, they were routinely exposed to toxic aerosols, powders and liquids.

The Occupational Safety and Health Administration (OSHA) first issued handling guidelines for hazardous drugs in 1986, calling for, among other things, the use of gloves, gowns and biological safety cabinets or respirators with high-efficiency filters. These were voluntary measures, however, not rules. OSHA still has no regulatory standards for cancer-fighting drugs and NIOSH says adherence to the guidelines is spotty.

Over the past six years, chemist Sessink has analyzed "wipe samples" -- residue collected from counters, floors and other surfaces -- from about 30 U.S. hospitals. The results indicated that drug-handling at two-thirds of the hospitals was sloppy and employee exposures were "far higher than we have here [in Europe]," he said. He would not identify the hospitals.

Sessink said he finds it "rather amazing" that the U.S. government took so long to warn workers about the dangers. He wonders if pharmaceutical manufacturers and hospitals -- mindful of possible liability -- had something to do with the delay.

Polovich, who had a hand in the NIOSH alert and sat in on many planning meetings, said she saw no evidence of industry intransigence; indeed, a number of hospital and drug-company representatives were on the advisory panel and endorsed the idea of a nationwide warning. However, she said, she isn't sure why "it took us four years to get the alert published. We were a little frustrated."

Exposure-control technologies are available. Colorado-based Baxa Corp., for example, distributes a plastic device that keeps drugs from escaping vials, syringes or IV connectors. The device, called PhaSeal, costs about $12 per patient dose.

Not every hospital or clinic, however, can afford such equipment or recognizes the need for it. Meanwhile, health care workers are seeing more cancer patients, using higher doses of drugs and delivering them in new combinations.

"I think the potential for [worker] exposures is going to increase," said NIOSH's Connor. Spokesman Blosser said the CDC will continue to discuss the proposed three-hospital study with the OMB. Blosser said there is no reason to believe the initiative is dead.

The study can't begin soon enough for Borwegen, the union official.

"These products are produced under very pristine conditions by drug manufacturers, but once they leave the facility the controls aren't really in place," he said. "Most [health care] workers are clueless about how toxic these agents are."•

Jim Morris is a deputy editor for Congressional Quarterly.