

Infection Prevention in Outpatient Oncology Settings

Dr. Alice Guh, Centers for Disease Control and Epidemiology

A Webber Training Teleclass

Infection Prevention in US Outpatient Oncology Settings

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Hosted by Dr. Lynne Sehulster
Centers for Disease Control and Epidemiology



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Speaker Disclosures

- Disclosures: None
- The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention

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Outline

- Review U.S. outbreaks associated with outpatient oncology care
- Outline recommended infection prevention practices for U.S. outpatient oncology settings
- Describe CDC tools for preventing infections among oncology patients

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Shift in Healthcare Delivery to Outpatient Settings

- ~5000 outpatient oncology facilities in the United States
- >1 million U.S. patients with cancer receive outpatient chemotherapy and/or radiation each year
- Distribution of outpatient chemotherapy services among Medicare recipients*
 - 67% in physician offices
 - 24% in hospital-based outpatient settings
 - 9% in both settings

*Source: Millman's analysis of Medicare 5% Sample, 2006-2009.

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Concerns About Outpatient Care

- Expansion of services without proportionally expanded infection control oversight
 - Infection control practices vary greatly
 - Some facilities lack written infection control policies and procedures for patient protection
- Outpatient oncology settings are not routinely inspected for infection control practices
- Lack systematic surveillance to detect infections originating in outpatient settings

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Oncology Patients: Risks for Infection

- Immunosuppression
 - Medications
 - Underlying disease
- Invasive long-term central lines
 - Essential: infusion of chemotherapy, blood draws
 - Provide direct portal-of-entry to bloodstream



<http://www.icumed.com/media/16766/eg-clave-header.jpg>

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U.S. Outbreaks Associated with Outpatient Oncology Settings

State	Year	Predominant Infection Type(s)	No. of Cases
NE	2002	Hepatitis C infection	99
CA	2002	<i>Alcaligenes xylosoxidans</i> bloodstream infection	12
IL	2004	<i>Klebsiella oxytoca</i> and/or <i>Enterobacter cloacae</i> bloodstream infection	27
GA	2004	<i>Burkholderia cepacia</i> bloodstream infection	10
GA	2007	Polymicrobial bloodstream infection	13
NJ	2009	Hepatitis B infection	29
NJ	2011	<i>K. pneumoniae</i> bloodstream infection	11
MS	2011	<i>K. pneumoniae</i> and/or <i>Pseudomonas aeruginosa</i> bloodstream infection, skin/soft tissue infection	17
WV	2011	<i>Tsukamurella</i> spp. bloodstream infection	15
IL	2012	<i>Pantoea</i> spp. bloodstream infection	11

Example 1: Hepatitis C Virus Outbreak in Nebraska

- **2002 – gastroenterologist reported to state health department a cluster of 4 HCV infections**
 - Patients who received care at single hematology/oncology clinic
 - All genotype 3a (rare)
- **Health department conducted investigation**
 - 613 patients notified to be tested for HCV
 - At least 99 patients with HCV identified
 - Lacked previous evidence of HCV infections
 - Genotype 3a in all available samples (n=95)

Macedo de Oliveira A et al. Ann Intern Med 2005;142:898-902.

HCV Outbreak – Nebraska, 2002 Infection Control Assessment

- **Nurse reused syringes to access saline bag for flushes**
 - After syringes were used to withdraw blood from patients' catheters
 - Patient recalled seeing blood in saline bag
- **Saline bag used as common-source supply for multiple patients**
 - Contaminated bag could have served up to 25-50 patients
- **Breaches came to light in 2001, but never reported to public health authorities**

Macedo de Oliveira A et al. Ann Intern Med 2005;142:898-902.

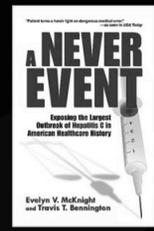
Following the Nebraska HCV Outbreak: One Survivor's Response



Evelyn's Story

Dr. Evelyn McKeight is a nationally recognized patient safety advocate and survivor of one of the largest viral outbreaks in American health care history. Dr. McKeight turned her own personal tragedy into a crusade to save lives.

Evelyn is co-founder and president of HONOReform and HONOReform Foundation. She is co-author of *A Never Event: Exposing the Largest Outbreak of Hepatitis C in American Healthcare History*, in which she details the 2001 Nebraska outbreak. Evelyn presents at local, regional and national conferences; she recently presented at conferences led by ANNA, APIC, the CDC and the CDC Foundation, and she presented at the World Vaccine Congress, among many others. All honoraria she receives help fund HONOReform.



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Example 2: Hepatitis B Virus Outbreak in New Jersey

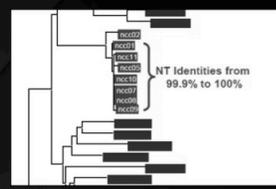
- **2009 – gastroenterologist reported to state health department 2 patients with acute HBV infection**
 - No traditional risk factors
 - Both received care at same hematology/oncology clinic
- **Freestanding hematology/oncology clinic**
 - Small number of clinical staff
- **State and local health department initiated investigation**

Greasley RD et al. Am J Infect Control 2011; Oct:39-663-70.

HCV Outbreak – New Jersey, 2009 Case-Finding

- **4600 patients notified to be tested**
- **At least 29 outbreak-associated HBV cases**

Molecular Testing:
HBV
sequence
analysis



Greasley RD et al. Am J Infect Control 2011; Oct:39-663-70.

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HCV Outbreak – New Jersey, 2009
Infection Control Assessment

Suboptimal hand hygiene and glove use

Greeley RD et al. Am J Infect Control 2011; Oct:39:663-70.

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HCV Outbreak – New Jersey, 2009
Infection Control Assessment

Suboptimal hand hygiene and glove use



Use of saline bags as common-source supply

Photos courtesy of Ms. Rebecca Greeley
Greeley RD et al. Am J Infect Control 2011; Oct:39:663-70.

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HCV Outbreak – New Jersey, 2009
Infection Control Assessment

Suboptimal hand hygiene and glove use



Use of saline bags as common-source supply



Storing opened single-dose vials for future use

Photos courtesy of Ms. Rebecca Greeley
Greeley RD et al. Am J Infect Control 2011; Oct:39:663-70.

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HCV Outbreak – New Jersey, 2009
Infection Control Assessment

Suboptimal hand hygiene and glove use



Use of saline bags as common-source supply



Storing opened single-dose vials for future use



Suboptimal chemotherapy preparation

Photos courtesy of Ms. Rebecca Greeley
Greeley RD et al. Am J Infect Control 2011; Oct:39:663-70.

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HCV Outbreak – New Jersey, 2009
Infection Control Assessment

Blood Stain on Floor in Chemotherapy Room



Photo courtesy of Ms. Rebecca Greeley
Greeley RD et al. Am J Infect Control 2011; Oct:39:663-70.

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HCV Outbreak – New Jersey, 2009
Additional Actions

- Hematology/Oncology practice was closed
- Board of Medical Examiners suspended physician's license

Unpublished data by New Jersey Department of Health and Senior Services

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Example 3:
Outbreak of *Pseudomonas aeruginosa* and *Klebsiella pneumoniae* Bloodstream Infections – Mississippi, 2011

- July 2011 – local hospital reported to state health department a cluster of bloodstream infections among 4 patients:
 - *P. aeruginosa* with identical antimicrobial resistance patterns
 - 2 also with *K. pneumoniae*
 - All had received infusion at same outpatient cancer facility
- Freestanding cancer center
 - Single-physician owned, small number of staff
- State and local health department investigated

Unpublished data by Mississippi State Department of Health

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***P. aeruginosa* / *K. pneumoniae* Outbreak – MS, 2011**
Case-Finding

- 16 patients with bloodstream infections with *P. aeruginosa*, *K. pneumoniae*, or both

Pseudomonas aeruginosa

Klebsiella pneumoniae

Unpublished data by Mississippi State Department of Health

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***P. aeruginosa* / *K. pneumoniae* Outbreak – MS, 2011**
Infection Control Assessment

- Unlicensed individual functioning in nurse role (infusing chemotherapy)
- Recent decision by facility to reuse heparin and saline syringes as cost savings measure
 - Directly reused syringes between patients; discarded only when blood visible in syringe
- Used common-source saline bag to flush ports
 - Reused syringes throughout the day for same patient

Photo courtesy of Dr. Thomas Dobbs
Unpublished data by Mississippi State Department of Health

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***P. aeruginosa* / *K. pneumoniae* Outbreak – MS, 2011**
Infection Control Assessment

- Prepared syringes containing non-chemotherapy medications, kept for multiple days
 - Opportunity for contamination
- Long-standing practice

Photos courtesy of Dr. Thomas Dobbs
Unpublished data by Mississippi State Department of Health

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***P. aeruginosa* / *K. pneumoniae* Outbreak – MS, 2011**
Additional Actions

- Facility closed by state health department at onset of investigation
- Investigation by law enforcement due to fraudulent billing by facility
- Egregious lapses in injection safety prompted patient notification for bloodborne pathogen testing
 - 623 patients notified to be tested for HBV, HCV, HIV
 - Testing performed by local health department

Unpublished data by Mississippi State Department of Health

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Example 4:
Outbreak of *Tsukamurella* spp. Bloodstream Infections – West Virginia, 2011-2012

- October 2011 – local hospital reported increase in number of blood cultures growing bacillus
 - All in patients receiving care at same oncology clinic
- Subsequent testing of isolates indicated they were *Tsukamurella* spp. instead
 - Environmental pathogen
 - Rare cause of disease, mostly among immunosuppressed patients with central lines

Left photo from Shim HE et al, Korean J Lab Med (2009)

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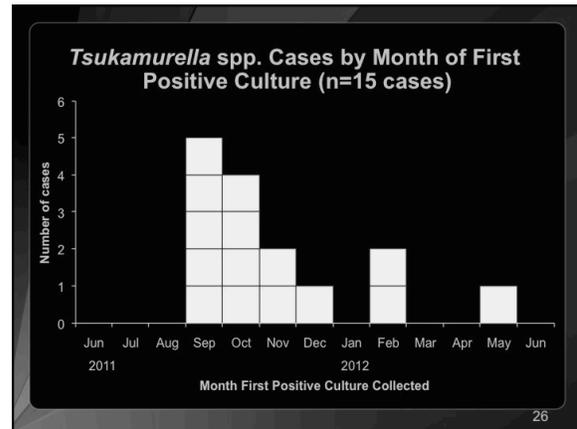
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Tsukamurella spp. Outbreak – WV, 2011-2012
Health Department Investigation

- ❑ **Oncology clinic located on hospital campus, but independently owned and operated**
- ❑ **Site inspection by state and regional epidemiologists**
 - Infection control lapses were identified and remediated
 - Sporadic cases occurred in 2012
- ❑ **CDC field assistance in June 2012**

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Tsukamurella spp. Outbreak – WV, 2011-2012
Potential Clues: Specific Exposures

- ❑ **Only known common exposure among all cases was receipt of care at oncology clinic**
- ❑ **Several cases: only clinic exposure was saline flush**
 - Received no chemotherapy prior to infection
- ❑ **Late-onset cases**
 - All had lines accessed in September/October 2011 (known infection control lapses present in clinic)
 - No novel exposures later in time uncovered

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Tsukamurella spp. Outbreak – WV, 2011-2012
Infection Control Assessment

- ❑ **Prior to November 2011**
- ❑ **Used saline bag as common-source supply for saline flushes for multiple patients**
- ❑ **Used non-sterile cotton balls moistened with alcohol to clean catheter hubs prior to access**

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Tsukamurella spp. Outbreak – WV, 2011-2012
Infection Control Assessment

- ❑ **Prior to November 2011**
- ❑ **Used saline bag as common-source supply for saline flushes for multiple patients**
Changed to commercially packaged saline flush syringes
- ❑ **Used non-sterile cotton balls moistened with alcohol to clean catheter hubs prior to access**
Changed to sterile commercially packaged 70% isopropyl alcohol pads

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Tsukamurella spp. Outbreak – WV, 2011-2012
Additional Observations of Concern

Unsafe injection practices:

- ❑ **Using single-dose vials for >1 patient over multiple days**
- ❑ **Using same syringe/needle to access medication vials that were used for >1 patient**

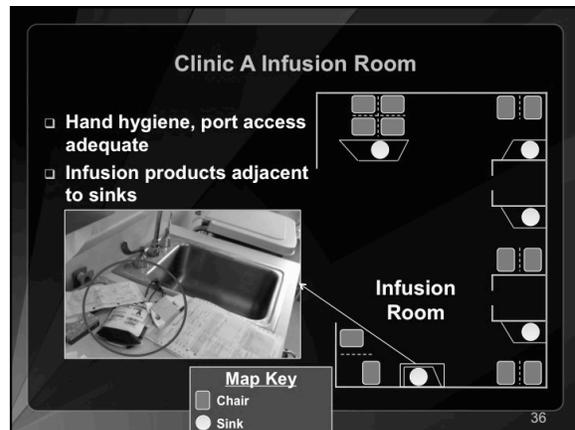
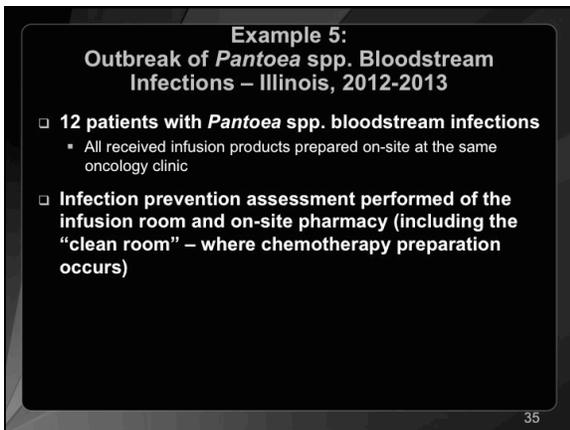
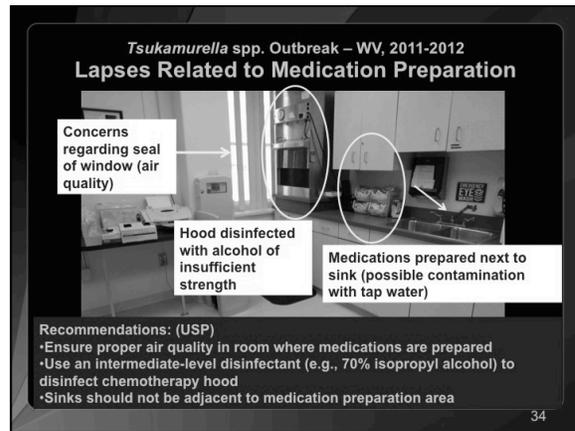
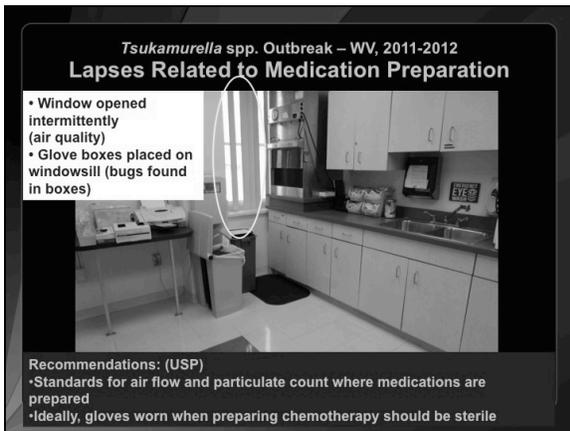
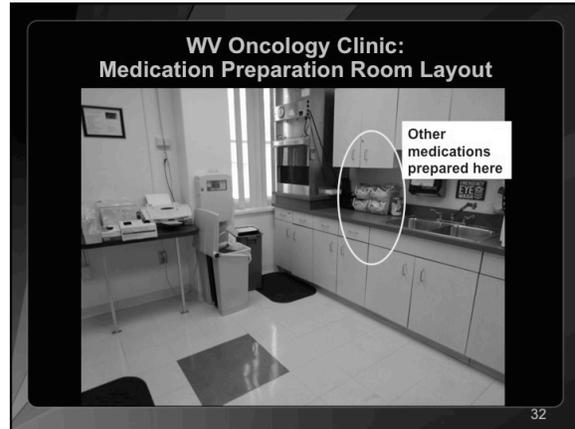
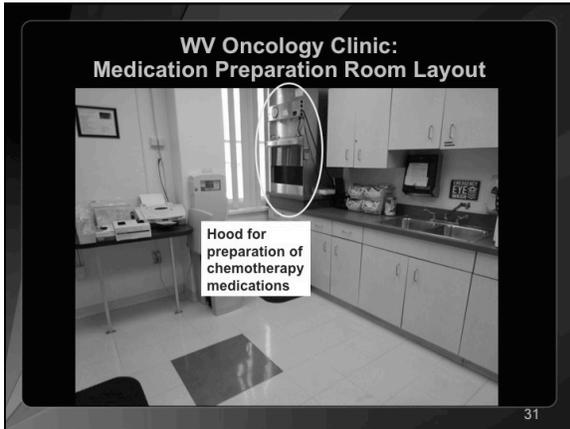
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Clean Room Concerns

Pharmacy

Clean Room

Contrary to guidelines

- ❑ Hand hygiene gaps
- ❑ Medication vial septa inadequately cleaned

Clean Room Concerns

Pharmacy

Clean Room

Contrary to guidelines

- ❑ Hand hygiene gaps
- ❑ Medication vial septa inadequately cleaned
- ❑ Presence of sink

Environmental Culture Results

Pharmacy

Clean Room

Pantoea

Infusion Room

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Pantoea spp. Outbreak – IL, 2012-2013

Additional Results

- ❑ **10 of 12 patient isolates and *Pantoea* isolate from clean room sink matched by PFGE**
 - Suggesting outbreak may have resulted from tap water contamination of infusates (during preparation) or subsequent surface contamination of infusate bag/container
- ❑ **Deficiencies in clinic's water system**
 - Substantial dead space piping
 - Scant chlorine residual (<0.2 ppm) in all 3 sinks of pharmacy and 4 of 5 infusion room sinks
 - Water heterophile plate count exceeded EPA limits for all 8 sinks tested

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Summary of Infection Control Lapses

- ❑ **Unsafe injection practices**
 - Storing opened single-dose vials for use over multiple days
 - Use of single-dose vials for >1 patient
 - Use of saline bag as common source for >1 patient
 - Storing prefilled or unwrapped saline/heparin syringes for later use
 - Reuse of syringes to access medication vials/bags
 - Direct syringe reuse from one patient to another
- ❑ **Inadequate environmental conditions for chemotherapy preparation and suboptimal handling / placement of infusion products**
- ❑ **Suboptimal disinfection for accessing central line and poor hand hygiene**

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Just Scratching the Surface...

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What Are Key Areas for Infection Prevention in Outpatient Oncology Settings?

- Increased attention to preparation and administration of injectable medications
- Maintain appropriate environment and procedures for chemotherapy preparation
- Ensure appropriate central line access and care

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Injection Safety

- Proper use and handling of parenteral medications and related supplies for any injection procedure:
 - Syringes, needles, intravenous tubing, medication vials, and parenteral solutions

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Injection Safety: Key Recommendations

- Dedicate SDVs for single patient use and do not store opened SDVs for future use
- Avoid using saline bags as common-source supply for >1 patient
- Use new syringe/needle to access medication vial/bag
- Avoid prefilling and storing batch-prepared syringes (outside of pharmacy setting)
- Whenever possible, use commercially manufactured or pharmacy-prepared prefilled syringes (saline, heparin)

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What Are Key Areas for Infection Prevention in Outpatient Oncology Settings?

- Increased attention to preparation and administration of injectable medications
- Maintain appropriate environment and procedures for chemotherapy preparation
- Ensure appropriate central line access and care

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Guidance for Sterile Compounding: USP<797>

- Segregated compounding area (separate from patient care)
 - No unsealed windows, doors connecting to high traffic flow, etc.
 - No sink in clean room
 - Meet specified air quality
- Use chemo hood meeting standard requirements
- Don appropriate PPE
- Follow aseptic technique for sterile compounding, with appropriate beyond-use-dating

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What Are Key Areas for Infection Prevention in Outpatient Oncology Settings?

- Increased attention to preparation and administration of injectable medications
- Maintain appropriate environment and procedures for chemotherapy preparation
- **Ensure appropriate central line access and care**

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Central Line Access and Care



- **Scrub access port with appropriate antiseptic**
 - Chlorhexidine, povidone iodine, 70% alcohol
- **Access only with sterile device**
- **Ensure appropriate saline and/or heparin flush of line**
 - Preparation, administration

Critical to disinfect properly before access

<http://rgmotion.org/Personal%20Care.htm>

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CDC Tools for Outpatient Oncology Care

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CDC Campaign – October 2011: Preventing Infections in Cancer Patients

- **Joint effort between Division of Healthcare Quality Promotion (DHQP) and Division of Cancer Prevention and Control (DCPC)**
 - DHQP – Tool for healthcare providers: **Basic Infection Control and Prevention Plan for Outpatient Oncology Settings**
 - DCPC – Resources for patients and caregivers: interactive educational website that assesses patient's risk for infection and provides information to prevent infections

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Preventing Infections In Cancer Patients: Tool for Healthcare Providers

Development of a Basic Infection Control and Prevention Plan for Outpatient Oncology Settings

- Standardize and improve infection prevention practices
- Essential elements to meet minimal expectations of patient safety
- Based on guidelines from CDC and professional societies

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Main Components of the Basic Infection Control and Prevention Plan

- **Education and Training**
- **Surveillance and Reporting**
- **Standard Precautions**
- **Transmission-Based Precautions**
- **Central Venous Catheters**



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**Infection Prevention Plan
Education and Training**



- ❑ **Education and training of all facility staff**
 - At orientation and repeated at least annually and anytime policies or procedures are updated
 - Job- or task-specific infection prevention practices
- ❑ **Competency evaluations**
 - Regular audits to assess staff adherence to recommended practices

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**Infection Prevention Plan
Surveillance and Reporting**

- ❑ **Purposes: case-finding, outbreak detection, and improving healthcare practices**
- ❑ **Conduct facility surveillance for healthcare-associated infections and/or process measures**
 - Central-line associated bloodstream infections
 - Hand hygiene
- ❑ **Adhere to local, state, and federal requirements for reportable diseases and outbreak reporting**

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**Infection Prevention Plan
Standard Precautions**



- ❑ **Hand hygiene**
- ❑ **Use of personal protective equipment**
- ❑ **Respiratory hygiene and cough etiquette**
- ❑ **Safe injection practices (including appropriate medication storage and handling)**
- ❑ **Safe handling of potentially contaminated equipment or surfaces in the patient environment**

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**Standard Precautions:
Respiratory Hygiene**

- ❑ **Identifying patients and visitors with respiratory symptoms at the point of entry into healthcare facility**
 - Reception/waiting area
- ❑ **Instituting measures to prevent spread of respiratory infections**
 - Spatial separation, facemask use
 - Ensuring availability of supplies
- ❑ **Promoting cough etiquette**
- ❑ **Enhancing measures during periods of increased respiratory virus activity**



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**Standard Precautions:
Injection Safety**



- ❑ **Outlines practices for:**
 - General safe injection practices
 - Spinal injection procedures
 - Phlebotomy procedures
- ❑ **Describes storage and handling of parenteral medications (outside of pharmacy setting)**
 - Single-dose and multi-dose vials
 - Specific steps for medication preparation
 - When to discard



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**Standard Precautions:
Cleaning and Disinfection of Devices and Environmental Surfaces**

- ❑ **Pertains to disinfection of:**
 - Noncritical patient-care devices (e.g., blood pressure cuff)
 - Environmental surfaces in patient-care and common-use areas
 - Exam rooms, chemotherapy suite
 - Bathrooms
- ❑ **Focus cleaning on high-touch surfaces**





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Infection Prevention Plan Transmission-Based Precautions

- ❑ **Intended to supplement Standard Precautions**
 - Use when route of transmission is not completely interrupted by Standard Precautions
- ❑ **Identifying potentially infectious patients for applying additional precautions**
 - Contact Precautions
 - Suspected infectious diarrhea, draining wounds or skin lesions
 - Droplet Precautions
 - Respiratory viruses
 - Airborne Precautions
 - Tuberculosis, disseminated herpes zoster

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Infection Prevention Plan Central Venous Catheters



- ❑ **General maintenance and access procedures**
 - Use of aseptic technique for accessing central venous catheters
 - Blood draws from catheters
 - Changing catheter site dressing and injection caps
- ❑ **Catheter-specific recommendations:**
 - Peripherally inserted central catheters (PICCs)
 - Tunneled catheters
 - Implanted ports

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Appendix Section (I)

- ❑ **List of Persons Designated to Specific Tasks**

Appendix A.
Example List of Contact Persons and Roles/Responsibilities

Contact Person(s) (Name/Title)	Contact Information	Roles/Responsibilities
Phone: Pager: Email:		<ul style="list-style-type: none"> • Infection prevention personnel/consultant • Assist with infection control assessment, contact tracing, and implementation of interventions • Identify potential for spreading patients who require additional measures of isolation
Phone: Pager: Email:		<ul style="list-style-type: none"> • Educate and train facility staff including Environmental Health and Safety (EHS) personnel • Assist with competency of staff/able to access records • Assist with infection control assessment • Proper use of PPE • Environmental cleaning/sterilization • Disinfection of surfaces • Precautions services, such as enhanced respiratory screening • Cleaning when for enhanced respiratory screening • Ensure facility sick leave policies are in place and followed
Phone:		<ul style="list-style-type: none"> • Collect, manage, and analyze data for surveillance purposes

- ❑ **List of Reportable Diseases/Conditions**
 - Facility to obtain information from health department websites

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Appendix Section (II)

- ❑ **CDC Infection Prevention Checklist for Outpatient Settings**
 - Tailor to oncology settings to evaluate personnel competency and adherence to recommended practices

Section II: Personnel and Patient-care Observations		
Hand hygiene performed correctly	Practice Performed	If answer is No, document plan for remediation
A. Before contact with the patient or their immediate care environment (even if gloves are worn)	Yes No	
B. Before exiting the patient's care area after touching the patient or the patient's immediate environment (even if gloves are worn)	Yes No	
C. Before performing an aseptic task (e.g., insertion of IV or preparing an injection) (even if gloves are worn)	Yes No	
D. After contact with blood, body fluids or contaminated surfaces (even if gloves are worn)	Yes No	

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Additional Resources

- ❑ **Web links to national guidelines**
 - Occupational health requirements
 - Appropriate preparation and handling of antineoplastic agents
 - Infection prevention issues unique to blood and marrow transplant centers
 - Clinical recommendations and guidance for treatment of patients with cancer

Additional Resources

Selected information about each of the topics below can be found in the accompanying resources.

- Infection prevention issues unique to blood and marrow transplant centers (A.S.A. Bone Marrow Transplant or Stem Cell Transplant Centers)
- Guidelines for Handling Opportunistic Infections Among Hematopoietic Stem Cell Transplant Recipients (available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm59a04a01.htm>)
- Guidelines for Handling Medical Contaminations among Hematopoietic Cell Transplantation Recipients in Outpatient Settings (available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm59a04a02.htm>)
- Occupational health requirements, including infectious pathogen training, health care personnel immunization, and other personnel protective equipment for hematopoietic stem cell transplantation
- Appropriate preparation and handling (e.g., reconstituting, mixing, diluting, compounding) of sterile medications, including antineoplastic agents
- United States Pharmacopoeia Chapter $C790$ Guidelines for Pharmaceutical Compounding—Sterile Ophthalmics
- International Society of Clinical Pharmacy Practitioners Standards of Practice (available at <http://www.iscpharm.org/standards-of-practice>)
- American Society of Health-System Pharmacists Guidelines for Handling Hazardous Drugs (available at <http://www.ashp.org/DocLibrary/BestPractices/Prevalence/Handling.aspx>)
- Clinical recommendations and guidance for treatment of patients with cancer (including appropriate antineoplastic prescribing practices)

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Action Steps for Implementing the Basic Infection Control and Prevention Plan

Oncology facilities *without* a plan can start using this plan, and further supplement as needed.

Does not replace need for facilities to have regular access to an individual with training in infection control

Oncology facilities *with* an existing plan should ensure that essential elements are included.

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Patient and Caregiver Web Site
www.PreventCancerInfections.org

- The interactive online tool, called *3 Steps Toward Preventing Infections During Cancer Treatment*, helps cancer patients assess their risk for developing neutropenia and subsequent infections.
- Users complete a brief risk assessment to assess their risk.



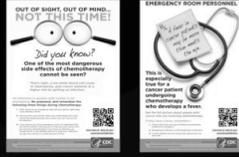
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CDC Campaign Materials

Fact Sheets



Posters



Campaign One-Pager



Patient Care Totes



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Next Steps for CDC

- **Increase understanding of current chemotherapy preparation practices to inform prevention efforts**
 - Performed in-depth interviews with small sample of outpatient oncology facilities (n=18) but need to conduct more interviews as well as observations
 - Engage pharmacy and oncology nursing professional organizations
- **Continued dissemination of Basic Infection Control and Prevention Plan**
 - Initial responses from facilities were positive, requesting additional materials including pocket guide

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Thank you

For more information please contact Centers for Disease Control and Prevention
 1600 Clifton Road NE, Atlanta, GA 30333
 Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
 E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

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.

National Center for Emerging and Zoonotic Infectious Diseases
 Division of Healthcare Quality Promotion



Coming Soon

- November 5 (Free WHO Teleclass – Europe)
GLOBAL APPLICATION OF BEHAVIOUR CHANGE MODELS AND INFECTION CONTROL STRATEGIES
 Dr. Michael Borg, St. Luke's Hospital, Malta
 Sponsored by the World Health Organization
- November 6 (Free Teleclass)
CBIC IS MAKING THE CERTIFICATION PROCESS WORK FOR ALL !
 Craig H Gilliam and Lita Jo Henman, Certification Board of Infection Control
- November 13 **EMERGING RESPIRATORY VIRUSES: ARE HEALTHCARE WORKERS PROTECTED?**
 Dr. Virginia Roth, The Ottawa Hospital
- November 20 **THE ROLE OF COMPANION ANIMALS IN INFECTION TRANSMISSION**
 Prof. Timothy Landers, Ohio State University & Prof. Jason Stull, University of Guelph

www.webbertraining.com/schedule1.php

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