



Outbreaks in Outpatient Oncology Settings: Lessons Learned and Key Considerations for Handling Sterile Medications

Thursday, August 9, 2018

The findings and conclusions in this presentation are those of the author and do not necessarily represent official position of the Centers for Disease Control and Prevention.

Program Objectives

PROGRAM DESCRIPTION:

- This webinar will discuss infectious outbreaks in outpatient oncology settings that have been linked to breaches in safe injection practices and sterile compounding standards. Key considerations for safe handling of sterile medications during compounding and administration will also be discussed.

OBJECTIVES:

- Identify unsafe injection and compounding practices that have been linked to healthcare-associated infection (HAI) outbreaks in outpatient oncology and other clinic settings.
- Identify the minimum standards for safe injection practices and when standards for sterile compounding are applicable.
- Describe the importance of early recognition and notification of potential HAI outbreaks to public health authorities.

Speakers

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Outpatient Oncology Settings are Important for Ensuring Patient Access to Care

- >1.7 million people are diagnosed with cancer each year
- > 1 million cancer patients receive outpatient chemotherapy or radiation
- Outpatient oncology settings provide several benefits:
 - avoid hospitalization and costs of inpatient stays,
 - treatment administered at patient convenience, familiar facility,
 - drug administration under close supervision of oncologist.

Infection Prevention in Oncology Settings is Critical for Patient Safety

- Attention to infection prevention in oncology settings is especially important due to patients' heightened risk of infection:
 - underlying malignancy and chemotherapy,
 - frequent contact with healthcare settings,
 - placement of indwelling intravascular access devices or undergo surgical procedures.
- Many outpatient oncology facilities lack infection control policies and procedures to ensure patient protection

Outbreaks in Outpatient Oncology Clinics Linked to Sterile Compounding and Unsafe Injection Practices

Infection Prevention in Oncology Settings is Critical for Patient Safety

It is important for outpatient oncology settings to:

- Recognize that **failure to adhere to safe injection practices and sterile compounding standards** **places patients at risk** for healthcare-associated infections (HAIs) and other adverse events
- Become familiar and **implement standards for basic infection control** and **safe injection practices**
- Know when medication preparation practices are subject to **sterile compounding standards** and **apply the appropriate standards for those practices**
- **Identify and report** suspected HAI outbreaks to public health authorities as soon as they are identified

Two Concepts Addressed Throughout

- Sterile compounding (focus of today's presentation)
- Safe injection practices

What are Safe Injection Practices?

- Set of measures taken to perform injections in an optimally safe manner for patients, healthcare personnel, and others
- Part of CDC's Standard Precautions, reflect **minimum standards** that healthcare personnel should follow to prevent transmission of infections in healthcare settings



- **Never** administer medications from the same syringe to more than one patient, even if the needle is changed or you are injecting through an intervening length of IV tubing.
- Do **not** enter a medication vial, bag, or bottle with a used syringe or needle.
- **Never** use medications packaged as single-dose or single-use for more than one patient. This includes ampoules, bags, and bottles of intravenous solutions.
- **Always** use aseptic technique when preparing and administering injections.

Failure to adhere to Standard Precautions, including safe injection practices, has resulted in **serious patient harm**, including **disease transmission and patient notifications.**

[Standard Precautions for All Patient Care](https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html) (https://www.cdc.gov/infectioncontrol/basics/standard-precautions.html)

[FAQs regarding Safe Practices for Medical Injections](https://www.cdc.gov/injectionsafety/providers/provider_faqs.html) (https://www.cdc.gov/injectionsafety/providers/provider_faqs.html)

What is Drug Compounding?

Definition

“Compounding is generally a practice in which a licensed **pharmacist**, [or] a licensed **physician** ...combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.” *

* [Human Drug Compounding](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm)

(<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>)

[Compounding Standards](http://www.usp.org/compounding) (<http://www.usp.org/compounding>)

Laws, Standards & Guidance

- **Federal Food, Drug, and Cosmetic Act** (Sections 503A and 503B)
 - **FDA** guidance (e.g., Insanitary Conditions)
 - Individual state pharmacy practice laws
 - Minimum practice standards:
 - **USP General Chapter <795> Pharmaceutical Compounding—Non-sterile Preparations**
 - **USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations**
 - **USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings**
-

Oversight & Enforcement

- Primarily: FDA, state boards of pharmacy
- Accreditors, certifiers also play a role

Failure to adhere to laws and minimum standards applicable to sterile compounding in healthcare settings (pharmacies, hospitals, and clinics) has resulted in serious patient harm, including disease transmission and patient notifications

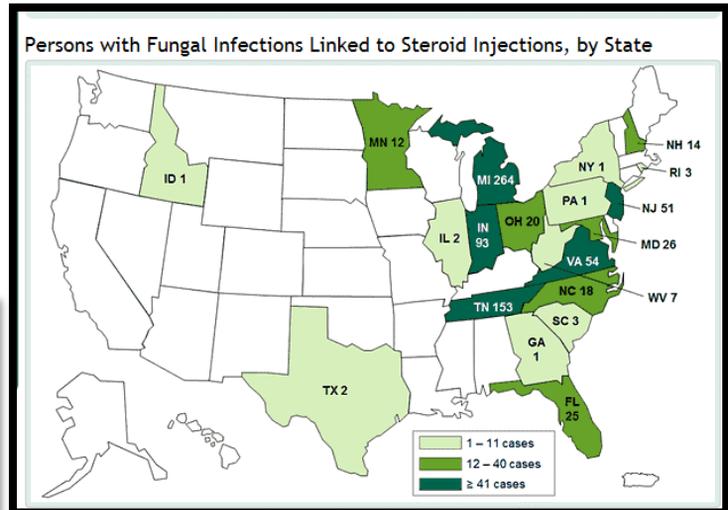
Sterile Drug Compounding – Examples

- Preparing **multiple** chemotherapy infusion bags for administration **later in the day**
- **Combining** multiple medications (e.g., antibiotics, heparin) in a saline bag
- **Re-packaging** contents of a saline or heparin bag into multiple syringes

Outbreaks linked to Compounded Drugs from **Pharmacy** Settings



‘Worried Sick’: Meningitis Risk Haunts 14,000



CDC and State Health Departments Are Increasingly Responding to Outbreaks in Outpatient Settings

[CDC](#) > [Healthcare-associated Infections \(HAI\)](#) > [Outbreak and Patient Notifications](#)

Outbreaks and Patient Notifications in Outpatient Settings, Selected Examples, 2010-2014



The following table includes selected examples of recent outbreaks and patient notification events. These events occurred in a variety of outpatient settings including primary care clinics, pediatric offices, cosmetic surgery centers, pain remediation clinics, imaging facilities, cancer (oncology) clinics, dental clinics, and health fairs. **This is not an exhaustive list but it serves as a reminder of the serious consequences that can result when healthcare personnel fail to follow basic principles of infection control.** Such consequences include: infection transmission to patients, notification of thousands of patients of possible exposure to bloodborne pathogens, referral of providers to licensing boards for disciplinary action, and malpractice suits filed by patients.

These events are preventable, yet they continue to occur. Facilities and healthcare personnel are urged to review the [Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care](#). This document is accompanied by an *Infection Prevention Checklist (Appendix A)* a tool to help outpatient facilities assess their policies and procedures. In order to prevent patient harm, facilities and healthcare staff members are encouraged to review practices to assure they are in accordance with CDC's evidence-based guidelines.

The table below provides updated information to the [Outbreaks and Patient Notifications in Outpatient Settings, 2007 – 2009 \(Archived\)](#).

Outbreaks in Outpatient Settings (Selected Examples)

Where Are Outbreaks Occurring?

- Ambulatory Surgical Centers (ASCs)
- Chiropractic clinics
- Cosmetic surgery clinics
- Dental / oral surgery clinics
- Orthopedic clinics
- **Oncology clinics**
- Pain management clinics
- Physician offices
- Plastic surgery centers
- Radiology clinics
- Rheumatology clinics
- Urology clinics

Outbreaks in Outpatient Settings

Why Are Outbreaks Occurring?

- Shift in healthcare delivery from inpatient settings to outpatient settings
- Breaches in **sterile compounding** and **safe injection practices** identified in outpatient settings

Consequences:

- Infection transmission to patients
- Notification of thousands of patients of possible exposure to bloodborne pathogens
- Disciplinary action, referral of providers to licensing boards
 - Malpractice suits filed by patients

Outbreaks in Outpatient Settings

What are the Medication Handling Breaches?

Medication Preparation

(Unsafe compounding practices)

- Failure to follow aseptic practices (incl. proper hand hygiene)
- Insanitary medication preparation areas
- Untrained/non-qualified personnel performing sterile compounding
- Absence of proper controls (e.g., ISO-class 5 hoods)
- Improper storage and labeling of sterile medication vials

Medication Administration

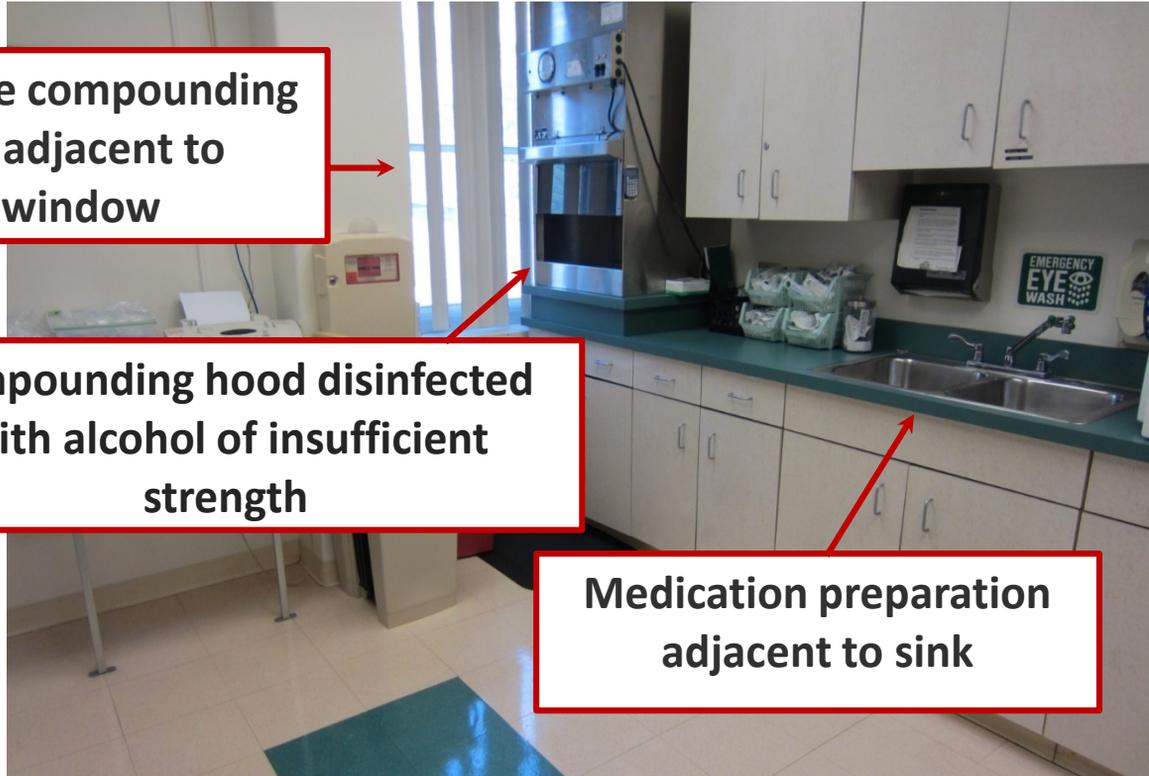
(Unsafe injection practices)

- Reuse of syringes for >1 patient
- Reuse of syringes to access medication vials for >1 patient
- Reuse of single-dose vials and saline bags for >1 patient
- Failure to wear facemasks when performing spinal injections
- Suboptimal procedures for IV line access and maintenance

Outbreaks in Oncology Settings (Examples)

Year (State)	Pathogen(s)	Infection(s), No. of Cases	Infection Control and Sterile Compounding Breaches	Reference
2004 (GA)	<i>Burkholderia cepacia</i>	Bloodstream infections, N=10	<ul style="list-style-type: none"> • Lack of adherence to sterile compounding standards in preparing chemotherapy and other medications (e.g., breaches in aseptic technique) • Common needle and syringe to access multiple multi-dose vials 	Abe K, et al. ICHE 2007;28:1311-13
2011 (MS)	<i>Pseudomonas aeruginosa</i> and <i>Klebsiella pneumoniae</i>	Bloodstream infections, N=14	<ul style="list-style-type: none"> • Syringe reuse among patients • Reuse of syringes to access medication containers used for >1 patient 	Dobbs TE, et al. AJIC 2014;42:731-4
2011 (WV)	<i>Tsukamurella species</i>	Bloodstream infections, N=15	<ul style="list-style-type: none"> • Lack of adherence to sterile compounding standards in preparing chemotherapy and repackaging sterile medications • Use of common-source bag of saline to prepare saline flush • Suboptimal procedures for central line access 	See I, et al. ICHE 2014;35:300-6
2012 (IL)	<i>Panotaea agglomerans</i>	Bloodstream infections, N=12	<ul style="list-style-type: none"> • Lack of adherence to sterile compounding standards in preparing chemotherapy and other medications (e.g., breaches in aseptic technique, hoods located next to sinks) 	Yablon BR, et al. ICHE 2017;38:314-9
2016 (NY)	<i>Exophiala dermatitidis</i>	Bloodstream infections, N=17	<ul style="list-style-type: none"> • Lack of adherence to safe injection practices • Lack of adherence to sterile compounding standards in preparing chemotherapy and other medications (e.g., breaches in aseptic technique, hoods located next to sinks) 	Vasquez AM, et al. MMWR 2016;65:1274-5

Outbreak of *Tsukamurella* Bloodstream Infections, Oncology Clinic, West Virginia, 2011



Sterile compounding hood adjacent to open window

Compounding hood disinfected with alcohol of insufficient strength

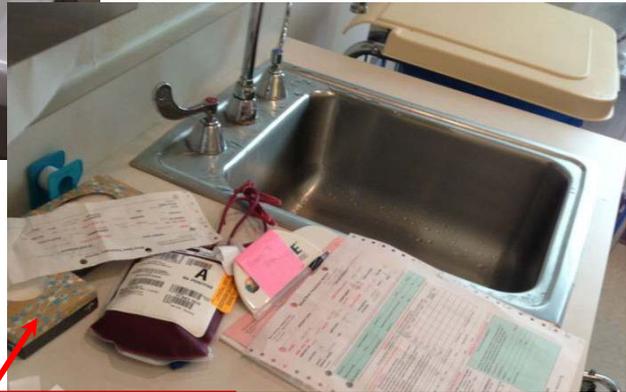
Medication preparation adjacent to sink

Outbreak of *Pantoea* Bloodstream Infections, Oncology Clinic, Illinois, 2012



Medication preparation adjacent to sink

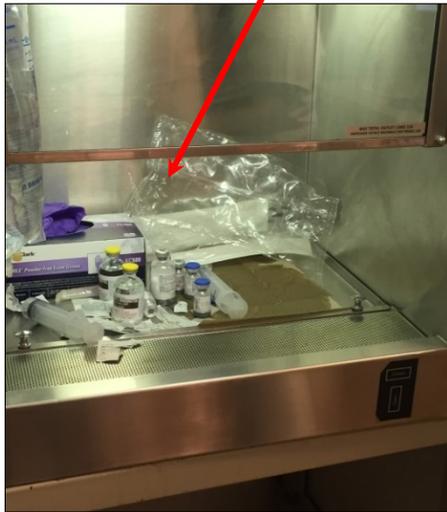
Breaches in aseptic handling of sterile medications



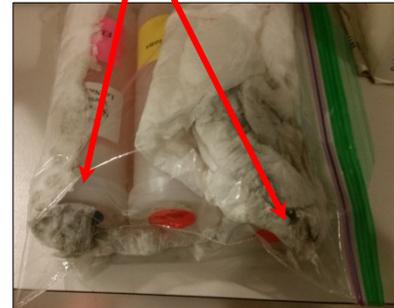
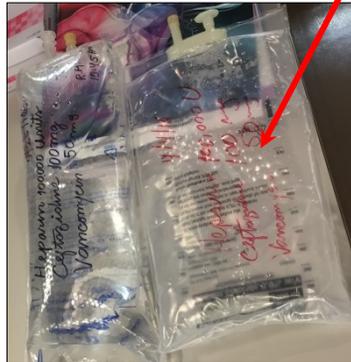
Infusion products adjacent to sink

Outbreak of *Exophiala* Bloodstream Infections, Oncology Clinic, New York, 2016

Exposure of critical sterile sites of hood to potentially contaminated materials



Medications improperly stored and labeled, with visible signs of contamination



Outpatient Settings Present Unique Challenges for Oversight and Prevention

- **Lack of oversight and accreditation** of outpatient settings relative to inpatient settings
 - *No clearly established authority for monitoring adherence to infection control and sterile compounding standards in these settings*—state public health departments, boards of medicine, boards of pharmacy, federal authorities?*

*CMS-certified facilities receive some oversight in adherence to infection control practices, but only a minority of outpatient facilities are certified.

- **Lack of infrastructure and resources** to support infection control and sterile compounding
 - *Sterile compounding is conducted in the absence of pharmacy controls and by inadequately trained personnel*

Outpatient Settings Present Unique Challenges for Oversight and Prevention

- **Highly variable** requirements for **provider training, licensure, certification, and continuing education**
 - *Physicians and allied health professionals may be unaware that the practices they engage in are subject to federal and state sterile compounding laws / standards*
- **Highly variable** requirements for **monitoring and reporting of HAIs and other adverse events** to state and federal authorities
 - *Delayed identification of and response to outbreaks, potentially leading to large patient notifications / harm*

Infection Prevention in Oncology Settings is Critical for Patient Safety

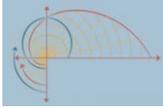
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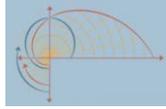
Key Facility and Personnel Requirements for Handling Sterile & Hazardous Drugs

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Acknowledgements

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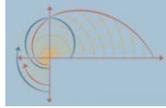
What Practice Standards Exist?

- American Society of Health-System Pharmacists (**ASHP**)
 - 1983 - First Hazardous Drug Technical Advisory Bulletin (TAB)
 - 2006 - Current version of ASHP Guidelines on Handling Hazardous Drugs (new version coming soon)
- Oncology Nursing Society (**ONS**)
 - Founded in 1975
 - 2018 - Safe Handling of Hazardous Drugs, 3rd edition
- American Society of Clinical Oncology (**ASCO**) / **ONS**
 - 2009 - Chemotherapy Administration Safety Standards (now 2016 course update)

[ASHP Guidelines on Handling Hazardous Drugs \[PDF - 34 pages\]](https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx) (<https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx>)

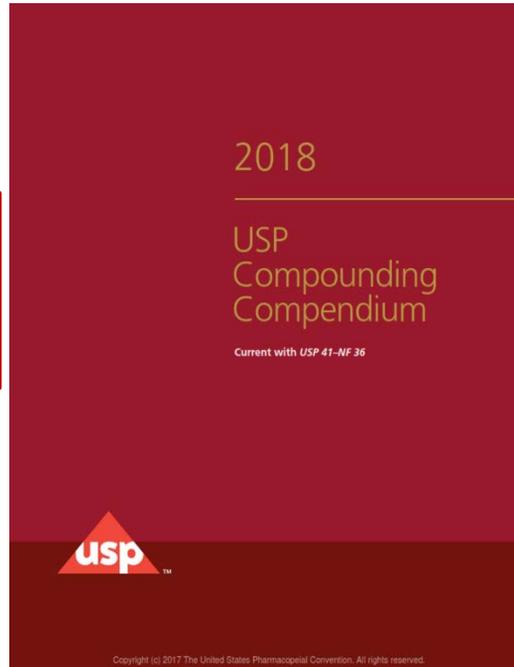
[Toolkit for Safe Handling of Hazardous Drugs for Nurses in Oncology](https://www.ons.org/toolkits/toolkit-safe-handling-hazardous-drugs-nurses-oncology) (<https://www.ons.org/toolkits/toolkit-safe-handling-hazardous-drugs-nurses-oncology>)

[Safe Handling of Hazardous Drugs Third Edition](https://www.ons.org/books/safe-handling-hazardous-drugs-third-edition) (<https://www.ons.org/books/safe-handling-hazardous-drugs-third-edition>)



What Regulations Exist?

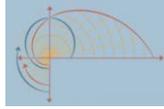
- USP <795> Pharmaceutical Compounding – Nonsterile Preparations
- USP <797> Pharmaceutical Compounding – Sterile Preparations
- OSHA regulations
- CMS Hospital Conditions of Participation
- State regulations



[Compounding Standards](http://www.usp.org/compounding) (<http://www.usp.org/compounding>)

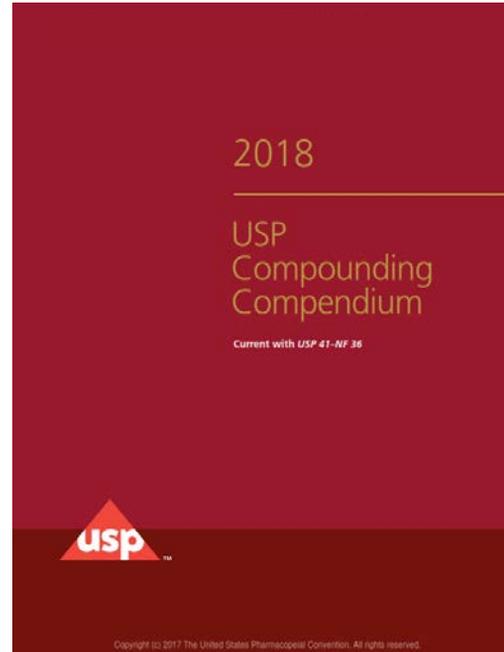
[Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications \[PDF - 45 pages\]](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-01.pdf)
(<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-01.pdf>)

[Hazardous Drugs](https://www.osha.gov/SLTC/hazardousdrugs/index.html) (<https://www.osha.gov/SLTC/hazardousdrugs/index.html>)



Identification of Issues

- Recognition that there is no federal standard that protects workers from hazardous drug (HD) exposure
- Professional organizational guidance documents are not regulations
- USP is recognized in the federal Food, Drug, and Cosmetic Act to set drug standards
- USP chapters numbered under <1000> are federally-enforceable standards

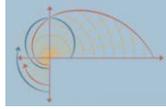


USP Chapter <797> Scope

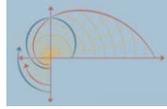


- Describes the minimum standards to prevent harm, including death, from:
 - microbial contamination (nonsterility),
 - excessive bacterial endotoxins,
 - variability in strength of correct ingredients,
 - chemical and physical contaminants,
 - ingredients of inappropriate quality in compounded sterile preparations (CSPs).
- Applies to:
 - all persons who prepare compounded sterile preparations
 - all places where CSPs are prepared
 - pre-administration manipulations of CSPs including storage, compounding, and transport
- Does not apply to administration!
- Specific chapter language:
 - “shall” is a requirement (must)
 - “should” is a recommendation

USP Chapter <800> Scope

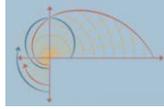


- Promotes patient safety, worker safety, and environmental protection. Handling hazardous drugs (HDs) includes, but is not limited to:
 - receipt, storage, compounding, dispensing, administration, disposal
- Applies to all healthcare personnel who handle HD preparations and all entities which store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, **patient treatment clinics, physicians' practice facilities**, or veterinarians' offices).
- Personnel who may potentially be exposed to HDs include, but are not limited to: pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians.



General Facility Elements

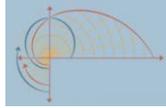
- Ceiling – epoxy-coated gypsum board or anodized aluminum T grids
 - Tiles must be caulked in place
- Walls – epoxy-coated gypsum board or interlocking panels
- Floors – wide-sheet vinyl or poured epoxy
- Sink – deep enough to perform hand hygiene to the elbows
- Lighting – sealed, flush mounted, easily cleanable



Engineering Controls



Engineering Controls for Containment: Definitions



Containment Primary Engineering Control (C-PEC)

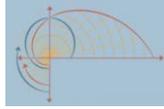
- Ventilated device to minimize worker and environmental exposure
- For sterile compounding, also provides product protection

Containment Secondary Engineering Control (C-SEC)

- The room in which the C-PEC is placed

Containment Supplemental Engineering Controls

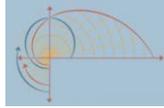
- Adjunct controls to offer additional levels of protection
- Closed System Drug-Transfer Devices (CSTDs)



Primary Engineering Controls

- Laminar Air Flow Workbench (LAFW)
- Biological Safety Cabinet (BSC)
- Compounding Aseptic Isolator (CAI & CACI)



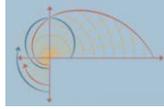


Secondary Engineering Controls

- Secondary Engineering Control is facility design
 - Positive Pressure - Net displacement of air *out* of the space
 - Negative Pressure - Net displacement of air *into* the space



**Traditional ISO Class 7
(Laminar Airflow Work hood) LAFW**



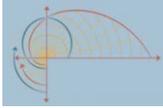
Supplemental Engineering Controls

- These devices are adjunct controls that may be used with C-PEC or C-SECs to offer additional levels of protection (containment)
- Facilitate enhanced occupational protection especially during administration
- Closed System Drug-Transfer Devices (CSTDs) are the only kind of Containment Supplemental Engineering Control available at this time



Remember:

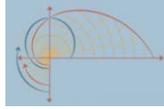
- CSTDs still can't prevent damage or spills from poor handling or transport!
- CSTDs are intended for use in an ISO Class 5 or better environment



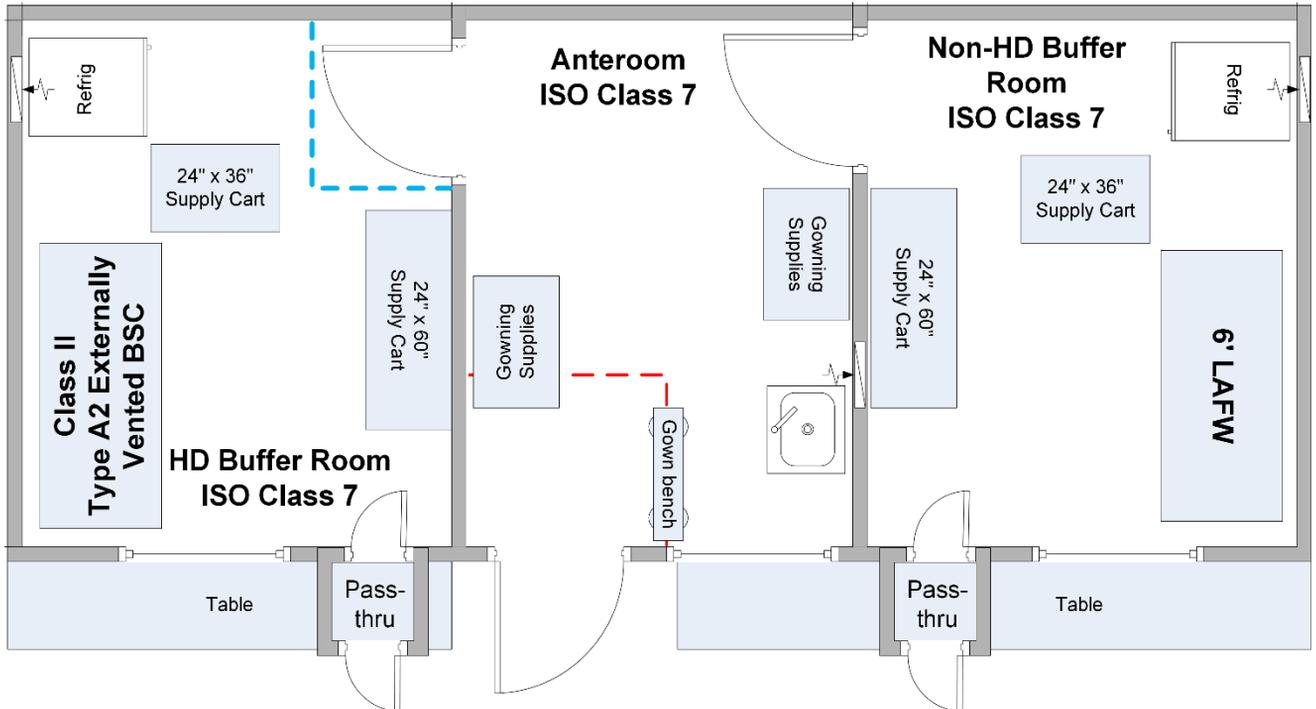
Use of Dispensing Devices Outside of Engineering Controls

- *Spiking a bag, vial, or bottle of sterile fluid with a dispensing device and leaving that device in place to withdraw medication for multiple patients increases the risk for microbial contamination. When performed outside of an ISO Class 5 environment, the device and subsequently the fluid can become contaminated. For this reason, using a dispensing device to spike parenteral solutions outside of an ISO Class 5 environment and leaving it in place to dispense medication for multiple patients puts patients at risk for infection and must be prohibited*

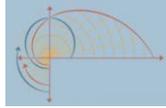
Cleanroom Suite



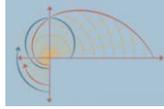
Hazardous applications: Anteroom must achieve at least ISO class 7 & be positive to uncontrolled spaces ➔ *Positive to the HD compounding room*



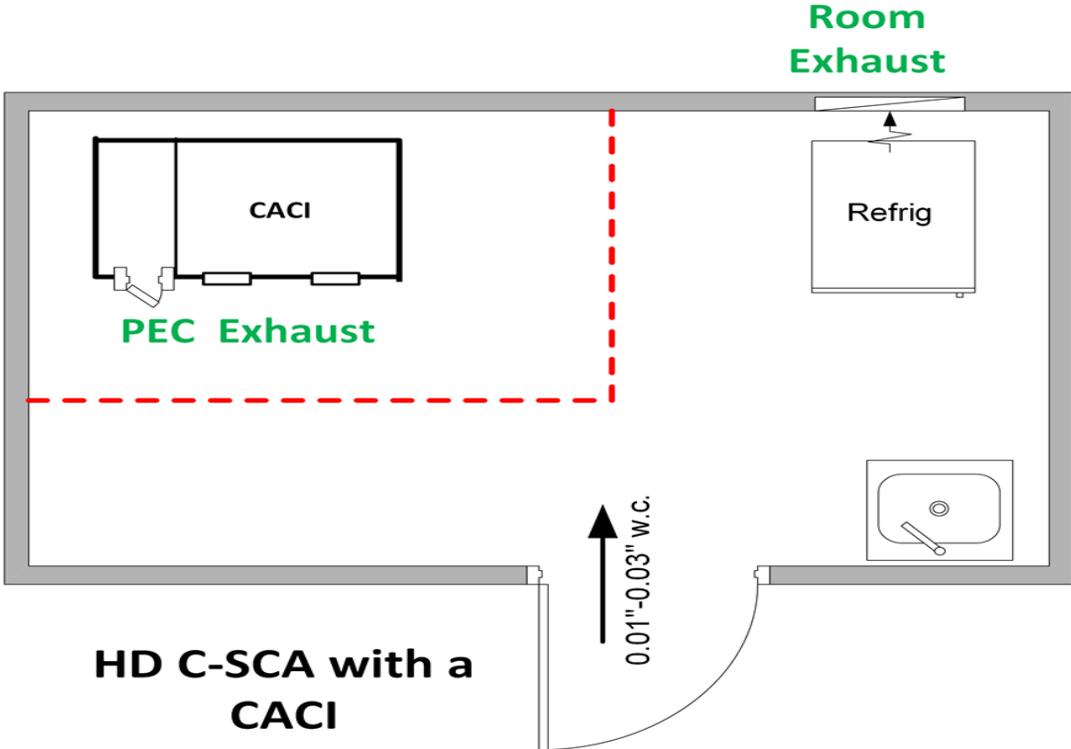
Containment Segregated Compounding Area (C-SCA)



- A type of Secondary Engineering Control
 - **Unclassified room with fixed walls dedicated to preparation of low to medium risk level HD CSPs**
 - Defined perimeter to separate functions
 - **Limited to 12 hour BUD** (proposed 797 is 12 hour room/24 hour refrigerated)
 - PEC must be externally vented
 - Minimum 12 ACPH
 - 0.01" w.c. to 0.03" w.c. negative pressure
 - **Hand washing sink at least 1 meter from C-PEC**
 - Can be either inside or directly outside the C-SCA



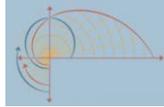
Containment Segregated Compounding Area (C-SCA) – Example



Beyond Use Dating



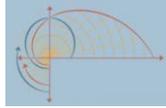
Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 Buffer Room	<ul style="list-style-type: none">Externally VentedExamples:<ul style="list-style-type: none">Class II BSCCACI	<ul style="list-style-type: none">30 ACPHExternally ventedNegative pressure between 0.01 and 0.03" w.c.	As described in <797>
C-SCA	<ul style="list-style-type: none">Externally VentedExamples:<ul style="list-style-type: none">Class II BSCCACI	<ul style="list-style-type: none">12 ACPHExternally ventedNegative pressure between 0.01 and 0.03" w.c.	12 hours



Storage and Handling

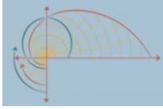


Requirements for Storing HD Inventory



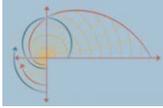
- HDs that may be stored with other inventory:
 - Non-antineoplastic
 - Reproductive risk only
 - Final dosage forms
- Antineoplastic HDs (requiring manipulation other than counting) and all HD APIs must be stored per all USP Chapter <800> requirements





Storage Requirements

- Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.
 - Minimum of 12 ACPH from exhaust
 - Negative pressure of 0.01 to 0.03” W.C.



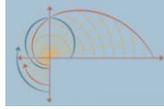
Personnel Training – Sterile Compounding

- All personnel who handle HDs must be trained based on their job functions
- Personnel competency must be reassessed at least every 12 months
- Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in process or SOP
- All training and competency assessment must be documented



Personnel Training – Hazardous Drugs

- The training must include at least the following:
 - Overview of entity's list of HDs and their risks
 - Review of the entity's SOPs related to handling of HDs
 - Proper use of PPE
 - Proper use of equipment and devices (e.g., engineering controls)
 - Response to known or suspected HD exposure
 - Spill management
 - Proper disposal of HDs and trace-contaminated materials



Thank You

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Oncology Nursing Perspectives

Martha Polovich, PhD, RN, AOCN

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Atlanta, GA

Preparation of Sterile Drugs

- Are you compounding?
 - Combining, mixing, or altering ingredients to create medication to meet unique needs of an individual patient

- USP Chapter <797> standards for sterile compounding
 - Clean room conditions
 - Competent personnel
 - Monitoring the environment

- Immediate use sterile compounding
 - Emergencies ONLY
 - Limited number of manipulations
 - Only non-hazardous drugs

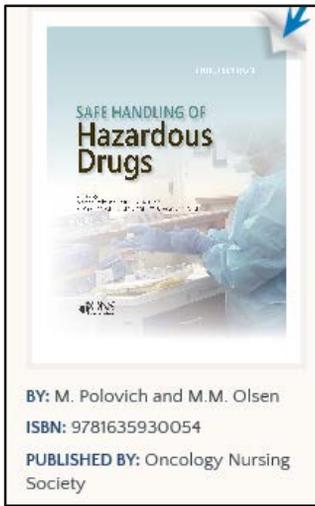
Prevention of Infections

- Aseptic technique for medication preparation and administration
- Minimize frequency of IV catheter manipulations
- Catheter care bundle to prevent CLABSI
 - Hand hygiene before insertion
 - Maximal sterile barrier precautions for insertion
 - Cleanse insertion site with >0.5% chlorhexidine with alcohol
 - Avoid femoral / jugular sites
 - Remove unnecessary catheters
 - “Scrub the hub”

Safe Injection Practices

- Perform drug preparation in a dedicated medication preparation area
- Scrub medication vial diaphragms with 70% alcohol and allow to dry
- Do not use single-dose vials for more than one patient
- Dedicate multi-dose vials to a single patient whenever possible
- Do not open syringe packages until needed
- Do not “batch” prepare syringes for later use outside of controlled environment
- Use commercially manufactured or pharmacy-prepared prefilled syringes (e.g., saline & heparin)

Resources from ONS



Safe Handling of Hazardous Drugs (Third Edition)

The third edition of *Safe Handling of Hazardous Drugs* provides nurses with the latest details and procedures needed to keep safe in the workplace. You'll find new chapters on post-administration issues, linen handling, disposal of hazardous drugs and hazardous drug waste, and the hazardous drug handling policy landscape. In addition to these new sections, each chapter includes key points to help highlight the most important information for nurses dealing with hazardous drugs.

Safe Handling of Hazardous Drugs is based on the recommendations of NIOSH, OSHA, ONS, the American Society of HealthSystem Pharmacists (ASHP), and USP. This essential guide is designed to help you translate safe handling recommendations into your daily practice as you handle HDs in the delivery of care to patients.

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Continuing Nursing Education | Member Center | Practice Resources | Advocacy and Policy | Help

Home > Practice Resources > Standards and Reports > ASCO/ONS Chemotherapy Standards

STANDARDS AND REPORTS

- Access Device Standards
- ASCO/ONS Chemotherapy Standards
- ONS Nursing Documentation Standards
- ONS Standard for Educating Nurses Who Administer Chemotherapy and Biotherapy
- Red Flags for Cancer Survivors
- Scope and Standards of Oncology Nursing Practice

ASCO/ONS Chemotherapy Administration Safety Standards

The American Society of Clinical Oncology (ASCO) and ONS are conducting an ongoing collaborative project to use a rigorous, consensus-based process to develop standards for the safe administration of chemotherapy. Current ASCO/ONS standards address the safety of all routes of chemotherapy administration to adult patients in the outpatient and inpatient settings.

The ASCO/ONS Chemotherapy Administration Safety Standards are intended to reduce the risk of error when providing adult patients with chemotherapy, and to provide a framework for best practices in cancer care. Your institution can use them to inform practice policies and procedures, internal quality assessment, and external quality monitoring.

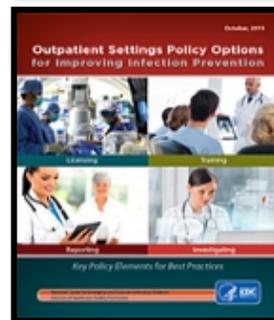
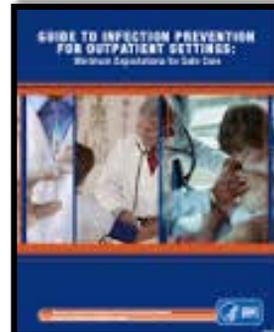
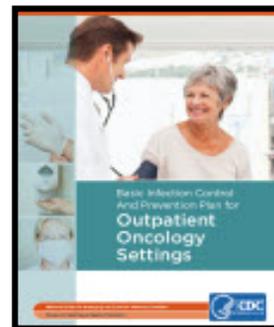
[Toolkit for Safe Handling of Hazardous Drugs for Nurses in Oncology](https://www.ons.org/toolkits/toolkit-safe-handling-hazardous-drugs-nurses-oncology) (<https://www.ons.org/toolkits/toolkit-safe-handling-hazardous-drugs-nurses-oncology>)

[Safe Handling of Hazardous Drugs Third Edition](https://www.ons.org/books/safe-handling-hazardous-drugs-third-edition) (<https://www.ons.org/books/safe-handling-hazardous-drugs-third-edition>)

Additional Information and Resources

CDC Resources: Infection Control

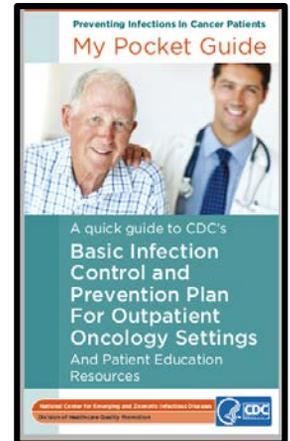
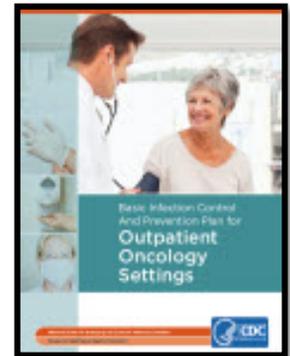
- **[Basic Infection Control and Prevention Plan for Outpatient Oncology Settings \[PDF - 32 pages\]](https://www.cdc.gov/hai/pdfs/guidelines/basic-infection-control-prevention-plan-2011.pdf)**
<https://www.cdc.gov/hai/pdfs/guidelines/basic-infection-control-prevention-plan-2011.pdf>
- ***Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care***
- **[Outpatient Settings Policy Options for Improving Infection Prevention \[PDF - 37 pages\]](https://www.cdc.gov/hai/pdfs/prevent/Outpatient-Settings-Policy-Options.pdf)**
<https://www.cdc.gov/hai/pdfs/prevent/Outpatient-Settings-Policy-Options.pdf>
- **[Injection Safety](http://www.cdc.gov/injectionsafety/providers/provider_faqs.html)**
http://www.cdc.gov/injectionsafety/providers/provider_faqs.html



CDC Resources: Infection Control

■ *Basic Infection Control and Prevention Plan for Outpatient Oncology Settings*

- I. Fundamental Principles of Infection Prevention
- II. Education and Training
- III. Surveillance and Reporting
- IV. Standard Precautions
 - A. Hand Hygiene
 - B. Personal Protective
 - C. Respiratory Hygiene and Cough Etiquette
 - D. Injection Safety**
 - E. Medication Storage and Handling**
 - F. F. Cleaning and Disinfection of Devices and Environmental Surfaces
- V. Transmission-Based
- VI. Central Venous Catheters



[Basic Infection Control and Prevention Plan for Outpatient Oncology Settings](https://www.cdc.gov/HAI/settings/outpatient/basic-infection-control-prevention-plan-2011/)

(<https://www.cdc.gov/HAI/settings/outpatient/basic-infection-control-prevention-plan-2011/>)

CDC Resources: Injection Safety



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

SEARCH



CDC A-Z INDEX ▾

Injection Safety



Injected medicines are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Unsafe injection practices put patients and healthcare providers at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures and settings. This harm is preventable. Safe injection practices are part of Standard Precautions and are aimed at maintaining basic levels of patient safety and provider protections. As defined by the World Health Organization, a safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community. [Visit the page on CDC's role in safe injection practices.](#)

[CDC](#) > [Injection Safety](#) > [Information for Providers](#) > [FAQs regarding Safe Practices for Medical Injections](#)

Frequently Asked Questions (FAQs) regarding Safe Practices for Medical Injections



Pages in this Report

1. Background
2. General
3. Medication Preparation
4. Medication Administration
5. Single-dose/Single-use vials
6. Multi-dose vials
7. References

[Injection Safety](https://www.cdc.gov/injectionsafety/) (https://www.cdc.gov/injectionsafety/)

[FAQs regarding Safe Practices for Medical Injections](https://www.cdc.gov/injectionsafety/providers/provider_faqs_general.html) (https://www.cdc.gov/injectionsafety/providers/provider_faqs_general.html) 56

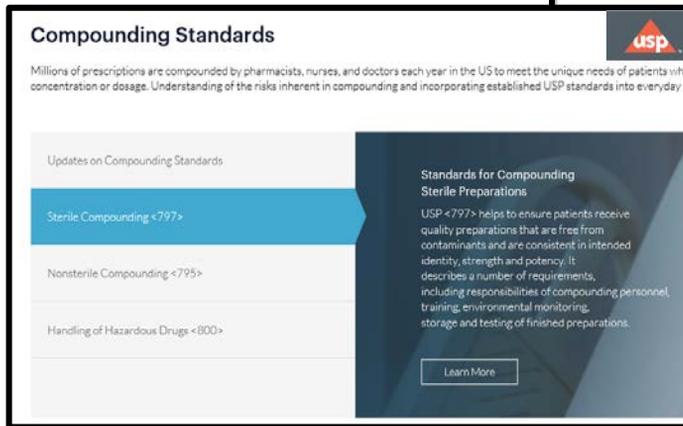
FDA & USP Resources: Sterile Compounding

- [FDA: Human Drug Compounding](http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/default.htm)

<http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/default.htm>

- [USP: Compounding Standards](http://www.usp.org/compounding)

<http://www.usp.org/compounding>



Compounding Standards

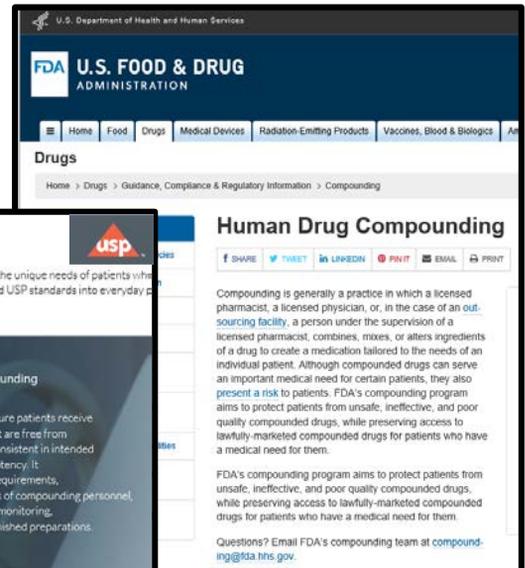
Millions of prescriptions are compounded by pharmacists, nurses, and doctors each year in the US to meet the unique needs of patients with unique concentration or dosage. Understanding of the risks inherent in compounding and incorporating established USP standards into everyday practice is essential.

- Updates on Compounding Standards
 - Sterile Compounding <797>**
 - Nonsterile Compounding <795>
 - Handling of Hazardous Drugs <800>

Standards for Compounding Sterile Preparations

USP <797> helps to ensure patients receive quality preparations that are free from contaminants and are consistent in intended identity, strength and potency. It describes a number of requirements, including responsibilities of compounding personnel, training, environmental monitoring, storage and testing of finished preparations.

[Learn More](#)



U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics

Drugs

Home > Drugs > Guidance, Compliance & Regulatory Information > Compounding

Human Drug Compounding

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Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an [outsourcing facility](#), a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present a risk to patients. FDA's compounding program aims to protect patients from unsafe, ineffective, and poor quality compounded drugs, while preserving access to lawfully-marketed compounded drugs for patients who have a medical need for them.

FDA's compounding program aims to protect patients from unsafe, ineffective, and poor quality compounded drugs, while preserving access to lawfully-marketed compounded drugs for patients who have a medical need for them.

Questions? Email FDA's compounding team at compounding@fda.hhs.gov.

CDC's Preventing Infections in Cancer Patients Program

Lisa C. Richardson, MD, MPH
Director, Division of Cancer Prevention and Control

Division of Cancer Prevention and Control

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Preventing Infections in Cancer Patients (PICP) Program

Three websites for patients, caregivers & HCPs



30+ Campaign Materials
Fact sheets, posters, infographics, postcards, patient care totes, etc.



Preventing Infections in Cancer Patients (PICP) Program

- **>300 million** potential people exposed to PICP content
- PICP resources have been downloaded, received, or viewed more than **2 million** times since program was launched
- **40% increase** in PreventCancerInfections.org visitors from 2016 to 2017
- **47% improvement** in cancer patients indicating they received infection prevention education from their provider
- **25% increase** in patients and caregivers' understanding of neutropenia after visiting PCI.org

What's Next? Virtual Simulation Tools



An interactive role-play simulation featuring Tina and Joe...our virtual patient and provider



What's Next? Special Resources

3 STEPS TOWARD

Buscar en el sitio

Inicio | Acerca de Sitios | Contacto en Español | Contacto en Inglés | Inicio

Inicio de | Acerca de Sitios | Contacto en Español | Contacto en Inglés | Inicio

Prepararse

¿Qué es el cáncer?

¿Cómo se usa el cáncer?

Material educativo

Acerca de la campaña

Contenido destacado

EL CÁNCER ES UNA LUCHA. NO PERMITA QUE LA GRIPE LO NOQUEE.

**¡CONTRAATAQUE!
VACÚNESE CONTRA LA GRIPE**

Tome medidas para protegerse de la gripe, de modo que pueda concentrarse en librar la lucha más importante.

La gripe es grave para las personas con cáncer. Derriba la gripe con un golpe doble esta temporada:

1. Vacúnese contra la gripe (póngase la inyección, no utilice la vacuna antigripal en forma de aerosol nasal).
2. Asegúrese de que las personas que viven con usted o que lo cuidan se pongan también la vacuna antigripal.

La vacuna antigripal es su mejor protección contra la gripe esta temporada.

La prevención de infecciones en pacientes con cáncer es una iniciativa de gran envergadura dirigida por el Centro para el Control y la Prevención de Enfermedades (CDC) y la Fundación de los CDC que tiene por objeto reducir las infecciones en los pacientes con cáncer. Para obtener más información sobre este tema y conocer más acerca de este programa, visite www.PreventCancerInfections.org.

Este programa ha sido posible gracias a la asociación entre la Fundación de los CDC y Amgen, y el financiamiento recibido de esta compañía. En el marco de esta asociación, la Fundación de los CDC aprovechó la experiencia en oncología proporcionada por Amgen.

PreventCancerInfections.org/es

Educational Materials

Please visit
PreventCancerInfections.org
and
cdc.gov/cancer/preventinfections



Follow DCPC Online!



@CDC_Cancer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Division of Cancer Prevention and Control

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Infection Prevention in Oncology Settings is Critical for Patient Safety

It is important for outpatient oncology settings to:

- Recognize that **failure to adhere to safe injection practices and sterile compounding standards** **places patients at risk** for healthcare-associated infections (HAIs) and other adverse events
- Become familiar and **implement standards for basic infection control** and **safe injection practices**
- Know when medication preparation practices are subject to **sterile compounding standards** and **apply the appropriate standards for those practices**
- **Identify and report** suspected HAI outbreaks to public health authorities as soon as they are identified

Thank You

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Outbreak inquiries and guidance:
haioutbreak@cdc.gov

Injection safety inquiries and guidance:
injectionsafety@cdc.gov

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