Pharmaceutical
Waste Solutions

Workplace Contamination of Chemotherapy and Other Hazardous Drugs

WHITE PAPER

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The Problem

Chemotherapy drugs, also known as antineoplastics, cytotoxics and other hazardous drugs, are potent and toxic agents that cause adverse side effects in patients and pose a grave health risk to healthcare workers, including waste workers. Chemotherapy drug residue is found on most surfaces in workplaces where these drugs are prepared for and administered to patients. When remaining drug delivery materials (e.g., intravenous bags, tubing, needles, personal protective equipment (PPE) or gauze pads), are discarded as trace or bulk chemotherapy waste the risk to waste workers needs to be considered. Drug residue can be transferred from contaminated surfaces to workers; the active drug being absorbed through unprotected skin where it can produce harmful health effects.

Regulations

Chemotherapy and other hazardous drugs are occupational health hazards requiring worker safety management, to be regulated under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) [OSHA 2012]. Many chemotherapy drugs are also regulated as listed hazardous waste by the EPA under the Resource Conservation and Recovery Act (RCRA). Non-listed chemotherapy drugs may also be identified as chemicals that meet one or more characteristics of hazardous waste under RCRA (ignitability, corrosivity, reactivity, or toxicity). In some instances, chemotherapy administration generates wastes consisting of sharps (e.g. syringes with attached needles), and other regulated medical waste; these wastes may also be regulated under the OSHA Bloodborne Pathogens Standard [OSHA, 2012a] and under state regulated medical waste regulations.

Detecting Drug Residue in the Workplace and Workers

With the development of sensitive and specific assays to detect several common chemotherapy drugs, chemotherapy residue has been measured on surfaces in treatment centers where the drugs are received, stored, compounded, administered, spilled, and collected for disposal. Drug residue has been measured in storage areas and on waste containers. Extensive research in this area has documented that chemotherapy drug residue can be measured throughout healthcare settings most likely due to transfer of drug contamination during routine handling, transport and waste disposal [Sessink 1992; Sessink 1997; Sessink 1999; Connor 1999; Connor 2010; Hon 2011; Chu 2012; Hon 2013]. These assays have also been used to determine drug residue in urine samples collected from exposed workers [Suspiro 2011]. A review of 20 urine sampling studies conducted between 1992 and 2011 looked for 10 different chemotherapy drugs in the urine of healthcare workers assigned to cancer treatment areas [Suspiro 2011]. Seventeen of the 20 studies detected one or more of the study drugs in the samples. It can be extrapolated that these drugs exist in the wastes generated during these activities and healthcare waste workers could be impacted if not properly protected as multiple different drugs are deposited in a single container.

Environmental Wipe Sampling

Environmental wipe sampling, where moistened swabs or filters are used to wipe a pre-measured surface area, is used to collect and measure drug residue [Pretty 2010; Connor 2016]. The sample is extracted and the extract analyzed for the marker chemotherapy drugs. The analysis is sensitive and allows detection of very small amounts of drug residue in any sample. The amount of drug detected, however, is impacted by the ability of the wipe sampling method to remove (i.e. recover) the drug from the surface being sampled [Connor 2016]. Some surfaces, like stainless steel, are easy to sample with recovery of some marker drugs from stainless steel exceeding 90%. Other surfaces, like vinyl floors, retain the drug resulting in lower recoveries and under reporting of the contamination. Some surfaces, like plastics for totes, bins and trays, have not been tested to determine accurate recoveries of chemotherapy drugs; however, it is reasonable to assume wastes deposited into waste containers are likely to have been contaminated with these drugs. Currently, it is possible to identify and quantitate six to eight drugs with this technique.

Follow the Drug and Waste Process

A series of studies done in five cancer treatment centers in British Columbia, Canada, observed the surfaces contacted by all workers entering the chemotherapy treatment area, identified the job category of each worker, wipe sampled the work surfaces and collected urine samples from each of the workers [Hon 2011; Hon 2013; Hon 2015]. The researchers identified surfaces not usually sampled, such as the pen in the compounding area, the IV pump in the administration area and the elevator buttons in the waste accumulation area, which had the largest frequency of touch contact. The wipe sampling demonstrated that those surfaces had extensive contamination. Unit clerks, transport workers, ward aides, dietitians, and oncologists, (workers not usually considered at high risk of drug exposure) were observed touching contaminated surfaces in the administration area. Urine samples collected on these workers contained the marker drug, cyclophosphamide, demonstrating that workers in the drug administration setting, even those who were not responsible for administering the drugs to patients (i.e., volunteers, oncologists, ward aides, and dietitians), had the largest proportion of urine samples exceeding the limit of detection (LOD) for cyclophosphamide [Hon 2015]. These workers were found to be the least aware of the potential for exposure and the least trained to protect against it. This series of studies clearly demonstrates a direct correlation of environmental contamination to worker contamination by the transfer of drug residue from surfaces to drugs being absorbed and passed through the workers as measured in excreted urine samples. The workers most affected had no direct contact with the recovered drug during their normal work duties except for contact with contaminated surfaces. They were the least aware of potential exposure and did not use any protective clothing or equipment while in the treatment area [Hon 2015]. In this Canadian study, drug waste was looked at as both disposal and waste retrieval. However, only one of five sites was wipe sampled for waste as four of the sites contracted waste handling and the contractors declined to participate in the study. Six samples were taken in the waste area of this one site: Cart (N = 2); Door handle (N = 2); Elevator button (N = 2). Of the samples, 83% of were above the limit of detection (LOD) for the assay [Hon 2013]. The selection of sampling locations demonstrates that contamination during waste handling is transferred to other surfaces. Other studies have measured contamination during waste handling. In a multi-site study done in the U.S. the highest concentration of marker drug 5-fluorouracil (910 ng/cm2) was measured on the lid of a hazardous waste container in a nursing area at Site 3 [Connor 2010].

Decontaminating: Deactivating, Cleaning, and Disinfecting

USP Chapter 800, Hazardous Drugs—Handling in Healthcare Settings, addresses the various processes that can be used to eliminate contamination from surfaces (i.e. decontaminating): disinfecting, deactivating, and cleaning [USP 2016].

Disinfecting

It is important to note that contamination in healthcare can refer to chemical hazards or biohazards: drugs or bugs! Biohazards are living hazards that cause harm, such as infection, and may be decontaminated or deactivated by disinfecting, autoclaving or microwaving. These decontamination processes are not effective for chemical hazards. Chemotherapy drugs (with the exception of a few biologicals, e.g. BCG) are chemicals and are not deactivated or decontaminated by disinfecting, autoclaving or microwaving.

Deactivating

Ideally, chemotherapy and other hazardous drugs would be deactivated and rendered inert or inactive on contaminated surfaces prior to cleaning with a detergent and rinsing to remove all contamination. However, there is no one proven method for deactivating all compounds [USP 2016]. In addition, chemicals used to "deactivate" certain chemotherapy drugs may produce more toxic by-products, generate respiratory hazards, or result in caustic damage to the work surfaces [USP 2016].

In the workplace, chemotherapy waste is a mix of RCRA listed drugs, which require RCRA-permitted incineration for deactivation, and non-listed drugs. Incineration is the most thorough method of deactivating chemotherapy and other hazardous drugs [EPA 1976; NIOSH 2004; OSHA 2016].

Cleaning

As inactivating or neutralizing chemotherapy drugs is not an option, decontamination generally occurs by cleaning, i.e. physically removing chemotherapy drug residue from non-disposable surfaces and transferring it to disposable materials (e.g., wipes, pads, or towels) appropriate to the type of surface being cleaned. As several chemotherapy drugs are RCRA listed wastes, rinse water or any cleaning solution that contains active drug must be collected and also disposed of as hazardous waste [EPA 1976]. Additionally, many chemotherapy drugs are characteristically hazardous and may have additional management requirements (such as state requirements). These rinse waters may not be placed in any wastewater sewer drain if they were used to clean up a listed waste spill or exhibit a hazardous waste characteristic.

Because there are many chemotherapy drugs with varying chemical properties, no one agent is capable of cleaning or decontaminating contaminated surfaces [Roberts 2006; Touzin 2010; Chu 2012; Lé 2013; Lamerie 2013; Hon 2013; Hon 2014]. There are some commercially available products for cleaning/decontaminating chemotherapy drugs available. Testing has reported the effectiveness of these products as inconsistent. Lamerie has tested a number of novel cleaning solutions on two surfaces with varying results [Lamerie 2013]. Proposed methods of cleaning surfaces contaminated with chemotherapy drugs should be tested and proven effective by analytical methods before being adopted.

Cleaning Evaluation

Surface wipe sampling provides a mechanism to evaluate the effectiveness of cleaning processes. The type and texture of the surface may also affect the effectiveness of the cleaning process. Vinyl and other plastics appear to retain more drug residue during use and this retention makes it harder to measure during wipe sampling. Retaining drug residue may inhibit cleaning of these surfaces as well. Several studies using wipe sampling to evaluate cleaning chemotherapy drugs from surfaces have demonstrated that some techniques and/or solutions have resulted in moving the contamination around rather than actually removing it [Sessink 1992; Hon 2013]. Hon reports that in a cross tabulation of surface contamination levels by reported drug handling and surface cleaning, the sampled drug was not reported as handled/prepared/administered on the work shift for 56% of the samples with detectable levels of the sampled drug [Hon 2013]. In addition, the highest amounts of contamination of the sampled drug were found when the drug was reported as used and the surface reported to have been cleaned [Hon 2013]. This is probably the result of ineffective cleaning processes.

Trace Waste

RCRA allows for the exemption of "empty containers" from hazardous waste regulations [EPA 1976]. Empty containers are defined as those that have held U-listed or characteristic wastes and from which all wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container and no more than 3% by weight of the total capacity of the container remains in the container [CFR 2012]. Disposal guidelines developed by the National Institutes of Health (NIH) and published in 1984 coined the term "trace-contaminated" waste based on the RCRA 3% "empty" rule [Vaccari 1984]. In this guideline, NIH differentiated "trace-contaminated wastes" as containing minimal or "trace" amounts of drugs and which are disposed of by on-site incineration as opposed to RCRA "bulk" waste which requires incineration in an EPA permitted facility.

In 2019, the EPA adopted a regulation specific to the disposal of hazardous waste pharmaceuticals. This regulation continues to reference the 3% "empty" rule, however, it also provides simpler methods for determining when containers are empty. For example, IV bags are considered empty and their residues not regulated as hazardous waste provided the pharmaceuticals in the bag have been fully administered to a patient. The volume of waste that is handled as "not bulk" chemotherapy waste has increased substantially from 1984, when the NIH guidelines were written. Since sharps and potentially infectious materials may also be included in the "trace contaminated materials," destruction of this waste should occur at a regulated medical waste incinerator rather than an autoclave or microwave [NIOSH 2004; OSHA 2016].

Chemotherapy "trace" waste now includes chemotherapy drug vials which have been shown to have significant amounts of drug on the outside of the vials [Power 2014]. Many chemotherapy drugs, especially the platinum-containing compounds, are not destroyed by standard incineration temperatures [Castegnaro 1985]. As RCRA hazardous waste, chemotherapy drugs must be incinerated at an EPA appropriately permitted facility. Best practice may be to place all drug vials in RCRA "bulk" waste to ensure proper destruction or at a minimum to segregate for processing through incineration.

Conclusion

Based on the studies conducted, there is evidence that there is likely widespread contamination with drug residue in healthcare settings where chemotherapy is received, stored, prepared, administered and disposed of. There are many sources of drug contamination and the various processes used to deliver the drugs to patients and to remove the used drug and wasted equipment results in measurable transfer of the drug residue. Cleaning and decontamination treatments, for example the washing of waste containers, with currently available technologies are not adequately effective. New technology would require evaluation of its effectiveness in removing both chemical and pathogenic residue from containers. Reuse of equipment that cannot be properly cleaned or decontaminated should be avoided. Ultimately this could result in drug and residue contamination of materials getting into the waste stream. It is important that waste workers are adequately protected and that wastes are managed by appropriate means to ensure the drug does not further contaminate the environment.

Information on Exposure to Hazardous Drugs

Background information on exposure may be found in the NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings published in September 2004, http://www.cdc.gov/niosh/docs/2004-165/. Additional information and an extensive bibliography are available on the NIOSH Workplace Safety and Health Topics webpage on hazardous drug exposures in healthcare, https://www.cdc.gov/niosh/topics/hazdrug/default.html.

OSHA also has an updated Safety and Health Topics page on hazardous drugs, https://www.osha.gov/SLTC/hazardousdrugs/index.html.

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