Safe Handling of Hazardous Drugs - Wipe Sampling

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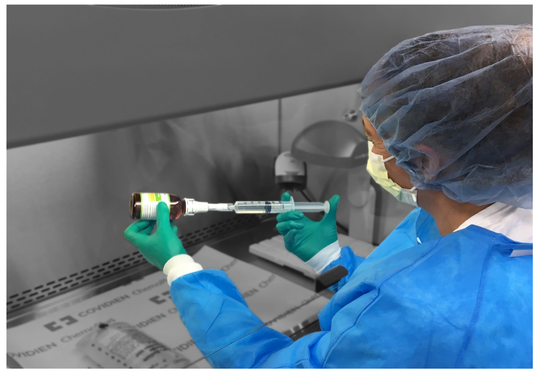
Description

In 2017, Barnes-Jewish Hospital completed an assessment of hazardous drug risk, in accordance with regulatory and consensus guidelines, including those defined by the United States Pharmacopeial Convention (USP) 800 and the National Institute for Occupational Safety and Health (NIOSH). Assessment included activity-specific safe work practices, engineering controls & personal protective equipment for each hazardous drug dosage formulation.

During the assessment, a database providing a list of hazardous drugs was created, detailing determined exposure risk, engineering controls and required PPE, for all handling and manipulation activities. Hazardous drug policies, procedures and training materials were developed and implemented based on established database.

To determine a baseline of existing conditions and later measure effectiveness of established protocols, a wipe sampling program was implemented in late 2017. As a result, a Certified Industrial Hygienist (CIH) established initial program protocols. Wipe sampling continues semi-annually to identify presence of hazardous drugs on working surfaces, assess program effectiveness and aid in advancement of exposure prevention protocols.



Purpose

While completing an assessment of hazardous drug risk in 2017, Barnes-Jewish Hospital recognized need to adopt recommendations from USP 800, NIOSH and the Occupational Safety & Health Administration (OSHA) and perform objective environmental wipe sampling for hazardous drug surface residue. Sampling results used to develop summary of existing conditions and determine areas of emphasis when implementing hazardous drug management procedures. Additionally, baseline data to be combined with subsequent wipe sampling events to determine effectiveness of implemented management procedures.

USP 800 recommends environmental wipe sampling for hazardous drug surface residue initially as a benchmark, and at least every six (6) months thereafter, to verify containment. If measurable contamination is detected, USP 800 further recommends action be taken to identify the cause and corrective actions be implemented to properly contain the hazardous drug. Additionally, repeat sampling recommended to validate effectiveness of corrective actions.

Methods

When completing the assessment of risk, the multidisciplinary BJH Hazardous Drug Committee identified representative locations for wipe sampling and retained the services of a CIH to perform sampling. CIH observed employee work tasks in each selected location and used professional judgement to select an appropriate and representative surface location to sample. Committee also identified the most commonly used hazardous drug(s) in each location, including:

- Cyclophosphamide
- Methotrexate
- Tacrolimus
- Paclitaxel
- Doxorubicin
- Etoposide Phosphate
- Carboplatin
- Cisplatin

The standard sampling kit used during wipe sampling activities includes 20 swabs, methanol wetting agent, wipe templates with a 100-square centimeters (cm^2) surface area and return vials. Up to four (4) hazardous drugs can be analyzed from each swab/wipe sample, with the exception of Tacrolimus, which requires a separate swab and analysis. Tacrolimus was identified as one of the highest use hazardous drugs at the selected locations, so sampling at these locations required side-by-side wipes with one (1) swab analyzed only for Tacrolimus. Prior to each sample, the CIH donned a clean pair of chemical gloves and the sampling procedure followed the method provided in the ChemoAlert™ sampling kit. Samples were placed in a shipping container with a freeze-pack, a chain-of-custody was prepared and samples were shipped overnight to the selected laboratory for analysis.

Outcomes

Of the initial sampled locations, only two (2) had any measurable concentration of hazardous drug residue. Both results were below 1 nanogram (ng) per cm^2. Detections were both within the non-sterile, hazardous drug storage and compounding room in the main pharmacy. Cyclophosphamide was found on the ledge of a storage carousel and Tacrolimus was present inside a biological safety cabinet on a preparation surface. Lab results were used to develop baseline data and determine areas of emphasis for management protocols. Following implementation of protocols, verification sampling was completed. Semi-annual sampling and subsequent verification sampling continue at the facility.

References:
1) American Industrial Hygiene Association
2) National Institute for Occupational Safety and Health
3) OSHA Technical Manual, Section 6, Chapter 2
4) United States Pharmacopeial Convention (USP) 797
5) United States Pharmacopeial Convention (USP) 800

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