Outline

- Background
- Outbreaks associated with outpatient oncology care
- Infection prevention
Shift in Healthcare Delivery to Outpatient Settings

- Outpatient settings: physician offices, hospital-based outpatient clinics, nonhospital-based cancer centers
- >1 million 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: Milliman’s analysis of Medicare 5% Sample, 2006-2009.
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
Oncology Patients: Risks for Infection

- **Immunosuppression**
  - Medications
  - Underlying disease

- **Invasive long-term central lines**
  - Catheters inserted into large vein
  - Essential: infusion of many chemotherapy (cancer-treating) drugs
  - Used to obtain blood for tests
  - Provide direct portal-of-entry to bloodstream

Central Line Access and Care

Critical to disinfect properly before access

Requires flushing with saline after access and intermittently to maintain patency

http://rgmorton.org/Personal%20Care.htm
http://www.icumed.com/media/16766/ag-clave-header.jpg
<table>
<thead>
<tr>
<th>State</th>
<th>Year</th>
<th>Predominant Infection Type(s)</th>
<th>No. of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>NE</td>
<td>2002</td>
<td>Hepatitis C infection</td>
<td>99</td>
</tr>
<tr>
<td>CA</td>
<td>2002</td>
<td><em>Alcaligenes xylosoxidans</em> bloodstream infection</td>
<td>12</td>
</tr>
<tr>
<td>IL</td>
<td>2004</td>
<td><em>Klebsiella oxytoca</em> and/or <em>Enterobacter cloacae</em> bloodstream infection</td>
<td>27</td>
</tr>
<tr>
<td>GA</td>
<td>2004</td>
<td><em>Burkholderia cepacia</em> bloodstream infection</td>
<td>10</td>
</tr>
<tr>
<td>GA*</td>
<td>2007</td>
<td>Polymicrobial bloodstream infection</td>
<td>13</td>
</tr>
<tr>
<td>NJ</td>
<td>2009</td>
<td>Hepatitis B infection</td>
<td>29</td>
</tr>
<tr>
<td>NJ</td>
<td>2011</td>
<td><em>K. pneumoniae</em> bloodstream infection</td>
<td>11</td>
</tr>
<tr>
<td>MS</td>
<td>2011</td>
<td><em>K. pneumoniae</em> and/or <em>Pseudomonas aeruginosa</em> bloodstream infection, skin/soft tissue infection</td>
<td>17</td>
</tr>
<tr>
<td>WV</td>
<td>2011</td>
<td><em>Tsukamurella spp.</em> bloodstream infection</td>
<td>15</td>
</tr>
</tbody>
</table>

*Outpatient Bone Marrow Transplant Facility
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)

- Hematology/oncology clinic
  - Located inside hospital complex, but independently owned
  - Single-physician clinic, small staff

- Health department conducted investigation

HCV Outbreak – Nebraska, 2002

Case-Finding Results

- 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)
  - All received care at the clinic before July 2001
    • Nurse dismissed in July 2001 due to infection control breaches

### Table 2. Unconditional Multivariable Analysis of Risk Factors for Hepatitis C Virus Infection Using the 56 Case-Patients with Estimated Dates of Onset and 56 Controls, March 2000–July 2001*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Case-Patients (n = 56)</th>
<th>Controls (n= 56)</th>
<th>Crude Odds Ratio (95% CI)</th>
<th>Adjusted Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men, n (%)</td>
<td>27 (48)</td>
<td>19 (34)</td>
<td>1.8 (0.8–4.2)</td>
<td>2.7 (0.7–10.3)</td>
</tr>
<tr>
<td>Presence of central venous catheter, n (%)</td>
<td>47 (84)</td>
<td>13 (23)</td>
<td>17.3 (6.7–44.5)</td>
<td>2.8 (0.4–18.3)</td>
</tr>
<tr>
<td>Cancer as underlying diagnosis, n (%)</td>
<td>54 (96)</td>
<td>40 (71)</td>
<td>10.8 (2.3–49.7)</td>
<td>1.2 (0.1–14.3)</td>
</tr>
<tr>
<td>≥1 subcutaneous injection, n (%)</td>
<td>21 (38)</td>
<td>6 (11)</td>
<td>5 (1.7–15.6)</td>
<td>2.6 (0.2–30.4)</td>
</tr>
<tr>
<td>Mean saline flushes (range), n†</td>
<td>8.9 (2–30)</td>
<td>1.1 (0–12)</td>
<td>NA</td>
<td>2.1 (1.3–3.2)</td>
</tr>
</tbody>
</table>

* Each value was adjusted for other risk factors in the model and number of clinic visits. NA = not available.
† Number of saline flushes was analyzed as a continuous variable.

HCV Outbreak – Nebraska, 2002
Infection Control Assessment

- Prior to July 2001
- 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

Following the Nebraska HCV Outbreak: One Survivor’s Response

HONOREform Foundation

Evelyn's Story

Dr. Evelyn McKnight is a nationally recognized patient safety advocate and survivor of one of the largest viral outbreaks in American health care history. Dr. McKnight 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 AANA, APIC, the CDC and the CDC Foundation, and she presented at the World Vaccine Congress, among many others. All honoraria she receives help support the efforts of HONOREform.
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

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

HCV Outbreak – New Jersey, 2009
Infection Control Assessment

Suboptimal hand hygiene and glove use

Suboptimal hand hygiene and glove use

Use of saline bags as common-source supply

Photos courtesy of Ms. Rebecca Greeley
HCV Outbreak – New Jersey, 2009

Infection Control Assessment

Suboptimal hand hygiene and glove use

Storing single-dose vials for future use

Use of saline bags as common-source supply

Photos courtesy of Ms. Rebecca Greeley
HCV Outbreak – New Jersey, 2009
Infection Control Assessment

Suboptimal hand hygiene and glove use

Storing single-dose vials for future use

Use of saline bags as common-source supply

Suboptimal chemotherapy preparation

Photos courtesy of Ms. Rebecca Greeley
HCV Outbreak – New Jersey, 2009
Infection Control Assessment

Blood Stain on Floor in Chemotherapy Room

Photo courtesy of Ms. Rebecca Greeley
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
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
  - Facility converted from a commercial building

- State and local health department investigated

Unpublished data by Mississippi State Department of Health
16 patients with bloodstream infections with *P. aeruginosa*, *K. pneumoniae*, or both

Unpublished data by Mississippi State Department of Health
P. aeruginosa / K. pneumonias 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
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
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

- **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)

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
### Tsukamurella spp. Cases by Month of First Positive Culture (n=15 cases)

<table>
<thead>
<tr>
<th>Month First Positive Culture Collected</th>
<th>Number of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun 2011</td>
<td></td>
</tr>
<tr>
<td>Jul 2011</td>
<td></td>
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<tr>
<td>Aug 2011</td>
<td></td>
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<tr>
<td>Sep 2011</td>
<td>5</td>
</tr>
<tr>
<td>Oct 2011</td>
<td>4</td>
</tr>
<tr>
<td>Nov 2011</td>
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<tr>
<td>Dec 2011</td>
<td>2</td>
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<tr>
<td>Jan 2012</td>
<td></td>
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<tr>
<td>Feb 2012</td>
<td>2</td>
</tr>
<tr>
<td>Mar 2012</td>
<td></td>
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<tr>
<td>Apr 2012</td>
<td></td>
</tr>
<tr>
<td>May 2012</td>
<td>1</td>
</tr>
<tr>
<td>Jun 2012</td>
<td></td>
</tr>
</tbody>
</table>

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

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

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
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
WV Oncology Clinic: Medication Preparation Room Layout

Hood for preparation of chemotherapy medications
WV Oncology Clinic: Medication Preparation Room Layout

Other medications prepared here

Lapses Related to Medication Preparation

- Window opened intermittently (air quality)
- Glove boxes placed on windowsill (bugs found in boxes)

Recommendations: (USP)
- Standards for air flow and particulate count where medications are prepared
- Ideally, gloves worn when preparing chemotherapy should be sterile
Lapses Related to Medication Preparation

- Concerns regarding seal of window (air quality)
- Hood disinfected with alcohol of insufficient strength
- Medications prepared next to sink (possible contamination with tap water)

Recommendations: (USP)
- Ensure proper air quality in room where medications are prepared
- Use an intermediate-level disinfectant (e.g., 70% isopropyl alcohol) to disinfect chemotherapy hood
- Sinks should not be adjacent to medication preparation area
Summary of Infection Control Lapses

- **Unsafe injection practices**
  - Reuse of syringes to access medication vials/bags
  - Use of saline bag as common source for >1 patient
  - Storing opened single-dose vials for use over multiple days
  - Use of single-dose vials for >1 patient
  - Direct syringe reuse from one patient to another

- **Inadequate environmental conditions for chemotherapy preparation**

- **Suboptimal disinfection for accessing central lines**

- **Poor hand hygiene**
Just Scratching the Surface...

Tip of the iceberg
INFECTION PREVENTION
Important Role of State and Local Health Departments in Infection Prevention

- Continue to conduct outbreak investigations in outpatient oncology settings

- Promote use of CDC’s new oncology infection prevention resources and tools
  - Disseminate materials through targeted outreach to outpatient oncology facilities, can start locally

- Provide education and training to oncology providers

- Develop partnerships
  - Local and state chapters of professional societies
  - Licensing boards
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
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
Main Components of the Basic Infection Control and Prevention Plan

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

- **Key recommendations include:**
  - Avoid using saline bags as common source of supply for >1 patient
  - Dedicate single dose-vials for single patient use and do not store opened single-dose vials for future use
  - Use new syringe/needle to access a 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)
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**
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
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
Appendix Section (I)

- List of Persons Designated to Specific Tasks
  - Facility to obtain information from health department websites

- List of Reportable Diseases/Conditions
  - Collect, manage, and analyze HAI data for surveillance purposes
Appendix Section (II)

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

<table>
<thead>
<tr>
<th>Section II: Personnel and Patient-care Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hand hygiene performed correctly</strong></td>
</tr>
<tr>
<td>A. Before contact with the patient or their immediate care environment (even if gloves are worn)</td>
</tr>
<tr>
<td>B. Before exiting the patient’s care area after touching the patient or the patient’s immediate environment (even if gloves are worn)</td>
</tr>
<tr>
<td>C. Before performing an aseptic task (e.g., insertion of IV or preparing an injection) (even if gloves are worn)</td>
</tr>
<tr>
<td>D. After contact with blood, body fluids or contaminated surfaces (even if gloves are worn)</td>
</tr>
</tbody>
</table>
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
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.
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.
CDC Campaign Materials

Fact Sheets

Posters

Campaign One-Pager

Patient Care Totes
Dissemination of Materials to Oncology Providers, Patients, and Caregivers

- **CDC Website**

- **Partner outreach**
  - Professional societies
  - Patient advocacy groups
  - Medscape

- **Media outlets**
  - Television
  - Radio
  - Internet, print
  - Social media

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**Facebook**

**Twitter**
Next Steps

- Increase understanding of current chemotherapy preparation practices to inform prevention efforts
  - In-depth interviews with sample of outpatient oncology facilities
  - Engage pharmacy and oncology nursing professional organizations

- Continued dissemination along with evaluation of Basic Infection Control and Prevention Plan
  - Assess for facility awareness of the plan, implementation, usefulness and impact
One Last Resource…

- To help public health authorities manage communication issues related to patient notifications for bloodborne pathogen testing

- **CDC Patient Notifications Toolkit in development**
  - Intended users: Primarily state and local health departments
  - Resource for managing notification process
  - Outlines communications strategies for handling media inquiries, press releases
  - Contains sample patient letters
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.