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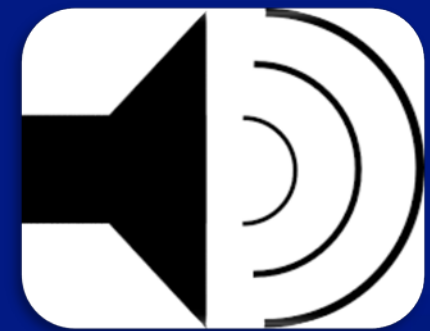


Lessons from an Outbreak Investigation: Improving Medication Preparation, Use, and Other Infection Control Practices in Outpatient Oncology Clinics

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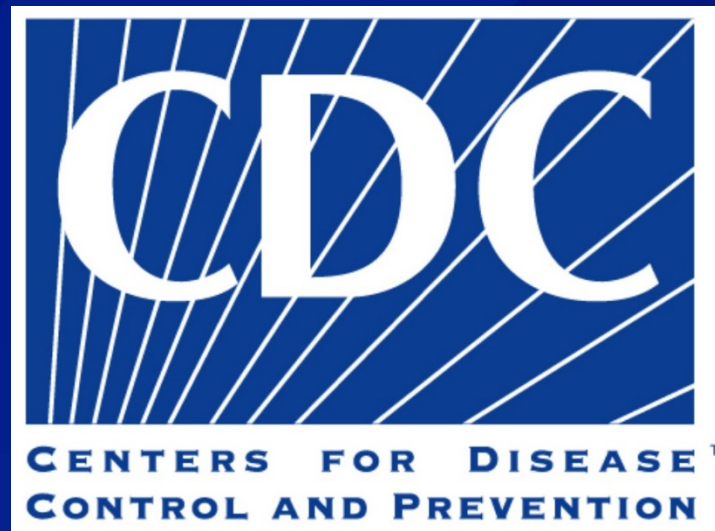
Continuing Education Information

PROGRAM DESCRIPTION:

- ❑ Compounding and infusion of intravenous medications occur in many outpatient settings. Without consistent knowledge and enforcement of proper practices, standards and regulations, patient and provider safety is at risk. This presentation will discuss an outbreak of fungal bloodstream infections due to improper medication compounding and poor infection control practices at an outpatient oncology clinic and review the oversight and enforcement landscape of safety standards in outpatient settings.

OBJECTIVES:

- ❑ Describe infection control techniques that reduce the risk and spread of healthcare-associated infections (HAI).
- ❑ Identify unsafe practices that place patients at risk for HAIs.
- ❑ Describe best practices for infection control and prevention in daily practice in healthcare settings.
- ❑ Apply standards, guidelines, best practices, and established processes related to safe and effective medication use.



Lessons from an Outbreak Investigation: Improving Medication Preparation, Use, and Other Infection Control Practices in Outpatient Oncology Clinics

Joe Perz, DrPH, MA

Team Leader, Quality, Standards, and Safety
Division of Healthcare Quality Promotion, CDC

April 18, 2017

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



Featured Speakers

- ❑ Amber Vasquez, MD, MPH , EIS Officer, Class of 2015, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention
 - Outbreak of fungal bloodstream infections associated with an outpatient oncology clinic-New York City, 2016

- ❑ Joel Ackelsberg, MD, MPH, Medical Epidemiologist, Bureau of Communicable Disease, NYC Department of Health and Mental Hygiene
 - The Wild Wild West: Public Health Options to Expand Oversight of Outpatient Oncology Practices



CDC Disclaimer: The findings and conclusions in this presentation are those of the presenter(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Featured Speakers

- Lisa C. Richardson, MD, MPH , Director,
Division of Cancer Prevention and Control,
Centers for Disease Control and Prevention
 - Infection Control and Prevention in the Outpatient Oncology Setting: CDC Resources for Protecting Your Patients and Your Practice



Before We Get Started...

- **To submit a question:**
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The speakers’ slides will be provided to participants in a follow-up email.



Outbreak of fungal bloodstream infections associated with an outpatient oncology clinic — New York City, 2016

Amber Vasquez, MD, MPH

EIS Officer, Class of 2015

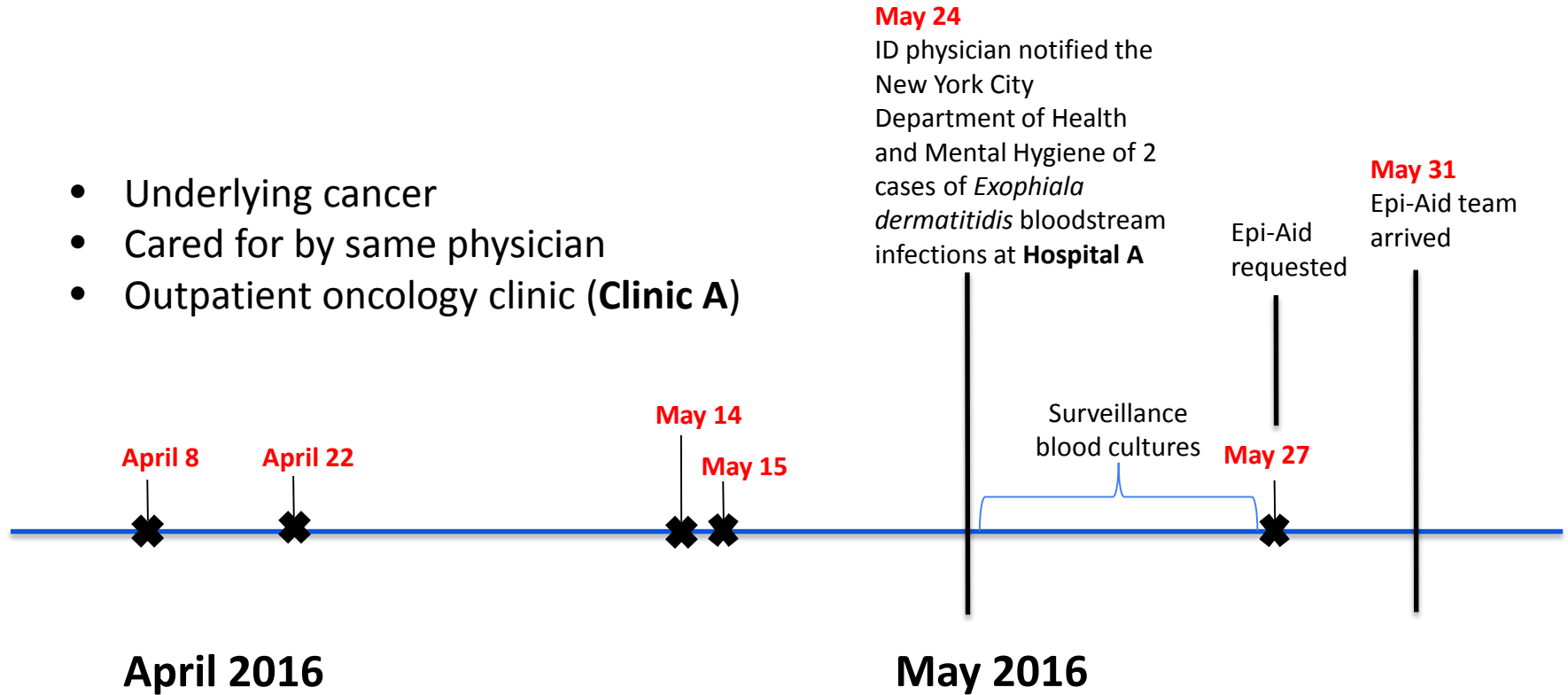
Division of Healthcare Quality Promotion

Centers for Disease Control and Prevention

April 2017

The Call...

- Underlying cancer
- Cared for by same physician
- Outpatient oncology clinic (**Clinic A**)

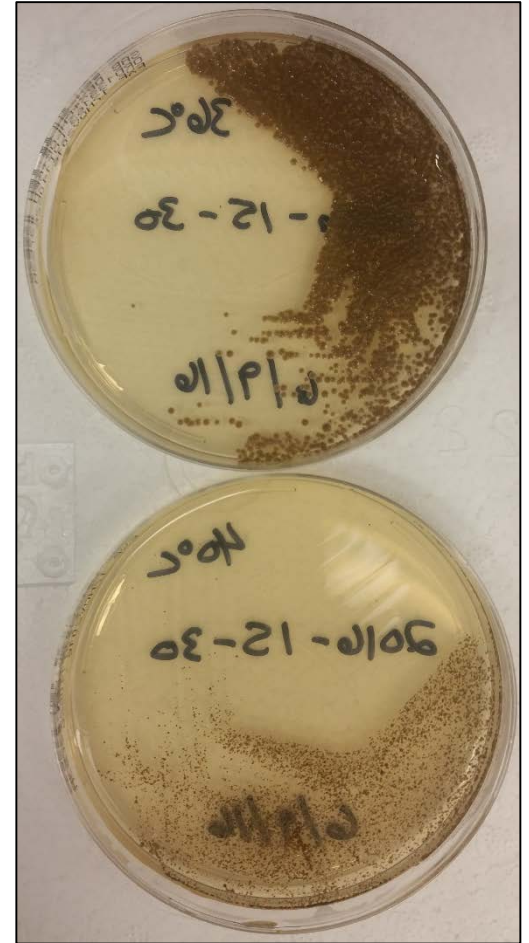


Background



Exophiala (Wangiella) dermatitidis

- Common environmental fungus
 - Black yeast/mold
- Prior outbreak of neurologic infections
 - Steroid injections from compounding pharmacy¹
- Infections are rare
- Bloodstream infections are **extremely** rare



¹Morbidity and Mortality Weekly Report. Exophiala Infection from Contaminated Injectable Steroids Prepared by a Compounding Pharmacy, United States, July-November 2002. MMWR December 2002, 51(49);1109-1112.

Oncology Patients at Increased Risk

- Immunosuppression
 - Medications
 - Underlying cancer
- Long-term central venous catheters (CVCs)



**Implanted port catheter
(Port)**



**Peripherally-inserted central catheter
(PICC)**

Clinic A Description

- 1 physician, 1 nurse, 1 phlebotomist, front desk staff
 - Medical evaluations and follow-up visits
 - Phlebotomy services
 - Chemotherapy infusions
- Patients use Hospital A for select services
 - Inpatient admission
 - Procedures (port placement)



Clinic A infusion room

Case Investigation



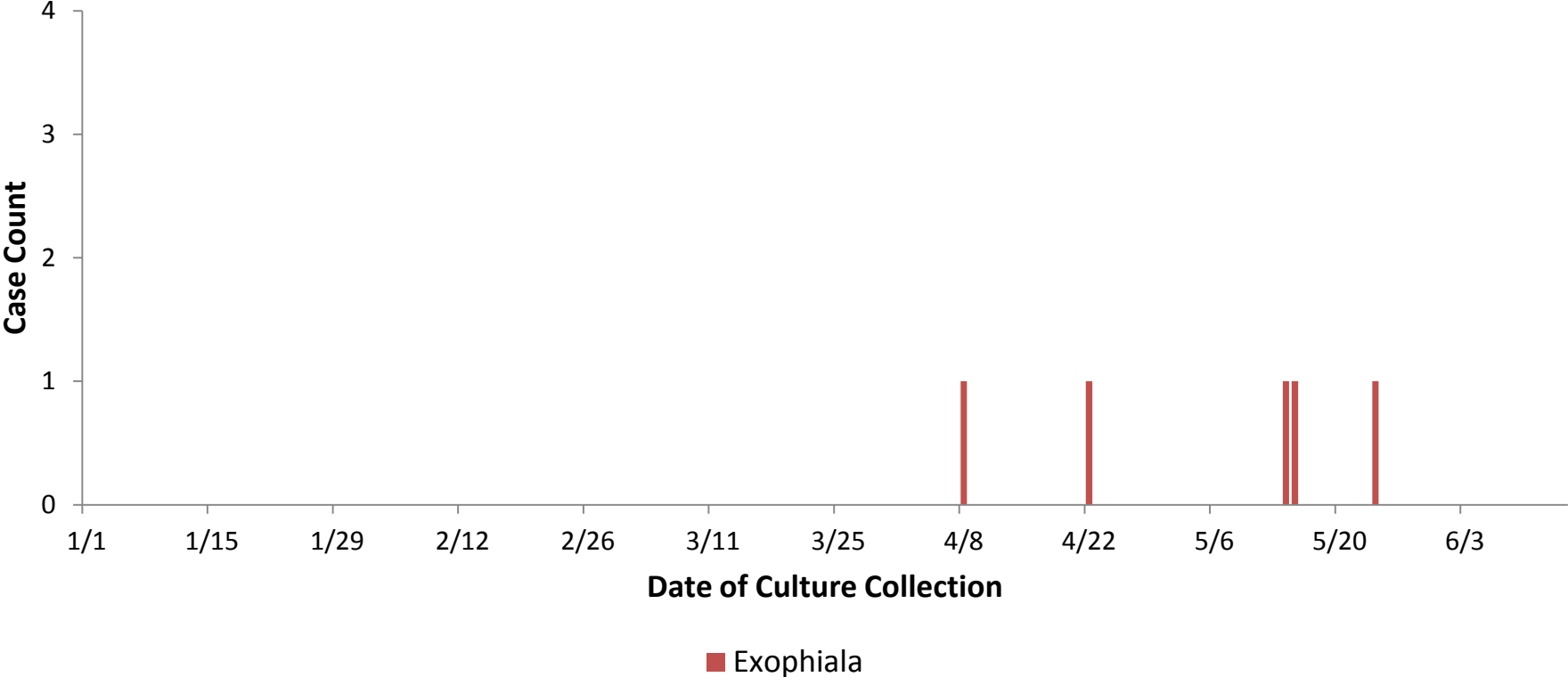
Case Definition

- Any non-*Candida* yeast or mold identified on culture of blood or CVC from a patient who received care at Clinic A during January 1–May 31, 2016

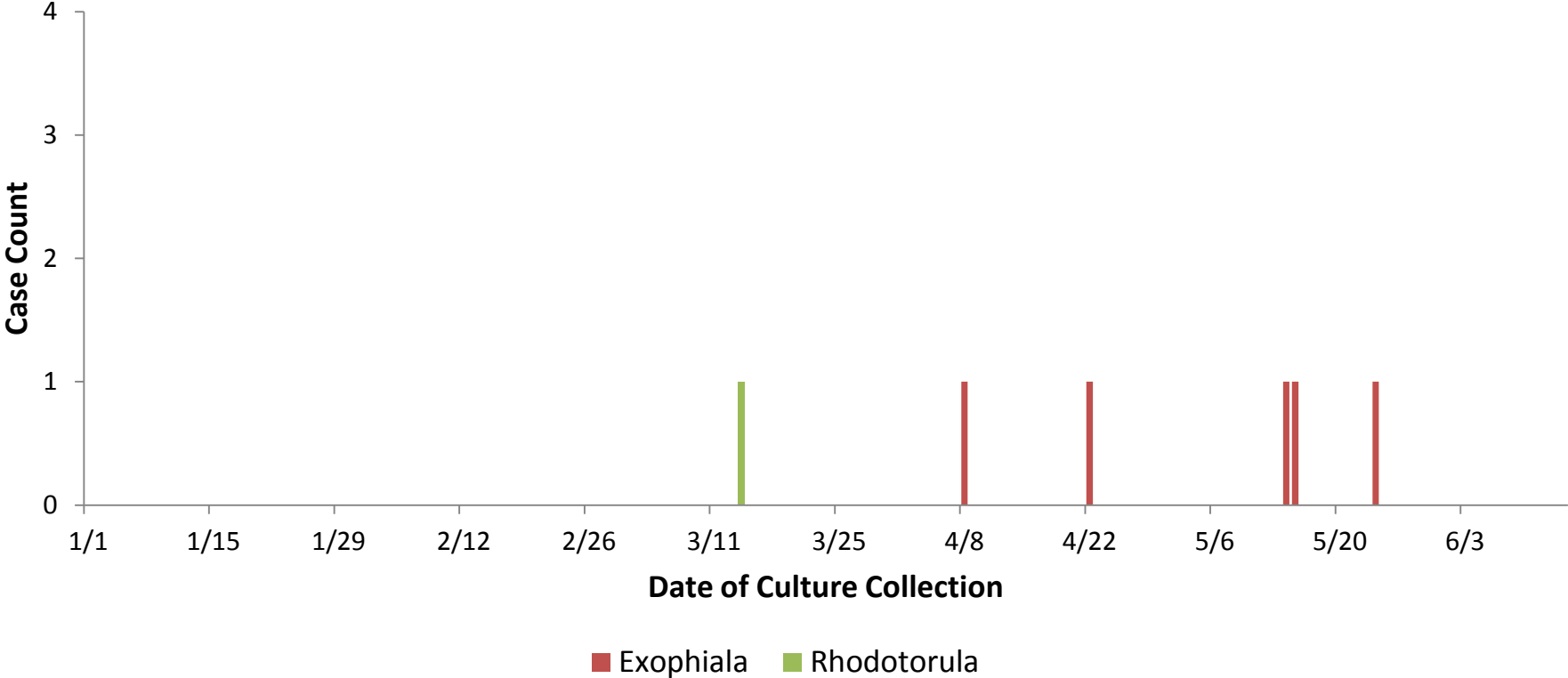
Case Finding

- Review of microbiology records at Hospital A's network laboratory
- Review of Clinic A records to identify patients who:
 - Had a CVC or received any IV medication
- Surveillance blood cultures
 - All patients with a CVC or received IV medication in the clinic
- Medical record review of deceased patients

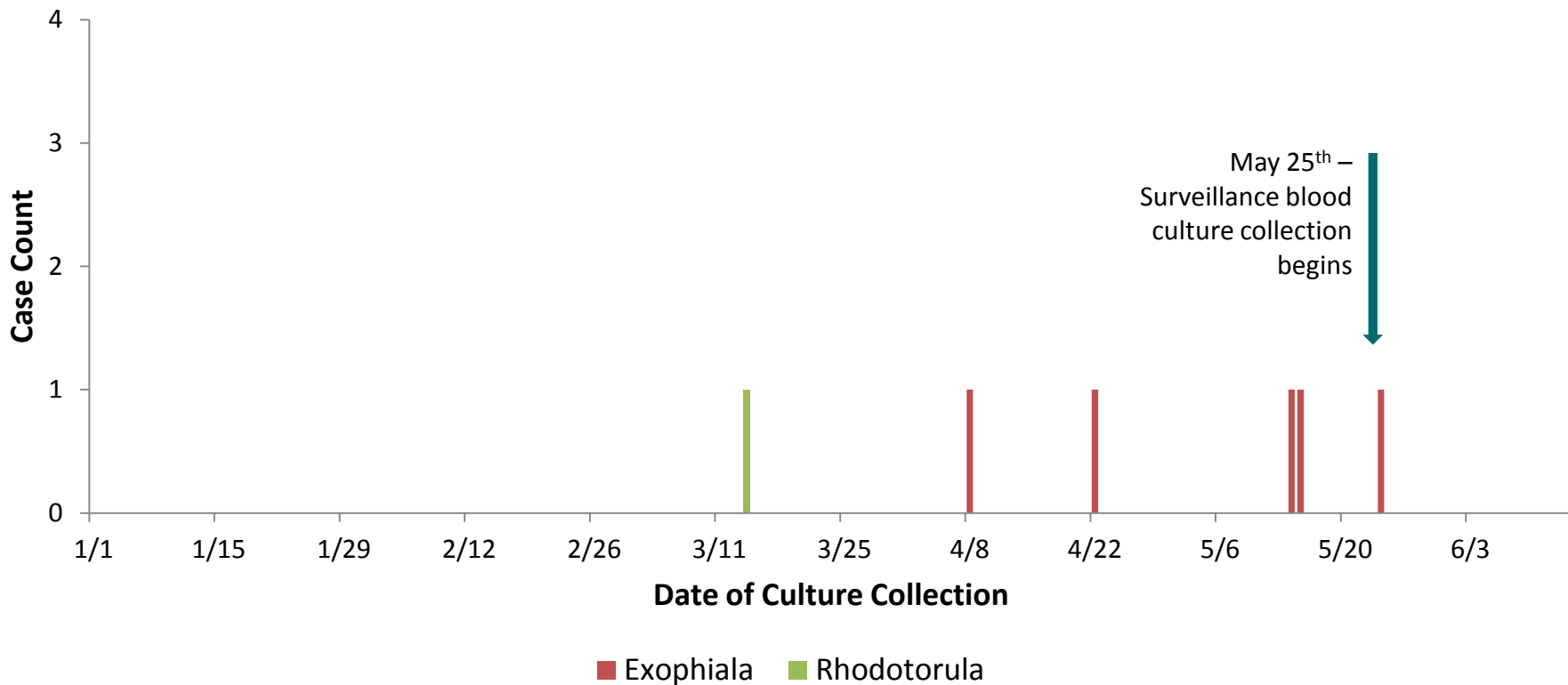
Cases of fungal bloodstream infection associated with Clinic A by date of culture — January 1–May 31, 2016



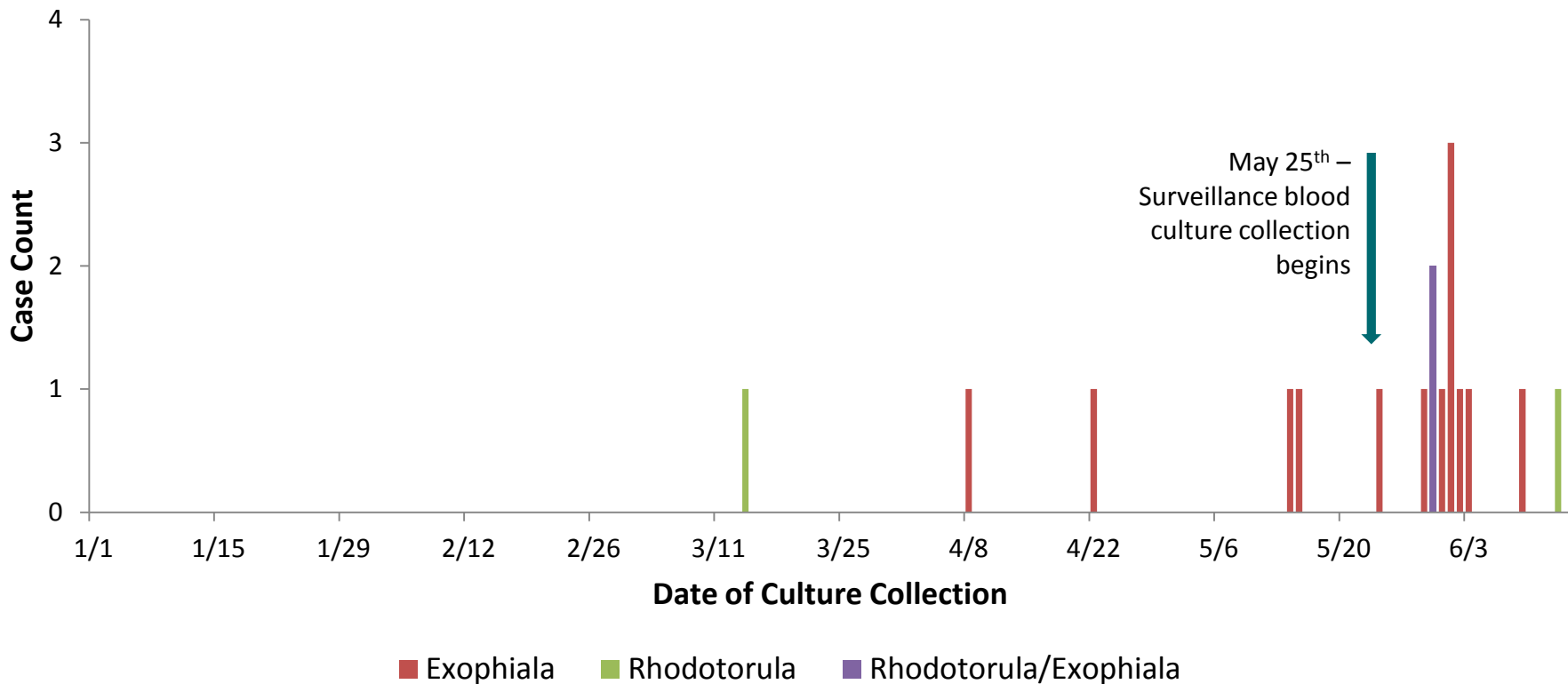
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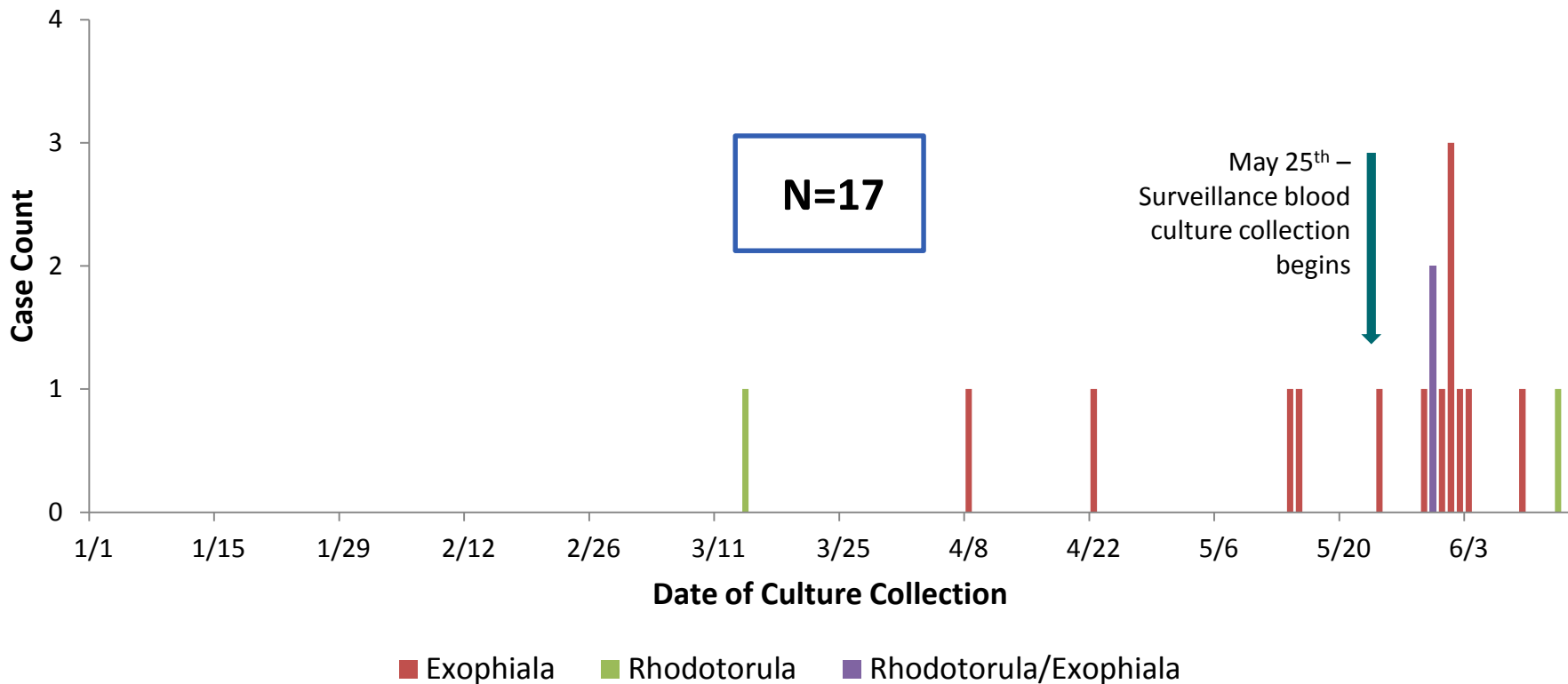
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Cases of fungal bloodstream infection associated with Clinic A by date of culture — January 1–May 31, 2016



Cases of fungal bloodstream infection associated with Clinic A by date of culture — January 1–May 31, 2016



Case Description: Demographics (n=17)

Characteristic	Median (range)
Age in years	64 (22-95)

Characteristic	n	(%)
Gender, Male	10	(59)

Case Description: Clinical Characteristics (n=17)

Characteristic	n	(%)
Malignancy	17	(100)
Solid organ	15	(88)
Lymphoma	2	(12)
Presence of a CVC	17	(100)
Port	16	(94)
PICC	1	(6)
Clinical Presentation		
Symptomatic	5	(29)
Asymptomatic	12	(71)

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Case Description: Microbiology (n=17)

Characteristic	n	(%)
Microbiology		
<i>E. dermatitidis</i>	13	(76)
<i>R. mucilaginosa</i>	2	(12)
<i>E. dermatitidis</i> + <i>R. mucilaginosa</i>	2	(12)

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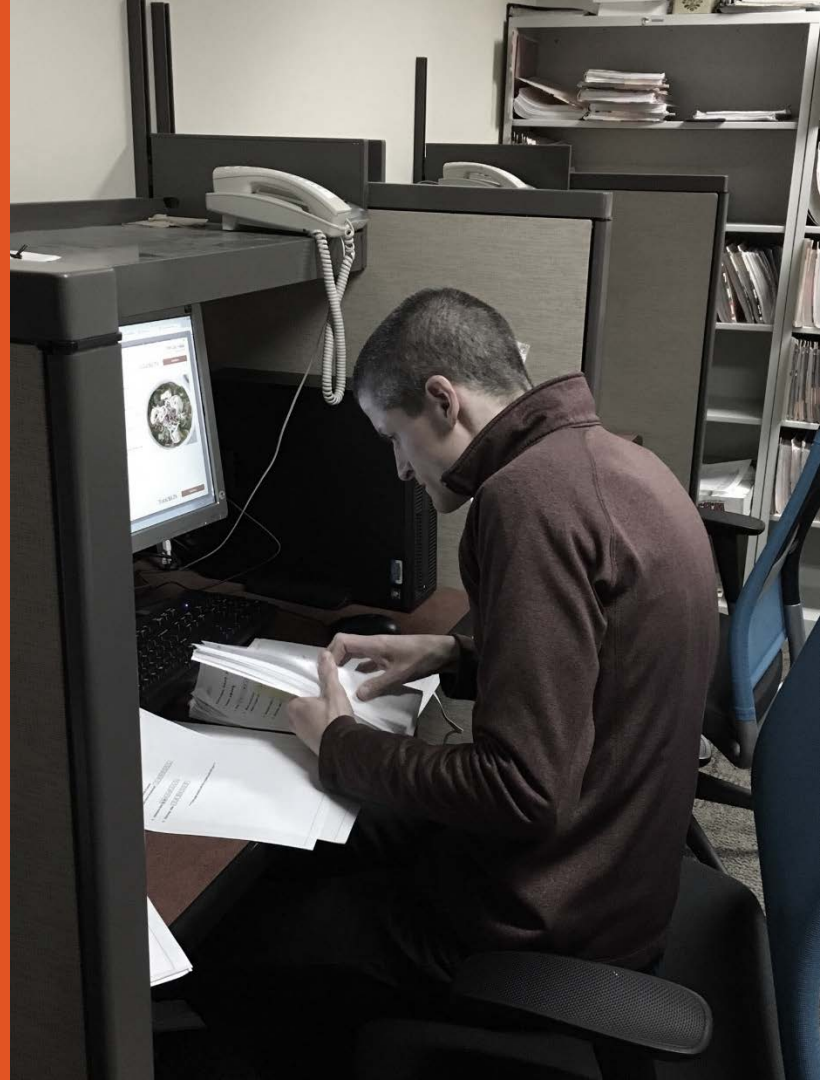
Case Description: Outcomes (n=17)

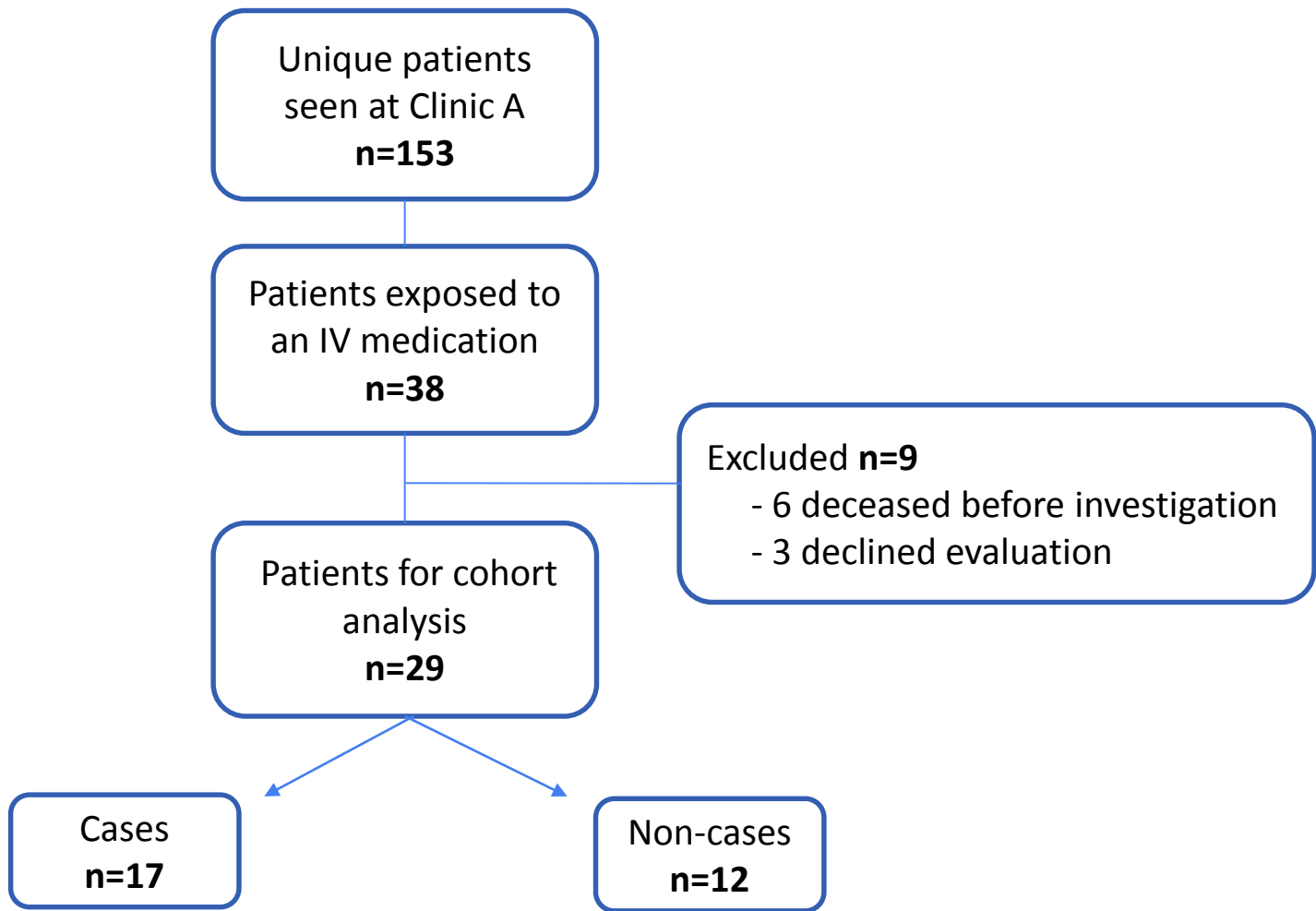


Sampling of an explanted port

- All treated with CVC removal and antifungal therapy
- 90-day mortality: 18% (3/17)
 - Case-patients died at 10, 74, and 78 days after diagnosis

Cohort Investigation





Chemotherapy

Chemotherapy Medication	n (%)				Fisher Exact p-value
	Cases (n=17)		Non-cases (n=12)		
Bevacizumab	8	(47.1)	1	(8.3)	0.04
Navelbine	5	(29.4)	1	(8.3)	0.35
Nivolumab	5	(29.4)	0	(0)	0.06
Gemcitabine	4	(23.5)	4	(33.3)	0.68
Vinblastin	1	(5.9)	0	(0)	1.00
Bleomycin	1	(5.9)	0	(0)	1.00
Cisplatin	1	(5.9)	1	(8.3)	1.00
Cetuximab	0	(0)	1	(8.3)	0.41

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Non-chemotherapy IV Medications

Non-chemotherapy IV Medications	n (%)				Fisher Exact p-value
	Cases (n=17)		Non-cases (n=12)		
Dexamethasone (Decadron)	12	(71)	1	(8)	0.44
Diphenhydramine (Benadryl)	11	(65)	5	(42)	0.27
Palonosetron (Aloxi)	7	(41)	1	(8)	0.09
Ondansetron (Zofran)	6	(35)	2	(17)	0.41
Compounded Flush Solution	17	(100)	12	(100)	0.84

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Dose-response

	n (range)				Kruskal-Wallis p-value
	Cases (n=17)		Non-cases (n=12)		
Median number of flushes	12	(2-20)	4	(1-12)	0.004

Clinic A CVC flushes

- Compounded solution at the clinic
 - 1 liter normal saline bag
 - Antibiotics: vancomycin, ceftazidime
 - Blood thinner: heparin
- Stored in a refrigerator
 - Accessed multiple times a day
 - Drawing 10 ml aliquots from 1 liter bag
 - 4 to 8 week period



Compounded IV Flush Bag Exposure

		n (%)				
Flush Bag	Date Compounded	Cases (n=17)		Non-cases (n=12)		Fisher Exact p-value
Bag #1	12/27/2015	11	(64.7)	3	(25)	0.06
Bag #2	2/7/2016	17	(100)	5	(41.7)	<0.001
Bag #3	4/3/2016	13	(76.5)	9	(75)	1.00

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Flush Bag	Date Compounded	Cases (n=17)		Non-cases (n=12)		Fisher Exact p-value
Bag #1	12/27/2015	11	(64.7)	3	(25)	0.06
Bag #2	2/7/2016	17	(100)	5	(41.7)	<0.001
Bag #3	4/3/2016	13	(76.5)	9	(75)	1.00

Laboratory Investigation



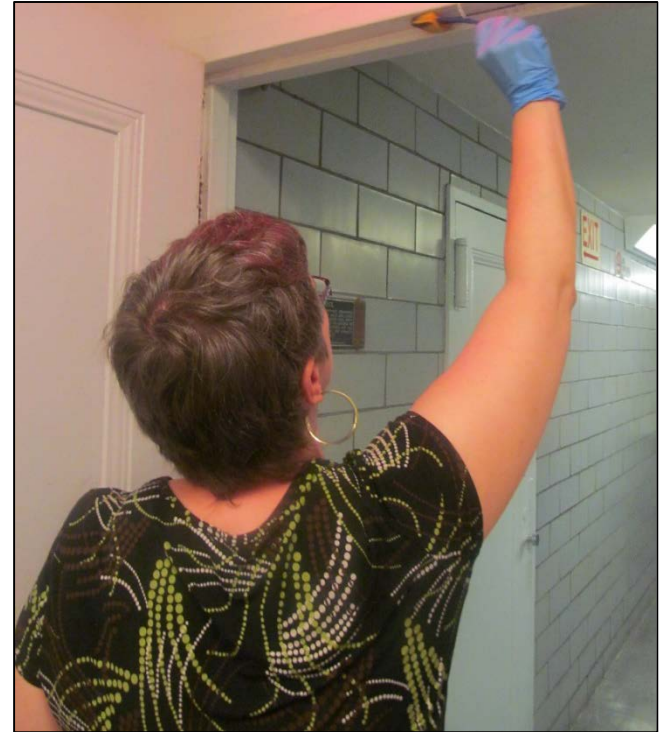
Medication and Environmental Sampling

- IV flush bag #2
 - Unavailable for sampling
- IV flush bag #3
 - No growth of organisms



Medication and Environmental Sampling

- IV flush bag #2
 - Unavailable for sampling
- IV flush bag #3
 - No growth of organisms
- Environmental samples
 - Some growth of common fungi
 - No *Exophiala* or *Rhodotorula*



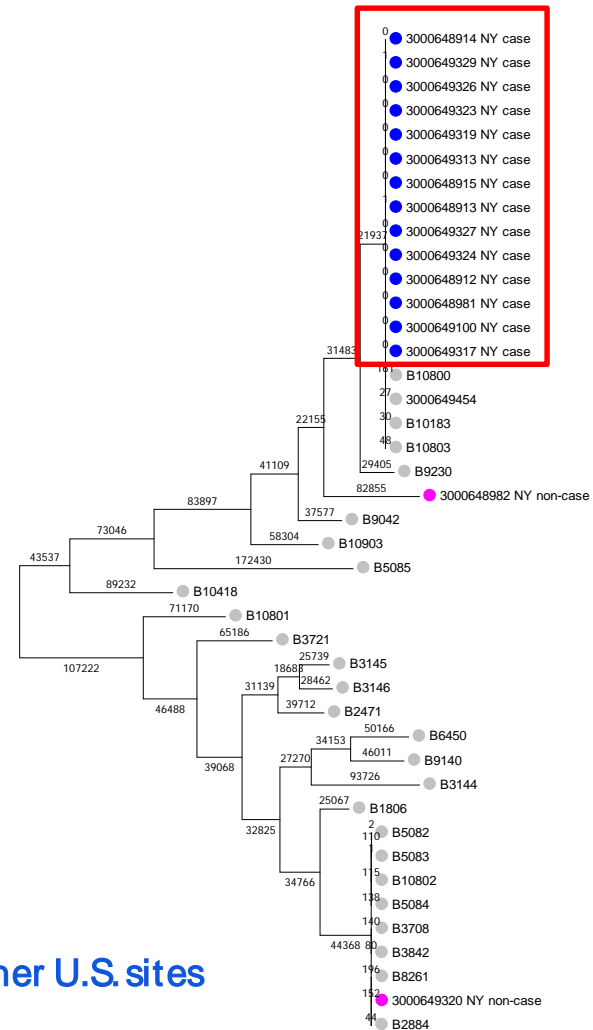
Whole Genome Sequencing

- 14 unique case-patient *E. dermatitidis* isolates
- 2 *E. dermatitidis* clinical isolates from NYC unrelated to the outbreak
- Historical *E. dermatitidis* isolates from other U.S. locations to act as controls

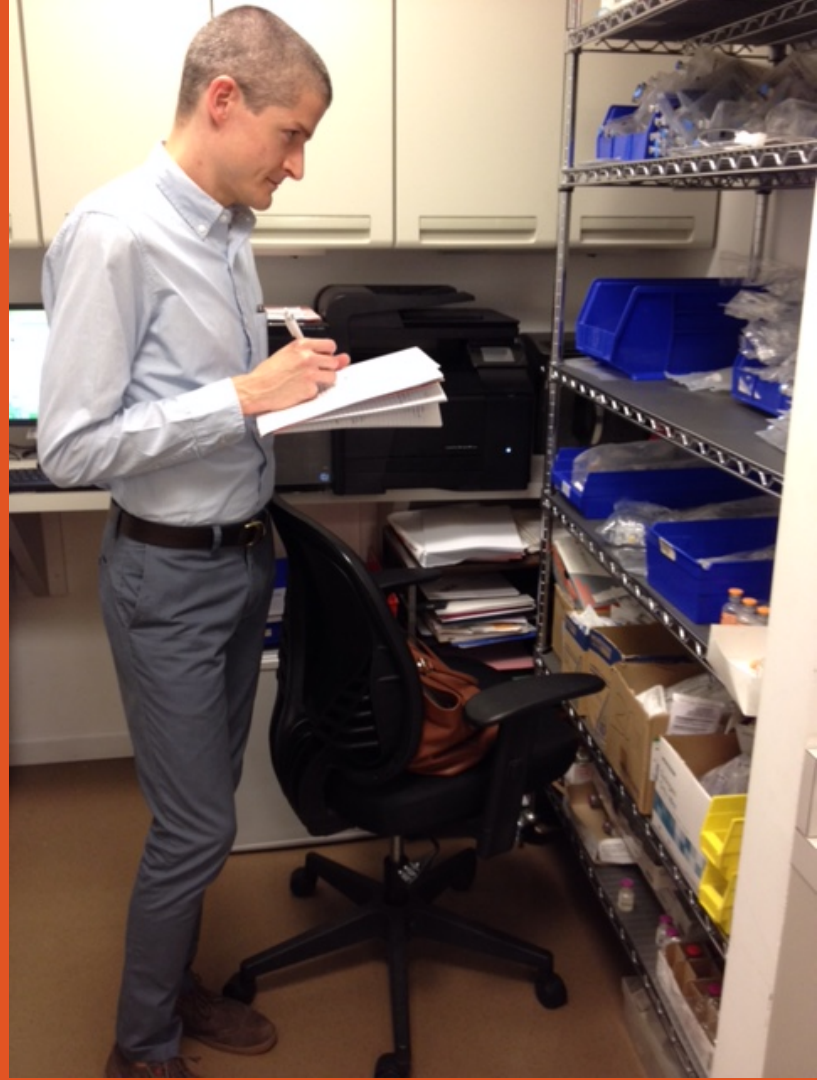
Whole Genome Sequencing

- Consistent with point source for the outbreak

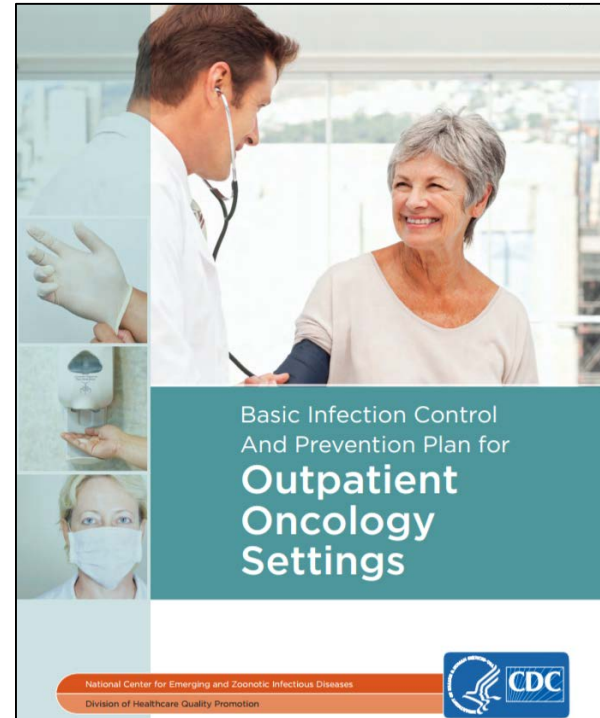
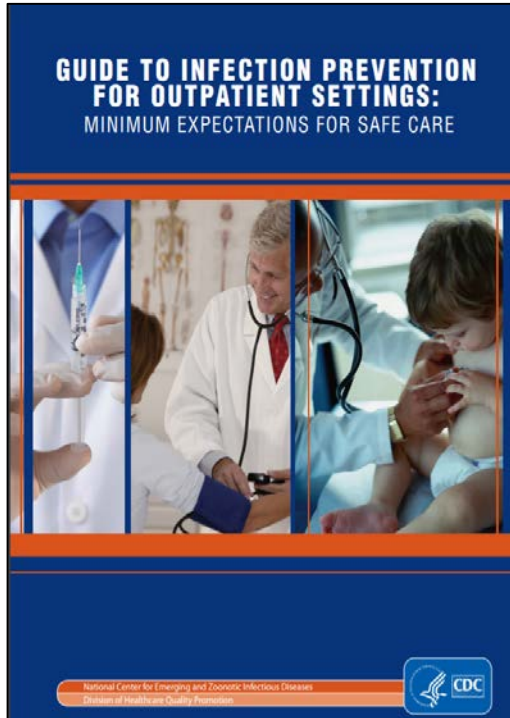
- Case
- Unrelated NYC isolates
- Historical isolate from other U.S. sites



Infection Control Assessments



Applicable CDC Guidance



General Infection Control Practices and Procedures

Recommended Practice	Clinic A Findings
Develop written infection control and prevention policies and procedures based on guidelines, regulations, or standards	No formal or written policies or procedures No individual designated to enforce policies
Healthcare personnel infection control training provided upon hire and repeated annually	Only one staff member received infection control training 4 years prior; no documentation could be provided

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Injection Safety

Recommended Practice	Clinic A Findings
Medications should be drawn up in a designated clean medication area	No designated clean medication area
Avoid prefilling and storing batch-prepared syringes	Batches of IV flush syringes prepared each morning based number of patients scheduled that day.

Injection Safety

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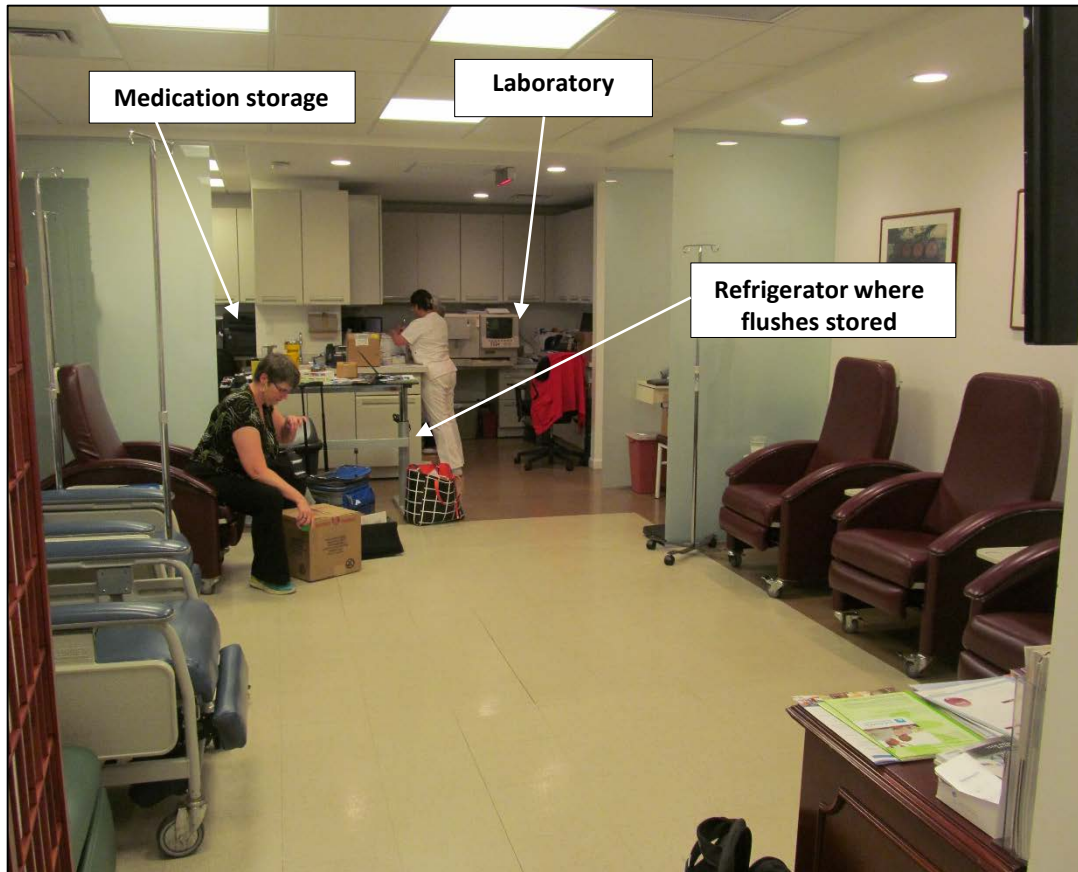
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Medication Handling and Storage

Recommended Practice	Clinic A Findings
Store medications that require refrigeration in a dedicated, labeled refrigerator	IV flush solution bag and syringes stored in a refrigerator also used for storage of staff food items

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Clinic A infusion area



Visible grime

Refrigerator for flush storage



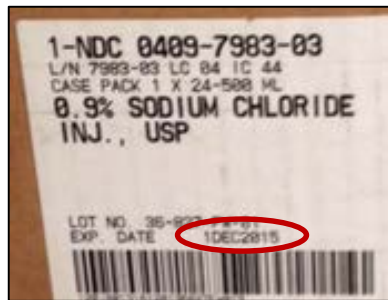
Moldy materials in same refrigerator

Medication Handling and Storage

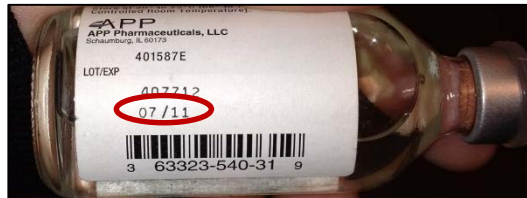
Recommended Practice	Findings
Medications should always be discarded according to the manufacturer's expiration date, even if not opened	Expired medications found throughout the clinic; unclear how frequently outdated medications may have been used

Medication Handling and Storage

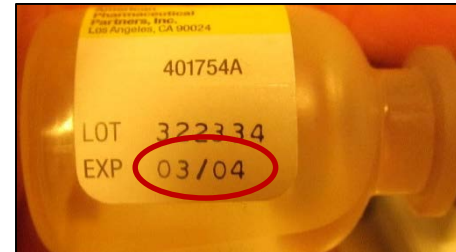
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Normal saline



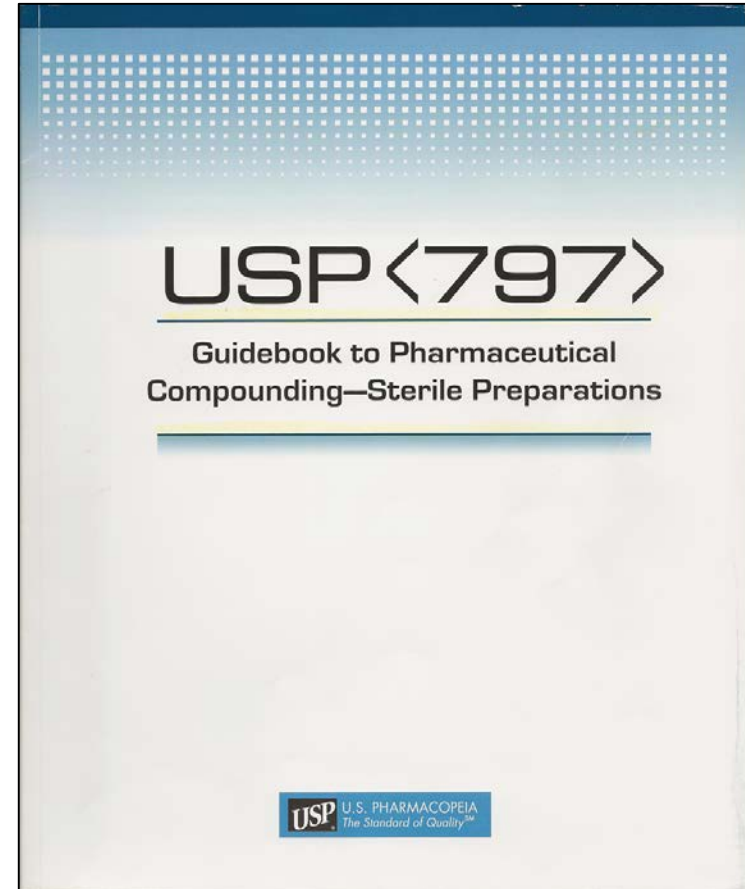
Heparin



Potassium chloride

Medication Compounding

- The United States Pharmacopeia (USP)
 - Scientific nonprofit organization
 - Sets standards for the quality and purity of medicines
- USP Chapter <797>
 - Provides procedures and requirements for compounding sterile preparations

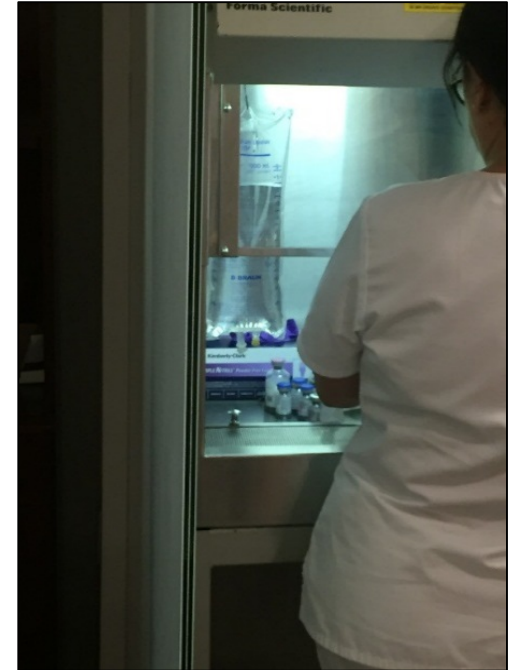


USP Chapter <797> Standards

- Personnel training in aseptic manipulation
 - Trained by expert personnel
 - Pass skills assessment
- Medication labeling and storage
- Hand-washing, sterile glove use
- Environmental control
 - Separation of compounding area from other areas by a buffer room
 - Routine environmental monitoring
 - Detailed cleaning and sanitizing procedures

Clinic A Flush Compounding: Personnel Training

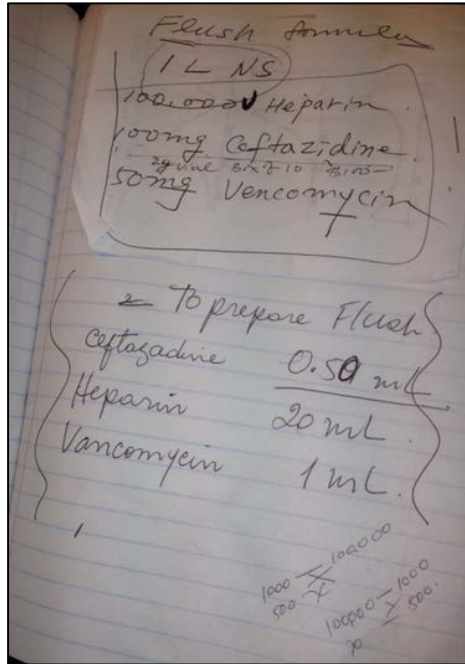
- Performed by nurse
 - No training in pharmaceutical compounding
 - No performance assessment
- No supervising pharmacist or other personnel trained in sterile compounding



Nurse simulating flush compounding

Clinic A Compounding: Preparation and Storage

- No formal written protocols
- Improper labeling and storage



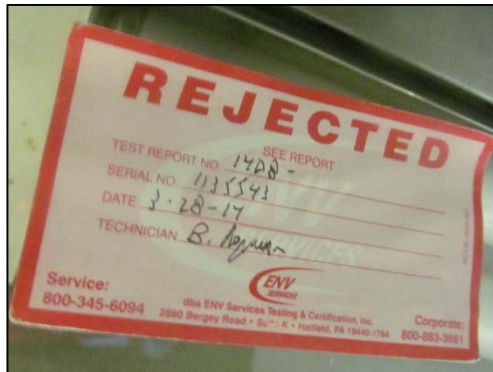
Nurse notes for compounding



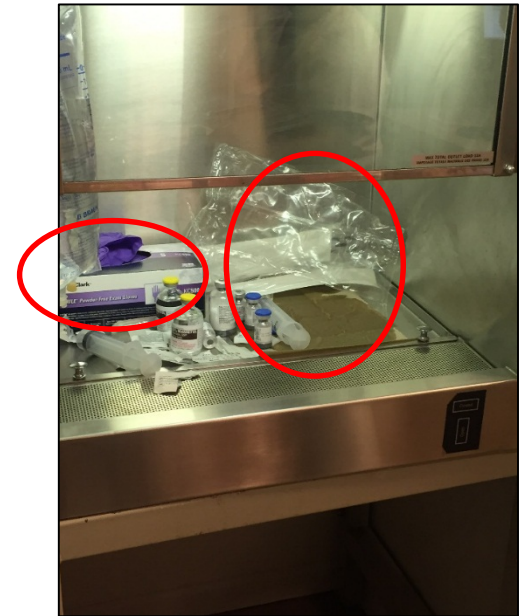
IV flush bags

Clinic A Compounding: Environmental Control

- Compounded underneath Biological Safety Cabinet
 - Intended to protect personnel and product
 - Potentially contaminated materials in critical sterile area
 - Did not meet regulatory testing



Rejection notice found on the hood



Biological Safety Cabinet after compounding demonstration

Clinic A Compounding: Environmental Control

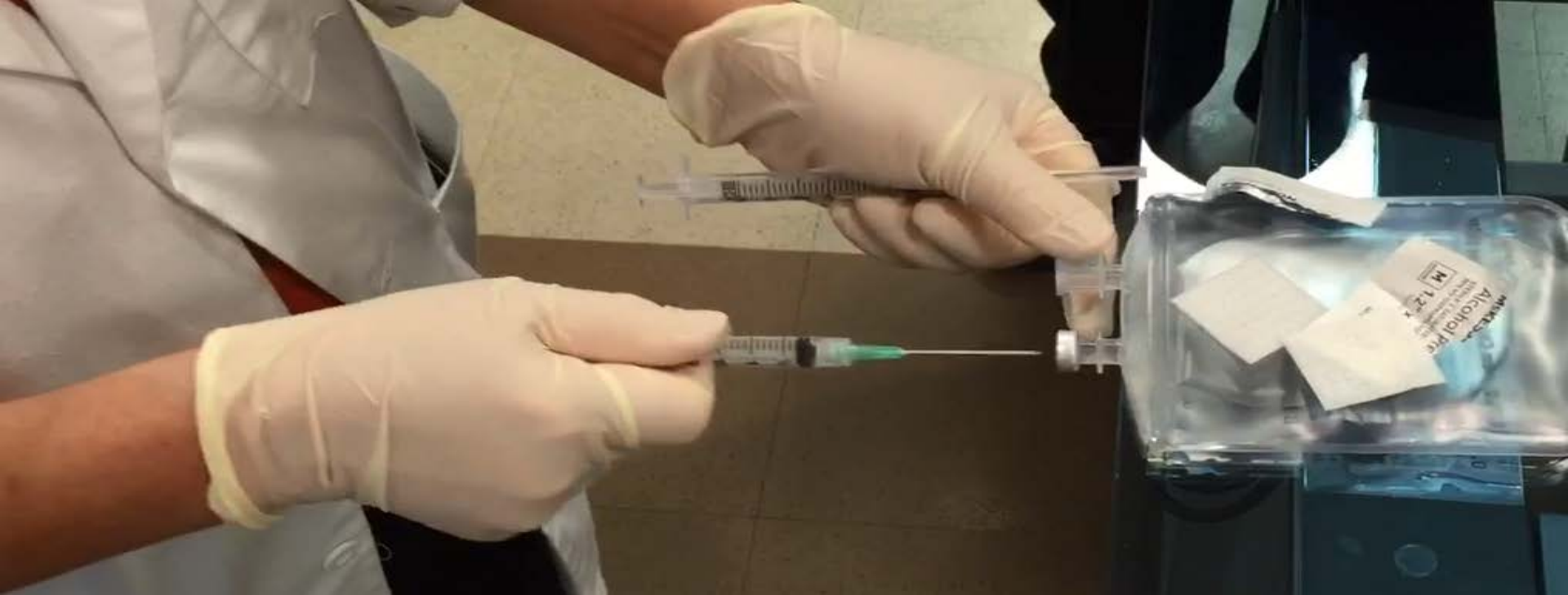
- No separation of compounding area



Clinic A Compounding: Environmental Control

- No separation of compounding area
- No environmental monitoring
- No cleaning procedures





Discussion

Contributing Factors

- Substandard compounding
 - IV flush solution
 - Only common exposure among all case-patients
 - Dose-response relationship
 - Bag #2 statistically significant exposure
 - WGS consistent with a point source
- Unsafe injection practices
- Improper medication storage

Contributing Factors

- Lack of awareness in basic infection control and prevention practices
- Failure to be aware of and meet minimum standards for infection control and patient safety
- Failure to be aware of and meet standards for compounding of sterile medications
- Lack of oversight in enforcement of these standards for independently managed outpatient clinics

General Recommendations for Clinic A

- Completion and documentation of infection control training for each staff member engaged in direct patient care
- Assessment of oncology practice by infection control professional
- Practices at Clinic A must become commensurate with standards
 - CDC Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care
 - CDC's Basic Infection Control and Prevention Plan for Outpatient Oncology Settings
 - USP Chapter <797>

Commissioner's Order

- May 31st cease and desist order
- Amended on June 22nd
 - Specific expectations for remediation
- October 5th, order was lifted
 - Remediation efforts guided by infection control practitioner and pharmacist
 - Demonstrated safe medication preparation and delivery
 - No longer compounding

ORDER OF THE COMMISSIONER

WHEREAS, on May 24, 2016, the New York City Department of Health and Mental Hygiene (the "Department") received a report of a cluster of *Wangiella (Exophiala) dermatitidis* infections, which is reportable to the Department pursuant to §11.03(c)(1) of the New York City Health Code (the "Health Code") and § 2.1 of the New York State Sanitary Code [10 N.Y.C.R.R. Part 2] (the "Sanitary Code"), occurring in five patients of this practice, and which may have been contracted during injections given to such patients; and

WHEREAS, pursuant to § 2.6 of the Sanitary Code and § 11.03(e) of the Health Code, the Department is required "to conduct such investigation as may be necessary to ascertain sources or causes of infection, to discover contacts and unreported cases, and...[to]...take such steps as may be necessary to prevent morbidity and mortality" from such communicable disease; and

WHEREAS, § 2.6 of the Sanitary Code further authorizes and requires the Department "to collect and submit, or cause to be collected and submitted, for laboratory examination such specimens as may furnish necessary or desirable information in determining the source of the infection or in assisting diagnosis...."; and

Outpatient Oncology Clinic Outbreaks

Outbreak of *Tsukamurella* Species Bloodstream Infection among Patients at an Oncology Clinic, West Virginia, 2011–2012

Isaac See, MD;^{1,2} Duc B. Nguyen, MD;^{1,2} Somu Chatterjee, MD, MPH;³ Thein Shwe, MPH, MS, MBBS;³ Melissa Scott, RN;³ Sherif Ibrahim, MD, MPH;³ Heather Moulton-Meissner, PhD;² Steven McNulty, BS;⁴ Judith Noble-Wang, PhD;² Cindy Price, RN, BSN, CIC;⁵ Kim Schramm, MT(ASCP);⁶ Danae Bixler, MD, MPH;³ Alice Y. Guh, MD, MPH²

Outbreak of *Pantoea agglomerans* Bloodstream Infections at an Oncology Clinic—Illinois, 2012-2013

Brian R. Yablon, MD;¹ Raymund Dantes, MD, MPH;^{1,2} Victoria Tsai, MPH;^{3,4} Rachel Lim, RN, MPH, CIC;⁵ Heather Moulton-Meissner, PhD;² Matthew Arduino, DrPH;² Bette Jensen, MMSc;² Megan Toth Patel, MPH;⁶ Michael O. Vernon, DrPH, CIC;⁶ Yoran Grant-Greene, PhD, MPH;^{1,3} Demian Christiansen, DSc, MPH;⁶ Craig Conover, MD;³ Alexander Kallen, MD, MPH;² Alice Y. Guh, MD, MPH²

Challenges in Outpatient Healthcare Settings

- Oncology clinics at risk
 - Vulnerable patient population
 - Scope of medical practice
- Challenges exist across many outpatient settings
 - Pain management clinics
 - Orthopedic clinics
- Likely many outpatient facilities performing similar services

Lack of Oversight and Accreditation

- Few outpatient healthcare facilities are licensed or accredited
 - Opened and operated without being held to safety standards
- May offer invasive procedures without being subject to on-site inspections
- No clearly established authority for monitoring adherence to infection control and sterile compounding standards
 - State Boards of Pharmacy
 - Food and Drug Administration (FDA)

Lack of Infrastructure and Resources

- Lack of infrastructure and resources to support infection control and sterile compounding
 - Conducted in absence of pharmacy controls
- Personnel often inadequately trained
 - Continuing education requirements and other training vary greatly
 - Providers may be unaware their practices are subject to federal and state sterile compounding laws and standards

Variable Requirements for Monitoring/Reporting

- Highly variable requirements for monitoring and reporting of healthcare-associated infections and other adverse events
 - Delayed identification of and response to outbreaks
 - Often reported by someone other than practice provider

Progress and Ongoing Efforts

- **Outpatient Settings Policy Options for Improving Infection Prevention**
 - Facility licensing/accreditation
 - Healthcare provider training, licensing, certification
 - Reporting requirements
 - Investigation authority
- Partnership with health authorities
- Raising awareness via specialty boards and professional organizations

**Outpatient Settings Policy Options
for Improving Infection Prevention**

Licensing Training

Reporting Investigating

Key Policy Elements for Best Practices

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

Summary

- Outbreak of 17 cases of *Exophiala dermatitidis* or *Rhodotorula mucilaginosa* bloodstream infections associated with single oncology clinic
- Lapses in infection control and prevention practices
- Substandard sterile compounding, storage, and handling
 - Compounded IV flush suspected to be the source

Conclusions

- Oversight of infection control practices and medication compounding in outpatient oncology settings is an issue of public health importance
- Immunosuppressed patient population
- CDC working with public health partners
- Close the gap in awareness and enforcement of infection control and compounding standards in outpatient settings

Acknowledgements

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 - Joel Ackelsberg, Chris Lee, Megan Halbrook, Stephanie Ngai, David Chou, Isaac Benowitz, Paula Del Rosso, Mike Antwi, David Yang, Jay Varma, Marci Layton, Anna Tate
- New York State Department of Health
 - Jane Greenko, Eleanor Adams
- CDC Mycotic Diseases Branch
 - Snigdha Vallabhaneni, Tom Chiller, Shawn Lockhart, Nancy Chow, Anastasia Litvintseva, Brendan Jackson
- CDC Division of Healthcare Quality Promotion
 - Jason Lake, M. Shannon Keckler, Heather Moulton-Meissner, Kiran Perkins, Judith Noble-Wang, Joe Perz
- Staff at Clinic A and Hospital A
- And many others!!

Thank You

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



The Wild Wild West:
Public Health Options to Expand Oversight
of Outpatient Oncology Practices

Joel Ackelsberg, MD, MPH

New York City Department of Health and Mental Hygiene

Bureau of Communicable Disease

Compounding Interest



A Multistate Outbreak of *Serratia marcescens* Bloodstream Infection Associated with Contaminated Intravenous Magnesium Sulfate from a Compounding Pharmacy

Rebecca H. Sunenshine,^{1*} Esther T. Tan,^{1,2*} Dawn M. Terashita,² Bette J. Jensen,¹ Marilyn A. Kacica,³ Emily E. Sickbert-Bennett,⁷ Judith A. Noble-Wang,¹ Michael J. Palmieri,⁴ Dianna J. Bopp,⁵ Daniel B. Jernigan,¹ Sophia Kazakova,⁶ Eddy A. Bresnitz,² Christina G. Tan,² and L. Clifford McDonald¹

¹Centers for Disease Control and Prevention, Atlanta, Georgia; ²New Jersey Department of Health and Senior Services, Trenton, New Jersey; ³Los Angeles County Department of Health Services, Los Angeles, California; ⁴New York State Department of Health and ⁵New York State Department of Health Wadsworth Laboratory, Albany, and ⁶Food and Drug Administration Northeast Regional Laboratory, Jamaica, New York; and ⁷University of North Carolina, Chapel Hill

Background. In contrast to pharmaceutical manufacturers, compounding pharmacies adhere to different quality-control standards, which may increase the likelihood of undetected outbreaks. In 2005, the Centers for Disease Control and Prevention received reports of cases of *Serratia marcescens* bloodstream infection occurring in patients who underwent cardiac surgical procedures in Los Angeles, California, and in New Jersey. An investigation was initiated to determine whether there was a common underlying cause.

Methods. A matched case-control study was conducted in Los Angeles. Case record review and environmental testing were conducted in New Jersey. The Centers for Disease Control and Prevention performed a multistate case-finding investigation; isolates were compared using pulsed-field gel electrophoresis analysis.

Results. Nationally distributed magnesium sulfate solution (MgSO₄) from compounding pharmacy X was the only significant risk factor for *S. marcescens* bloodstream infection (odds ratio, 6.4; 95% confidence interval, 1.1–38.3) among 6 Los Angeles case patients and 18 control subjects. Five New Jersey case patients received MgSO₄ from a single lot produced by compounding pharmacy X; culture of samples from open and unopened 50-mL bags in

Multistate Outbreak of *Pseudomonas fluorescens* Bloodstream Infection after Exposure to Contaminated Heparinized Saline Flush Prepared by a Compounding Pharmacy

Mark D. Gershman,^{1,2} Donald J. Kennedy,⁴ Judith Noble-Wang,² Curt Kim,^{3,4} Jessica Gullion,⁷ Marilyn Kacica,² Bette Jensen,² Nell Pascoe,⁶ Lisa Salzman,¹⁰ Jean McHale,¹¹ Melinda Wilkins,⁴ Dianna Schoonmaker-Bopp,² Joshua Clayton,^{12,13} Matthew Arduino,² and Arjun Srinivasan,² for the *Pseudomonas fluorescens* Investigation Team¹

¹Epidemic Intelligence Service (assigned to Michigan Department of Community Health) and ²Clinical and Environmental Microbiology Branch and ³Response Team, Division of Healthcare Quality Promotion, National Center for Preparedness, Detection and Control of Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia; ⁴Division of Infectious Diseases and Immunology, St. Louis University School of Medicine, St. Louis, Missouri; ⁵Preventive Medicine Residency, University of Michigan School of Public Health, Ann Arbor, and ⁶Division of Communicable Diseases, Michigan Department of Community Health, Lansing; ⁷Denton County Health Department, Denton, and ⁸Texas Department of State Health Services, Austin, Texas; ⁹New York State Department of Health, Albany, and ¹⁰Department of Pediatrics, Columbia University School of Medicine, New York, New York; and ¹¹McHale Institute, Sioux Falls, and ¹²South Dakota Department of Health, Pierre, South Dakota

Background. Pharmaceutical compounding, the manipulation of ingredients to create a customized medication, is a widespread practice. In January 2005, the Centers for Disease Control and Prevention was notified of 4 cases of *Pseudomonas fluorescens* bacteremia that were traced to contaminated heparinized saline intravenous flush syringes prepared as a compounded medical product.

Patients and Methods. We reviewed medical records of symptomatic patients with *P. fluorescens*-positive cultures of blood specimens or sections of explanted catheters, reviewed the production process of syringes, performed syringe cultures, compared isolates by pulsed-field gel electrophoresis (PFGE), and examined catheters by scanning electron microscopy.



Courtesy of Minnesota Department of Health / MGN

Early Compounders

First Half of Twentieth Century



Evolution of Sterile Medication Preparation in Hospital Pharmacies

■ SPECIAL FEATURES Sterile compounding

History of sterile compounding in U.S. hospitals: Learning from the tragic lessons of the past

CHARLES E. MYERS

After yet another widely publicized tragedy related to microbial contamination of compounded injections,¹ there is value in reviewing the long history of problems associated with sterile compounded medicines in the United States. The ultimate elimination of these problems must be built on an understanding of how we arrived at the situation we are in today. The purpose of this paper is to aid that understanding by reviewing, in the context of hospital patient care, how the technology associated with injections has evolved, the major previous incidents of morbidity and mortality associated with compounded sterile medicines, and the efforts made over the years to improve compounding practices. In addition, several ideas are offered for helping address this seemingly intractable issue.

The exact prevalence of compounding in general is not known.^{2,4} It is estimated that 60% of the medications dispensed in pharmacies in the 1930s and 1940s in the United States were compounded.² An analysis in 2006 estimated that compounding (mostly nonsterile) occurred in fewer than 1% of com-

Purpose. The evolution of sterile compounding in the context of hospital patient care, the evolution of related technology, past incidents of morbidity and mortality associated with preparations compounded in various settings, and efforts over the years to improve compounding practices are reviewed.

Summary. Tightened United States Pharmacopel Convention standards (since 2004) for sterile compounding made it difficult for hospitals to achieve all of the sterile compounding necessary for patient care. Shortages of manufactured injections added to the need for compounding. Non-hospital-based compounding pharmacies increased sterile compounding to meet the needs. Gaps in federal and state laws and regulations about compounding pharmacies led to deficiencies in their regulation. Lapses in sterility led to injuries and deaths. Perspectives offered include potential actions, including changes in practitioner education, better surveillance of sterile compounding, regulatory reforms, reexamination of the causes of drug shortages, and the development of new technologies.

Conclusion. Over the years, there have been numerous exhortations for voluntary better performance in sterile compounding. In addition, professional leadership has been vigorous and extensive in the form of guidance, publications, education, enforceable standards, and development of various associations and organizations dealing with safe compounding practices. Yet problems continue to occur. We must engage in diligent learning from the injuries and tragedies that have occurred. Assuming that we are already doing all we can to avoid problems would be an abdication of the professional mission of pharmacists. It would be wrong thinking to assume that the recent problems in large-scale compounding pharmacies are the only problems that warrant attention. It is time for a systematic assessment of the nature and the dimensions of the problems in every type of setting where sterile compounding occurs. It also is time for some innovative thinking about ensuring safety in sterile compounding.

Am J Health-Syst Pharm. 2013; 70:1414-27

munity pharmacies.⁶ In numbers attributed to the president of the International Academy of Compounding Pharmacies (IACP), there were 5000 compounding pharmacies in 2009

and 7500 in 2012.⁵ (The number in the United States was not stated.) How many of these specialized in compounding as their predominant activity is unknown.

CHARLES E. MYERS, M.S., M.B.A. (retired), was Group Vice President, American Society of Health-System Pharmacists, Bethesda, MD. Address correspondence to Mr. Myers at 6832 Westcott Drive, Richmond, VA 23225 (cem299@gmail.com).

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Pharm.D., M.S.; Joseph E. Gallotti, Ph.D.; William M. Heller, Ph.D.; Jay M. Mirtallo, M.S., BCNSP, FASHP; and Paul G. Pierpaoli, M.S.

The author has declared no potential conflicts of interest.

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Evolution of Sterile Medication Preparation in Hospital Pharmacies



Bellevue Hospital Dispensary

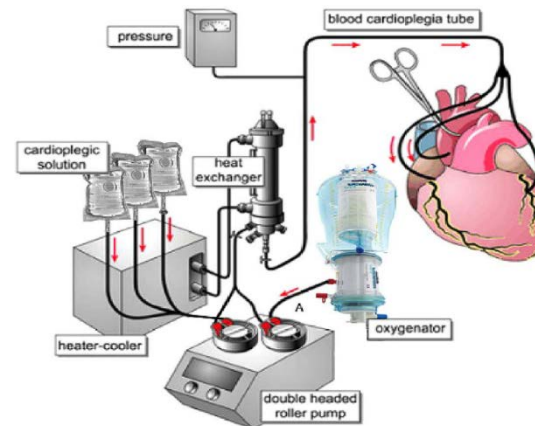
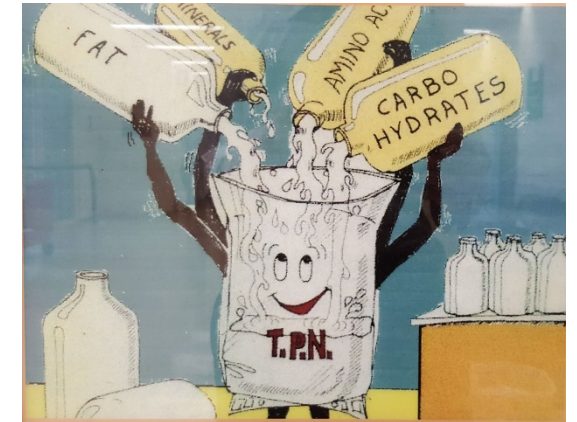
Early 1900s

1930s -1950s

1960 – 1970s

1980s+

Shift of Sterile Medication Preparation from Hospital Pharmacies to Commercial Facilities – I



Shift of Sterile Medication Preparation from Hospital Pharmacies to Commercial Facilities – 2

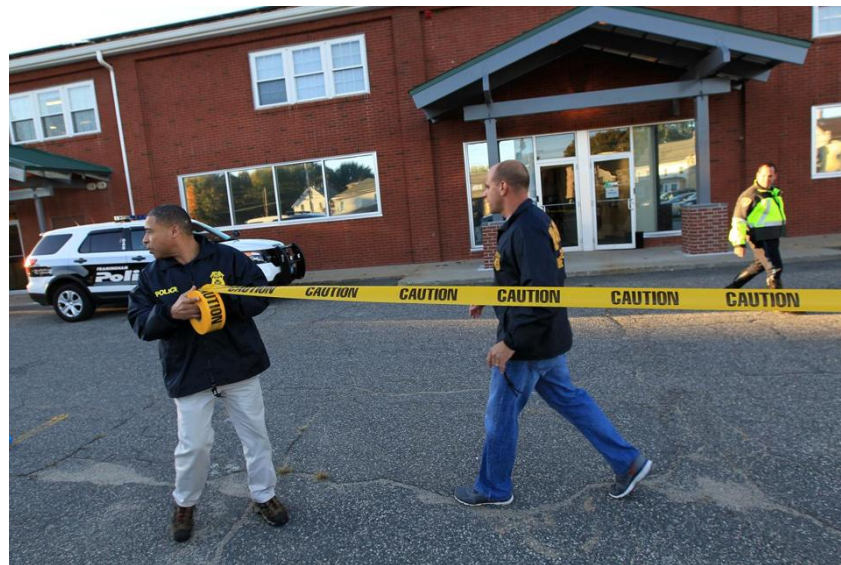


Shift of Sterile Medication Preparation from Hospital Pharmacies to Commercial Facilities – 3

- ◆ By 2001, shortages of drugs manufactured by generic manufacturers became frequent and long-lasting
- ◆ Medicare Prescription Drug, Improvement, and Modernization Act of 2003 may have reduced profit margins for drug manufacturers
- ◆ By 2012, injection drug shortages were common-place
- ◆ Compounding pharmacies became a more important source for injected medications

Regulatory Response to Evolving Medication Preparation Terrain

Food, Drug, and Cosmetic Act, amended 2013



New England Compounding Center

Sec. 503A

FEDERAL FOOD, DRUG, AND COSMETIC ACT

166

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and
(ii)(I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) COMPOUNDED DRUG.—

(1) **LICENSED PHARMACIST AND LICENSED PHYSICIAN**.—A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations

(i) that—

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;



On-The-Ground Regulation of Medication Preparation

- ◆ Food, Drug, and Cosmetic Act sets the legal standards
- ◆ Food and Drug Administration (FDA) inspects manufacturers
- ◆ State Boards of Pharmacy charged with enforcement locally

Outbreak of Bacteremia Due to *Burkholderia contaminata* Linked to Intravenous Fentanyl From an Institutional Compounding Pharmacy

Rebekah W. Moehring, MD, MPH; Sarah S. Lewis, MD; Pamela J. Isaacs, BSN, MHA; Wiley A. Schell, MS; Wayne R. Thomann, DrPH; Mary M. Althaus; Kevin C. Hazen, PhD; Kristen V. Dicks, MD; John J. LiPuma, MD; Luke F. Chen, MBBS, MPH; Daniel J. Sexton, MD

Outbreak of *Serratia marcescens* Infections following Injection of Betamethasone Compounded at a Community Pharmacy

Rachel Civen,¹ Duc J. Vugia,² Richard Alexander,⁴ Wendel Brunner,⁴ Sirlura Taylor,⁴ Nancy Parris,⁵ R. Wasserman,⁵ Sharon Abbott,³ S. B. Werner,² and Jon Rosenberg²

Multistate Outbreak of *Pseudomonas fluorescens* Bloodstream Infection after Exposure to Contaminated Heparinized Saline Flush Prepared by a Compounding Pharmacy

Mark D. Gershman,^{1a} Donald J. Kennedy,⁴ Judith Noble-Wang,⁷ Cui Kim,^{1a} Jessica Gallion,⁷ Marilyn Kacica,⁷ Bette Jensen,⁷ Neil Pascoe,⁸ Lisa Saiman,¹¹ Jean McHale,¹¹ Melinda Wilkins,⁸ Dianna Schoonmaker-Bopp,⁷ Joshua Clayton,^{11a} Matthew Arduino,⁷ and Arjun Srinivasan,⁷ for the *Pseudomonas fluorescens* Investigation Team⁸

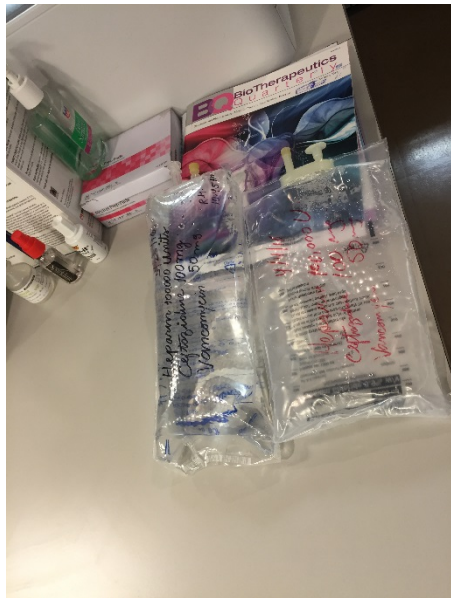
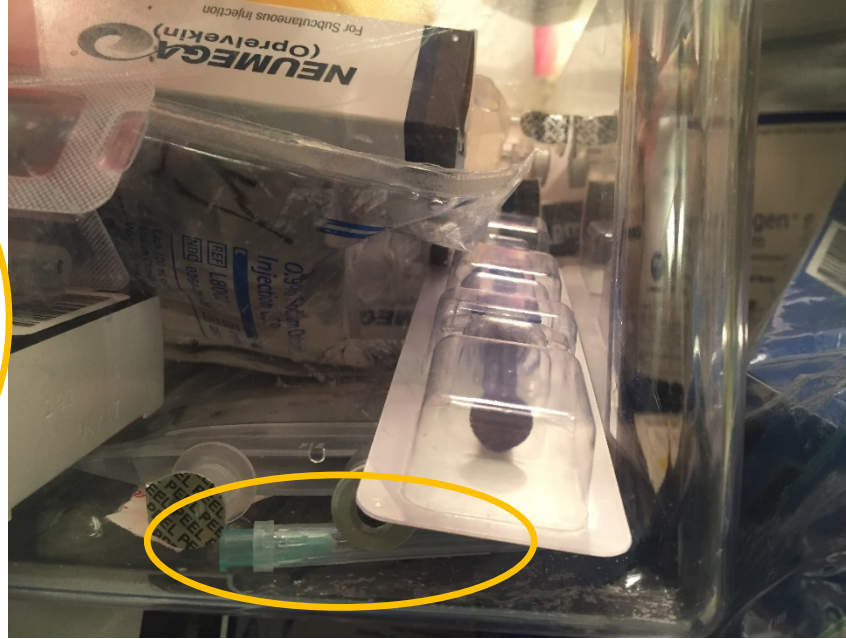
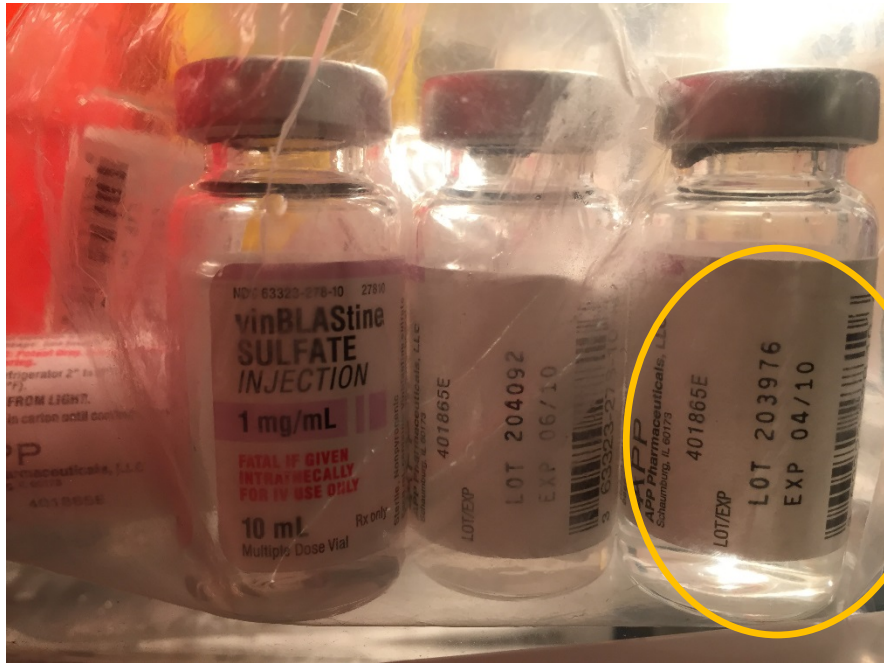
ORIGINAL ARTICLE

Fungal Infections Associated with Contaminated Methylprednisolone Injections

Rachel M. Smith, M.D., M.P.H., Melissa K. Schaefer, M.D., Marion A. Kainer, M.B., B.S., M.P.H., Matthew Wise, Ph.D., Jennie Finks, D.V.M., M.V.P.H., Joan Duwve, M.D., M.P.H., Elizabeth Fontaine, M.S.P.H., Alvina Chu, M.H.S., Barbara Carothers, L.P.N., Amy Reilly, R.N., Jay Fiedler, M.S., Andrew D. Wiese, M.P.H., Christine Feaster, M.S.M., Lex Gibson, B.S., Stephanie Griese, M.D., Anne Purfield, Ph.D., Angela A. Cleveland, M.P.H., Kaitlin Benedict, M.P.H., Julie R. Harris, Ph.D., M.P.H., Mary E. Brandt, Ph.D., Dianna Blau, D.V.M., Ph.D., John Jernigan, M.D., J. Todd Weber, M.D., and Benjamin J. Park, M.D., for the Multistate Fungal Infection Outbreak Response Team

NECC co-owner convicted in meningitis outbreak





The State Health Department Does Not Regulate Most Outpatient Physician Offices

- ◆ By default, it falls to the New York City Health Department
- ◆ The NYC Health Code does not authorize the Health Department to regulate outpatient settings not overseen by the State
- ◆ The Health Code does authorize the Health Department to close establishment if considered an “abatement of a public nuisance.”

Commissioner’s Order to the Oncologist

WHEREAS, pursuant to Health Code § 3.07, “no person shall do or assist in any act which is or may be detrimental to the public health or to the life or health of any individual...or fail to do any reasonable act or take any necessary precaution to protect human life and health:” and

WHEREAS, during a May 26, 2016 visit to the above referenced practice, Department staff observed the following lapses in accepted infection control practice:
Single use medication vials are used for multiple patients;
Multiple expired medications are kept in a refrigerator;
A custom flush solution was mixed and held for more than 30 days, and multiple patients were treated with flush solution from the same intravenous infusion bag; and

WHEREAS, such lapses in infection control and the additional cases reported indicate that the number of patients at risk of serious illness and death could be large; and

WHEREAS, such conditions constitute a nuisance that if not abated will endanger the health and safety of patients of this practice; and

Characterizing “the Wild Wild West”

- ◆ Was this an anomaly?
- ◆ How to identify?:
 - Universe of solo practice-like New York City oncologists not under the aegis of an academic medical center or hospital
 - Distribution in the five boroughs
- ◆ Medicare Provider Utilization and Payment Public Use Files
 - All requests for reimbursement from *Medicare fee-for-service* for products and services
 - Aggregates all charges by single provider (NPI number)
 - Filtered by:
 - Charges for chemotherapeutics and services that are used by oncologists
 - Providers self-identifying as oncologists
 - Providers who practice at an addresses reported by 1 – 3 oncologists and who are not associated with an academic medical center

Public Health Options

- ◆ Sampling of the outpatient oncologists identified to survey by phone and directly observe
- ◆ Based on findings:
 - Consider regulatory options by the State Department of Health (e.g., require accreditation by approved organization)
 - Consider expansion of professional standards by ASCO
- ◆ Discussions are ongoing with the State Health Department to explore these options

Infection Control and Prevention in the Outpatient Oncology Setting: Protecting Your Patients and Your Practice

Lisa C. Richardson, M.D., M.P.H.

Director, Division of Cancer Prevention and Control
U.S. Centers for Disease Control and Prevention

Webinar: April 18, 2017

Further Evidence....Public Health Concern

- ❑ 650,000 cancer patients receive outpatient chemotherapy
- ❑ 60,000 cancer patients are hospitalized for chemotherapy-induced neutropenia and infections
- ❑ One patient dies every two hours from this complication
- ❑ Cancer patients may not be aware of this risk and actions they can take to help

Objective & Strategies

❑ Objective:

- Raise awareness among patients, caregivers and healthcare providers about steps they can take to prevent infections during cancer chemotherapy treatment.

❑ Strategies:

- Develop improved and consistent infection control information for outpatient oncology providers.
- Create user-friendly resources to help patients better understand their risk of developing neutropenia and infections during chemotherapy.

Preventing Infections In Cancer Patients: CDC 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

Basic Infection Control & Prevention Plan



Education & Training



Education & training of all facility staff

Competency evaluations

Surveillance & Reporting



Purposes: case-finding , outbreak detection, and improving healthcare practices

Conduct facility surveillance for healthcare-associated infections and/or process measures

Adhere to local, state, and federal requirements for reportable diseases and outbreak reporting

Standard Precautions



Hand hygiene

Personal protective equipment

Safe handling of contaminated equipment

Respiratory hygiene

Injection safety

Basic Infection Control and Prevention Plan

Transmission-Based Precautions



Contact precautions

Droplet precautions

Airborne precautions

Central Venous Catheters



Use of aseptic technique

Blood draws from catheters

Proper flushing techniques

Changing site dressing and injection caps

Additional Resources in the Plan

Contacts/Roles & Responsibilities

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

Contact Person(s)* (Names/Titles)	Contact Information	Roles/Responsibilities
	Phone: Pager: Email:	<ul style="list-style-type: none"> Infection prevention personnel/consultant Assists with infection control plan development, update/revision, and implementation Including a protocol for transferring patients who require Airborne Precautions (if applicable)
	Phone: Pager: Email:	<ul style="list-style-type: none"> Educate and train facility staff (including Environmental Services/housekeeping) Assess for competency of jobs/tasks (examples provided): <ul style="list-style-type: none"> Hand hygiene performance/compliance Proper use of PPE Environmental cleaning/disinfection Triage/screening, taking vital signs Phlebotomy service Determine when to implement enhanced respiratory screening measures Ensure facility sick leave policies are in place and followed
	Phone:	<ul style="list-style-type: none"> Collect, manage, and analyze HAI data for surveillance purposes

List of persons designated to specific tasks and list of reportable diseases/conditions

Infection Prevention Checklist

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	

Tailor to oncology settings to evaluate personnel competency and adherence to recommended practices

Additional Resources

Detailed 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.k.a. bone marrow transplant or stem cell transplant centers)
- Guidelines for Preventing Opportunistic Infections Among Hematopoietic Stem Cell Transplant Recipients (available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4910a1.htm>)
- Guidelines for Preventing Infectious Complications among Hematopoietic Cell Transplantation Recipients: A Global Perspective (available at: http://www.idsociety.org/uploadedFiles/IDSA/Guidelines-Patient_Care/PDF_Library/OL.pdf)
- Occupational health requirements, including bloodborne pathogen training, health-care personnel immunizations, and recommended personal protective equipment for
 - Appropriate preparation and handling (e.g., reconstituting, mixing, diluting, compounding) of sterile medications, including antineoplastic agents
 - United States Pharmacopeia Chapter <797> Guidebook to Pharmaceutical Compounding—Sterile Preparations
 - International Society of Oncology Pharmacy Practitioners Standards of Practice (available at: http://opp.sagepub.com/content/13/3_suppl)
 - American Society of Health-System Pharmacists Guidelines for Handling Hazardous Drugs (available at: <http://www.ashp.org/DocLibrary/BestPractices/PrepGdl-HazDrugs.aspx>)
 - Clinical recommendations and guidance for treatment of patients with cancer, including appropriate antimicrobial prescribing prac-

Additional Resources

Includes links to national guidelines

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.

Find the Plan here:



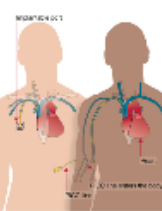





<https://www.cdc.gov/hai/settings/outpatient/basic-infection-control-prevention-plan-2011/index.html>

PreventCancerInfections.org

The screenshot shows the homepage of PreventCancerInfections.org. At the top left is the logo '3 STEPS TOWARD Preventing Infections During Cancer Treatment PREPARE - PROTECT - PREVENT'. Below the logo is a navigation menu with links: 'About This Site', 'Know Your Risk', 'Discover the 3 Steps', 'Health Tip Sheets', 'Program Materials', 'FAQs', and 'Glossary'. A search bar is located in the top right. The main heading reads 'STEP 1: PREPARE KNOW YOUR RISK AND TAKE OUR RISK ASSESSMENT TEST'. Below this, a text block explains that a few questions will help estimate the risk for developing a low white blood cell count (neutropenia) during chemotherapy, and users are prompted to click on a button below. Three buttons are visible: 'I am a Patient', 'I am a Caregiver', and 'I am a Healthcare Provider'. A red arrow points from the 'I am a Healthcare Provider' button towards the right-hand text. Below the main heading are four content blocks: 'Health Tip Sheets', 'FAQs', 'Do You Know Your Risk?', and 'Program Materials'. At the bottom, there are sections for 'About the Program' and 'Recent News'.

- ❑ Helps cancer patients assess their risk for developing neutropenia and subsequent infections
- ❑ Provides action steps to help prevent infections
- ❑ Features a risk assessment tool
- ❑ User can choose one of three portals to enter
 1. Patient
 2. Caregiver
 3. Healthcare Provider

Risk Assessment Results – Health Tip Sheets

 <p>Basic Hygiene Practices</p> <p>Following basic hygiene practices can help prevent infection during treatment. This Health Tip Sheet provides information on hand washing, mouth care, skin care, bathing, preventing cuts and scrapes, and wound care.</p> <p>View Tip Sheet ></p> <p>Download PDF</p>	 <p>Caring for Children With Cancer</p> <p>If you are a family member or friend caring for a child with cancer, this Tip Sheet covers the risks for infection and the signs and symptoms of infections in children.</p> <p>View Tip Sheet ></p> <p>Download PDF</p>	 <p>Caring for Your Catheter</p> <p>This Health Tip Sheet describes the types of catheters used for chemotherapy treatment and provides instructions for caring for these devices.</p> <p>View Tip Sheet ></p> <p>Download PDF</p>	 <p>Caring for Your Pet</p> <p>Learn how to reduce your risk for infection while caring for your pet.</p> <p>View Tip Sheet ></p> <p>Download PDF</p>
 <p>Food and Kitchen Safety</p> <p>It is important to keep your body strong by eating the right foods. This Health Tip Sheet provides information on proper meal preparation and foods you should avoid in order to limit your risk for infection.</p> <p>View Tip Sheet ></p> <p>Download PDF</p>	 <p>Friends, Family and Public Places</p> <p>This Health Tip Sheet describes steps you can take to limit your risk for infection when visiting public places and spending time with friends and family.</p> <p>View Tip Sheet ></p> <p>Download PDF</p>	 <p>Gardening and Housekeeping</p> <p>This Tip Sheet offers gardening, housekeeping, and disinfecting advice for helping to prevent infections while in treatment.</p> <p>View Tip Sheet ></p> <p>Download PDF</p>	 <p>Medication</p> <p>You should always take your medication as prescribed. This Health Tip Sheet provides tips to help you make sure you are following the medication treatment plan your doctor has set up for you.</p> <p>View Tip Sheet ></p> <p>Download PDF</p>

Health Tip Sheet Topics:

- Basic Hygiene Practices
- Caring for Children w/Cancer
- Caring for your Catheter
- Caring for your Pet
- Friends, Family & Public Spaces
- Food & Kitchen Safety
- Gardening and Housekeeping
- Medication
- Signs & Symptoms of Infection
- Understanding Your Risk for Infection and a LWBC count
- Vaccinations

More Than Just a Web Site-Educational Resources

CANCER IS A FIGHT. DON'T LET THE FLU KNOCK YOU DOWN.



FIGHT BACK! GET YOUR FLU SHOT

Take action to protect yourself against the flu, so you can focus on the fight that matters most.

The flu is serious for people who have cancer. Give the flu the one-two punch this season:

1. Get the flu shot—the nasal spray vaccine.
2. Make sure the people you live with or who care for you get the flu shot, too.

A flu shot is your best protection against the flu this season.

Learn more at: www.cdc.gov/cancer/preventinfections



WHAT THE FLU MEANS FOR YOU

FLU PREVENTION AND TREATMENT

Why does cancer put me at risk for developing an infection and sepsis?

What is the difference between infection and sepsis?

How does chemotherapy increase my risk for infection and sepsis?

Is there a specific time I may be more likely to get an infection?

How will I know if I have neutropenia?

How can I prevent an infection?




CANCER, INFECTION AND SEPSIS FACT SHEET

A POTENTIALLY DEADLY COMBINATION EVERY CANCER PATIENT SHOULD KNOW ABOUT

Why does cancer put me at risk for developing an infection and sepsis?

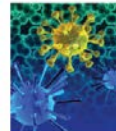

What is the difference between infection and sepsis?

How does chemotherapy increase my risk for infection and sepsis?

Is there a specific time I may be more likely to get an infection?

How will I know if I have neutropenia?

How can I prevent an infection?

EMERGENCY ROOM PERSONNEL

A fever in cancer patients may be more than meets the eye.

This is especially true for a cancer patient undergoing chemotherapy who develops a fever.

Get the full picture about people with cancer who are receiving chemotherapy.

If they have a fever, remember—

1. A fever may be the only sign of infection and should be treated as an emergency.
2. Developing an infection is a life-threatening complication.
3. A severe infection can turn serious fast. Quick action can save a life.

Learn more at: www.cdc.gov/cancer/preventinfections




ONCOLOGY PROVIDERS: YOUR PATIENTS MAY NOT UNDERSTAND THEIR RISK OF INFECTION

1.6 million people in the United States diagnosed with cancer each year

650,000 people receive chemotherapy

60,000 of those receiving chemotherapy are hospitalized for chemotherapy-related neutropenia and infection

1 of these patients dies every 2 hours as a result of the complication neutropenic sepsis (NS), a life-threatening infection

Do your patients know they're at risk? Or, are they among the 104,000 that were not aware of neutropenia? Or, among the 52,000 that didn't know to call their doctor at the first sign of a fever?

What if they knew more? A new survey conducted among people with cancer and their caregivers by Cancer.Net, the CDC Foundation and Regen highlights the need for education about neutropenia and infection risk.

There's help. PreventCancerInfections.org

80% of respondents could correctly define neutropenia

9 to 10 respondents recognized the importance of calling their doctor at the first sign of a fever—the most important action a patient can take to prevent an infection from becoming deadly

DON'T LET YOUR PATIENTS BECOME A STATISTIC... SHARE PREVENTCANCERINFECTIONS.ORG WITH THEM TODAY.



Fact sheets/brochures
Posters
Post cards
Infographics
Health-e-cards

OUT OF SIGHT, OUT OF MIND... NOT THIS TIME!



Did you know?

One of the most dangerous side effects of chemotherapy cannot be seen?

That's right, a low white blood cell count, or neutropenia, puts cancer patients at a higher risk for getting an infection.

An infection in people with cancer is an emergency. Be prepared, and remember the following three things during chemotherapy:

1. Treat a fever as an emergency, and call your doctor right away if you develop a fever!
2. Find out how your doctor when your white blood cell count will be lowest because this is when you are most at risk for infection.
3. If you have to go to the emergency room, it's important that you tell the person checking you in that you have cancer and are receiving chemotherapy. If you have an infection, you should not sit in the waiting room for a long time. Infections can get very serious in a short amount of time.

Learn more at: www.cdc.gov/cancer/preventinfections



THANK YOU!

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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.



Before We End Today's Webinar...

- **Question and Answer Session**
 - *Please submit your questions via the chat window, located on the lower left-hand side of the webinar screen.*

Before We End Today's Webinar...

□ Continuing Education

- Detailed instructions for taking the post-test and evaluation will appear on your screen as soon as today's webinar concludes.
 - www.cdc.gov/tceonline; Access Code: **WC0418**
- If you exit out of the webinar prior to taking the post-test and evaluation, you can access the continuing education information in an email that will be sent to you following today's webinar.

THANK YOU