Recommended PPE by Hazard Category

The following PPE and engineering controls are recommended for the following risk categories:

Cytotoxic chemotherapy high exposure risk drugs – parenteral, splash risk, inhalant, or manipulated oral

- Biological safety cabinet
- Double pair chemotherapy gloves
- Chemotherapy gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (in BSC or sterile areas only)
- Eye & face protection for splash hazards
- Surgical mask

High hazard high exposure risk – BCG, ribavirin, etc.

- Biological safety cabinet
- Double pair medical gloves
- Gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (in BSC or sterile areas only)
- Eye & face protection for splash hazards
- Surgical mask

High exposure risk – Intravenous and other high splash risk liquids, bulk powders, and inhalants

- Appropriate engineering controls or Biological safety cabinet
- Double pair medical gloves
- Gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)

- Hair cover (in BSC or sterile areas only)
- Eye & face protection for splash hazards
- Surgical mask (aseptic technique)

Moderate exposure risk – oral liquids and IM, SQ, intrathecal (low splash risk)

- Single pair medical gloves
- Gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (sterile areas only)

Moderate risk cytotoxic chemotherapy – Uncoated tablet or contained manipulation, and liquid transfer

- Single pair chemotherapy gloves
- Chemotherapy gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (sterile areas only)

Low exposure risk – topical and oral solids that are manipulated

- Single pair medical gloves
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (in BSC or sterile areas only)

Low risk cytotoxic chemotherapy – capsule and coated tablet

- Single pair chemotherapy gloves
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (in BSC or sterile areas only)

Existing precautions

- Current exposure precautions and PPE use is acceptable
- Additional PPE use is optional and at the discretion of the pharmacy personnel
- Additional PPE use is not precluded

Gowning Sequence

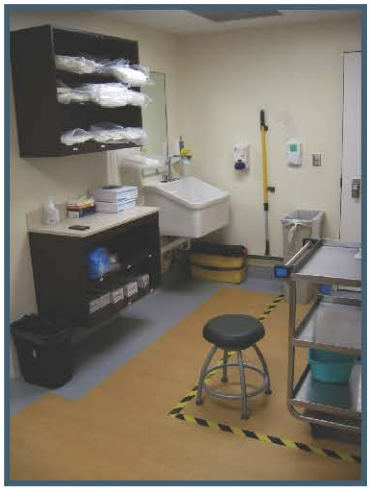
It is important that a proper gowning sequence take place in order to protect the preparation and prevent contamination by the preparer. It should be noted that there are conflicting opinions with regard to gowning sequences among various guidance documents and publications. It is important for the pharmacist and pharmacy to consider the gowning practices recommended by their respective accrediting agencies, professional practice standards, safety & health regulatory agencies, and guidelines when making their policy and procedure decisions regarding the gowning sequence they select based on their specific need.

Donning PPE - Double gloving and removal sequence
The following gowning sequence is specific to gowning up when using double gloves.

- Enter the designated gowning area
- Remove street clothes & don scrubs
- Wash and dry hands with soap and water only (Alcohol hand gels and wipes are not acceptable)
- Don dedicated shoes and shoe covers one at a time and enter dirty/change area one foot at a time
- Don hair covers and mask
- Apply alcohol-based hand gel to hands and allow to dry
- Don inner pair of gloves
- Don gown and keep inner pair of gloves underneath the gown cuffs
- Don eye/face protection (if necessary)
- Don outer gloves and pull up over top of cuffs (Note: outer gloves may be put on in sterile work area)
- Enter sterile work area

The following gown removal sequence is specific to double gloving.

- Remove outer pair of gloves in sterile prep room and discard
- Enter dirty/change area
- Remove eye/face protection (if necessary)
- Remove hair and facial hair covers and mask and discard
- Remove gown and discard
- Remove inner gloves and discard
- Remove shoe covers and designated shoes one after the other and enter outer/clean area one foot at a time
- Wash hands in clean area with soap and water only (Alcohol hand gels and wipes are not acceptable)



Ante room showing well-marked clear dirty/clean floor delineation, seat for changing into clean and out of dirty areas, sink and hand sanitizing station, and gown and glove storage area.

Training

Staff is required to receive training on the selection, proper use, and care and maintenance of the PPE provided. Documentation of training is required under WAC 296-800-16035 and documentation must include:

- Written documentation that each employee using PPE has received and understood their training.
- The employee's name, the training date(s), and the name of the subject/topic taught.

At a minimum, annual re-training is recommended and immediately at any time it is recognized that staff do not understand the appropriate PPE procedures and use, there has been a change in PPE and/or use, and when the previous training has become out of date. It is recommended that training records be kept and maintained for documentation purposes.

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RESPIRATORY PROTECTION

Respiratory protection is used to protect the wearer from exposure to airborne contaminants. Contaminants exist in different physical forms: solid, liquid, vapor, and gas. Hazardous drugs are manufactured as solids and liquids. Some hazardous drugs volatilize (evaporate) at room temperature and produce vapor. These drugs include carmustine, cisplatin, cyclophosphamide, etoposide, and fluorouracil, for example. Hazardous drug gases ~~that~~ are not typically produced in most pharmacies, however, some specialty pharmacies may handle anesthetic gases such as nitrous oxide, sevoflurane, and isoflurane.

Airborne exposure to hazardous drugs during handling and manipulation is controlled by the use of engineering controls such biological safety cabinets, compounding aseptic isolators, and closed system transfer devices; substitution of a less challenging drug form instead of a more challenging drug form such as single-dose tablets for bulk powder, coated tablets for uncoated tablets, and manufacturer prepared single-dose vials for multi-dose vials; and work practice techniques such as wet crushing of tablets versus dry crushing. Despite the use of these controls, there are foreseeable instances where pharmacy and other (e.g. spill response, environmental services, ~~etc.~~) staff can be potentially exposed to aerosolized hazardous drugs and may include cleaning the inside and outside of a biological safety cabinet, ~~and~~ cleaning up spills inside and outside of a biological safety cabinet. The use of respiratory protection in these instances can further reduce the potential exposure to hazardous drugs. It is important to note that respirators are worn and designed to protect the wearer, and, with few exceptions, are not intended to protect the preparation.

Regulations

The use of respiratory protection is regulated in Washington State by the Department of Labor & Industries (WAC 296-842) and by OSHA at the federal level (29 CFR 1910.134). These regulations require the following:

- A written Respiratory Protection Program and Program Administrator
- The Program is required to have the following program elements:

  Respirator selection, use, and care procedures

  Medical evaluations for wearers

  Fit testing procedures

Wearer training

- Hazards
- Care & maintenance
- Donning, doffing & limitations of use
- Emergency use

Employee respirator use for routine, infrequent, and emergencies

Respirator maintenance

- Cleaning & disinfection
- Storage
- Inspection & repair
- Removal from service
- Filter/chemical change out schedule & rationale
- Supplied air respirator air delivery & quality procedures

Program efficacy evaluation procedures

Please refer to 29 CFR 1910.134 (federal) or WAC 296-842 (Washington State) for specific regulatory requirements.

It is important to emphasize the importance of having a written and detailed respiratory protection program to insure that staff is trained, the respirator fit tested, the appropriate respirator is selected and used correctly, and the equipment is properly maintained. The equipment and training is specialized and requires a level of expertise above and beyond what can be provided by a retail building supply store.

Respirator categories

Respirators are categorized according to their performance and physical characteristics.

Positive and negative pressure respirators
Respirators deliver breathing air to the wearer by either positive pressure or negative pressure. Positive pressure respirators deliver or "push" air into the respirator. Positively pressurized air is "pumped" into the respirator from a motor/fan, compressor, or pressurized tank via a tube, or in some cases, the motor/fan is attached directly to the respirator. There is minimal exertion required by the wearer to receive air and the

respirator is designed to maintain positive pressure as the wearer breathes. Airborne contaminants are not able to reach the wearer when the respirator is under constant positive pressure because air will flow out of the respirator wherever it may leak.

The wearers of negative pressure respirators use the power of their own breathing to draw air into the respirator. The physical exertion required of the wearer is greater for negative pressure respirators. Airborne contaminants may be able to infiltrate the respirator and reach the wearer via leaks in the respirator sealing surface due to inward air flow because the respirator will be under negative pressure each time the wearer inhales.

Respirator styles

There are four basic respirator "styles" and they include filtering face piece respirators, half-face respirators, full-face respirators, and loose fitting hoods.

Filtering face piece respirators

Filtering face piece respirators are typically constructed almost entirely of the actual filter media with support material that allows the respirator to cover the nose, mouth, and chin, and is attached around the wearer's head using elastic straps. The outer edge of the respirator's sealing surface may have additional material (e.g. foam rubber) to improve the seal and a bendable, metal reinforcing strip may be installed over the bridge of the nose to improve the fit and seal of the respirator over the nose. They are commonly, but inappropriately, referred to as "dust masks" in retail building supply stores. Some specialized filtering face piece respirators come equipped with face shields for splash protection. All filtering face piece respirators are negative pressure respirators.

Half face respirators

Half face respirators are made from rubber, silicon, or other flexible, elastomeric material that typically provide a tighter and improved face seal as compared to filtering face piece respirators. Half face respirators cover the wearer's mouth and nose and are attached around the wearer's head using elastic straps. Half face respirators are typically used as negative pressure respirators when they are equipped with filter cartridges. Half face respirators may also be used as positive pressure respirators when used in a supplied air system and/or used as a face piece option in a powered air purifying respirator.

Full face respirator

Full face respirators are made from rubber, silicon, or other flexible, elastomeric material that typically provides a tighter and improved face seal as compared to filtering face piece and half face respirators. Full face respirators cover the wearer's entire face (mouth, nose, and eyes), have a clear shield to provide vision and eye protection, and are attached around the wearer's head using elastic straps. Full face respirators are typically used as negative pressure respirators when they are equipped with filter cartridges, but may also be used as a face piece option for positive pressure respirators when used in a supplied air system and or used as a face piece option for a powered air purifying respirator.

Loose fitting hood

Loose fitting hoods are simply that, a loose fitting hood that is put on over the head, may or may not have a supporting interior head band, and has a clear viewing shield. They are only available for use in combination with a supplied air system or as part of a powered air purifying respirator, and as such, loose fitting hoods are always under positive pressure.

Air purifying respirators

Air purifying respirators "clean," or "purify" the air source by using filter cartridges. Dust, solid particulate matter, and liquid aerosols (mists) are captured and removed from the breathing air by mechanical filters. Chemical vapors and gases are removed by filters made from absorbent filter media that is used to capture specific contaminants (e.g. mercury), or broad classes of, vapors and gases. For example, filters that contain activated charcoal are used to capture and remove organic vapors from the air stream. Filters are rated and tested against a variety of chemical compounds and those compounds are listed by the manufacturer. Filters also have a useful life span that varies with use, filter loading, and the chemical compound. Most filters are now equipped with an "End of Life" indicator that informs the wearer when the filter is no longer effective and needs to be changed. However, there are not End of Life indicators for all filter cartridges or for all chemical compounds and it becomes incumbent on the pharmacy and their safety department to make its' best estimate regarding filter change out policies. Air purifying respirators are used in both negative and positive pressure respirators.

Powered air purifying respirators

Powered air purifying respirators (PAPRs) are unique in that they maintain positive pressure and deliver filtered air for the wearer. PAPRs provide filtered air to the wearer using a battery-powered motor and fan. The motor and fan are intended to maintain positive pressure within the respirator through a constant flow of air. PAPRs are available for use with a half face, full face, or loose-fitting hood attachment. The fan and motor are typically attached to the wearer using a belt, however, the motor and fan may be affixed directly to full-face piece in some models.

In terms of functional PAPR operation, breathing air is drawn by negative pressure through the filter, passes motor and fan where the air becomes positively pressurized, and is directed to the face piece via a tube.

Supplied air respirators

Supplied air respirators bring air from some other source to the wearer. The respirator source air may be purified at an air compressor where is it either distributed to the wearer(s) via a panel or used to fill air tanks for storage purposes that is utilized later by the wearer. Supplied air respirator systems are complicated, require significant training to use and maintain, and are expensive to own and operate.

Solids and liquid aerosols

Exposure by inhalation to solid and liquid forms of hazardous drugs requires that the drug particles or droplets be small enough to be inhaled (approximately </= 50 microns). Inside and outside of pharmacy, potential aerosolization is expected to occur during activities that include handling or weighing bulk powders, tablet crushing, liquid transfers, mixing (e.g. topical creams and food), accidental spills, ~~and etc~~. Aerosolization requires a physical action that plays upon the drug. Potential exposure to solid aerosol exposure from solid crushing can be mitigated by using a closed crushing device, however, it is important to recognize that the transfer or pouring of the crushed drug can become aerosolized and contaminate hands, clothing, and surfaces.

Filtration

Air filtering respirators are typically used to prevent exposure to aerosols and N95 rated filters are the most commonly used in industry. N95 and P95 filters can remove small particulate from atmospheric breathing air at an efficiency of 95%. The N designation refers to respirators that are not resistant to oil and the P designation refers to filters that are resistant to oil. N95 filter cartridges are available for tight-fitting elastomeric half-, full-, and powered air purifying respirators, as well as filtering facepiece and surgical face masks. Higher efficiency filter cartridges such as HEPA-filters (High Efficiency Particulate Air) are available and are classified as either N100 or P100, however, they are not available as filtering face piece respirators or surgical masks at this time. N100/P100/HEPA filters are capable of removing particulate matter from breathing air at an efficiency of 99.97%.

Standard mechanical air filter media is designed to remove aerosols and particulate but is not capable of removing vapor or gases unless the media is specifically treated to do so.

Respirator selection

The inhalation hazards presented to pharmacists, pharmacy technicians, and other staff from hazardous drugs is likely limited to the following scenarios:

- Spilled drug in packages at Receiving/Processing
- Spilled drug in the BSC
- Spilled drug outside the BSC

Selecting respiratory protection for non-volatile hazardous drug solid and liquid aerosols is straightforward. Properly fitted half-face and full face negative pressure air purifying respirators equipped with N95/P95 or N100/P100 filter cartridges are acceptable for the cleanup of spilled solids and liquids, as are fitted N95 filtering face piece respirators and N95 surgical masks. They do not, however, provide protection from hazardous drug vapor.

Selecting respiratory protection for the cleanup of volatile hazardous drugs is more challenging because there is no data available that shows that the filter cartridges typically used for organic vapors are effective for these drugs.

Powered air purifying respirator

Powered air purifying respirators (PAPRs) equipped with combination HEPA/organic vapor cartridges and a loose fitting hood are preferred for use in pharmacy for cleaning up hazardous drug spills inside and outside of biological safety cabinets. PAPRs have several advantages over negative pressure air purifying respirators and they include the following:

- Source air does not originate in the breathing zone (face). The motor/fan and filter unit is belted to the waist and situated on the small of the back or hip. Cleaning and wiping up spilled drug using hands means that the face and breathing zone are close to the drug. Air provided by a PAPR is further away

and not in the breathing zone.

- Positive pressure is maintained within the hood. Air is forced outward from the hood and that prevents the infiltration of aerosols and vapor. Infiltration can occur in negative pressure respirators that have leaks around the face seal because they are under negative pressure when the wearer inhales.

- Loose fitting hoods designed to fit all head sizes. Negative pressure respirators come in a variety of sizes and can accommodate most, but not all, people.

- Loose fitting hoods provide splash protection whereas filtering face piece and half face respirators do not.

- Training on the use of PAPRs is generally simpler because of its ease of use as compared to negative pressure respirators. Hospital-affiliated pharmacies benefit by the hospital having a PAPR program in place that they use for TB patients, and other patients placed in respiratory precautions.

- Fit testing is not required for PAPRs with loose fitting hoods.

PAPRs have the following advantages over supplied air respirators:

- Less expensive, easier to use, and require less expertise to operate and maintain.

- More portable and convenient to use.

Combination HEPA/organic vapor filter cartridges are recommended for use in PAPRs used for cleaning up hazardous drugs for the following reasons:

- The combination filter cartridge allows the wearer to clean up spills of both non-volatile and volatile hazardous drugs.

- The organic vapor component, while not proven, is expected to limit potential exposure to volatile hazardous drugs to some degree.

- The location of the motor/filter unit on the hip or small of the back typically provides cleaner air because it is further away from the spilled hazardous drug.

5
RECEIVING AND STORAGE

Intro

Hazardous and non-hazardous drugs are typically delivered at the receiving dock and may be unpacked at the dock location or transferred for unpacking at the pharmacy. Hazardous and non-hazardous drug deliveries may, or may not, arrive segregated from one another, and mixed shipments are common.

Inspection & acceptance

Visual inspection of the outer packaging and segregation of the hazardous drugs from the non-hazardous drugs is best performed by trained pharmacy personnel at the receiving dock. It is recommended that pharmacy be notified as drug shipments arrive in order minimize the opportunity for contact and handling of the drug packages by unauthorized or untrained personnel.

It is recommended that personnel engaged in receiving and sorting wear one pair of chemotherapy gloves when unloading, processing, and inspecting hazardous drug deliveries. Chemotherapy gloves are recommended because chemotherapy agents can be shipped mistakenly with other drug orders and it can't be known until inspection if a chemotherapy drug container has leaked. Leaking or stained packages should be immediately rejected, placed in a plastic, leak proof bin or tub, and isolated. The shipper should be informed that the rejected package contains hazardous drugs and will be held, sorted, and the leaking container and waste disposed of by the receiver. The damaged package and any leaked or spilled solid, powder, or liquid product at the receiving dock should be isolated, removed, and cleaned in accordance with the spill cleanup policy and procedure. It is a best practice to segregate hazardous drugs within a HEPA-filtered negative pressure hood or negative pressure room for the purpose of isolating the area in the event of a spill or release.

Undamaged, segregated hazardous drug packages should be delivered to pharmacy on a designated hazardous drug cart or container for unpacking in a dedicated hazardous drug processing area.

Unpacking

Packaging, wrapping, stuffing, and cartons have the potential of being contaminated with hazardous drugs from residual contamination on the drug vials and containers by either the manufacturer or distributor. There may also be breakage of vials and containers during transport that have contaminated the interior package. For these reasons, it is safer to assume that the materials and product inside the shipping package are contaminated and pharmacy processing hazardous drug packages should wear chemotherapy gloves.

Hazardous drugs should be unpacked/processed at a dedicated work table. The table should be covered

with, and packages placed on, a disposable, plastic-backed, absorbent pad that will absorb contamination from the outer cardboard packaging, the package exteriors and leaking vials or containers.

Packages with broken, spilled, or leaking vials or containers should be isolated, removed, and cleaned in accordance with spill cleanup policy and procedures. Undamaged packages and contents should be unpacked and appropriately stored. Hazardous drug containers and vials can be pre-cleaned to remove potential contamination using disposable, microfiber wipes containing a surfactant (e.g. Wet-Ones™ - see IRSST reference) or water and a mild detergent, and placed in dedicated, leakproof storage bins. The wipes or wiping material should be disposed as drug contaminated waste. In the event that hazardous drug containers and vials are not cleaned at this stage, they should be placed in dedicated, leakproof storage bins or bags and marked or flagged in such a way that indicates that they have not yet been cleaned (Note that some drug vials may arrive with a plastic covering. These coverings are typically added at the end of the manufacturing cycle and are intended to provide an uncontaminated surface for safe handling and prevent breakage. The covering does not have to be removed.). The bins should then be relocated using a dedicated safe cart (i.e. has raised sides to prevent falls and breakage) and stored in dedicated hazardous drug areas (e.g. cabinets, shelves, refrigerators, ~~etc.~~) in the pharmacy.

Storage

The hazardous drug storage area should be separate from the unpacking area. Counters and shelving should have guarded sides to prevent drug container falls and breakage. Storing hazardous drugs in plastic, leak-proof bins on counters and shelving is preferred for stability and containment of leaks or spills. Maintaining separation of hazardous drugs from non-hazardous drugs is important to prevent cross-contamination ~~and~~ segregated and designated hazardous drug refrigerators and freezers are preferred~~,~~ however, hazardous and non-hazardous drugs can be stored within the same refrigerator and freezer provided they are on different shelves.

For Cytotoxic Chemotherapy High Exposure Risk, High Hazard High Exposure Risk, and High Exposure Risk drugs, the hazardous drug storage room or area should be under negative pressure and the ventilation system should provide both general exhaust ventilation and at least 12 air changes per hour to dilute and remove potential hazardous drug vapors/contamination.

6

SPILL CLEANUP

Exposure to spilled hazardous drugs by pharmacists, pharmacy technicians, and other staff ~~from hazardous drugs~~ is likely limited to the following scenarios:

- Spilled drug in packages at Receiving/Processing
- Spilled drug outside the BSC
- Spilled drug in the BSC

The cleanup of spilled hazardous drug requires the use of PPE and respiratory protection, the isolation of the drug and immediate area, the cleanup of the spilled drug, and the disposal of the cleanup and waste materials.

All drugs, hazardous or not, and drug forms can be spilled, and spills can happen anytime they are handled, transferred, manipulated, or stored. The degree and type of PPE and respiratory protection necessary to safely cleanup hazardous drugs varies with regard to the drug's exposure risk and the size and location of the spill. Exposure risk, as presented in the algorithm is based on hazard (e.g. cytotoxicity, carcinogenicity, teratogenicity, reproductive, organ toxicity, genotoxicity, and mimicry), and formulation (e.g. liquid, powder, uncoated tablet, capsule, ~~etc.~~) and potential exposure. For example, the cleanup of cytotoxic chemotherapy high exposure risk drugs requires the use of more extensive PPE and respiratory protection than cleanup of low exposure risk drugs.

In terms of size, small liquid spills of moderate and low exposure risk drugs (i.e. </= 30 ml inside the BSC and </= 5 ml outside the BSC), will require less PPE and respiratory protection than large spills (> 30 ml inside the BSC and > 5 ml outside the BSC). In terms of formulation, the PPE and respiratory protection necessary for coated tablet and capsule spills will be less than that needed for bulk powders.

It is important emphasize that all staff need to be aware of how to manage a hazardous drug spill and to understand that only those staff members that are trained in spill response and cleanup are allowed to proceed with the cleanup. It is important for staff to recognize that there can be significant risk involved during the cleanup of even small spills of cytotoxic chemotherapy agents. Staff should not conduct cleanup beyond their level of training no matter how seemingly insignificant a spill may appear. Improper cleanup can cause more contamination and potential for exposure than the original spill.

PPE and respiratory protection

The cleanup of spilled hazardous drug involves direct contact with undiluted or diluted drug with potential exposure via inhalation, skin and mucous membrane contact, and ingestion. The following PPE and respiratory protection represents best practice for hazardous drug cleanup given the broad spectrum of drug agents, the amount of drug spilled, and the number potential cleanup environments.

PPE

Cytotoxic chemotherapy high exposure risk drugs – parenteral, splash risk, inhalant, or manipulated oral

- Double pair chemotherapy gloves
- Chemotherapy gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (in BSC or sterile areas only)
- PAPR equipped with combination HEPA/acid gas/organic vapor cartridges and loose fitting hood

High hazard high exposure risk – BCG, ribavirin, etc.

- Double pair medical gloves
- Gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (in BSC or sterile areas only)
- PAPR equipped with combination HEPA/acid gas/organic vapor cartridges and loose fitting hood

High exposure risk – Intravenous and other high splash risk liquids, bulk powders, and inhalants

- Double pair medical gloves
- Gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (in BSC or sterile areas only)
- PAPR equipped with combination HEPA/acid gas/organic vapor cartridges and loose fitting hood

Moderate exposure risk – oral liquids and IM, SQ, intrathecal (low splash risk)

- Single pair medical gloves
- Gown

- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (sterile areas only)

Moderate risk cytotoxic chemotherapy – Uncoated tablet, or contained manipulation, and liquid transfer

- Single pair chemotherapy gloves
- Chemotherapy gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (sterile areas only)
- Large spill requires - PAPR equipped with combination HEPA/acid gas/organic vapor cartridges and loose fitting hood

Low exposure risk – topical and oral solids that are manipulated

- Single pair medical gloves
- Gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (in BSC or sterile areas only)

Low risk cytotoxic chemotherapy – capsule and coated tablet

- Single pair chemotherapy gloves
- Chemotherapy gown
- Dedicated shoes & shoe covers (prevent contamination and tracking/spread of contamination)
- Hair cover (in BSC or sterile areas only)

Existing precautions

- Single pair medical gloves

Spilled Drug at Receiving/Processing

Spilled or leaking drugs are most likely to be discovered when the shipment arrives because the outer package is stained, discolored, or leaking, or during unpacking the shipping container. Recall that receiving and sorting personnel wear one pair of chemotherapy gloves when handling hazardous drug packages (See Chapter 5, Receiving and Storage).

Leaking or stained packages
Leaking or stained packages should be immediately rejected, isolated, and marked (e.g. warning cones or tape). Leaking, stained or broken packages discovered inside the shipping container should be left inside the shipping container and the container similarly staged and isolated.

Don appropriate PPE and respiratory protection, place package in plastic leak proof bin/tub/overpack container or on absorbent pad(s) as necessary (to contain leaking drug), and inspect package exterior. Place the package in an appropriate waste container or waste bag for return to shipper or disposal when the exterior shows signs of staining or liquid breakthrough, and assume package contents are contaminated. If the package is returned to the shipper, inform the driver and shipping company by phone and in writing that the package contains spilled hazardous drug and that the package is contaminated. Clean the area (described below) and return area to service. Place all spilled hazardous drug, cleanup materials, and used, disposable PPE in an appropriate waste container or waste bag for disposal.

Broken containers or spilled drug in shipping package
Secure and isolate the package as described above and inspect package interior and contents when spilled drug or broken containers are observed during unpacking and storage. Assume contents are contaminated until proven otherwise. Put on appropriate PPE and respiratory protection prior to inspecting package contents.

If readily accessible, remove the broken or damaged container(s) from the package and place on absorbent pad or in an appropriate waste container or waste bag for return to shipper or disposal. Assume packing material (e.g. foam, bubble wrap, plastic peanuts, ~~etc.~~) is contaminated and place in an appropriate waste container or waste bag for disposal. Remove and segregate drug packages on absorbent pad from the container for inspection and cleaning. Place shipping container in an appropriate waste container or waste bag for disposal.

Visually inspect hazardous drug containers for signs of obvious contamination and place in an appropriate waste container or waste bag for disposal. Clean and wipe visibly non-contaminated drug containers with disposable wipes (~~i.e.~~ Wet-Ones) to remove exterior contamination and segregate on an absorbent pad. Remove and replace gloves with a single pair of chemotherapy outer gloves. Remove drug container from secondary packaging, if any, and place in appropriate storage bin or container for use.

Place all spilled hazardous drug, cleanup materials, and used, disposable PPE in an appropriate hazardous drug waste container or waste bag for disposal.

Spilled drug outside the BSC

The procedures for cleaning up spilled drug in areas outside a BSC are similar to those described for shipping and receiving, however, the difference is that the spills are generally more "out in the open" as compared to being inside a shipping package. Hazardous drug spill kits are typically used to clean spilled drugs in open, uncontrolled environments.

Hazardous drug spill kits
Hazardous drug spill kits are available commercially and can also be assembled individually. Hazardous drug spill kits should be readily available wherever hazardous drugs are handled. Hazardous drug spill kits

typically contain the following components:

- Respiratory protection (not typically provided in a commercial kit)
- PPE (gown, shoe covers, gloves, hair cover, faceshield/safety glasses)
- Warning pop-up signs
- Absorbent pads/towels
- Solidifying/congealing absorbent pads
- Solidifier
- Waste bags/containers
- Disposable scoop and scraper
- Cleaning wipes

Kits may also include:

- A hazardous drug warning signs or cones
- Absorbent pads/towels to cover and remove drug from surfaces (i.e. simple towels or pads that contain a solidifier that congeals in the presence of liquid or water. Congealing products are preferred for hard surfaces and application for both solid and liquid spills)
- Solidifying powder
- Waste bags and containers
- Disposable scoops and scrapers

Best Practice Safety Tools recommends disposable cleaning wipes containing a surfactant (e.g. Wet Ones) for final cleaning purposes once the bulk drug has been removed from the surface, and a loose-fitting PAPR equipped with combination organic vapor, acid gas, and HEPA/N or P100 filters for respiratory protection, and a gown (or chemotherapy gown as appropriate), 2 pairs of gloves (or chemotherapy gloves as appropriate), and polyethylene coated shoe covers for PPE when cleaning up large quantity hazardous drug spills outside a biological safety cabinet.

Large quantity spilled drug

No matter the size of a hazardous drug spill, it is important to stay calm and proceed carefully and methodically. A large quantity liquid spill is considered to be >5 ml outside the BSC and >30 ml inside the BSC.

A large quantity solid spill is >5 tablets ~~and~~ capsules with visible residue present, and >5 mg of bulk powder, for the purpose of this ~~*Best Safety Practice Tool*~~. The absence of visible residue from a tablet or capsule spill defaults to a small spill.

Liquids

Spilled hazardous drugs and leaking or broken containers should first be isolated. The person attending the spill should direct people away and out of the immediate area so that they do not expand the footprint of the spill. If absorbent pads are immediately available, the spill should be covered directly and at the spill perimeter to prevent the spill from spreading. Next, the attendant should direct someone to bring the spill kit (if not immediately available) and/or notify the spill team members. Upon arrival of the kit or team, the warning cones or tape should be placed at all potential access points to the spill to keep unauthorized personnel away.

The spilled material should be covered with an absorbent pad (if it ~~hasn't~~ already been covered) and additional pads placed at the perimeter of the spill to prevent the spill from spreading. The individuals that intend to follow through with the clean up should locate themselves in a clean area away from the immediate spill area don their PPE and respiratory protection accordingly:

1. Wash hands
2. Inner gloves
3. ~~Foot~~ covers
4. PAPR belt and motor/filter unit (Do not don the hood)
5. Gown (sleeves should cover inner gloves and be over the PAPR belt and motor/filter unit)
6. Outer gloves
7. PAPR hood (and turn on)

Prepare the waste bag(s) by rolling down the sides outwardly in order to make it easier to deposit waste materials inside and/or open/remove the lid from the waste container. Prepare separate waste and disposable PPE waste bags/containers. Approach the spill carefully in order to avoid contact and maintain balance. Use the disposable scoop(s) and scraper(s) to remove and lift the pads, drug, and drug container into the waste bag or waste container. Take care to remove any and all glass fragments from the surface in order to prevent damaging the gloves or cutting the fingers or hands during final cleaning.

Wipe the spill area three times using individual disposable wipes for each cleaning and place in waste bag or container. Roll up waste bag and seal with zip tie or internal drawstring/closure mechanism.

Remove outer glove and place in PPE waste bag/container. Remove gown and shoe covers and place in waste bag/container. Remove inner gloves and respirator. Wash hands and face thoroughly and repeatedly with soap and water.

Solids

Spilled hazardous drugs and leaking/broken containers should first be isolated. The person attending the spill should direct people away and out of the immediate area so that they do not expand the footprint of the spill. If absorbent pads are immediately available, the spill should be covered directly and at the spill perimeter to prevent the spill from spreading. Next, the attendant should direct someone to bring the spill kit (if not immediately available) and/or notify the spill team members. Upon arrival of the kit or team, the warning cones or tape should be placed at all potential access points to the spill to keep unauthorized personnel away.

The spilled material should be covered with an absorbent pad (if it hasn't already been covered) and additional pads placed at the perimeter of the spill to prevent the spill from spreading. The individuals that intend to follow through with the clean up should locate themselves in a clean area away from the immediate spill area don their PPE and respiratory protection accordingly:

1. Wash hands
2. Inner gloves
3. ~~Foot~~ covers
4. PAPR belt and motor/filter unit (Do not don the hood)
5. Gown (sleeves should cover inner gloves and be over the PAPR belt and motor/filter unit
6. Outer gloves
7. PAPR hood (and turn on)

Prepare the waste bag(s) by rolling down the sides outwardly in order to make it easier to deposit waste materials inside and/or open/remove the lid from the waste container. Prepare separate waste and disposable PPE waste bags/containers. Approach the spill carefully in order to avoid contact and maintain balance.

For solidifying/congealing absorbent pads, apply water to absorbent pad and allow pad to break down and congeal over the spilled solid. For non-solidifying/congealing pads, lift pad off of spilled solid and gently sprinkle and completely cover spilled drug with solidifying granules. Cover granules and drug with non-plastic-backed, absorbent pad and apply water to the pad. Soak/saturate the pad and solidifier and wait ~3 to 5 minutes for the solidifier to congeal with the drug.

Use the disposable scoop(s) and scraper(s) to remove and lift the pads, drug, and drug container into the waste bag or waste container. Take care to remove any and all glass fragments from the surface in order to prevent damaging the gloves or cutting the fingers or hands during final cleaning. Wipe the spill area three times using individual disposable wipes for each cleaning and place in waste bag or container. Roll up waste bag and seal with zip tie or internal drawstring/closure mechanism.

Remove outer glove and place in PPE waste bag/container. Remove gown and shoe covers and place in waste bag/container. Remove inner gloves and respirator. Wash hands and face thoroughly and repeatedly with soap and water.

Small quantity spilled drug

A small quantity liquid spill is considered to be </=5 ml outside the BSC and </= 30 ml inside the BSC. A small quantity solid spill is </= 5 tablets ~~and~~ capsules with no visible residue present, and </= 5 mg of bulk powder, for the purpose of this Best Practice Tool. Small quantity spilled drugs should be cleaned up using the same techniques as described above, however, less PPE is necessary due to the size of the spill and the limited ~~time it~~ is expected to clean up the spill. A single pair of chemotherapy or medical gloves and gown, as appropriate is all that is needed to be worn for PPE for most small spills. The exception to this is the use of a single pair of medical gloves when existing precautions warranted.

Spilled drug in the BSC

Hazardous drugs spilled in a BSC present different challenges to those spilled outside a BSC. The BSC is a controlled environment and the immediate risk of a spill is minimized because the BSC is under negative pressure and the drug cannot exit the BSC. It is likely that for this reason that the ASHP Guidelines recommend using a spill kit if the volume of the spill exceeds 30 ml or the contents of one drug vial or ~~ampul~~. However, cleaning large and small spills may require the pharmacist or technician to open the sash that, in turn, reduces negative pressure in the BSC, and to reach inside the hood, and possibly break the plane of the ~~hood~~ with the head. Both of these conditions can increase the risk of exposure.

The PPE used for sterile prep at the BSC doesn't change, however, respiratory protection (PAPR equipped with combination HEPA/organic vapor cartridges and loose fitting hood) is necessary whenever the sash is raised and when the pharmacist or technician's head may break the plane of the sash during clean up. The cleanup procedures are similar to spilled drug cleanup conducted outside the BSC.

Liquids

Cover large and small liquid spills with non-solidifying/non-congealing absorbent pad if the spill has extended beyond the bottom pad where the drug is compounded. Dispose of the absorbent pad(s) in an appropriate waste container or waste bag and repeat application of absorbent pads until all liquid is removed. Wipe the clean up area and materials/containers/instruments/etc. with a disposable wipe containing a surfactant (e.g. Wet Ones) and discard wipe in waste container or waste bag. Repeat wiping two additional times for a total of three cleanings. Place all spilled hazardous drug, cleanup materials, and used, disposable PPE in an appropriate waste container or waste bag for disposal. Discard PPE used for cleanup and don new change of PPE for BSC disinfection. Perform hood disinfection in accordance with USP 797 and pharmacy policy and return BSC to service.

Solids

Use disposable wipes containing a surfactant (e.g. Wet Ones) to remove all bulk drug from surfaces and place in appropriate waste container or waste bag. Wipe up cleaned surfaces and materials/containers/instruments/etc. with additional disposable wipe and dispose of wipe in waste container or waste bag. ~~Repeat wiping two additional times for a total of three cleanings and return area to service.~~ Repeat wiping two additional times for a total of three cleanings. Place all spilled hazardous drug, cleanup materials, and used, disposable PPE in an appropriate waste container or waste bag for disposal. Discard PPE used for cleanup and don new change of PPE for BSC disinfection. Perform hood disinfection in accordance with USP 797 and pharmacy policy and return BSC to service.

Carpet and upholstery spills

Hard surface flooring materials such as vinyl tile and sheeting, and rolled flooring are typical of pharmacy floor finishes because they do not generate dust and particulate matter, and cleaning spills off of solid surfaces is much easier than cleaning spills from fleecy surfaces such as carpet. The same holds true for pharmacy furniture and solid surface (e.g. plastic/vinyl covered) furniture is typically used for the same reason.

However, hazardous drugs spills can occur outside the pharmacy during transport in carpeted and furnished corridors and waiting areas, for example, and cleanup of spills on carpet, upholstered furniture, and fleecy surfaces (e.g. room dividers) presents different challenges.

Carpet cleanup

It is extremely difficult to completely remove spilled solid or liquid hazardous drug from fleecy surfaces. Removing the affected carpet is the only way to be sure that no drug residue or contamination remains.

Carpet removal

Isolate the spill area and the person attending the spill should direct people away and out of the immediate area so that they do not expand the footprint of the spill. If absorbent pads are immediately available, the spill should be covered directly and at the spill perimeter to prevent the spill from spreading. Next, the attendant should direct someone to bring the spill kit (if not immediately available) and/or notify the spill team members. Upon arrival of the kit or team, the warning cones or tape should be placed at all potential access points to the spill to keep unauthorized personnel away.

The spilled material, solid or liquid, should be covered with a non-congealing/solidifying absorbent pad (if it hasn't already been covered) and additional pads placed at the perimeter of the spill to prevent a liquid spill from spreading. The individuals that intend to follow through with the clean up should locate themselves in a clean area away from the immediate spill area don their PPE and respiratory protection accordingly:

1. Wash hands
2. Inner gloves
3. ~~Foot~~ covers
4. PAPR belt and motor/filter unit (Do not don the hood)
5. Gown (sleeves should cover inner gloves and be over the PAPR belt and motor/filter unit)
6. Outer gloves
7. PAPR hood (and turn on)

Prepare the waste bag(s) by rolling down the sides outwardly in order to make it easier to deposit waste materials inside and/or open/remove the lid from the waste container. Prepare separate waste and disposable PPE waste bags/containers. Approach the spill carefully in order to avoid contact and maintain balance.

Apply tape over the absorbent pad edges and seal to the carpet to prevent aerosolization of the spilled material. Outline and cut through the carpet ~3" or more ~~out~~ from the taped perimeter using a razor knife. Use a metal scraper to help peel back the carpet from the floor surface below and lift and place the carpet section, pad, and drug into the waste bag.

If spilled solid or liquid drug is observed on the solid floor underneath the removed carpet section, place ~~an absorbent pad~~ over the drug ~~and~~ apply water ~~to~~ and allow it to break down and congeal. If solidifying/congealing pads are not available, gently sprinkle and completely cover spilled drug with solidifying granules. Cover granules and drug with non-plastic backed, absorbent pad and apply water to the pad. Soak/saturate the pad and solidifier and wait ~3 to 5 minutes for the solidifier to congeal with the drug.

Use the disposable scoop(s) and scraper(s) to remove and lift the pads, drug, and drug container into the waste bag or waste container. Take care to remove any and all glass fragments from the surface in order to prevent damaging the gloves or cutting the fingers or hands during final cleaning. Wipe the spill area three times using individual disposable wipes for each cleaning and place in waste bag or container. Roll up waste bag and seal with zip tie or internal drawstring/closure mechanism.

Remove outer glove and place in PPE waste bag/container. Remove gown and shoe covers and place in waste bag/container. Remove inner gloves and respirator. Wash hands and face thoroughly and repeatedly with soap and water.

Carpet and upholstery cleaning

It is assumed that the purpose of cleaning hazardous drug from carpet and upholstered furniture is to re-use them. A dedicated, HEPA-filtered vacuum cleaner is required for this purpose for both solid and liquid drug.

Isolate and secure the spill area as described above but cover the spill with a non-congealing/solidifying absorbent pad. The individuals that intend to follow through with the clean up should locate themselves in a clean area away from the immediate spill area don their PPE and respiratory protection accordingly:

1. Wash hands
2. Inner gloves
3. ~~Foot~~ covers
4. PAPR belt and motor/filter unit (Do not don the hood)
5. Gown (sleeves should cover inner gloves and be over the PAPR belt and motor/filter unit)
6. Outer gloves
7. PAPR hood (and turn on)

Prepare the waste bag~~(s)~~ by rolling down the sides outwardly in order to make it easier to deposit waste materials inside and/or open/remove the lid from the waste container. Prepare separate waste and

disposable PPE waste bags/containers. Approach the spill carefully in order to avoid contact and maintain balance.

For solid spills, HEPA-vacuum the carpet gently to remove the solid drug from the surface and prevent spreading the drug due to recoil from the carpet or furniture. Continue and repeat vacuuming until no more visible solid is present, or no more visible solid can be removed. Seal the HEPA-vacuum opening with a piece of duct tape with the vacuum running, immediately shut off the vacuum once the opening is sealed, and wipe the surface of the vacuum with a disposable wipe (e.g. Wet Ones) and discard the wipe in a waste bag.

Wipe the carpet surface with an alkaline detergent (pH 8 to 9) and sponge, repeat wiping two additional times, and dry carpet by repeatedly applying non-congealing/solidifying absorbent pads until dry. Allow the carpet to air dry for an additional 20 to 30 minutes, conduct a final HEPA-vacuuming, and return the area to service.

For liquid spills, repeatedly apply non-congealing/solidifying pads until the drug has been sufficiently removed. Wipe the surface with an alkaline detergent (pH 8 to 9) and sponge, repeat wiping two additional times, and dry carpet by repeatedly applying non-congealing/solidifying absorbent pads until dry. Allow the surface to air dry for an additional 20 to 30 minutes, conduct a final HEPA-vacuuming, and return to service.

Accidental personal exposure and cleanup

Accidental exposure to hazardous drugs can occur ~~at~~ almost any time hazardous drugs are handled. Leaking packages, broken vials, leaking IV bags, syringe malfunctions, and other accidents can occur. This can result in hazardous drugs making contact with clothing, skin, ~~and~~ eyes, ~~and~~ being injected through intact skin via needle sticks or broken glass. It is important to seek medical attention following an accidental personal exposure.

Clothing, linen and skin contact

It is important to immediately remove contaminated clothing after it has become in contact with a hazardous drug. The clothing can be placed in a plastic waste bag for disposal or for temporary holding pending laundering. Wash the affected skin area with soap and water and repeat washing as many as three times in order to be confident that the drug has been removed. If the contact area is large or in an awkward area (e.g. back, waist, head, ~~etc.~~) taking a series of showers may be necessary.

Keep the wash sink or shower off limits to others while waiting for it dry, and once it is dry, don a single pair of chemotherapy gloves and completely wipe with disposable wipes (e.g. Wet Ones). Place the used wipes and gloves in a plastic waste bag or container, seal, and discard appropriately. Return the sink or shower to service following wiping.

Contaminated clothing and linen can be laundered and re-used if desired. It is important to notify the laundry that the clothing submitted is contaminated with hazardous drugs and what form the drug is in (i.e. liquid or solid) so ~~that~~ they can take precautions and choose appropriate PPE. Gowns and a single pair of gloves are appropriate for liquid-contaminated clothing. Gowns, gloves, and a properly fitted particle-filtering respirator (e.g. filtering face piece N/P95 respirator, half-face N/P95 air purifying respiratory, or PAPR equipped with N/P95 filter cartridges) are appropriate for solid-contaminated clothing. The washing machine should be run a second time without a load for rinsing purposes following the initial cleaning.

Eye contact

It is important to immediately begin flushing a person's eyes when they come into contact with hazardous drugs. An emergency eyewash station that can provide warm potable water is preferable to a portable station in that warm water is easier on the person whereas flushing with cold water can be an awful experience. It is also important to remove contact lenses, if worn. Contact lenses do not offer protection and can increase exposure if the drug is trapped between the lenses and eyes, or is adhered to the lenses ~~and exposure time is increased as a result.~~ Contaminated contact lenses should be discarded because there is no known or validated way to clean and remove hazardous drugs from them. Please note that it ~~is~~ difficult for the person to keep their eyes open during flushing and assistance from another person may be needed to hold the eyes open ~~and~~ the assistant should wear a pair of chemotherapy gloves. The eyes should be flushed for at least 15 minutes.

The affected person should wash their face and hands with soap and water following flushing. The person assisting should also wash their hands following flushing. Keep the eye wash sink/eye wash area off limits to others while waiting for it dry, and once it is dry, don a single pair of chemotherapy gloves and completely wipe with disposable wipes (e.g. Wet Ones). Place the used wipes and gloves in a plastic waste bag or container, seal, and discard appropriately. Return the eye wash sink/eye wash area to service following wiping.

Injection

Hazardous drugs can be injected through intact skin via needle sticks and broken glass (e.g. glass vial). In order to limit the absorption of drug, don a clean pair of chemotherapy gloves and massage in the direction of the wound to make it bleed. Be careful to avoid pinching the wound because it can cause suction and restricts the flow of blood. Remove and discard gloves in a plastic waste bag or container and proceed to wash the wound with soap and water. Repeat washing three times and cover the wound with a bandage.

Keep the wash sink off limits to others while waiting for it dry, and once it is dry, don a single pair of chemotherapy gloves and completely wipe with disposable wipes (e.g. Wet Ones). Place the used wipes and gloves in a plastic waste bag or container, seal, and discard appropriately. Return the wash sink to service following wiping.

Report all accidental exposures by injection to management.

7

CLOSED SYSTEM TRANSFER DEVICES

Closed system transfer devices (CSTDs), in the simplest terms, are mechanical devices that are used to prevent the release of a hazardous drug, and protect against its' contamination, when it is removed or added from one container to another container (e.g. vial to syringe to vial, vial to syringe to IV bag, ~~etc.~~). Similarly, CSTDs are used for the same purpose during the introduction of a diluent into a hazardous drug vial for ~~the~~ reconstitution.

CSTD technology continues to develop and evolve as manufacturers attempt to perfect a CSTD that is easy to use, protective, and cost effective. CSTDs in general, have been shown to reduce hazardous drug releases that occur ~~at~~ transfer with some CSTDs being more efficient and effective than others. Recent studies of some CSTDs have reported extraordinary results where contamination of the pharmacy and clinic was all but eliminated over a short period of time following their introduction and use. It is important, however, to recognize that all CSTDs have limitations, and understanding and adapting to their limitations will be critical to their success in reducing contamination. As such, it is recommended herein and by ASHP, USP 797, ISOPP, and NIOSH, that CSTDs always be used inside a BSC that provides an ISO Class 5 Environment.

Theory of operation

CSTDs are intended to establish a fully enclosed "system" where the changing internal pressure of vials, syringes, and receiving containers (e.g. IV bags) during drug withdrawal and reconstitution does not result in environmental releases and contamination.

Air exchange occurs when a liquid drug is withdrawn from a rigid vial using a syringe. The withdrawal of the liquid from a vial using a syringe causes the vial to become negatively pressurized and atmospheric air can be drawn into the vial via leaks in the seal and/or when the syringe is removed. Positive pressurization occurs in rigid glass vials when diluent is introduced during drug reconstitution. Drug can escape from the vial as the pressure inside the vial overcomes the seal. Drug can also escape a vial during transfer on the surface of the syringe needle, at the interfacing connection/mating/sealing surfaces (e.g. vial seal, Luer Lok connections, ~~etc.~~), and from rebound of the rubber seal when the syringe is withdrawn.

Connections

The connecting unit system between the vial and syringe, and syringe IV bag/administration port is a key component of all CSTDs. Needleless enclosed systems are variations on the male/female locking system (e.g. Luer Lok ~~&~~ Clave) where the syringe can interface with both the vial and and the IV bag interchangeably via elastomeric sealing surfaces. There are also ~~enclosing~~ systems for securing needles. Systems vary with

regard to the number and degree of their safety features that include: needle stick prevention, spill prevention, autolocking features when not engaged/attached, and critical sealing surface integrity. Challenges the connecting systems pose for users include drug residue on the connecting system mating/sealing surfaces, disinfection and cleaning of mating surfaces, and seal integrity.

There are systems that utilize a separate connecting/sealing device that is directly attached to the vial. Attaching these devices to the vial also simultaneously spikes the vial. The potential release of drug during the attachment and spiking of the vial has not been studied in the peer reviewed literature. This is an important reason why ~~CTSD systems~~ need to be used within a BSC.

Locking systems, like CSTDs, have limitations and it is important to evaluate strengths, limitations, and fit with regard to selecting the most appropriate system for each pharmacy and institution. Further development and improvement in locking systems and CSTDs is expected as market demand increases and the technologies improve.

Pressure relief

All CSTDs address both positive and negative pressurization differences that occur during drug transfer. The two most common approaches use either pressure equalization or venting systems.

Pressure equalization

Pressure equalization systems are intended to allow drug transfers without generating significant pressure changes between the source container and syringe, or syringe and receiving container that could result in the introduction of environmental contaminants to the drug or prep, and the release of drug into the environment. All pressure equalization systems are dependent on the locking mechanism connection seal. The equalization system will not work as intended if the seal fails.

The PhaSeal ~~system~~ diaphragm (PhaSeal Protector) is spiked into the vial using an attachment device and becomes permanently connected to the vial. The diaphragm fills when air or fluid is injected into the vial and contracts when the syringe is removed from the vial. Contamination of the attachment device is a concern for all ~~CTSD systems~~ and the obstruction of airflow in the BSC is a concern for this ~~system~~ specifically.

The Genie Vial Access ~~system~~ utilizes a sterile, internal balloon that is spiked by hand into the vial. The balloon fills with external environmental air when the vial becomes negatively pressurized during drug transfer. The air remains inside the balloon and does not make contact with the vial contents. Both the PhaSeal and Genie Vial Access equalization systems can be used with multi-dose vials.

The Equashield system uses dual needles and a sealed air chamber to equalize pressure between the vial and syringe. Similar to the above systems the vial is spiked by hand with an adapter. The syringe unit is attached to the adapter, and the sealing surface membrane on the vial adapter and the syringe unit make contact as the syringe is depressed. The dual needles then penetrate both membranes. One needle is connected to the drug transfer chamber and the other is connected to the sealed sterile air chamber behind the piston. As one needle withdraws drug the other supplies sterile air to the vial, thereby equalizing pressure. During reconstitution, diluent is added through syringe into the vial while the other needle extracts air from the vial that is stored in the back of the syringe to equalize pressure. The system can be used with multi-dose vials.

Each of the above example pressure equalization systems ~~is~~ fully enclosed.

Venting

Venting is another method used to equalize pressure in CSTD ~~systems.~~ The ~~vented~~ systems employ a vented vial adapter that is hand spiked into the vial. Air pressure between the syringe and vial is equalized by the introduction of environmental air via a filter during withdrawal when the system becomes negatively pressurized. The filter is also used to prevent the escape of drug when the vial becomes positively pressurized when a diluents is added during drug reconstitution, for example.

The mechanical filter media used typically has a pore size of 0.2 microns and is intended to capture aerosols. The mechanical filter is often paired with a charcoal impregnated membrane that is intended capture hazardous drug vapor. There are needle and needleless systems available and most can be used with both single- and multi-dose vials.

Alarmed manometers can warn staff of improper pressurization conditions.

Evaluation and selection considerations

CSTDs have been shown to reduce environmental contamination in pharmacy and clinical areas~~.~~ however, all devices have limitations. The evaluation and selection of CSTDs is ~~necessarily~~ pharmacy specific given the differences in types and volumes of hazardous drugs processed, the physical layout of the facility, and the patients served. Pharmacists should consider the ease of use, ergonomic factors, work flow and production impacts, additional training and labor costs, waste generation, and CSTD cost when evaluating CSTDs.

An economic argument has been put forth regarding an assertion that spiking vials with a ~~CTSD~~ can prolong the sterility of vial ~~that~~ can result in longer expiration dating which can lead to considerable cost savings. However, the evaluation of this claim is beyond the scope of ~~this Best Safety Practice Tools~~. Pharmacists are advised to consult the peer reviewed literature, USP 797, and the FDA with regard to evaluating this claim.

Pharmacists are urged to confer with peers that use or have trialed a device, consult with nursing regarding CSTD ~~system~~ compatibility with drug administration, research the peer reviewed literature about a specific CSTD, and review the FDA adverse events reports as devices are selected for trial. Consult with staff during and after the trial period for feedback on ease of use, complexity, productivity, and ergonomic issues. Tracking events such as spills ~~and~~ needlesticks, waste volume changes, ~~and~~ etc. during the trial period can be used for comparison with other CSTD ~~systems,~~ and current practices.

8

AUTOMATED DISPENSING SYSTEMS

Automated dispensing systems are ~~in common use in pharmacy for the purpose of~~ filling individual patient prescriptions and unit-dose orders, filling prescriptions in "remote" locations outside the main pharmacy (e.g. clinical unit), and for other purposes. Automated dispensing systems offer benefits that include improved inventory control, reduced labor costs, responsive delivery times, and tracking.

Background

Automated dispensing systems typically store drugs in bins, hoppers, drawers, or hooks , and the drugs are loaded by hand. The drugs may be loaded as bulk stock (e.g. coated or uncoated tablets, capsules, ~~etc.)~~, packaged (e.g. blister packaged or vial), or as administration ready (e.g. loaded syringe). Dispensing may withdraw drugs using a robotic arm that deposits the drug package into a receiving bin/hopper, fill a vial/bottle placed underneath a drug bin/hopper using gravity, deliver a drug bin/hopper to a receiving window via a conveyor, unlock a secured drawer, or by some other method.

Potential Hazardous Drug Contamination

The potential for hazardous drug contamination exists for automated dispensing systems as it does for human systems. The challenge for automated dispensing systems is recognizing and limiting contamination without the benefit of human interface and judgment in real time.

Contamination can take place during almost every phase of use. Bin loading, internal equipment failure (e.g. hopper fails to close), and transfer (unloading) to the receiving vial (e.g. misalignment between the bin/hopper and the receiving vial) can result in spills or contamination that may not be immediately recognized. Pharmacy technicians may not be able to recognize or diagnose a problem unit equipment maintenance and service, or routine cleaning is performed.

To this end, the technology is not sufficiently developed to be compatible with hazardous drugs. Best Practice Tools agrees with ASHP Guidelines on the Safe Use of Automated Dispensing Devices that hazardous drugs are not appropriate for Automated Dispensing Systems.

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