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Hazardous Drug Wipe Sampling in Healthcare Facilities

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ABSTRACT

Hazardous drugs are associated with causing acute and chronic side effects to healthcare workers that experience occupational exposures. Antineoplastic drugs are known to cause headaches, nausea, vomiting, hair loss, mutagenic activity, spontaneous abortions, infertility, and congenital malformations. Currently, there are no acceptable thresholds for exposures to this type of hazardous drugs. The use of as low as reasonably acceptable (ALARA) is used for exposures to these types of drugs. Occupational exposure risk should be evaluated within facilities where they are used. Performing hazardous drug wipe sampling in areas that are high risk for contamination can provide information to facilities on how to protect their employees.

Introduction and Background

Antineoplastic drugs are a workplace hazard. These drugs are known to be toxic to cells that are non-cancerous (Vyas, Yiannakis, Turner and Sewell, 2013). These types of drugs are associated with adverse side effects for employees with both acute and chronic exposures. Some of the earliest reports of these drugs posing occupational risks was in 1979 (Soteriades et al., 2020). The levels were quantifiable in the urine of nurses handling these mutagenic drugs. Previously, the worker exposures were higher levels (e.g., mg/mL) and currently the exposures are much lower. Most exposures recently are nanograms per milliliter (ng/mL) (Soteriades et al., 2020). Since the 1940's, the toxicity of cancer treatments has been known to cause side-effects to both patients and to the healthcare workers handling these drugs while performing their daily duties (Soteriades et al., 2020). Because healthcare workers handle these toxic drugs, the occupational risk should be evaluated.

The symptoms associated with occupational exposure to Antineoplastic drugs include headaches, nausea, vomiting, hair loss, hypersensitivity, mutagenic activity, spontaneous abortions, infertility, and congenital malformations (Vyas, Yiannakis, Turner and Sewell, 2013). These symptoms have been reported in healthcare workers that are being exposed to these cytotoxic drugs at much lower doses than patients (Dugheri et al, 2018). The drugs are also known to cause irritation and/or damage to the skin, eyes, and mucous membranes. In another study, it was been shown that the compounds were mutagenic to mammalian cells in cell cultures (Harrison, Peters, and Bing, 2006). Antineoplastics have no therapeutic relevance to individuals that do not require these types of drug therapies.

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By 2020, it was expected that there will be a rise in yearly cancer diagnoses to 16 million, globally (Dugheri et al., 2018). The market for cancer treatment drugs is expected to generate approximately US $161.3B by the end of 2021. Treatments included in the estimate are chemotherapy, hormone therapy, immunotherapy, and targeted therapy, with chemotherapy projected to be 50% of the revenue. Antineoplastic drugs are classified as hazardous chemicals by National Institute for Occupational Safety and Health (NIOSH) (Dugheri et al., 2018).

NIOSH published the Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings Alert in 2004. The list was recently updated in May 2020 to include newly approved drugs by the Food and Drug Administration (NIOSH, 2020). Of the drugs on this list from NIOSH, roughly half of them are antineoplastics. The purpose of this alert was to bring awareness to employees the risk involved with the handling of these drugs and outline protective measures they could implement for their facility (Fuller, Bain, Sperrazza, and Mazzuckelli, 2007).

Currently, there is no safe occupational threshold, such as a Permissible Exposure Limit (PEL), for hazardous drugs, however, there have been proposals for possible threshold limits for single drugs only (NIOSH, 2020). Healthcare facilities are trying to minimize the occupational exposure by utilizing the NIOSH hierarchy of controls, by implementing engineering controls, administrative controls and personal protective equipment, as well as environmental monitoring (i.e. wipe sampling) and biological monitoring (laboratory testing) as a method to identify problems and create more worker awareness (Dugheri et al., 2018).

The occupational exposure to hazardous drugs by healthcare workers is proposed to happen most commonly by dermal contact. It is not likely that healthcare workers are exposed via inhalation of the hazardous drugs. Hazardous drugs that have a low molecular weight (< 500 Daltons) are of concern because these drugs are easily absorbed through the skin, whereas some of the current hazardous drugs have a molecular weight of >40,000 Daltons (Conner and Smith, 2016; Connor, Zock and Snow, 2016).

The larger molecular weight limits the dermal uptake from contaminated surfaces. However, nurses have a higher risk of exposure and possible dermal uptake of these higher molecular weight drugs due to constant hand-washing practices, which damages their skin and causes cracks that these drugs can penetrate through (Conner and Smith, 2016; Connor, Zock and Snow, 2016).

Wipe sampling is one of the most common practices for hazardous drug contamination assessment (Conner and Smith, 2016; Connor, Zock and Snow, 2016). Environmental monitoring has shown that hazardous drugs can be found in the air and on work surfaces in sterile compounding rooms, manufacturing and packaging areas for the compounded sterile products and clinical administration areas (Harrison, Peters, and Bing, 2006). Performing hazardous drug wipe sampling in areas at risk for exposure can provide information for environmental monitoring on cleaning processes and handling of hazardous materials.

Environmental wipe sampling has been used for the last 20 years in healthcare facilities to evaluate contamination within the workplace. Conner, Zock and Snow (2016) stated that other reasons for surface sampling is as follows: hazard identification and evaluation, exposure assessment, facility characterization, housekeeping, selection of engineering controls, evaluation of engineering and administrative/work practice controls, evaluation of exposure pathways, selection of personal protective equipment, compliance with regulations and standards, source identification, education and training, and investigation of complaints. The samples that were collected in the facilities of were not used for worker exposure but to look at the environmental contamination as a possibility for worker exposure (Conner and Smith, 2016; Connor, Zock and Snow, 2016).

Recommended Wipe Sampling Methods

Wipe sampling was originally developed to evaluate other agents such as lead, asbestos, methamphetamine, and antibiotics (Connor and Smith, 2016; Connor, Zock and Snow, 2016). This methodology was evaluated and applied to hazardous drugs. However, not all hazardous drugs can be analyzed because not all drugs have methods designed to analyze them in a laboratory. Additional methods can be developed for other drugs that do not currently have a testing method determined, as long as there are antibodies available for the drug (Conner and Smith, 2016; Connor, Zock and Snow, 2016).

When performing hazardous wipe sampling, there is a need to have a strategy in mind for which factors are to be assessed and what variables may be present in the sampling evaluation. Some factors to consider are the types of hazardous drugs that are being used and quantities stored and used within the facility. Once a sampling plan has been completed, a certified laboratory and/or industrial hygiene professional that conducts this type of sampling should be identified. Currently, there are no standards for sampling and analysis for these drugs, therefore it is essential to identify a laboratory that is experienced with hazardous drug wipe sampling analysis (Power, Sessink, Gesy, and Charbonneau, 2014). The laboratory should have a validation process for the drugs their facility evaluates. These validation methods should include how samples are stored for stability, medium desorption efficiency, limits of detection and quantitation, calibration curves and quality control methods. Their method should give greater than 90% extraction efficiency, which is preferred, however greater than 75% extraction is acceptable (Conner & Smith, 2016).

When hazardous drug wipe sampling is performed, the sample size should be no less than 100 cm^2, however if a smaller sample size is used, more samples must be taken which can increase the cost of this testing since the cost is per wipe rather than per drug being tested for. A more acceptable size would be 400 cm^2, which would give a larger sampling area and reduce the cost by not needing as many samples for one location. A sampling plan should be devised so that the facility knows exactly what locations were sampled and make note of what type of activity takes place in those locations (i.e., surface of the biological safety cabinet – admixing of hazardous drugs). Common locations for hazardous drug wipe sampling would be the geometric center of the engineering controls (biological safety cabinet or compounding aseptic containment isolator), where the direct compounding area is located. The floors directly below the engineering controls, pass-throughs from the hazardous drug storage into the negative pressure hazardous drug ISO Class 7 buffer areas and the pass through from the hazardous buffer areas to the general pharmacy, equipment, counters, storage containers, door handles, high touch areas, and computer keyboards (Conner and Smith, 2016; Connor, Zock and Snow, 2016).

Once the sampling has been completed, samples are sent overnight to a laboratory where the samples are processed and analyzed. Typical methods used for specimen recovery and analysis are gas chromatography, liquid chromatography, high-performance liquid chromatography, ultra-high-performance liquid chromatography along with mass spectrometry, tandem mass spectrometry or inductively coupled plasma mass spectrometry. These methods determine the concentration of hazardous drugs present on the wipe samples that have been collected within the healthcare facility (Conner and Smith, 2016; Connor, Zock and Snow, 2016).

Summary and Conclusions

Currently, no standards or regulations exist for an acceptable level of exposure to hazardous drug, and nothing is known about the synergistic effects multiple drugs could elicit in human systems. The only allowable standard for exposure is as low as reasonably achievable (ALARA). A common approach is

put in place workplace controls, as well as implementation of personnel training on the handling of hazardous drugs, cleaning, deactivation and decontamination of work surfaces and surveys given to healthcare staff involved with the processes of admixture and administration of these therapies could work to lower potential contamination and the exposure of employees to these toxic drugs in the workplace (Soteriades, et al., 2020). Despite the usual healthcare protocols, workers may not be fully protected in their facilities. The overwhelming evidence is that an occupational risk persists for those handing antineoplastic drugs. The highest risk groups include pharmacists and their team that compounds antineoplastic drugs and the nursing staff that administers these drugs to patients (Vyas, Yiannakis, Turner and Sewell, 2013). Surface sampling should be used as part of an environmental monitoring program. In doing so, results will inform staff the larger picture of possible contamination and exposures on within the facility (Conner and Smith, 2016; Connor, Zock and Snow, 2016).

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