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Case Studies

Huntsman Cancer Institute and PhaSeal®:

Reducing Chemotherapy Exposure in a Brand-New Facility

Overview

The Huntsman Cancer Institute (HCI) of the University of Utah is a world leader in cutting-edge cancer research. A member of the National Comprehensive Cancer Network, and a National Cancer Institute-designated cancer center, HCI prepares and administers more than 15,000 chemotherapy doses per year. Created through an endowment from Jon M. Huntsman, a philanthropist and cancer survivor, HCI's professional staff includes nationally and internationally recognized researchers and physicians.

Located in Salt Lake City, HCI was dedicated in 1999, and today operates high-risk clinics focusing on breast cancer, colon cancer and melanoma. More than 18,000 patients have been treated since the clinic's opening.

When it opened, HCI became the center for world-class cancer research and treatment, particularly in the field of genetics. The newness of its facilities made HCI the perfect venue for a study to determine the biological uptake of chemotherapy drugs in pharmacy and nursing personnel. The facility performed a baseline study of surface contamination and employee exposure to chemotherapy, then repeated the testing following the implementation of the PhaSeal System for safe handling of hazardous drugs. Data demonstrated the effectiveness of the PhaSeal System in reducing both environmental contamination and personnel exposure. The study was published in the November 15, 2003 issue of the American Journal of Health-System Pharmacy[1].

State-of-the-Art Safety

At the time of construction, the safety measures implemented in Huntsman's new ambulatory oncology clinics and infusion center were state-of-the-art. A Class 100, segregated, positive-pressure cleanroom with outside-vented Class II biological safety cabinets (BSCs) was built specifically for chemotherapy preparation. Personal protective measures were adopted, as were policies for personnel and for processes such as drug handling, storage and disposal. A hospital-based training program ensured that all personnel were chemotherapy-certified.

"We didn't want to just take directly from existing guidelines," says James Jorgenson, RPh, MS, Director of Pharmacy and Associate Dean for Professional Affairs at the University of Utah, who led HCI's safety planning team. For this reason, they conducted their own Failure Modes and Effects (FMEA) analysis to uncover potential breakdowns

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and sources of error in their processes. They also contracted for an external review by the Institute for Safe Medication Practices. They then combined the results of both reviews.

"We actually made sixty-three course corrections based on these reviews," says Mr. Jorgenson. "So when Huntsman opened, we felt pretty good."

Keeping Up with Advancing Knowledge of Safety

The standards and technologies current at the time were developed from knowledge that had been increasing since the early 1980s about the hazards of handling cancer chemotherapeutic drugs in the workplace. A 1982 study at the MD Anderson Cancer Center, for example, greatly influenced the acceptance of the BSC technology for chemotherapy preparation[2].

New knowledge about workplace contamination continued to percolate even as Jorgenson and his colleagues were fine-tuning their safety measures. In January 2000, just three months after HCI opened; Jorgenson attended a seminar given by Thomas H. Connor, PhD, Roger W. Anderson, PharmD and others. There, Jorgenson heard Connor, Senior Service Fellow at the National Institute for Occupational Safety and Health, and Anderson, Head of the Division of Pharmacy at MD Anderson, discuss their experiences in studying chemotherapy contamination in the workplace.

The PhaSeal System

One study discussed at the seminar proved especially interesting for Jorgenson. Drs. Connor and Anderson and their colleagues had discovered chemotherapy contamination in BSCs and on other work surfaces in a newly rebuilt IV preparation facility at MD Anderson[3]. Their findings also indicated that they could contain additional surface contamination by preparing drugs using a new closed-system containment technology from Europe called the PhaSeal System. Dr. Anderson responded to the study data by implementing the PhaSeal System throughout MD Anderson hospital.

"Listening to them, I became aware of additional routes of chemotherapy hazard exposure that we hadn't thought of," says Jorgenson. "I also learned about PhaSeal for the first time."

The Huntsman Study

Jorgenson and his colleagues decided that they would conduct a study in HCI's brand-new ambulatory oncology clinics and infusion center to assess both chemotherapy surface contamination and personnel exposure before and after implementing the PhaSeal System. "I was intrigued to see if we had a problem," recalls

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Jorgenson, “because we felt that at the time we opened, HCI’s equipment and facilities were the best we could purchase, and our procedures were as tightly controlled as we could make them.”

The HCI study began in December 2001. Urine samples were collected from pharmacy and nursing personnel to obtain baseline measurements of employee exposure to cyclophosphamide and ifosfamide. Wipe samples were taken from selected facility and equipment surfaces as a baseline measure of surface contamination. A special assay method developed for this study enabled the investigators to detect both drugs in a single sample using mass-spectrometry with liquid chromatography.

Results Show Biological Uptake in Personnel

“We had no idea what we’d find,” relates Jorgenson. “We were surprised.” The baseline urine tests revealed that there had been biological uptake of both of the chemotherapy drugs tested in infusion center pharmacy and nursing staff. Even more surprising, the only chemotherapy exposure for the pharmacy technician who tested positive was from checking in and shelving the daily drug order. As for surface contamination, all of the wipe tests yielded positive results.

PhaSeal Use Reduced Personnel Exposure

In January 2002, after the baseline measurements had been made, the chemotherapy infusion center implemented the PhaSeal System, while continuing the preparation and administration safeguards already in use. Six months later, in June 2002, the urine and surface wipe tests were repeated.

The results – following six months of PhaSeal System use – demonstrated that cyclophosphamide and ifosfamide (the two drugs included in the testing) were no longer detectable in urine samples. Contamination from the two drugs on facility surfaces was significantly reduced.

PhaSeal Implemented System-Wide

“Because of this study, we’ve now extended the use of the PhaSeal System from Huntsman to everywhere within the University of Utah Hospitals and Clinics where cancer chemotherapy is handled and prepared,” says Jorgenson. Other changes have also been made. Policies and procedures for handling antineoplastic agents have been revised. Segregated storage locations are planned for all pharmacies. The center is also considering mandating protective gloves for personnel handling chemotherapy drug, including when checking in new drug orders, handling packages and checking prepared products.

Huntsman Center Today

Today, HCI’s infusion center serves about 60 patients daily. Using an interdisciplinary approach encompassing treatment, genetic

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counseling, educational and support resources and palliative care, it strives to provide the highest standard for cancer care. As part of its continued development, HCI will open a new cancer specialty hospital in 2004. Thanks to Jim Jorgenson and his colleagues, this growing institution has contributed new knowledge about workplace contamination while becoming a safer place for both its patients and its employees.

References:

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For More Information on Huntsman Cancer Institute:

Visit the HCI Web site at www.hci.utah.edu.

For More Information on the PhaSeal System, Contact:

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