

USP 800: Clinical

1. USP 800: Clinical

1.1 Welcome

A training slide for USP 800. It features a large orange semi-circle on the left side. The text 'USP 800' is prominently displayed in a bold, orange font. Below this, the target audience is defined: 'Target Audience: Clinical staff who would be working with hazardous medications or potentially be exposed through an accidental spill'. In the bottom left corner, there is a small box containing '1 / 29'. In the bottom center, there is a copyright notice: '© 2023 HCA Healthcare. All rights reserved. CONFIDENTIAL – Contains proprietary information. Not intended for external distribution.' In the bottom right corner, the HCA Healthcare logo is visible, consisting of the letters 'HCA' in a bold, blue font with a red cross symbol to its right, and the word 'Healthcare' in a smaller, blue font below it.

USP 800

Target Audience: Clinical staff who would be working with hazardous medications or potentially be exposed through an accidental spill

© 2023 HCA Healthcare. All rights reserved.
CONFIDENTIAL – Contains proprietary information. Not intended for external distribution.

HCA Healthcare®

1 / 29

Notes:

Hello and welcome to USP 800 training. This course is designed to outline the requirements of USP 800. The target audience includes anyone who would be working with hazardous medications or potentially be exposed through an accidental spill. If you feel you have been assigned this module in error, please exit the module and speak with your manager.

1.2 Learning Objectives

Learning Objectives

- 1 Recognize list of Hazardous Drugs (HDs) used and associated risks
- 2 Identify proper use of Personal Protective Equipment (PPE)
- 3 Describe proper use of equipment and devices
- 4 Detail response to known or expected exposure
- 5 Outline how to manage a spill
- 6 Identify proper disposal of HDs and trace-contaminated materials

2 / 29



Notes:

By the end of this module, participants should be able to:

1. Review the Hazardous Medications Policy
2. Recognize list of Hazardous Drugs (HDs) used and associated risks
3. Identify proper use of Personal Protective Equipment (PPE)
4. Describe proper use of equipment and devices
5. Detail response to known or expected exposure
6. Outline how to manage a spill
7. Identify proper disposal of HDs and trace-contaminated materials

1.3 Hazardous Drugs

National Institute for Occupational Safety and Health (NIOSH)



Hazardous Drugs

National Institute for Occupational Safety and Health (NIOSH)



 <p>Carcinogenicity or cancer formation</p>	 <p>Organ Toxicity at low doses</p>
 <p>Teratogenicity or other developmental toxicity to an embryo or fetus</p>	 <p>Genotoxicity or having a destructive effect on cell's genetic material-DNA or RNA</p>
 <p>Reproductive Toxicity or interfering with normal reproduction or fertility</p>	 <p>Genotoxicity Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria</p>

3 / 29

Notes:

The National Institute for Occupational Safety and Health (NIOSH) maintains and updates a list of antineoplastic and other Hazardous Drugs. These drugs include more than just chemotherapy drugs, such as Phenytoin, Estrogen, and Warfarin. Drugs are considered hazardous if they exhibit one or more of the following characteristics in humans or animals:

- Carcinogenicity or cancer formation
- Teratogenicity or other developmental toxicity to an embryo or fetus
- Reproductive toxicity or interfering with normal reproduction or fertility
- Organ toxicity at low doses
- Genotoxicity or having a destructive effect on cell's genetic material-DNA or RNA
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

1.4 Antineoplastics



Antineoplastics

- 5-Fluorouracil
- Bleomycin
- Gemcitabine
- Mitomycin



Commonly called chemotherapy

4 / 29

HCA+
Healthcare®

Notes:

NIOSH categorizes hazardous drugs into three categories. The Group 1 Antineoplastic drugs are most commonly called chemotherapy. There are specific requirements for the storage and handling of these drugs, as well as the personal protective equipment that should be utilized when handling these drugs.

1.5 Non-antineoplastics

**NIOSH
Group
2**

Non-antineoplastics

- Estradiol
- Conjugated estrogens
- Phenytoin



Commonly found in
hormone therapy

5 / 29

HCA 
Healthcare®

Notes:

The NIOSH Group 2 drugs are non-antineoplastics that meet one or more of the 6 NIOSH criteria for hazardous drugs.

1.6 Reproductive Risk



Reproductive Risk

- Ergonovine/
Methlyergonovine
- Misoprostol
- Oxytocin
- Warfarin



Potential Occupational Hazard for

- Males and females who are trying to conceive
- Women who are pregnant or may become pregnant
- Women who are breastfeeding

6 / 29

HCA+
Healthcare®

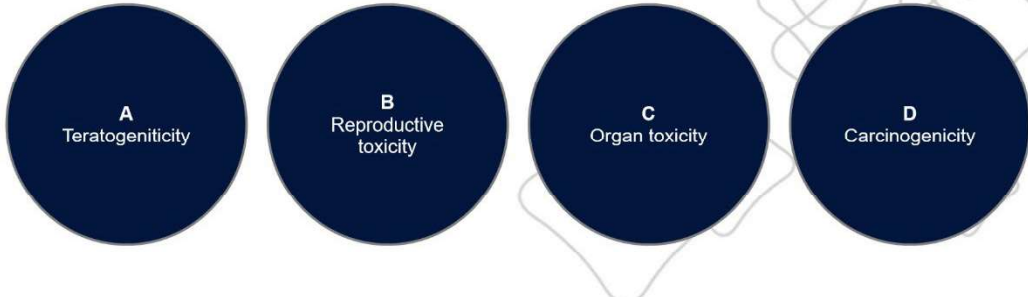
Notes:

The Group 3 drugs primarily meet the NIOSH criteria for reproductive hazards. These drugs may represent a potential occupational hazard to males or females trying to reproduce, women who are pregnant or may become pregnant, or women who are breastfeeding.

1.7 Knowledge Check 1

Knowledge Check 1

Group 3 hazardous drugs primarily meet the criteria for what type of hazard?



A
Teratogenicity

B
Reproductive toxicity

C
Organ toxicity

D
Carcinogenicity

7 / 29

HCA+
Healthcare®

Correct	Choice
	A Teratogenicity
X	B Reproductive toxicity
	C Organ toxicity
	D Carcinogenicity

Feedback when correct:

That's right! You selected the correct response.

Group 3 drugs primarily meet the criteria for reproductive hazard.

Feedback when incorrect:

You did not select the correct response.

1.8 Knowledge Check 2

Knowledge Check 2

The following medications are Group 1 hazardous drugs according to the assessment of risk:

A 5-Fluorouracil B Bleomycin C Mitomycin D Gemcitabine E All of the above

8 / 29

HCA+ Healthcare®

Correct	Choice
	A 5-Fluorouracil
	B Bleomycin
	C Mitomycin
	D Gemcitabine
X	E All of the above

Feedback when correct:

That's right! You selected the correct response. 5-Fluorouracil, Bleomycin, Mitomycin, and Gemcitabine are all Group 1 hazardous drugs.

Feedback when incorrect:

You did not select the correct response.

1.9 Storage and Transport of HDs

Identification of Hazardous Medications

Hazardous medications will be stored in a hazardous container and have hazardous drugs sticker placed on them for identification.



9 / 29

HCA+
Healthcare®

Notes:

Hazardous medications will be stored in a hazardous container, such as a bag or a bin. Whether the hazardous drugs are stored in a bag or a bin in your facility, each of the hazardous drugs should have a caution sticker on them.

1.10 Assessment of Risk

Assessment of Risk

HAZARDOUS MEDICATION ASSESSMENT OF RISK (AoR)

— ENTITY NAME —

SUMMARY OF HD DRUG RISK CHARACTERISTICS & EXPOSURE RISKS:
(include sources below)

HD DRUG NAME: _____

DOSEAGE FORM: Ampule
 Capsule/Tablet
 Injection, vial
 Infusion
 Liquid, oral
 Powder, for Injection
 Powder/Solution, for Aerosol or Inhalation
 Solution, Irrigation
 Topical
 Other (describe): _____

PACKAGING: Unit Dose
 Unit of Use
 Bulk
 OTHER (describe): _____

TYPE OF HD*: Antineoplastic (table 1—final dosage form)
 Non-antineoplastic (table 2)
 Reproductive Risk (table 3)
 Facility Identified HD

Review Type: Initial AOR Date: _____
 Review AOR Date: _____

SOURCES: _____

*AOR: Alternative Containment strategies are not allowed for Table 1 HDs (antineoplastic) that are not in final dosage form or any API HDs, regardless of HD category. These must be handled with all USP 800 requirements.

TYPE OF ACTIVITY	TYPE OF MANIPULATION(S) (may be more than one type of manipulation during activity) <small>EXAMPLES: Crib, Pour, Decantation, Transfer, Ampule, Syringe, Inject, Mix, etc.</small>	EXPOSURE RISK(S) (may be more than one and/or may be situational)	Minimum USP <800> Requirements for API and Table 1 Antineoplastics not in final dosage form, and any HDs without AOR. INCLUDE ANY ADDITIONAL REQUIREMENTS SPECIFIC TO HD	Organizational Policy	
				N/A	Follow <800> Entity Exemption/Alternative Containment Strategy and comments Consider engineering controls, PPE controls, and administrative controls such as personal protection, process, workflow, training, use of equipment such as delivery robots, Pylo, etc.
RECEIVING			Engineering Controls: Unpack in neutral/normal pressure area. Administrative Controls: Spill kit and respirator available. PPE: Single gloves (ASTM D637) recommended		
TRANSPORT Within Pharmacy (to/from storage & preparation areas)			Administrative Controls: In container that minimizes risk of leakage or leakage. No use of pneumatic tube system.		

Notes:

Each facility will perform an assessment of risk as shown. This assessment will help guide what personal protective equipment is needed for safety.

1.11 Personal Protective Equipment (PPE)

Personal Protective Equipment (PPE)

Appropriate PPE must be worn for

- Receipt
- Storage
- Transport
- Administration
- Deactivation/Decontamination
- Cleaning
- Disinfection
- Spill control
- Waste disposal

Full-coverage head & hair covers, beard/moustache covers if applicable.

2 PAIRS of powder-free gloves, both tested for chemotherapy use. Replace gloves every 30 minutes.

Gown must be chemo-rated, disposable, seamless, with long sleeves and knitted or elastic cuffs. Gown must extend below knee and close in the back. Replace gown every 2-3 hours.

Full face shield protects eyes from splashes & goggles protect eyes if any potential for splash exposure.

Fit-tested NIOSH-certified N95 respirator mask protects against airborne particles, provides a barrier to splashes, droplets, and sprays.

Shoe covers worn in HD handling areas must not be worn to other areas.

11 / 29

HCA+ Healthcare®

Notes:

There are specific PPE requirements for receiving and administering hazardous drugs. Appropriate PPE must be worn for receipt, storage, transport, administration, deactivation/decontamination, cleaning, disinfection, spill control, and waste disposal.

Gloves may require a single or double pair depending on the activity, gowns need to be impervious to liquids, eye/face masks should be worn when there is a splash risk, and respiratory protection is needed when there is a risk for inhalation. Remember that shoe covers worn in HD handling areas must not be worn to other areas.

Gloves should be replaced every 30 minutes and gowns should be replaced every 2 to 3 hours.

1.12 Donning of PPE

Donning of PPE

After donning bouffant cap and shoe covers, don gown and tie at back of neck and waist

Don 1st pair of gloves, tucking them under the cuffs of gown

Don 2nd pair of gloves, making sure to cover cuffs of gown

Don respirator, doing a fit-test to ensure proper seal

Next, don goggles

Finally, don face shield

12 / 29

HCA+
Healthcare®

Notes:

This illustration will show the proper steps for putting on your PPE. After donning bouffant cap and shoe covers, don gown and tie at back of neck and waist. Don 1st pair of gloves, tucking them under the cuffs of gown. Don 2nd pair of gloves, making sure to cover cuffs of gown. Don respirator, doing a fit-test to ensure proper seal. Next, don goggles. Finally, don face shield.

1.13 Doffing of PPE



Notes:

This illustration shows the proper steps for taking off your PPE. Remove gown by firmly grasping the outside of the waist. Pull up and out to break the ties. With the sleeves rolled down, use the gown as a barrier and remove the outer set of gloves. Roll the outer gloves and gown into a ball and dispose. Remove the face shield, goggles, mask, cap and shoe covers with the inner layer of gloves. Remove the inner layer of gloves and dispose of everything in the appropriate waste bin.

Remember to dispose of the PPE according to your facilities regulations.

1.14 Knowledge Check 3

Knowledge Check 3

What is the correct order to don Personal Protective Equipment (PPE)?

A

1. Bouffant cap
2. Gown
3. Shoe covers
4. 1st pair of gloves (tucked into gown)
5. 2nd pair of gloves (covering cuffs of gown)
6. Respirator
7. Goggles
8. Face shield

B


1. Bouffant cap
2. Shoe covers
3. Gown
4. 1st pair of gloves (tucked into gown)
5. 2nd pair of gloves (covering cuffs of gown)
6. Respirator
7. Goggles
8. Face shield

C

1. Bouffant cap
2. Shoe covers
3. 1st pair of gloves (tucked into gown)
4. Gown
5. 2nd pair of gloves (covering cuffs of gown)
6. Respirator
7. Face shield
8. Goggles

D

1. Gown
2. Shoe covers
3. Bouffant cap
4. 1st pair of gloves (tucked into gown)
5. 2nd pair of gloves (covering cuffs of gown)
6. Respirator
7. Goggles
8. Face shield



14 / 29

Correct	Choice	
	A Bouffant cap Gown Shoe covers 1st pair of gloves (tucked into gown)	2nd pair of gloves (covering cuffs of gown) Respirator Goggles Face shield
X	B Bouffant cap Shoe covers Gown 1st pair of gloves (tucked into gown)	2nd pair of gloves (covering cuffs of gown) Respirator Goggles Face shield
	C Bouffant cap Shoe covers 1st pair of gloves (tucked into gown) Gown	2nd pair of gloves (covering cuffs of gown) Respirator Face shield Goggles
	D Gown Shoe covers Bouffant cap 1st pair of gloves (tucked into gown)	2nd pair of gloves (covering cuffs of gown) Respirator Goggles Face shield

1.15 Exposure

Exposure

Unintentional entry of hazardous drugs into the body.

Routes of Entry

- Dermal Absorption
- Mucosal Absorption
- Inhalation
- Injection
- Ingestion



Potential exposure activities include receipt, administration, patient care activities, spills, transport, and waste.

15 / 29

HCA 
Healthcare®


Notes:

Exposure is the unintentional entry of hazardous drugs into the body. Both clinical and non-clinical staff can come into contact with a hazardous drug through dermal and mucosal absorption, inhalation, injection or ingestion. There is an opportunity for this exposure during receipt, administration, patient care activities, spills, transport, and waste.

1.16 Safety Data Sheets

Safety Data Sheets

- Print
- Telephone
- Online



<https://chemicalsafety.com/sds-search/>

16 / 29

HCA+
Healthcare®

Notes:

Each facility will make available the safety data sheets for any of the Hazardous Drugs the personnel may potentially come in contact with. The safety data sheets will be readily accessible either in print, via telephone, or online at <https://chemicalsafety.com/sds-search/>. The facility will also make sure that the personnel with reproductive capability confirms in writing that they understand the risks of handling hazardous drugs.

1.17 Knowledge Check 4

Knowledge Check 4

Exposure to hazardous drugs can occur through all of the following routes except?

A Inhalation

B Injection

C Dermal absorption

D Ingestion

E Irrigation

17 / 29

HCA+
Healthcare®

Correct	Choice
	A Inhalation
	B Injection
	C Dermal absorption
	D Ingestion
X	E Irrigation

1.18 Knowledge Check 5

Knowledge Check 5

Potential opportunities for exposure to hazardous drugs can occur in all of the following areas except:



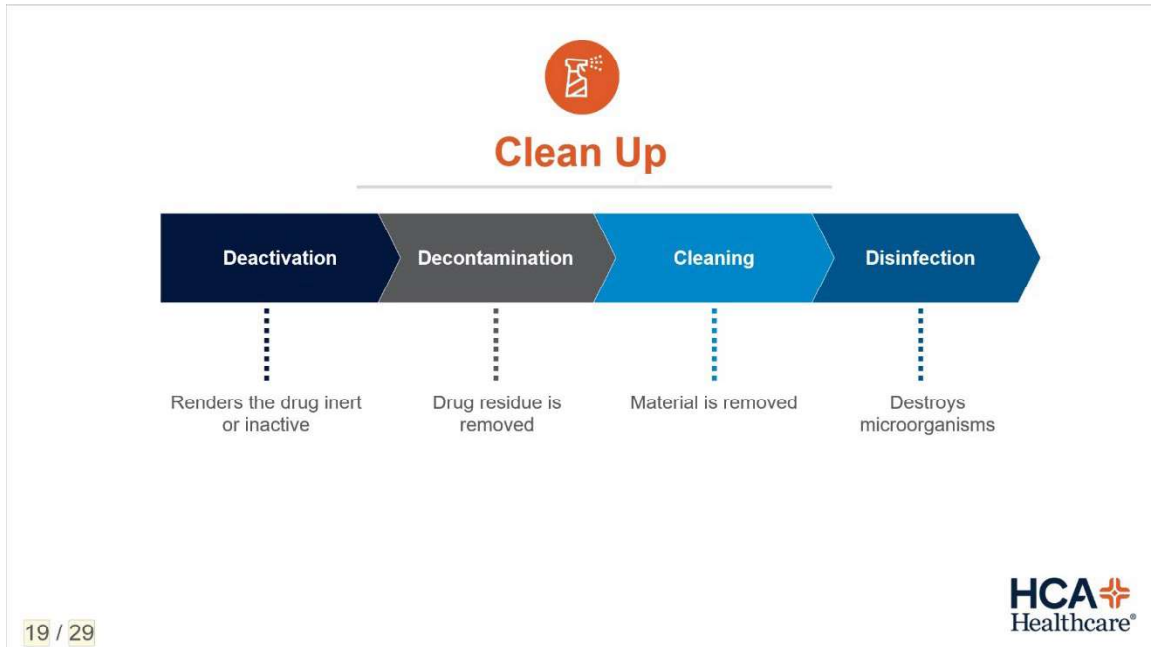
- A Receipt
- B Storage
- C Billing
- D Transport
- E Administration

18 / 29

HCA+
Healthcare®

Correct	Choice
	A Receipt
	B Storage
X	C Billing
	D Transport
	E Administration

1.19 Clean Up



Notes:

Clean up is the most important step of handling hazardous drugs. There are four steps that must be completed during the clean. The deactivation process renders the drug inert or inactive. During decontamination, the drug residue is removed. The organic and inorganic material is removed during the cleaning phase. Finally, the disinfection step destroys microorganisms. The area and all equipment potentially involved in the spill must go through the cleaning process. Supply chain leadership will determine the products that should be utilized during the clean up. Some of the products may accomplish more than one of these steps simultaneously.

1.20 Spills



Notes:

What do you do if there is a spill? How do you know if it is safe to clean up? Is it volatile? Employees who may be required to clean up HD spills will receive proper training in spill management. This training will include spill management, how to use the spill kits, proper PPE, and NIOSH certified respirators, if applicable. Spill kits will be readily available in all areas where HDs are routinely handled. The kits will include signs for restricting access to spill areas. Spills must be contained and cleaned immediately only by qualified personnel, wearing appropriate PPE. Documentation of spills must be completed as a variance. In the following slides, we will discuss the steps for a general spill procedure.

1.21 Steps for General Spill Procedure (1 - 6)



Notes:


Here are the steps for general spill procedure.

1. Clear personnel and restrict access to area adjacent to spill
2. Do not leave spill unattended
3. Place appropriate signage to alert others that spill event is in progress
4. Assess size and scope of spill. When assessing the spill, call for trained help, if necessary. If the area is greater than 1 square foot or a spill that cannot be handled with a spill kit, contact the local Fire or Hazmat Departments.
5. Obtain spill kit and respirator, if needed
6. Don PPE


1.22 Steps for General Spill Procedure (7 - 11)

Steps for General Spill Procedure (7 - 11)

<p>7</p> <p>Once donned, contain spill using spill kit</p>	<p>8</p> <p>Carefully remove any broken glass fragments and place in puncture resistant container</p>	<p>9</p> <p>Absorb liquids with spill pads or toweling</p>
<p>10</p> <p>Absorb powder with damp disposable pads or soft toweling</p>	<p>11</p> <p>Spill clean up should proceed progressively from areas of lesser to greater contamination</p>	



22 / 29

HCA 
Healthcare®

Notes:

7. Once donned, contain spill using spill kit
8. Carefully remove any broken glass fragments and place in a puncture resistant container
9. Absorb liquids with spill pads or toweling
10. Absorb powder with damp disposable pads or soft toweling
11. Spill clean up should proceed progressively from areas of lesser to greater contamination

1.23 Steps for General Spill Procedure (12 - 18)

Steps for General Spill Procedure (12 - 18)

12 Completely remove and place all contaminated material in HD waste disposal bags	13 Rinse the area with water	14 Clean with detergent and neutralizer
15 Carefully remove and place all disposable PPE into disposable bags	16 Seal bags and place into appropriate final container	17 Wash hands thoroughly with soap and water
18 Once spill has been initially cleaned, decontaminate, deactivate, and clean the area		



23 / 29

HCA 
Healthcare®

Notes:

12. Completely remove and place all contaminated material in HD waste disposal bags
13. Rinse the area with water
14. Clean with detergent and neutralizer
15. Carefully remove and place all disposable PPE into disposable bags.
16. Seal bags and place into appropriate final container
17. Wash hands thoroughly with soap and water
18. Once spill has been initially cleaned, decontaminate, deactivate, and clean the area

1.24 Knowledge Check 6

Knowledge Check 6

A hazardous drug spill must be documented as a:


A
Reportable Issue

B
Medication Error

C
Variance

D
Close call

24 / 29



Correct	Choice
	A Reportable Issue
	B Medication Error
X	C Variance
	D Close call

1.25 Knowledge Check 7

Knowledge Check 7

Which of the following is false regarding hazardous drug spills?

A. Once the liquid is removed, the spill area should be rinsed with water and cleaned with detergent and neutralizer.

B. Spill cleanup should proceed progressively from areas of greater to lesser contamination.

C. The spill cannot be left unattended.

25 / 29

HCA
Healthcare®

Correct	Choice
	A. Once the liquid is removed, the spill area should be rinsed with water and cleaned with detergent and neutralizer.
X	B. Spill cleanup should proceed progressively from areas of greater to lesser contamination.
	C. The spill cannot be left unattended.

1.26 Disposal

Disposal



All PPE worn while handling HDs



Syringes, sharps, empty vials, administration sets, and other contaminated supplies used for HD administration



Collection and disposal of any hazardous waste and trace contaminated waste will be performed per the HCA Hazardous Waste Guidelines.

26 / 29

HCA 
Healthcare®

Notes:

The following hazardous materials must be disposed of per the HCA Hazardous Waste Guidelines:

- All PPE worn while handling HDs
- Syringes, sharps, empty vials, administration sets, and other contaminated supplies used for HD administration
- Collection and disposal of any hazardous waste and trace contaminated waste will be performed per the HCA Hazardous Waste Guidelines

1.27 Knowledge Check 8

Knowledge Check 8

USP 800 addresses the following except:

- A. Handling of hazardous drugs
- B. What PPE to wear when handling non-hazardous drugs.
- C. Proper disposal of hazardous drugs
- D. Spill management of hazardous drugs

27 / 29

HCA+
Healthcare®

Correct	Choice
	A. Handling of hazardous drugs
X	B. What PPE to wear when handling non-hazardous drugs.
	C. Proper disposal of hazardous drugs
	D. Spill management of hazardous drugs

1.28 More Information

More Information

The diagram features a central icon of a hand holding a telephone receiver, with a Wi-Fi symbol overlaid on the phone. Two dotted lines extend from this icon to two separate gray circles. The top circle is labeled 'Hazardous Drug Coordinator' and the bottom circle is labeled 'Pharmacy Staff'. The text 'More Information' is positioned at the top left of the diagram area. The HCA+ Healthcare logo is located in the bottom right corner of the diagram area.


28 / 29

HCA+
Healthcare®

Notes:

For more information, contact your center's Hazardous Drug Coordinator or your pharmacy staff.

1.29 Thank You!



Click ☰ icon to view menu.

Thank You!

Click EXIT to close.

EXIT

29 / 29

HCA+
Healthcare®

Notes:

Thank for completing this training on USP 800. You may now exit this course.