

Evaluation of Chemotherapy Drug Exposure in an Outpatient Infusion Center

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The cover photo is a close-up image of sorbent tubes, which are used by the HHE Program to measure airborne exposures. This photo is an artistic representation that may not be related to this Health Hazard Evaluation. Photo by NIOSH.

Highlights of this Evaluation

The Health Hazard Evaluation Program received a request from a regional hospital. The employer was concerned about possible adverse health effects in employees from handling chemotherapy drugs in the outpatient cancer and infusion center.

What We Did

- We visited the infusion center in June 2013.
- We observed how employees received, stored, administered, and disposed chemotherapy drugs.
- We talked to employees about their work and health concerns.
- We took samples from work surfaces to look for several chemotherapy drugs.
- We evaluated the airflow direction in the infusion center and isolator cabinet.
- We reviewed the employer's workplace injury and illness logs and employee health records.
- We reviewed environmental sampling and inspection reports, training documents, and standard operating procedures for handling hazardous drugs in the infusion center.

What We Found

- Some work surfaces had chemotherapy drugs on them.
- Many employees reported that previous symptoms had resolved.
- Employees reported inconsistent use of personal protective equipment.
- Procedures for handling hazardous drugs did not apply to all personnel who are exposed to chemotherapy drugs.
- Procedures for proper storage, routine housekeeping, medical surveillance, and the hazardous drug list were incomplete.
- Air from the pharmacy was not being drawn into the pass-through chamber on the isolator cabinet, as employees believed.

We evaluated employee exposure to chemotherapy drugs at an outpatient infusion center. We found low levels of surface contamination of platinum throughout the workplace. Handling platinum-containing compounds is the likely source of this contamination. Although we cannot definitively link all of the reported symptoms to chemotherapy drug exposures, many were consistent with those reported in the literature. Employees inconsistently used personal protective equipment. We recommended employees use chemotherapy gowns and gloves when handling chemotherapy drugs, and the company implement a medical surveillance program for employees potentially exposed to chemotherapy drugs.

What the Employer Can Do

- Require employees to wear chemotherapy gowns and gloves whenever handling chemotherapy drugs.
- Advise employees to wear safety goggles rather than prescription glasses when cleaning up a drug spill or when chemotherapy drugs might splash.
- Ensure employees who receive the chemotherapy drug shipments are aware of the potential for contamination of outer surfaces of drug containers and protect themselves.
- Start a medical surveillance program for employees who handle chemotherapy drugs.
- Train all employees about the short and long-term health effects of chemotherapy drug exposures.
- Update procedures for handling hazardous drugs safely.
- Encourage employees to report work-related illnesses to hospital occupational health and safety representatives as soon as possible.
- Ensure there is employee participation on the infusion center safety committee.
- Adjust the isolation cabinet height to fit employees.

What Employees Can Do

- Wear all required personal protective equipment when handling chemotherapy drugs.
- Report any workplace health concerns to the employer.

Abbreviations

µg	Microgram
µL	Microliter
ACGIH®	American Conference of Governmental Industrial Hygienists
ANSI	American National Standards Institute
cm ²	Centimeter squared
CETA	Controlled Environment Testing Association
CFR	Code of Federal Regulations
HEPA	High efficiency particulate air
HVAC	Heating, ventilation, and air-conditioning
IARC	International Agency for Research on Cancer
ng	Nanogram
NIOSH	National Institute for Occupational Safety and Health
OEL	Occupational exposure limit
OSHA	Occupational Safety and Health Administration
TLV®	Threshold limit value
TWA	Time-weighted average
WEEL	Workplace environmental exposure levels

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Introduction

The Health Hazard Evaluation Program received a request from a regional hospital. The employer was concerned about health symptoms (burning and itchy eyes, itchy skin, hair loss, and metallic taste in the mouth) among outpatient cancer and infusion center (referred to in this report as infusion center) employees potentially associated with chemotherapy drug exposure in the workplace. We visited the infusion center in June 2013 and shared our preliminary findings, observations, and recommendations with employer and employee representatives.

The infusion center opened in 2009 in a separate building approximately 1,500 feet from the hospital. The center employed 10 clinical and administrative staff and provided outpatient treatment to approximately 4 patients per day during the time of our visit which is the typical number of patients treated at this clinic.

Methods

Our main objectives of the evaluation were to assess whether (1) the infusion center's work surfaces were contaminated by chemotherapy drugs; (2) the cabinet used to compound chemotherapy drugs was operating as designed; (3) employee symptom reports could be related to chemotherapy drug exposure; and (4) procedures were adequate to protect employees from chemotherapy drug exposures.

Surface Wipe Samples

We collected surface wipe samples for platinum-containing drugs (cisplatin, carboplatin, oxaliplatin), gemcitabine, irinotecan, cyclophosphamide, and 5-fluorouracil (Table 1). We selected these drugs on the basis of (1) frequency of use in the infusion center, (2) presence on the National Institute for Occupational Safety and Health (NIOSH) hazardous drug list, and (3) availability of a sampling and analytical method. We selected wipe sample locations based on findings from previous health hazard evaluations and other research [Connor and McDiarmid 2006; NIOSH 2012b] and where employees could touch with non-gloved hands. We evaluated these surfaces before, during, and after drug administration. For each sample, we wore a clean pair of chemotherapy protective gloves and used a new 100 square centimeter (cm²) disposable template to determine the sampling area. We wiped the area twice, once with the first texwipe, texwipe swab, or Whatman filter, and then again with a second wipe as described in Connor et al. 2010.

Compounding Aseptic Containment Isolator Cabinet and General Ventilation Evaluation

We used a TSI Model 8386 VelociCalc®Plus Multi-Parameter Ventilation Meter for all ventilation measurements. We evaluated the direction of airflow between the pharmacy and the hallway, the infusion room and the hallway, and the hazardous waste storage room and the hallway to see if there was a potential for contaminated air to spread to other areas of the

Table 1. Sampling and analytical methods for chemotherapeutic agents in surface samples

Chemotherapeutic agent	Surface wipe/wetting agent	Surface area sampled	Analysis method/detection limits
Cisplatin Carboplatin Oxaliplatin (all as platinum)	Two Alpha® texwipes, or two Alpha texwipe swabs moistened with 250 microliters (µL) deionized water	100 cm ²	<ul style="list-style-type: none"> Inductively coupled plasma/mass spectrometry (Bureau Veritas North America) Limit of detection = 0.0009 micrograms (µg) platinum (swabs); 0.003 µg platinum (wipes) Limit of quantitation = 0.0029 µg platinum (swabs); 0.01 µg platinum (wipes)
Gemcitabine 5-Fluorouracil Irinotecan Cyclophosphamide	Two 42 millimeter diameter Whatman® filters moistened with 250 µL of a 50% acetonitrile/50% methanol solution	100 cm ²	<ul style="list-style-type: none"> Liquid chromatography/mass spectrometry/mass spectrometry (Bureau Veritas North America) A formal limit of detection/limit of quantitation study was not performed; 10 nanograms (ng) per sample of each drug were used as a low calibration standard. Results are semi-quantitative

infusion center. We also evaluated the direction and velocity of airflow in the isolator cabinet used for mixing chemotherapy drugs. In addition, we reviewed a hospital consultant’s report of an isolator cabinet evaluation.

Employee Interviews, Injury/Illness Logs, and Medical Records

We interviewed nine of 10 employees who worked in the infusion center. During these health interviews, we asked about work history, handling of chemotherapy drugs, acute and chronic health symptoms, personal cancer history, reproductive health history, use of personal protective equipment, and workplace health and safety training. We reviewed the Occupational Safety and Health Administration (OSHA) Form 300 Log of Work-Related Injuries and Illnesses for years 2008–2012. We reviewed employee records from medical evaluations performed by a physician contracted by the hospital’s employee health program in October 2012 to evaluate employee health concerns. The medical evaluations included physical exams, health histories, urinalyses, blood tests for liver and thyroid function, and complete blood counts, including the percentage of each type of white blood cell.

Review of Hazardous Drug Procedures

We reviewed the infusion center’s standard operating procedures for handling hazardous drugs, list of hazardous drugs at the infusion center, isolator cabinet use policies, isolator cabinet inspection reports, and list of personal protective equipment required by job title.

Results and Discussion

Observations

During our visit, a drug distributor shipped small boxes containing chemotherapy drugs to the hospital's main receiving area. These shipments occurred approximately 3 days a week. The infusion center's pharmacist picked up the drugs and transported them in a personal vehicle to the infusion center. The pharmacist unpacked the drugs in the infusion center and stored them in a locked Omnicell® cabinet in a room designed for preparing chemotherapy drug infusions. The pharmacist compounded the drugs in a compounding aseptic containment isolator cabinet designed for compounding sterile hazardous drug preparations (Figure 1). The isolator cabinet had a high efficiency particulate air (HEPA) filter air supply and exhausted 100% of the captured air to the outdoors through a second HEPA filter. Employees reported that the pass-through chamber was under negative pressure and that air flowed in from the surrounding pharmacy.

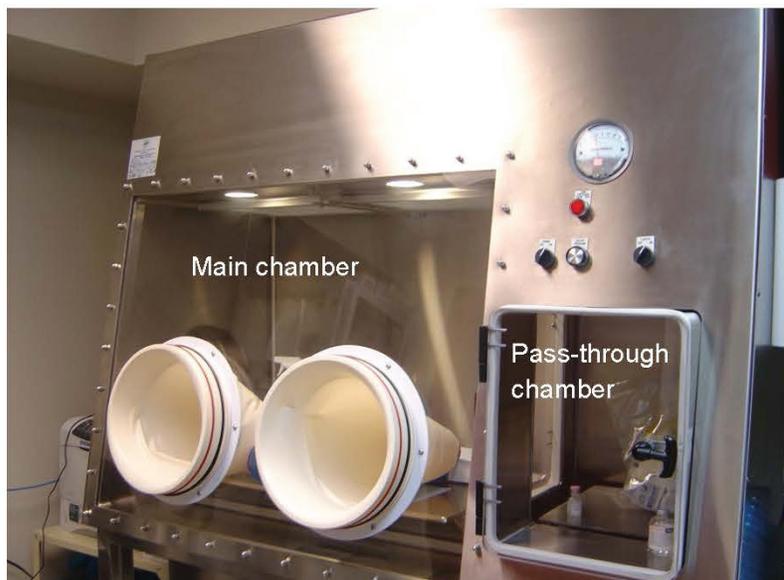


Figure 1. Compounding aseptic containment isolator cabinet.
Photo by NIOSH.

All employees in the infusion center who handled chemotherapy drugs were required to wear two pairs of chemotherapy protective gloves (double gloving). We observed some employees voluntarily wearing safety glasses to prevent eye contact with the chemotherapy drug in the event of a splash. Upon patient arrival, the pharmacist verified the dose and delivered the required drug to the nurse to administer in the treatment area. After verifying the chemotherapy drug treatment with the patient's medical record, the nurse administered the drug. This was done through a closed system with a needleless intravenous syringe or bag with tubing primed with a saline solution. The time it took to administer the chemotherapy drugs varied from minutes to hours depending on the treatment protocol. After completing the chemotherapy treatment, the nurse removed the intravenous line from the patient and disposed of all the chemotherapy drug-contaminated materials into a chemotherapy waste container. The nurse then removed both pairs of chemotherapy protective gloves, placed

them into the chemotherapy waste container, and washed his or her hands after removing the gloves. We observed no food or beverage consumption in the pharmacy or treatment area. We observed employees storing and preparing food, and eating in a break area away from where employees handled chemotherapy drugs.

Surface Wipe Samples

Appendix A, Tables A1 and A2 contain detailed surface wipe sample results. We detected platinum in 4 of the 50 surface wipe samples and gemcitabine, irinotecan, cyclophosphamide, and/or 5-fluorouracil in 18 samples. Of the detectable platinum results, levels ranged from 0.005–0.63 $\mu\text{g}/100\text{ cm}^2$. We measured the highest platinum level (0.63 $\mu\text{g}/100\text{ cm}^2$) inside the storage cabinet where vials were stored prior to compounding. A sample collected in the pharmacy in front of a computer touch screen used to track quantity and create vial labels contained detectable levels of all four of the other chemotherapy drugs: 1 ng/100 cm^2 of irinotecan, 2 ng/100 cm^2 cyclophosphamide, 50 ng/100 cm^2 5-fluorouracil, and 140 ng/100 cm^2 gemcitabine. The highest level of 5-fluorouracil (690 ng/ cm^2) was found in the sample from the isolator cabinet pass-through after 5-fluorouracil was used. We measured the highest level of gemcitabine (600 ng/100 cm^2) in front of the pharmacist's computer keyboard. Other locations that had detectable levels of chemotherapy drugs included the inner doorknob of the pharmacy, inside a vehicle used to transport chemotherapy drugs, the pharmacy counter left of the sink where intravenous bags were stored prior to carrying them to the infusion room, in the bin where chemotherapy drugs were stored prior to administration in the infusion room, and inside the isolator cabinet's gloves. We also found detectable levels of chemotherapy drugs on the outside of drug vials including 430 ng/100 cm^2 of 5-fluorouracil on the outside of the never opened 5-fluorouracil vial, and on the shelves where the vials were stored. The drug transport boxes did not test positive for chemotherapy drugs.

Although surface wipe samples detected the presence of platinum, likely from platinum containing chemotherapy drugs, and cyclophosphamide on some surfaces inside the infusion center, these contaminants were present in relatively low levels when compared to other NIOSH evaluations in similar environments [NIOSH 2012b,c]. The infusion center did not administer cyclophosphamide during our visit, yet it was detected in surface wipe samples. This suggests that cyclophosphamide was stable in the environment and that housekeeping procedures were not effectively removing this chemotherapy drug. We saw similar results in a previous evaluation at an oncology clinic. In that evaluation, the surface samples for cyclophosphamide remained positive for 3 days, even after housekeeping staff cleaned the surfaces [NIOSH 2012b]. Currently no occupational exposure limits (OELs) exist for chemotherapy drugs on surfaces or in the air. However, considering the carcinogenicity of these chemotherapy drugs [IARC 2004], precautions to eliminate or minimize exposures are appropriate.

Housekeeping

Although we did not observe housekeeping procedures, the employer reported that cleaning was conducted “in house” by hospital employees throughout the day as needed and after

hours. The hospital did not have a specific procedure for housekeeping services in the infusion center but it was reported that cleaning staff wore gloves.

The infusion center managers did not give employees formal guidance on avoiding take-home contamination with chemotherapy drugs. Shoe bottoms may carry traces of drugs that can be tracked outside the infusion center. If employees follow proper procedures while working, it is unlikely they will carry the drugs home. However, items such as the totes used to transport chemotherapy drugs between the main hospital and the infusion center could become contaminated and potentially contaminate areas outside of the pharmacy and treatment stations such as personal cars.

Review of Hazardous Drug Handling Procedures and Ventilation Evaluation Reports

The facility's standard operating procedures for handling hazardous drugs provided adequate guidance to pharmacy and nursing personnel on safe techniques in preparing, administering, and disposing of hazardous drugs as well as managing chemotherapy drug spills. The standard operating procedures, however, did not apply to other hospital employees with the potential for exposure, such as shipping and receiving personnel, custodial workers, laundry workers, and waste handlers. The standard operating procedures for the pharmacist and pharmacy technicians included guidance on the use of chemotherapy gloves and gowns when handling chemotherapy drugs; however, we observed that employees did not always follow this guidance. We found no information about proper storage, routine housekeeping, or medical surveillance for employees exposed to hazardous drugs. The hazardous drug list was incomplete. It included drugs and items that are not hazardous such as plastic bags and did not contain criteria for determining whether a drug is hazardous.

The isolator cabinet inspection testing was last performed in September 2012 (within 1 year of our evaluation) in accordance with the Controlled Environment Testing Association (CETA) Compounding Isolator Testing Guide CAG-002-2006, a consensus document of minimum testing criteria appropriate for all compounding isolators. The report found that the airflow in the main chamber was within acceptable limits; however, the consultant did not evaluate airflow in the pass-through chamber. We determined the air velocity inside the pass-through to the main chamber of the isolator cabinet to be 10 to 30 feet per minute in this location, which was similar to ambient air movement outside the chamber and was not under negative pressure. The report also found that the exhaust duct static pressure was within appropriate limits. The consultant collected a particle count and performed a smoke pattern test in the main chamber and pass-through chamber; both met the recommended guidelines. Recommendations from the report included storing the hazardous drugs separately from nonhazardous drugs and verifying negative pressurization of the pharmacy.

We reviewed a consultant's October 2012 report of indoor air quality testing for radon, aldehydes, organic vapors, spore trap analysis, carbon dioxide, and carbon monoxide. The report also contained platinum and fluorouracil analysis of the filters from the air filtration units. The consultant concluded that airborne contaminant levels were "below the most

protective regulatory and nuisance levels.” They recommended increasing the number of indoor air changes to improve the overall indoor air quality in the infusion center.

General Ventilation Evaluation

We used the VelociCalc® to evaluate the direction of airflow between the rooms; we found that air flowed as designed according to ANSI/ASHRAE/ASHE Standard 170-2013. We did not collect indoor relative humidity or temperature measurements; however, 50% of interviewed employees commented on the variable nature of the heating, ventilation, and air-conditioning (HVAC) system. In the United States, ASHRAE and American National Standards Institute (ANSI) recommend maintaining indoor relative humidity below 60% and temperatures between 70°F–75°F [ANSI/ASHRAE/ASHE 2013; ASHRAE 2013] for chemotherapy infusion rooms. ASHRAE guidelines provide specific details on ventilation system design for hospitals and clinics [ASHRAE 2013]. ANSI/ASHRAE Standard 170-2013: Ventilation of Health Care Facilities specifies controlling indoor relative humidity and temperature is an important factor in comfort in an occupational environment. ASHRAE states, “Acceptable air quality is defined as air in which there are no known contaminants at harmful concentrations as determined by cognizant authorities and with which a substantial majority (80% or more) of exposed employees do not express dissatisfaction [ANSI/ASHRAE 2010].”

Employee Interviews, Injury/Illness Logs, and Health Records

We interviewed nine out of 10 employees, including administrative and clinical personnel, working in the infusion center. The average length of employment at the infusion center was 7 years. Five infusion center staff reported handling chemotherapy drugs; of these employees, three reported eye and nose irritation, or headache that improved on their days off work, and a metallic taste while at work.

None of the interviewed employees reported any chronic conditions that have been found in the scientific literature to be associated with exposure to chemotherapy drugs. Employees reported receiving adequate training about the safe preparation, administration, and disposal of chemotherapy drugs. A few employees reported they did not receive enough training on the potential occupational health risks of handling chemotherapy drugs. Employees reported consistently double gloving with chemotherapy gloves and wearing disposable gowns when preparing or administering chemotherapy drugs. Most employees reported they thought the gowns were protective against chemotherapy drugs. A few employees reported they would wear safety goggles and disposable booties in the event of a chemotherapy drug spill but were unclear about what other occasions, such as drug splashes, would warrant use of safety goggles and disposable booties.

Regarding comfort issues unrelated to chemotherapy administration, employees reported fluctuating temperature changes throughout the day. Employees reported being uncomfortably warm when wearing personal protective equipment (gowns, gloves) when room temperatures were high.

No entries on the OSHA Logs of injuries or illnesses were recorded for infusion center employees. There was no medical surveillance program for those handling chemotherapeutic drugs. We reviewed employee health records from the medical evaluations and laboratory testing done in October 2012. All nine employees in the infusion center were asked by management to participate in these evaluations. Most physical exam findings and laboratory tests were within normal limits, but four out of the nine employees reported mucous membrane irritation, nausea, metallic taste, and tiredness intermittently in the past year while at work. One employee had a borderline low white blood cell count. We also obtained records of white blood cell counts from tests performed in 2009, 2011, and 2013 for this employee. All results fell below the normal range for the testing laboratory except for a result in 2013, which showed white blood cell counts within the reference range. The examiner did not make a determination if the symptoms reported by employees or the abnormal lab result were related to exposures at work. Employees received their individual exam results in writing. Aside from upper respiratory symptoms and metallic taste, the symptoms reported during the October 2012 examinations were not reported to us in June 2013.

The routes of exposure to chemotherapy drugs in healthcare settings are primarily inhalation and dermal, though ingestion could occur from contaminated surfaces and hand-to-mouth contact, as well as unintentional injection through a needle-stick or sharps injury. Inhalation exposure may occur from airborne droplets, vapors, or dust from tasks such as crushing tablets. We observed the risk of inhalational exposure to be low. Dermal exposure may occur when employees touch contaminated surfaces, and oral exposure may occur from hand-to-mouth transmission. Dermal exposure for most employees in the infusion center appeared to be minimal because of their use of gloves, including chemotherapy gloves. However, the potential for dermal exposure was greater in the pharmacy and receiving area where chemotherapy drugs were handled; here we found evidence of surface contamination and observed less consistent use of chemotherapy gloves.

Studies have documented adverse health effects such as nausea, headaches, vomiting, upper airway irritation, skin rash, hair loss, and dizziness in oncology staff handling chemotherapy drugs [McDiarmid and Egan 1988; Valanis et al. 1993; Krstev et al. 2003]. In addition to acute adverse effects, the literature has indicated an association of chemotherapy drug exposure in health care staff who work in oncology settings with the following long-term adverse effects: adverse reproductive health outcomes, genetic damage, and cancer [Skov et al. 1992; Valanis et al. 1999; Ratner et al. 2010; McDiarmid et al. 2014]. The overall health risk from hazardous drugs depends on toxicity of the drug, how much exposure an employee has to these drugs, and individual variation [NIOSH 2004]. Much of the literature documents these associations with symptoms in health care workers who handle chemotherapy drugs based on exposure group or job task but individual drugs were typically not identified. Although the literature is unclear in specifically associating the symptoms of upper respiratory symptoms and headache reported by employees with the drugs we found in surface wipe samples, these drugs are considered hazardous as listed in the 2012 NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings [NIOSH 2012a]. In order to minimize potential acute or long term health effects, it is recommended to prevent or reduce inadvertent exposure to these drugs as much as feasible [NIOSH 2004].

Metallic taste and other taste changes have been documented in patients who receive treatment with chemotherapy drugs such as 5-fluorouracil, cisplatin, carboplatin, cyclophosphamide, and methotrexate [Wickham et al. 1999]. Oncology staff have also been noted to report metallic taste changes when working with chemotherapy drugs [Connor 2013]. Pharmaceutical testing has shown that contact between small amounts of bitter active pharmaceutical ingredients and taste buds can result in metallic taste sensations [Gittings et al. 2014]. Given the presence of metal-containing hazardous drugs in the infusion center, staff reports of metallic taste may have been related to exposure to chemotherapy drugs in the infusion center. However, metallic taste or other change in taste perception is a symptom that is subject to inter-individual variation; its presence is difficult to validate and may not necessarily be associated with adverse health effects [Cowart 2011].

In our review of the laboratory reports from employees of the infusion center, there were laboratory values that showed borderline low white blood cell counts among one employee. Upon repeat testing, the values returned to within the normal range for the laboratory. With borderline abnormal laboratory values on one employee, we are unable to speculate on the cause of this result. Altered (decreased and or elevated) white blood cell counts have been documented as an effect in patients who received oral or intravenous chemotherapy drugs as a treatment for cancer [Yang et al. 2012]. One study of hematologic changes in oncology nurses who handle chemotherapy drugs did not find a statistically significant decrease in white blood cell count [Jochimsen et al. 1988]. No other evidence of altered white blood cell count from occupational exposure was found in the published scientific literature for employees handling chemotherapy drugs [Harrison 2001; Heron and Pickering 2003; Dranitsaris et al. 2005; Martin 2005; Connor et al. 2010; Fransman et al. 2014; McDiarmid et al. 2014] including those chemotherapy drugs used in this facility. Many factors can cause abnormal white blood cell counts, such as viral infections, certain medications, and vitamin deficiencies, and some healthy individuals have mild neutropenia (a low white blood cell count).

Routine or annual complete blood count testing is not currently recommended for employees handling chemotherapy agents [NIOSH 2013b]. This testing is only recommended for employees who have an acute exposure, such as a chemotherapy drug spill or needle stick injury [ONS 2011]. However, a medical surveillance program should be created for employees who handle hazardous materials and are therefore at risk of adverse health effects from exposure. Medical surveillance involves collecting and interpreting data to detect changes in the health status of working populations potentially exposed to hazardous substances. The elements of a medical surveillance program are used to establish an initial baseline of workers' health and then monitor their future health as it relates to their potential exposure to hazardous agents. Early identification of health problems can lead to the recognition of deficiencies in exposure controls and can also benefit individual workers [NIOSH 2013b].

Because many employees we spoke with had concerns about thermal discomfort and other indoor environmental quality issues, it is important to mention that poor indoor environmental quality has been associated with the types of upper respiratory symptoms reported to us. Studies have attributed these symptoms to problems with building airflow

and temperature as well as the presence of low levels of chemicals from office furnishings, office machines, cleaning products, personal hygiene products, and the building's structural components [EPA 2012]. We did not evaluate these factors.

Conclusions

We found low but detectable levels of chemotherapy drugs in surface wipe samples collected throughout the infusion center. This contamination included platinum-containing drugs (cisplatin, oxaliplatin, and carboplatin), gemcitabine, irinotecan, cyclophosphamide, and 5-fluorouracil in various areas around the pharmacy and infusion room. We detected cyclophosphamide even though it was not in use during our visit. Based on our review of available evidence and existing guidance, we do not recommend routine complete blood count tests for employees other than for acute exposure follow-up. Although we cannot definitively link the reported symptoms to chemotherapy drug exposures many symptoms were consistent with those reported in the scientific literature. Because chemotherapy drugs are hazardous, protective measures and controls should be followed to minimize the health risk to employees.

Recommendations

On the basis of our findings, we recommend the actions listed below. Use the existing regional hospital labor-management health and safety committee, with employee/management representation from the infusion center, to discuss our recommendations and develop an action plan.

Our recommendations are based on an approach known as the hierarchy of controls (Appendix B). This approach groups actions by their likely effectiveness in reducing or removing hazards. In most cases, the preferred approach is to eliminate hazardous materials or processes and install engineering controls to reduce exposure or shield employees. Until such controls are in place, or if they are not effective or feasible, administrative measures and personal protective equipment may be needed.

Engineering Controls

Engineering controls reduce employees' exposures by removing the hazard from the process or by placing a barrier between the hazard and the employee. Engineering controls protect employees effectively without placing primary responsibility of implementation on the employee.

1. Evaluate the HVAC system and make changes necessary to attain the ANSI/ASHRAE/ASHE standard 170-2013 indoor relative humidity and temperature levels for healthcare facilities [ANSI/ASHRAE/ASHE 2013; ASHRAE 2013].
2. Contact the manufacturer of the isolator cabinet and clarify the design specifications for the pass-through chamber. Examine the airflow of the isolator cabinet's pass-through chamber and ensure it is operating as designed.

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3. Make the isolator cabinet adjustable to employee's shoulder height to prevent upper extremity discomfort for the primary user and improve visibility inside the isolator cabinet.

Administrative Controls

The term administrative controls refers to employer-dictated work practices and policies to reduce or prevent hazardous exposures. Their effectiveness depends on employer commitment and employee acceptance. Regular monitoring and reinforcement are necessary to ensure that policies and procedures are followed consistently.

1. Train staff who may be exposed to chemotherapy drugs about safe handling techniques and about the potential health effects associated with exposure to chemotherapy drugs.
2. Implement a medical surveillance program for staff who directly handle chemotherapy drugs. Use the information obtained through medical surveillance to help affected workers and to identify and correct any system failures that may have resulted in harmful exposures. More information about specific elements of the program can be found in the NIOSH Workplace Solutions document, "Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs" at <http://www.cdc.gov/niosh/docs/wp-solutions/2013-103/> [NIOSH 2013b] and OSHA Technical Manual on "Controlling Occupational Exposure to Hazardous Drugs" at https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html [OSHA 1999].
3. Wash hands after removal of gloves used to handle chemotherapy drugs.
4. Discontinue the use of personal vehicles to transport hazardous drugs from the main hospital to the infusion center.
5. Use a tote specific to chemotherapy drugs to transport them to the infusion center from the hospital. Clean it thoroughly after each use.
6. Ensure employees who receive chemotherapy drug shipments are aware of the potential for contamination of outer surfaces of drug containers and of precautions for protecting themselves.
7. Include the employees who receive shipments of chemotherapy drugs in hazard communication training and revise the policy and procedures for handling hazardous drugs to include all employees who may have contact with chemotherapy drugs.
8. Update the hazardous drug list and make it available to the employees. The OSHA hazard communication standard [29 CFR 1910.1200] requires employers to develop a hazard communication program appropriate for their workplace. An essential part of the program is the identification of all hazardous chemicals an employee may be exposed to in the facility. Drug manufacturers and importers are required to evaluate the hazards of the chemicals they produce or import and prepare labels and safety data sheets to convey the hazard information. The employers are required to (1) determine if these drugs meet one or more of the criteria defining hazardous drugs; (2) maintain an inventory of hazardous drugs; and (3) provide information and training to all employees potentially exposed. NIOSH provides additional guidance on how to develop your own list of hazardous drugs <http://www.cdc.gov/niosh/docs/2012-150/pdfs/2012-150.pdf> [NIOSH 2012a].

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9. Develop a standard operating procedure for housekeeping. Good housekeeping procedures include: (1) cleaning work surfaces with an appropriate deactivation agent (if available) and cleaning agent before and after each activity and at the end of each work shift; (2) wearing two pairs of protective gloves and disposable gown if an employee must handle linens, feces, or urine from patients who have received hazardous drugs within the last 48 hours; (3) disposing of the gown after each use or whenever it becomes contaminated; (4) wearing face shields if splashing is possible; (5) removing the outer gloves and the gown by turning them inside out and placing them into the yellow chemotherapy waste container, repeating the procedure for the inner gloves; and (6) washing hands with soap and water after removing the gloves [NIOSH 2004].

Personal Protective Equipment

Personal protective equipment is the least effective means for controlling hazardous exposures. Proper use of personal protective equipment requires a comprehensive program and a high level of employee involvement and commitment. The right personal protective equipment must be chosen for each hazard. Supporting programs such as training, change-out schedules, and medical assessment may be needed. Personal protective equipment should not be the sole method for controlling hazardous exposures. Rather, personal protective equipment should be used until effective engineering and administrative controls are in place.

1. Wear chemotherapy gowns and gloves when handling chemotherapy or other hazardous drugs. If the gowns and gloves are chemotherapy protective, the box will have a label stating “chemotherapy protective.” The gowns should not have seams or closures that allow drugs to pass through and should be changed every 2–3 hours if no permeability information is available. Gowns made of polyethylene-coated polypropylene or other laminate materials offer sufficient protection from chemotherapy or other hazardous drugs. Further guidance on personal protective equipment for healthcare workers who work with hazardous drugs can be found at <http://www.cdc.gov/niosh/docs/wp-solutions/2009-106/> [NIOSH 2009].
2. Wear shoe covers to prevent tracking chemotherapy drugs through the infusion center.
3. Instruct all employees, including shipping and receiving personnel, to wear appropriate personal protective equipment including chemotherapy gloves when handling chemotherapy drugs.

Appendix A: Tables

Table A1. Surface wipe samples for chemotherapy drugs

Location	Platinum (µg/100 cm ²)	5-fluorouracil (ng/100 cm ²)*	Gemcitabine (ng/100 cm ²)*	Irinotecan (ng/100 cm ²)*	Cyclophosphamide (ng/100 cm ²)*
File/Breakroom					
Table 1§	ND	ND	ND	ND	ND
Table 2	ND	ND	ND	ND	ND
Photocopier	ND	ND	ND	ND	ND
Pharmacist desk					
Front of keyboard	ND	ND	ND	ND	ND
On keyboard‡	ND	ND	ND	ND	ND
Reception area, on checkout keyboard‡	ND	ND	ND	ND	ND
Hall floor from pharmacy to infusion center					
Sample 1¶	ND	ND	ND	ND	ND
Sample 2	0.052	ND	ND	ND	ND
Infusion room					
Nurse station					
Keyboard‡	ND	ND	ND	ND	ND
Floor	ND	ND	ND	ND	ND
Computer, pre administration	ND	ND	ND	ND	ND
Exit door knob‡	ND	ND	ND	ND	ND
Bin, storing chemotherapy before administration					
Sample 1	ND	ND	ND	ND	ND
Sample 2	ND	ND	2†	ND	3†
Hazardous waste storage room					
Enter doorknob‡	ND	ND	ND	ND	ND
Floor by biohazard waste bins	ND	ND	2†	ND	1†
Other					
Pharmacist car					
Passenger seat	ND	ND	ND	ND	ND
Agent transport case	ND	4†	4†	ND	ND
Steering wheel‡	ND	ND	ND	ND	ND

ND = Not detected above the limit of detection (see Table 1 for detection limits)

*Semiquantitative results

†Uncertainty is associated with these sample concentrations because they were above the detection limit, but below the low calibration standard of 10 ng/sample.

‡Estimated surface area of 100 cm²

§Wipe sample used three Whatman filters instead of two

¶Wipe sample taken with Alpha texwipes instead of Whatman filters

Table A2. Surface wipe samples for chemotherapy drugs in the pharmacy

Location	Platinum ($\mu\text{g}/100\text{ cm}^2$)	5-fluorouracil ($\text{ng}/100\text{ cm}^2$)*	Gemcitabine ($\text{ng}/100\text{ cm}^2$)	Irinotecan ($\text{ng}/100\text{ cm}^2$)*	Cyclophosphamide ($\text{ng}/100\text{ cm}^2$)*
Pharmacy					
In glovebox gloves‡	ND	110	ND	1†	ND
Pharmacy storage cabinet					
5-fluorouracil vials	ND	430	ND	0.7†	ND
5-fluorouracil boxes‡	ND	ND	ND	ND	ND
Before handling platins, storage cabinet handle‡	0.0048	ND	ND	ND	ND
In vial storage cabinet	0.63	ND	ND	ND	ND
Surface, agents are stored, left of sink	ND	14	4†	ND	7†
Exit doorknob‡	ND	4†	4†	ND	ND
Next to sink, drug storage	ND	ND	ND	ND	ND
Glovebox handle‡	ND	ND	ND	ND	ND
Center, pharmacy floor	ND	ND	ND	ND	ND
In front of computer, before any chemo	ND	65	600	1†	4†
Pass-through chamber deck, before handling drugs					
Sample 1	ND	ND	240	ND	13
Sample 2	0.01	ND	ND	ND	ND
Counter, before any chemo by computer	ND	ND	ND	ND	ND
Outside oxyplatin box‡	ND	ND	ND	ND	ND
Vial of oxyplatin‡	0.004	ND	ND	ND	ND
Pharmacy phone‡	ND	ND	ND	ND	ND
Pass-through after 5-fluorouracil processed	ND	690	76	0.4†	1†
Exit doorknob after 5-fluorouracil‡	ND	14	6†	ND	ND
In front of touch screen	ND	50	140	1†	2†

ND = Not detected above the limit of detection (see Table 1 for detection limits)

*Semi-quantitative results

†Uncertainty is associated with these sample concentrations because they were above the detection limit, but below the low calibration standard of 10 ng/sample.

‡Estimated surface area of 100 cm²

Appendix B: Occupational Exposure Limits and Health Effects

NIOSH investigators refer to mandatory (legally enforceable) and recommended OELs for chemical, physical, and biological agents when evaluating workplace hazards. OELs have been developed by federal agencies and safety and health organizations to prevent adverse health effects from workplace exposures. Generally, OELs suggest levels of exposure that most employees may be exposed to for up to 10 hours per day, 40 hours per week, for a working lifetime, without experiencing adverse health effects. However, not all employees will be protected if their exposures are maintained below these levels. Some may have adverse health effects because of individual susceptibility, a pre-existing medical condition, or a hypersensitivity (allergy). In addition, some hazardous substances act in combination with other exposures, with the general environment, or with medications or employee's habits to produce adverse health effects. Most OELs address airborne exposures, but some substances can be absorbed directly through the skin and mucous membranes.

Most OELs are expressed as a time-weighted average (TWA) exposure. A TWA refers to the average exposure during a normal 8- to 10-hour workday. Some chemical substances and physical agents have recommended short term exposure limit or ceiling values. Unless otherwise noted, the short term exposure limit is a 15-minute TWA exposure. It should not be exceeded at any time during a workday. The ceiling limit should not be exceeded at any time.

In the United States, OELs have been established by federal agencies, professional organizations, state and local governments, and other entities. Some OELs are legally enforceable limits; others are recommendations.

- The U.S. Department of Labor OSHA permissible exposure limits (29 CFR 1910 [general industry]; 29 CFR 1926 [construction industry]; and 29 CFR 1917 [maritime industry]) are legal limits. These limits are enforceable in workplaces covered under the Occupational Safety and Health Act of 1970.
- NIOSH recommended exposure limits are recommendations based on a critical review of scientific and technical information and the adequacy of methods to identify and control the hazard. NIOSH recommended exposure limits are published in the NIOSH Pocket Guide to Chemical Hazards [NIOSH 2010]. NIOSH also recommends risk management practices (e.g., engineering controls, safe work practices, employee education/training, personal protective equipment, and exposure and medical monitoring) to minimize the risk of exposure and adverse health effects.
- Other OELs commonly used and cited in the United States include the threshold limit values (TLVs), which are recommended by the American Conference of Governmental Industrial Hygienists (ACGIH), a professional organization, and the Workplace environmental exposure levels (WEELs), which are recommended by the American

Industrial Hygiene Association, another professional organization. The TLVs and WEELs are developed by committee members of these associations from a review of published, peer-reviewed literature. These OELs are not consensus standards. TLVs are considered voluntary exposure guidelines for use by industrial hygienists and others trained in this discipline “to assist in the control of health hazards” [ACGIH 2013]. WEELs have been established for some chemicals “when no other legal or authoritative limits exist” [AIHA 2013].

Outside the United States, OELs have been established by various agencies and organizations and include legal and recommended limits. The Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung (Institute for Occupational Safety and Health of the German Social Accident Insurance) maintains a database of international OELs from European Union member states, Canada (Québec), Japan, Switzerland, and the United States. The database, available at <http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Internationale-Grenzwerte-für-chemische-Substanzen-limit-values-for-chemical-agents/index-2.jsp>, contains international limits for more than 1,500 hazardous substances and is updated periodically.

OSHA requires an employer to furnish employees a place of employment free from recognized hazards that cause or are likely to cause death or serious physical harm [Occupational Safety and Health Act of 1970 (Public Law 91–596, sec. 5(a)(1))]. This is true in the absence of a specific OEL. It also is important to keep in mind that OELs may not reflect current health-based information.

When multiple OELs exist for a substance or agent, NIOSH investigators generally encourage employers to use the lowest OEL when making risk assessment and risk management decisions. NIOSH investigators also encourage use of the hierarchy of controls approach to eliminate or minimize workplace hazards. This includes, in order of preference, the use of (1) substitution or elimination of the hazardous agent, (2) engineering controls (e.g., local exhaust ventilation, process enclosure, dilution ventilation), (3) administrative controls (e.g., limiting time of exposure, employee training, work practice changes, medical surveillance), and (4) personal protective equipment (e.g., respiratory protection, gloves, eye protection, hearing protection). Control banding, a qualitative risk assessment and risk management tool, is a complementary approach to protecting employee health. Control banding focuses on how broad categories of risk should be managed. Information on control banding is available at <http://www.cdc.gov/niosh/topics/ctrlbanding/>. This approach can be applied in situations where OELs have not been established or can be used to supplement existing OELs.

Currently no OELs exist for the chemotherapy drugs for which we sampled. Limited information exists that describes specific health effects due to occupational exposure of the drugs we tested. Some have been classified as carcinogenic by the International Agency for Research on Cancer (IARC). Cisplatin is categorized as a Group 2A Carcinogen, (inadequate evidence to designate it as a human carcinogen); cyclophosphamide is categorized as a

Group 1 Carcinogen (carcinogenic to humans) and 5-fluorouracil has been categorized as a Group 3 Carcinogen (not classifiable as to its carcinogenicity to humans) by IARC [IARC 2004]. Collectively these drugs can be irritating to the eyes and respiratory tract and some are considered a reproductive hazard and harmful to the fetus [Murff 2012]. Healthcare personnel who prepare and administer parenteral chemotherapy may be at risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these materials if workplace exposures are not properly controlled; it would be prudent to maintain exposures as low as possible.

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