Identifying and Responding to Outbreaks Linked to Physician/Clinic Compounding

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Overview

- Outpatient settings (including, physician offices and other clinic settings) are being increasingly identified as sources of healthcare outbreaks linked to breaches in infection control and sterile compounding practices
- Outpatient settings pose unique challenges to federal and state authorities in outbreak investigations and in ensuring regulatory oversight of infection control and sterile compounding practices
- Outpatient settings warrant increased attention from local, territorial, and state health agencies, which are well-positioned to ensure that basic standards of infection control and sterile compounding are understood and observed consistently
- Coordination and communication among state (public health departments, boards of medicine and pharmacy, accreditation bodies) and federal authorities (FDA, CDC) will be key in identifying, responding, and preventing future outbreaks and patient harm

CDC's Role in Safe Injection Practices

- Promotion of safe injection practices
  - Collaboration with the Safe Injection Practices Coalition ***("One and Only Campaign")***
- Development of infection control guidelines
  - **2007 Guideline for Isolation Precautions** (including, **Safe Injection Practices** under **Standard Precautions** applicable to all healthcare settings)
- Improved basic infection control through collaborations with CMS, FDA, states, and industry
- Improved capacity in state health departments
- Responding to outbreaks in healthcare settings
  - In collaboration with states and the FDA

CMS = Centers for Medicare & Medicaid Services

CDC's Healthcare Outbreak Response Activities

- Responsibility for investigating infections and other adverse events related to healthcare delivery
- Consults (mostly with state health departments) are a major part of daily activity
  - Cases, clusters, infection control breaches
- Over the past five years, we have averaged about one field investigation ("Epi-Aid") per month

CDC Is Increasingly Responding to Outbreaks in Outpatient Settings

- Transition in healthcare delivery from acute care hospitals to ambulatory care settings
- Breaches in infection control and sterile medication handling practices (**including, sterile compounding**) identified in outpatient settings
- Consequences:
  - **infection transmission** to patients
  - **notification of thousands of patients** of possible exposure to bloodborne pathogens
  - referral of providers to licensing boards for **disciplinary action**
  - **malpractice suits** filed by patients

Outbreaks in Outpatient Settings, 2010-2014 (Selected Examples) – *Where Are Outbreaks Occurring?*

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

More recently: Chiropractic clinics

https://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

Outbreaks in Outpatient Settings, 2010-2014 (Selected Examples) – *What Are the Infection Control Breaches?*

Medication Preparation

- Failure to follow aseptic practices (incl. proper hand hygiene)
- Insanitary medication preparation areas
- Non-trained/non-qualified personnel performing sterile compounding
- Sterile compounding occurring in absence of proper controls
- Improper storage and labeling of sterile medication vials

Medication Administration

- Reuse of syringes to access medication vials for >1 patient
- Reuse of single-dose vials and common source bags for >1 patient
- Failure to wear surgical masks and gowns
- Suboptimal procedures for IV line access and maintenance

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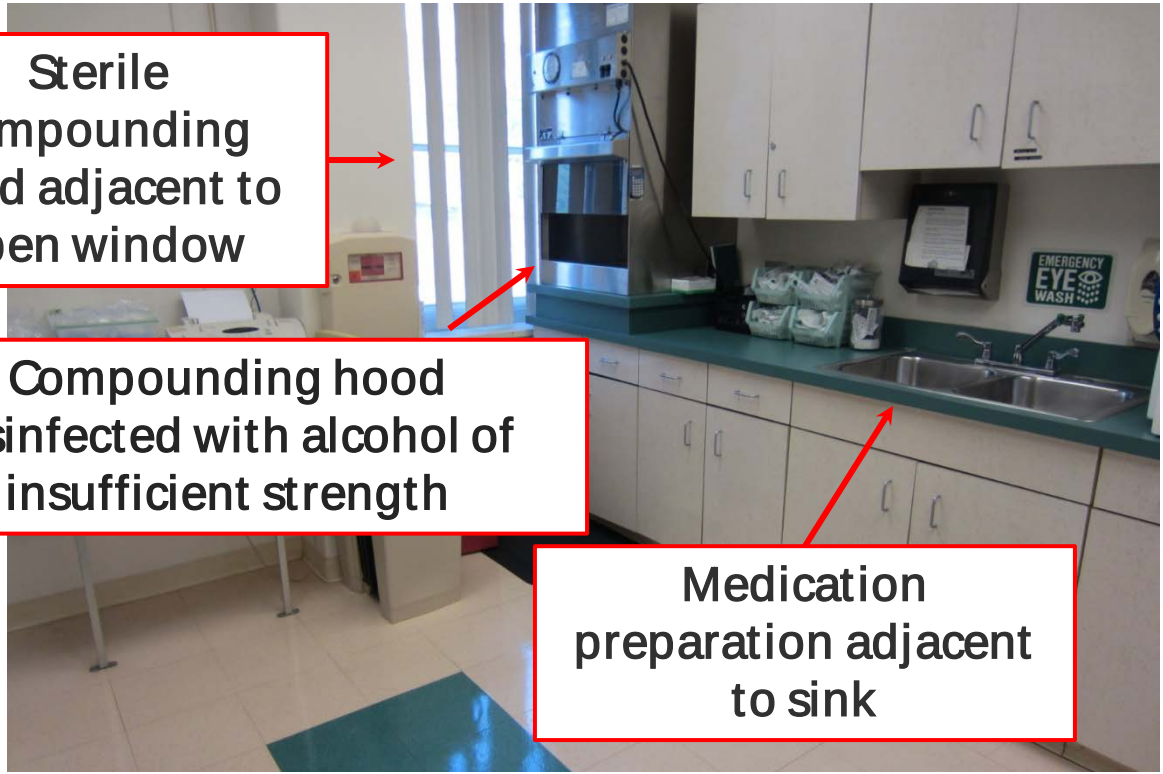
Outbreak of *Tsukamurella* Bloodstream Infections, Oncology Clinic, West Virginia, 2011-2012



See I, et al. *Infect Control Hosp Epidemiol* 2014;35(3):300-6.

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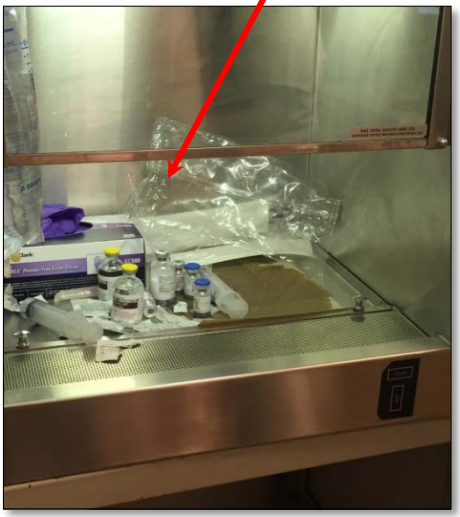
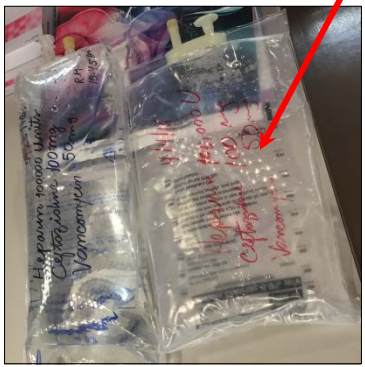
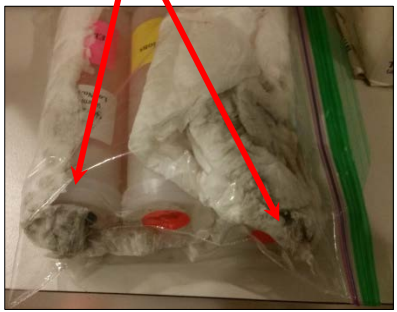
Outbreak of *Exophiala dermatitidis* Bloodstream Infections, Oncology Clinic, 2016*

Exposure of critical sterile sites of hood to potentially contaminated materials



Medications improperly stored and labeled, with visible signs of contamination





*Investigation ongoing

Outpatient Settings Present Unique Challenges for Outbreak Investigations, 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?*

- **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*

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

Outpatient Settings Present Unique Challenges for Outbreak Investigations, 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*

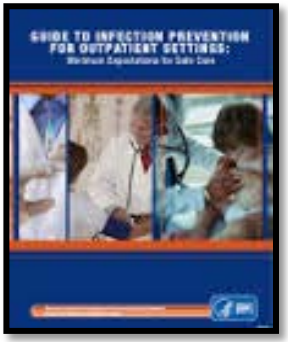
- **Highly variable** requirements for **monitoring and reporting of HAIs and other adverse events** to state and federal authorities
  - *Delayed identification of and response to outbreaks, potentially leading to large patient notifications / harm*

CDC Resources

- ***Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care***

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

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



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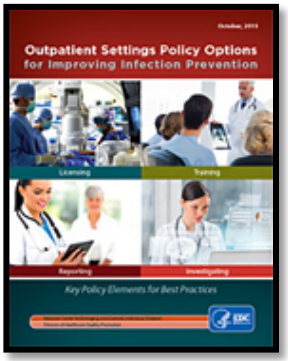
Outpatient Settings Policy Options for Improving Infection Prevention

This document is designed to assist state, local, and territorial health departments and policymakers at various levels to analyze current policies in outpatient settings, review proposed changes, and inspire possible changes to improve programs.

1) Facility licensing/accreditation requirements
2) Provider-level training, licensing, and certification
3) Reporting requirements
4) Establishment of effective application of investigative authorities



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Outpatient Settings Policy Options for Improving Infection Prevention

- Maintaining accurate information on the locations, numbers, and types of outpatient facilities within the state
- Requiring all outpatient healthcare facilities be registered
- Enhancing collaboration between the medical boards that license healthcare providers, the licensure agencies that license healthcare facilities, other state agencies (e.g., pharmacy boards), and accrediting agencies
- Designating license fees or fines for the support of education, technical assistance, and inspection/monitoring activities
- Working with medical liability and healthcare insurance companies to encourage them to assess the infection control practices used by insured or participating healthcare providers and facilities
- Using standard approaches such as state agency survey protocols to measure adherence to Standard Precautions

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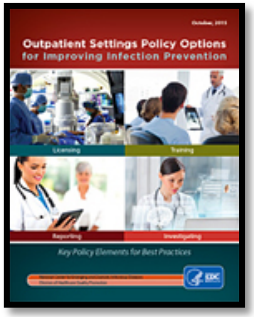

- *Enhancing collaboration and communication between medical boards, pharmacy boards, and state health authorities*

- ❒ Ensuring that accrediting agencies report adverse events or unsafe conditions identified during an accreditation survey to the appropriate local and/or state agency
- ❒ Requiring accrediting bodies to incorporate basic infection control practices in their initial accreditation, subsequent inspections, and applications for renewed accreditation
- ❒ Ensuring that pharmacy board requirements are communicated and monitored for any outpatient facility that is engaged in on-site drug compounding activities
- ❒ Requiring licensure for staffing agencies that place healthcare providers

Emerging "Outpatient" Settings –
Future Sites of Healthcare Outbreaks?

- **Hangover/Hydration clinics**
- **Platelet Rich Plasma clinics**
- **Ketamine clinics**
- **Others?**

Acknowledgements

Division of Healthcare Quality Promotion, CDC

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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

Thank You

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