



THE UNIVERSITY OF KANSAS HEALTH SYSTEM

Sterile Compounding Aseptics and PPE Review

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Objectives

- Understand basic aseptics and proper PPE for Pharmacy during HD and non-HD compounding
- Apply the CDC's Hierarchy of Controls to USP 800 implementation
- Understand the proper PPE for nursing during HD administration
- Discuss additional considerations for PPE

Core Aseptics Review

Contamination control vs. Exposure

- We must protect our employees
- We must keep a clean and safe environment for compounding

Cornerstones of Contamination Control

- Hand hygiene and garbing
- Material handling
- Conduct in the cleanroom

Is garbing important?

- We are the biggest “particle generators”
- We shed about 9 pounds of dead skin cells each year
- Particles act as transport vehicles for microorganisms (bacteria)



How many bacteria do we carry?

- Each of us carries 3-5 pounds of bacteria
- Bacterial cells outnumber human cells 10 to 1
- Bacterial cells are much smaller than human cells so they only account for 1-2% of our body mass

Garbing don'ts

- No cosmetics or make-up
- No jewelry (earring studs okay)
- No artificial nails
- No fingernail polish or shellac



Why no make up?

Makeup/Cosmetics ^{1,2}	Particles/Application
Eye shadow	82,000,000
Typical mascara application	3,000,000,000
Total for typical makeup application	5,100,000,000

- Men are higher particle generators than women

Nails

- Natural fingernails must be clean and “neatly trimmed”
 - Majority of microbial growth is along proximal 1mm of nail adjacent to subungual skin which harbors high concentrations of bacteria.
 - In other words, there is a lot of bacteria under your fingernails!
 - Staphylococci, gram-negative rods, pseudomonas, diptheroids, and yeasts are a few common growths found here.



Personal Electronics

- No personal electronic devices
 - Over 2,000 organisms per phone



1

2



Why is hand hygiene important?

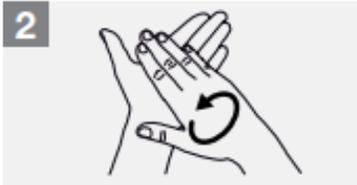
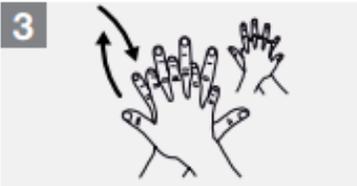
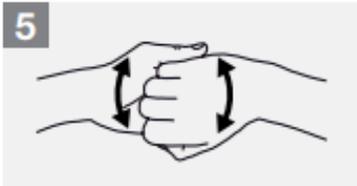
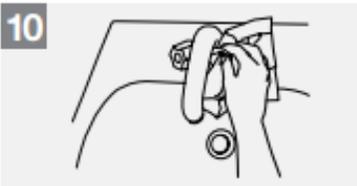
- There are anywhere between 10,000 and 10,000,000 microbes on each hand!
- Let's do the math:
 - If hand hygiene is performed with an agent and method that is 99.99% effective...
 - There will still be 100-100,000 left on your hands!
- **It only takes one to make a patient sick!**

SureWash!

- How do you teach employees how to wash their hands?
- World Health Organization has a guide
- <https://www.youtube.com/watch?v=8wITfKVwCIs>

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

 **Duration of the entire procedure: 40-60 seconds**

 <p>0</p>	 <p>1</p>	 <p>2</p>
<p>Wet hands with water;</p>	<p>Apply enough soap to cover all hand surfaces;</p>	<p>Rub hands palm to palm;</p>
 <p>3</p>	 <p>4</p>	 <p>5</p>
<p>Right palm over left dorsum with interlaced fingers and vice versa;</p>	<p>Palm to palm with fingers interlaced;</p>	<p>Backs of fingers to opposing palms with fingers interlocked;</p>
 <p>6</p>	 <p>7</p>	 <p>8</p>
<p>Rotational rubbing of left thumb clasped in right palm and vice versa;</p>	<p>Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;</p>	<p>Rinse hands with water;</p>
 <p>9</p>	 <p>10</p>	 <p>11</p>
<p>Dry hands thoroughly with a single use towel;</p>	<p>Use towel to turn off faucet;</p>	<p>Your hands are now safe.</p>

How to apply Purell

- 1 pump into palm
- Dip fingertips of 1 hand into product
- Bend other fingers into it
- Wipe hands together ensuring that all surfaces of fingers, palm, back of hand to wrist is coated
- Allow to dry before putting on sterile gloves



When should you not compound?

- There are some instances where you will have a higher rate of shedding and particle generation, thus increasing the possibility for contaminated Compounded Sterile Products (CSPs):
 - Severe skin rashes
 - Severe sunburn
 - Weeping sores
 - Conjunctivitis (“pink eye”)
 - Symptoms of respiratory infection



Preparation for Work

- Shower daily
- Keep skin moisturized to reduce flaking
 - Men's faces tend to shed more than women due to shaving and use of astringents during shaving
- Freshly laundered scrubs or clothing
- Use bathroom before entering controlled environment



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Garbing for Compounding

Donning and Doffing Procedures

ENTERING ANTEROOM – CONTROLLED ENVIRONMENT

Please follow these instructions to ensure a safe and clean environment is kept

Preparation to Enter

- Cosmetics, nail polish/false nails, and jewelry must be removed
- Tie up hair if necessary and remove outer garments

Clean Personal Glasses

- If wearing glasses, clean frame with germicidal detergent and lenses with lens cleaner

Prior to Entering Don Headcover

- Ensure all hair is securely captured under meathand that it is placed over ears - use mirror if necessary

Prior to Entering Don Beard Cover *(if needed)*

- Ensure beard is covered entirely including stubble
- If facial hair/full beard extends beyond reach of beard cover, full hood must be worn instead

Prior to Entering Don Facemask

- Ensure no gaps present by bending nose bar firmly over nose, mask is pulled down under chin, and ensure elastic secured behind ears/head

Enter Anteroom & Don Shoe Covers

- Ensure shoe completely incased the step over the line of demarcation one foot at a time after shoe cover placed

Once over the line of demarcation, proceed to sink to wash hands

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ENTERING COMPOUNDING AREA

Please follow these instructions to ensure a safe and clean environment is kept

Perform Appropriate Hand Hygiene

- Follow directions above sink on proper way to wash hands (use disposable nail pick every time) and use low-lint wipes to dry hands

Don Gown

- Ensure all buttons are snapped and ID badge remains under gown
- If not wearing scrubs, don bunny suit

Apply Hand Sanitizer

- Allow hand sanitizer to dry completely and pull gown elastics over thumbs

Enter cleanroom without touching other surfaces *(proceed to Entering Hazardous Compounding Room if necessary)*

Don Sterile Gloves

- Obtain correct glove size, remove outer package at empty surface, and appropriately don gloves
- Sanitize gloves with 70% IPA prior to entering hood

Remember Donning and Doffing should not occur at the same time in the anteroom.

Doff your PPE in the location it was Donned.

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ENTERING HAZARDOUS COMPOUNDING AREA

Please follow these instructions to ensure a safe and clean environment is kept for yourself, other healthcare personnel, and patients

Don 2nd Pair of Shoe Covers

- Prior to entering hazardous compounding room, ensure 2nd shoe cover completely incases first shoe cover

Don Hazardous Gown

- Prior to entering hazardous compounding room, don low-lint gown that ties at the back over current gown with new gown cuffs covering current gloves

Enter Hazardous Compounding Room

Don 2nd Pair of Sterile Gloves

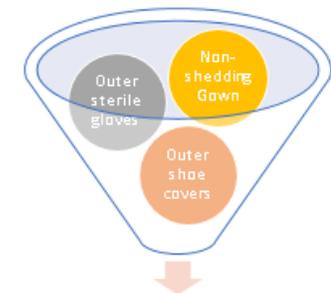
- Obtain correct glove size, remove outer package at an empty surface, and appropriately don 2nd pair of sterile gloves
- If entering without gloves, don 2 pair of sterile gloves

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EXITING HAZARDOUS COMPOUNDING AREA

Please follow these instructions to ensure a safe and clean environment

Remove the following items prior to leaving the Hazardous Compounding Room and place in yellow bin



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Entering the Anteroom

Entering the Compounding Area (non-haz)

Entering the Hazardous Compounding Area

Exiting the Hazardous Compounding Area

Understanding the Hazard

Understanding what makes a drug “Hazardous”

- NIOSH Hazardous Drug Criteria

Hazardous Drug Criteria	Definition
Carcinogenicity	May cause cancer
Teratogenicity or other developmental toxicity	Can alter the development of an embryo or fetus
Reproductive toxicity	May interfere with normal reproduction or fertility
Organ toxicity at low doses	May cause damage to organs or organ function
Genotoxicity	May cause mutations to genes

- NIOSH Hazardous Drug List

Table 1	Antineoplastic Drugs
Table 2	Drugs that meet one or more NIOSH Criteria for a HD
Table 3	Reproductive Risk Only Medications

Understanding the Hazard

- It's important to know why the drug is hazardous
 - Case reports describe congenital anomalies in infants exposed to in utero maternal fluconazole during most or all of the first trimester
- But we also must consider the dosage form and how we're going to manipulate it at our institution. USP 800 allows us the flexibility to do this.
 - Priming tubing on IV fluconazole may lead to more employee exposure than opening a unit dose container to administer to a patient
 - Crushing a tablet of fluconazole may lead to more employee exposure than not crushing it
 - Preparing an IV fluconazole in a clean room may lead to more employee exposure than buying pre-made bags

Risk Assessments for Non-Antineoplastic Parenteral Dosage Forms

- Parenteral Dosage Form Risk > Oral Dosage Form Risk

Treat like Chemotherapy = Full USP 800 Precautions

Drug	Hazardous Criteria
Chloramphenicol	IARC Group 2A carcinogen = probably carcinogenic
Cidofovir	Manufacturer Safe Handling Guidance
Cyclosporine	IARC Group 1 carcinogen = carcinogenic
Dexrazoxane	Manufacturer Safe Handling Guidance
Ganciclovir	Manufacturer Safe Handling Guidance
Inhaled Ribavirin	Pregnancy Category X

- IRAC Group 1 or 2A
- Pregnancy Category X
- Manufacturer Requires (MSHG)

Determine Alternative Safe Handling

IVPB Drug	Hazardous Criteria
Fosphenytoin	Metabolized to phenytoin. Phenytoin is an IRAC Group 2B carcinogen = possibly carcinogenic
Fluconazole	Case reports of congenital abnormalities in infants exposed in utero, same effects as seen in rats, preg category C
Mycophenolate mofetil	Black box warning for embryo fetal toxicity
Oxytocin	Hazardous only for women in the third trimester, preg category C
Pamidronate	Embryo-fetal toxicity
Phenytoin	IRAC Group 2B carcinogen = possibly carcinogenic
Tacrolimus	At therapeutic doses in patients receiving tacrolimus there is increased risk of lymphomas and other malignancies. Toxicity of IV > oral in rats / baboons. Preg category C
Valproic Acid	Black box warning for teratogenicity, congenital malformations, preg category D
Zidovudine	IRAC Group 2B carcinogen = possibly carcinogenic
Zoledronic Acid	Increase in stillbirths and decrease in neonate survival in lab studies

- **IRAC 2B or greater**
- **Manufacturer does not require**
- **Pregnancy Category C,D**
- **Hazardous data is at therapeutic doses (Black box warnings) or in animals**

IARC and Pregnancy Risk Classifications

IARC Classification	
Group 1	Carcinogenic to humans
Group 2A	Probably carcinogenic to humans
Group 2B	Possibly carcinogenic to humans
Group 3	Not classifiable as to its carcinogenicity to humans
Group 4	Probably not carcinogenic to humans

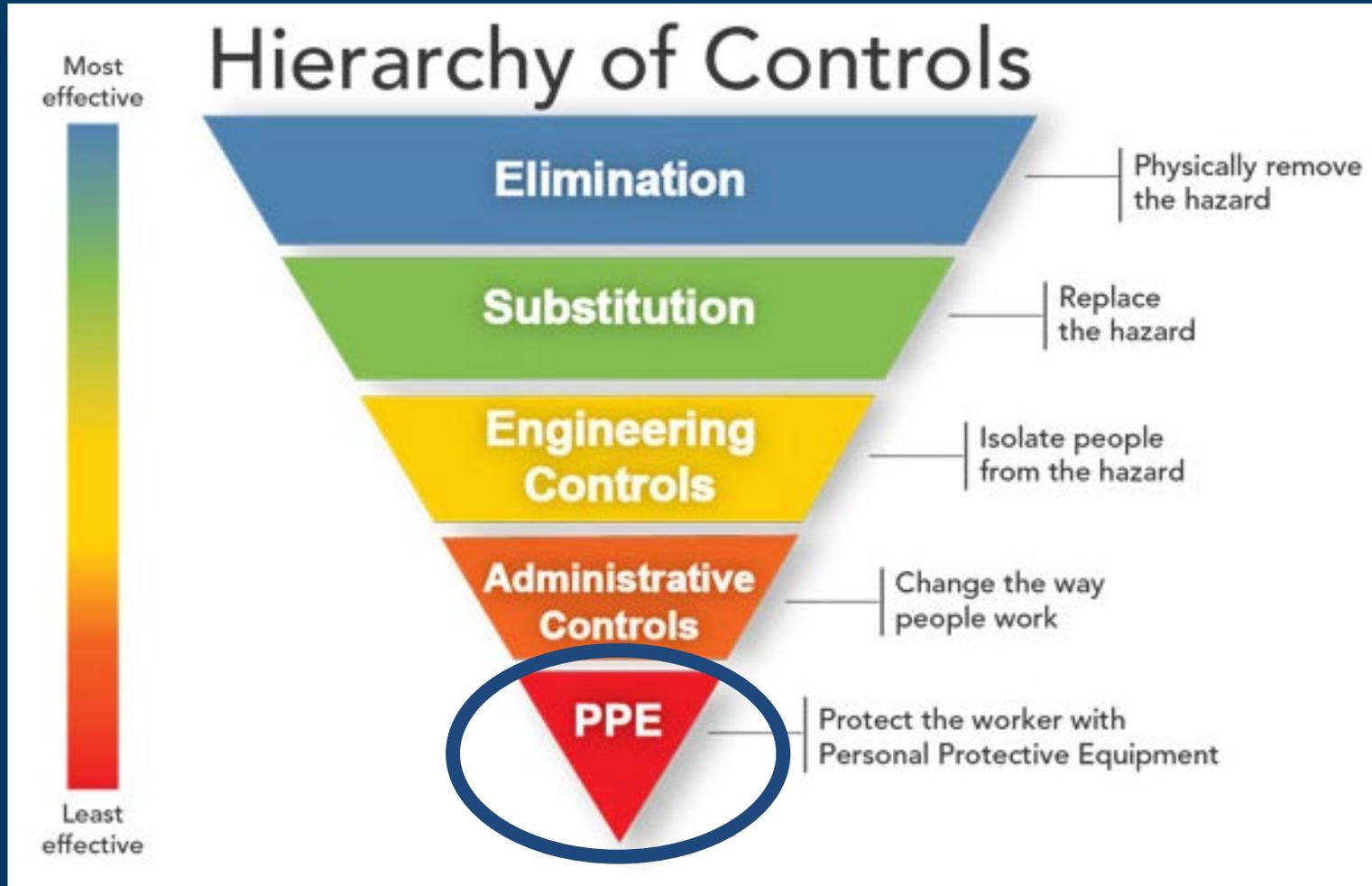
An agent is classified based on scientific evidence derived from human and experimental animal studies and from mechanistic and other relevant data

FDA Pregnancy Risk Classification	
A	No fetal risk
B	No risk to human fetus despite possible animal risk / studies
C	Risk cannot be ruled out, human studies are lacking
D	Positive evidence for risk to human fetus, but benefits may outweigh risk of drug
X	Contraindicated in pregnancy, studies demonstrate evidence of risk to fetus

FDA has decided to eliminate the pregnancy categories because they are often viewed as confusing and overly simplistic and don't effectively communicate the risk a drug may have during pregnancy and lactation and in females and males of reproductive potential.

Controlling the Hazard

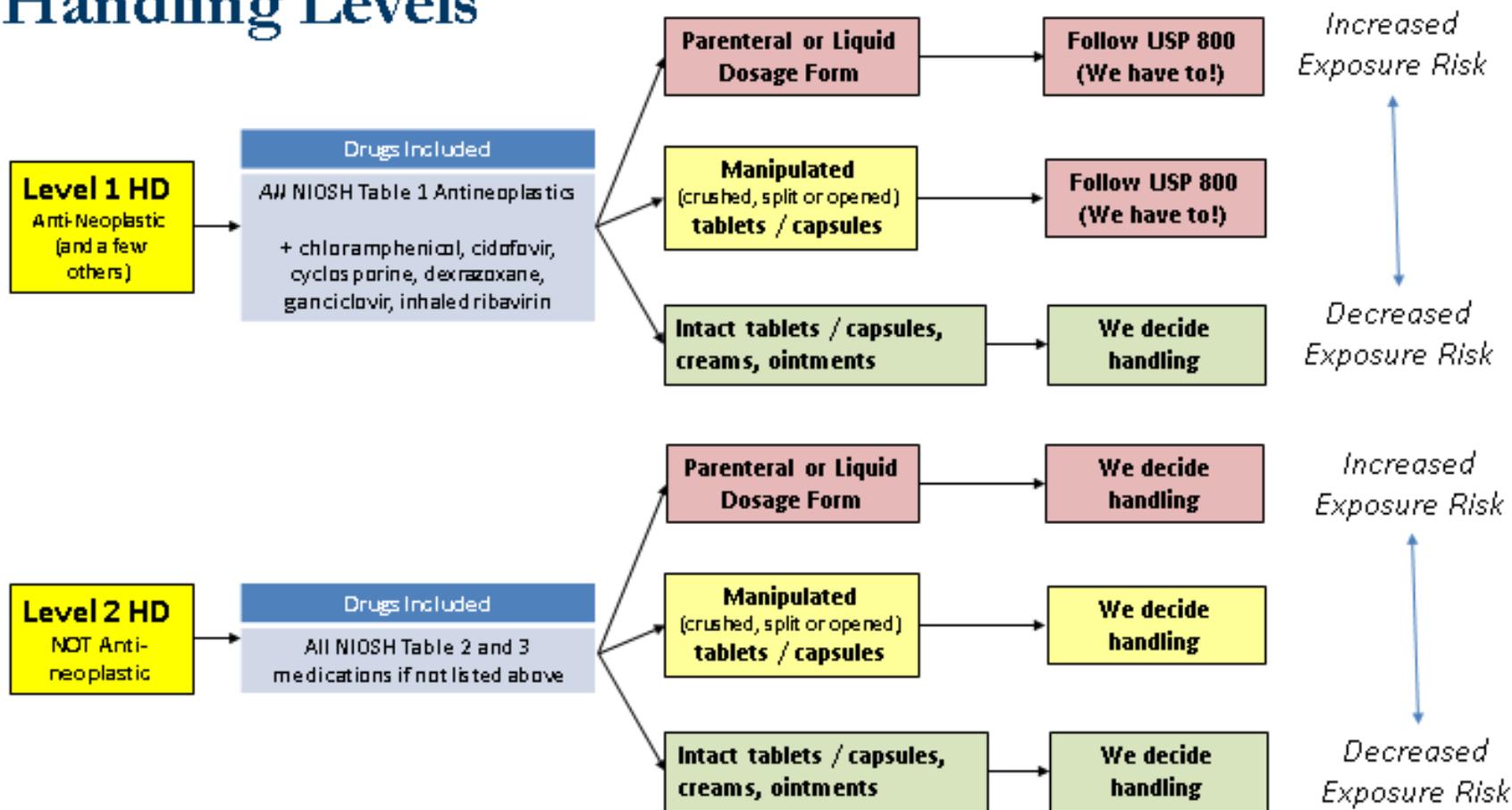
Controlling the Hazard



- Can drugs be removed from formulary or auto-substituted to another product not as hazardous?
- Can you limit the staff that have to interact with the product? (RN and RPh)
- Do you have proper engineering controls in place? (i.e. CSTDs)

What is KU planning on doing?

HD Handling Levels



KU HD Risk Levels

- Communication about the hazardous risk level will be
 - In a MAR message
 - On the label (if there is a label)
- Communication will be something like
 - “Level 1 Hazardous Drug”
- Staff will need to know what they must do to protect themselves when handling a “Level 1 Hazardous Drug”
 - Education will be provided; Policies will be available
 - EMR will not tell them

PPE and Safe Handling

- Table designed to outline proper PPE for Administration, Disposal, Excretion, and Spill cleanup
- Definition of “chemo gloves”
 - ASTM D6978 rated
- Excretion handling
 - Contaminated linens
 - Deactivating toilet bowl

The University of Kansas Health System HD Handling Precautions and PPE					
Risk Level	Drug Included	Administration	Discontinuation/ Disposal of drug	Excretion handling	Spill Cleanup
Level 1	41034 table 1 agents A40 See also 41034 table 2 and 5 agents -Chlorambucil -Cisplatin -Cyclophosphamide -Docetaxel -Etoposide -Fluorouracil -Irinotecan	Parenteral or manipulated pills/liquids: -Chemo-lead gown -2 sets of chemo gloves -Face shield/goggles if splashing likely -Gown and/or pad at all times to avoid any leakage of fluids	-Chemo-lead gown -2 sets of chemo gloves -Face shield/goggles if splashing likely -Gown and/or pad at all times to avoid any leakage of fluids	-Chemo-lead gown -2 sets of chemo gloves -Face shield/goggles if splashing likely -Leak-proofed towel over toilet	-Spill containment bag -Chemo-lead gown -2 sets of chemo gloves -Shoe covers -PAPR
		Injectables, creams, or ointments: -1 set of chemo gloves -Cover swab for creams/injectables	-1 set of chemo gloves		
		Inhaled: -Chemo-lead gown -2 sets of chemo gloves -Face shield/goggles if splashing likely -Gown and/or pad at all times to avoid any leakage of fluids	-Chemo-lead gown -2 sets of chemo gloves -Face shield/goggles if splashing likely -Gown and/or pad at all times to avoid any leakage of fluids	-Chemo-lead gown -2 sets of chemo gloves -Face shield/goggles if splashing likely -Leak-proofed towel over toilet	-Spill containment bag -Chemo-lead gown -2 sets of chemo gloves -Shoe covers -PAPR
Level 2	41034 table 2 and 5 medications except those listed above	All dosage forms: -1 set of standard gloves Manipulation of tabs/caps: -Chemo-lead gown -2 sets of chemo gloves	-1 set of standard gloves		

Other PPE considerations

- Disposable applicators/cotton swabs for topical antineoplastics
- Operating Room and Procedural areas
 - Sterile chemo gowns
- Volatile agents (eg, etoposide, carmustine, cyclophosphamide, thiotepa, nitrogen mustard, fluorouracil, cisplatin, and ifosfamide)
 - N95 will not protect you against vapors
 - Know when to use a PAPR



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