

NIOSH to issue chemo alert

Cancer chemotherapy is hazardous to your health. That's the unequivocal warning coming soon from NIOSH, the National Institute for Occupational Safety & Health. The agency is in the final stages of releasing its first-ever workplace alert on the dangers of preparing and administering antineoplastic agents and other pharmaceuticals in patient care settings.

"We've been anxiously awaiting that alert for two and a half years," said James Jorgenson, director of pharmacy services at the University of Utah Health Sciences Center. He is also a member of the NIOSH advisory committee drafting the alert. "The bar needs to be raised on the preparation, handling, and administration of chemo products," he said. "We have treated these things much too casually."

Insiders said the alert would be issued during the first quarter. A final draft was circulated to external reviewers in early December, with comments due shortly before Christmas. Final language has not been released, but advisory committee members said hospitals, ambulatory care clinics, and other healthcare settings would be warned that antineoplastics and about 30 other drug products pose a workplace hazard. Current measures designed to prevent environmental contamination and employee exposure to hazardous pharmaceutical products are inadequate.

Reviewers said the final draft strongly recommends the use of closed-system protective devices as the only means shown to significantly reduce or eliminate environmental and human contamination by antineoplastics and other hazardous drug products.

The only closed-system device currently on the market is PhaSeal, manufactured in Sweden by Carmel Pharma Ab and distributed in the United States by Baxa. The device traps any residues or leaks produced in the mixing or administration of drugs. A single chemotherapy treatment requires two PhaSeal units, one for drug preparation and one for drug administration.

Jorgenson said that using PhaSeal costs \$10 to \$15 per chemo administration. "A lot of people are saying they can't afford that," he noted. "But if you look at what we do in patient care compared with the rigor applied to a manufacturing facility, we have problems. Common sense says that if you have a known carcinogen, you don't want anything on board."

The NIOSH alert has roots in the 1980s. Roger Anderson, head of the division of pharmacy at M. D. Anderson Cancer Center in Houston, raised safety questions that eventually produced some of today's workplace standards, including biological safety cabinets, caps, gloves, gowns, and other safeguards.

A decade later, Dutch toxicologist Paul Sessink found widespread contamination by antineoplastics in hospital pharmacies, IV admix facilities, nursing stations, and patient care areas.

European safety standards and drug handling procedures were at least as strict as those in place in U.S. facilities, he told *Drug Topics* in 1997.

U.S. and Canadian studies found antineoplastic continuation patterns that matched Sessink's findings in hospitals across Europe. Jorgenson coauthored one of the most recent studies, published last November by ASHP.

Researchers at the University of Utah Hospitals and Clinics found that PhaSeal significantly reduced contamination by cyclophosphamide and ifosfamide on work surfaces and in employee urine samples. Employees tested included pharmacists who entered and checked chemotherapy doses, pharmacy techs who prepared the doses, and nurses who administered the drugs.

"There is a growing body of literature on contamination, both on surfaces and in the human body," said Mike Hurst, Baxa's VP for infusion systems. "This is an alert, not a requirement, but the statement saying that closed-system devices should be used is very definite."

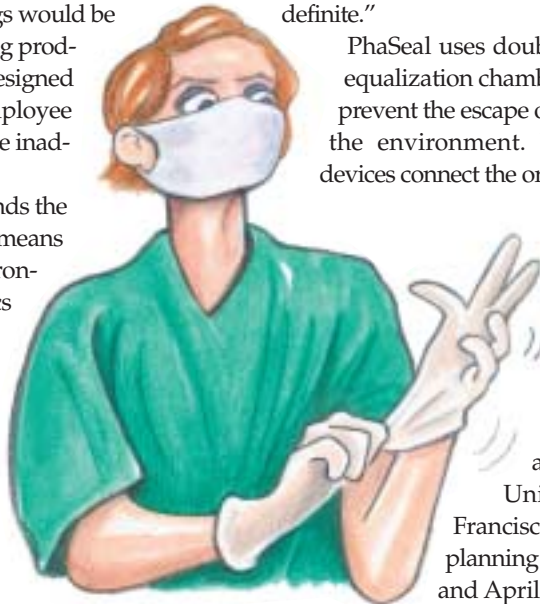
PhaSeal uses double membranes and a pressure equalization chamber to contain drug leakage and prevent the escape of drug aerosols and vapors into the environment. The disposable containment devices connect the original drug vial, syringe, and IV injection or infusion set into a single sealed pathway.

"This is really one more iteration of what has come out before," said advisory committee member Luci Power, president of pharmacy consultancy Power Enterprises and associate professor at the University of California San Francisco School of Pharmacy. "We are planning seminars on the alert for March and April."

The published alert is expected to include a four-page pullout section for quick reference, Power added.

Jorgenson said that once NIOSH issues its alert, other groups would step in with their own recommendations and requirements. He predicted that ASHP would revise its workplace standards to call for closed-system devices such as PhaSeal. OSHA, the Occupational Safety & Health Administration, will likely mandate the use of such devices, he added.

A Baxa spokeswoman said that about 120 institutions across the country are already using PhaSeal. Current users include M. D. Anderson, the University of Utah Hospitals and Clinics, Stanford University Medical Center, Dana Farber Cancer Institute, and other major cancer treatment centers.



Fred Gebhart

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