APPENDIX T2: EXTENDED GUIDANCE

Outbreak Investigation Guidance for Healthcare-Associated Infections

CURRENT HAI CONTEXT AND GOALS

Dr. Denise Cardo, Director of CDC’s Healthcare Quality Promotion, and other members of the SHEA HAI Elimination White paper Writing Group, “Moving toward elimination of healthcare-associated infections: A call to action,” said

The clear consensus among healthcare epidemiologists, infection preventionists, infectious disease physicians, and other clinicians attending the Fifth Decennial International Conference on Healthcare-Associated Infections 2010 is that now is the time to advance the cause of HAI elimination. . . . We are committed to working together to eliminate HAIs, recognizing that further work is needed to implement the steps identified in this call to action.

HAIs are an increasingly recognized problem. The number of people who are sickened or die and the financial impact from HAIs are unacceptably high. Intrinsic to the problem is the inconsistent implementation of proven preventive measures. Furthermore, we know little about the burden of infections outside hospitals, particularly in long-term care facilities, ambulatory surgical centers, and other outpatient settings, . . .

In addition, the emergence of HAIs caused by multidrug-resistant microorganisms is an increasing concern. . . .

The cornerstone of HAI elimination is to increase adherence to what we already know can be effectively implemented, on the basis of scientific evidence. . . .

The expertise and resourcefulness of healthcare epidemiologists, infection preventionists, infectious disease physicians, and other clinicians together with public health professionals can build on and can accelerate recent progress. We must continue to work together to increase adherence to practices supported by the body of knowledge on existing prevention interventions . . . We must invest in research to find innovative solutions to combat challenges, such as antimicrobial resistance, the increasing burden of HAIs outside
of traditional hospital settings, and the refinement of existing intervention bundles to be the safest and most cost-effective. . . . **HAI**s are preventable.

**BACKGROUND**

The general guidelines for all outbreaks (Attachment 1, Report of Immediately Reportable Outbreak, Incident, or Situation) should be followed and augmented as described below and/or as necessary for all reported HAI outbreaks. The sites of HAI are varied, and range from acute-care, to long-term care, to ambulatory care (e.g., centers for dialysis, surgery, oncology, and endoscopy) to senior housing and centers. All investigations will not only include implementation of control measures and evaluation, but also targeted delivery of pertinent educational messaging/training.

Many HAIs have been tracked in acute care settings since the late 1960’s. Recently, the Centers for Medicaid and Medicare (CMS) has not only begun to require acute care facilities to report HAIs, but has started tracking infections in ambulatory surgery centers (ASCs) and dialysis centers, with the promise of long-term care facilities (LTCFs) and other health care settings to come. It is important to remember that HAIs may lead to:

- Death;
- Additional HAIs;
- Excess cost/lost reimbursement, therefore less money to support safety and quality;
- Increased length of stay (LOS), which, in turn, increases the risk for other patient safety events (e.g., medication errors, fall, pressure ulcers);
- Decreased opportunity costs/reputational costs;
- Increased societal costs, including loss of trust, increased legislation and litigation; and
- Personal loss, i.e., decreased productivity and sense of wellbeing, and a negative impact on family and caregivers.

The Healthcare Infection Control Practices Advisory Committee’s (HICPAC) “Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007” updates and expands the 1996 Guideline for Isolation Precautions in Hospitals. This updated guideline responds to changes in healthcare delivery, namely the moving from hospitals to free-standing ambulatory service, long-term care, and home care. The guidance addresses new concerns about transmission of infectious agents to patients and healthcare workers in the United States (standard precautions now includes Respiratory Hygiene/Cough Etiquette and injection safety), and infection control (environmental controls, staffing levels, MDRO surveillance). The primary objective of the guideline is to improve the safety of the nation’s comprehensive healthcare delivery system by reducing the rates of HAIs.

>90% of NJ’s reported healthcare associated outbreaks fall into one of the following three categories: respiratory illness, gastrointestinal illness, and scabies infestation. For these categories, guidance for the investigative process is available:
• Guidelines for respiratory illness in healthcare facilities and other institutions can be
found at www.state.nj.us/health/flu/documents/outbreak_prevention.pdf.

• Guidelines for gastrointestinal illness in healthcare facilities and other institutions can
be found at www.state.nj.us/health/cd/manual/gi_ltc.pdf.

• Guidelines for scabies in healthcare facilities and other institutions is in DRAFT form
available by calling IZDP.

Other less commonly reported causes of HAI outbreaks may require an investigation involving
additional research into the organism, the vulnerable population impacted, nuances of the site
associated with the outbreak and/or the route of transmission. The investigation may require a
multi-disciplinary investigative team, including, but not limited to: the disease primary, an
environmental specialist, an infection preventionist, a representative from the licensing agency, a
laboratorian, and/or representatives from multiple states, CDC, FDA, OSHA, one or more
professional organizations, and possibly even representatives from law enforcement. Please become
familiar with the resources available on the CDC HAI website and those listed at the end of this
section.

ADDITIONAL HAI GUIDANCE BY SEGMENTED TOPIC

The following sections highlight guidance/lessons learned from past experiences in outbreaks
involving different organisms/sites. It is not meant to be all inclusive – just suggestive of the range
of types of outbreaks that occur, and the successful control measures that may be implemented.

Prior to beginning an investigation into a possible/confirmed HAI outbreak, notify the CDS HAI team.

Bloodborne Pathogens

Bloodborne pathogens are infectious microorganisms in human blood that can cause disease in
humans. These pathogens include, but are not limited to, hepatitis B (HBV), hepatitis C (HCV) and
human immunodeficiency virus (HIV).

Since 2000, a total of 33 outbreaks of patient-to-patient transmission of HBV or HCV due to
breaches in infection control by health care personnel have been reported in the US, with two
occurring here in New Jersey (NJ). Throughout the US, more than 60,000 patients were potentially
exposed, and 448 did, in fact, acquire HBV or HCV. Delivery of anesthesia was involved in 7 of the
33 outbreaks, and contaminated blood glucose monitoring equipment was implicated in another
15.

The CDC states, “These and other outbreaks of viral hepatitis could have been prevented by
adherence to basic principles of aseptic technique for the preparation and administration of
parenteral medications.” Aseptic technique for injection safety refers to the handling, preparation
and storage of medications, solutions and injection equipment, in a manner designed to prevent
microbial contamination. This applies to all supplies used for injections and infusions, including:
medication vials, ampules, syringes, cannulae, fluid containers and tubing. (See CDC Injection Safety
home page at [www.cdc.gov/injectionsafety/](http://www.cdc.gov/injectionsafety/) for additional information and public health education resources.)

Related problematic practices relevant to the delivery of anesthesia in any health care setting include:

- Using the same needle/cannula and/or syringe to administer intravenous medication to multiple patients;
- Inserting a used needle/cannula and/or syringe into a medication vial or solution container resulting in contamination of the contents and subsequent reuse for other patients; and
- Using single-dose vials as equivalent to multi-dose vials where the vial is entered on multiple occasions for different patients.

In 2012, Dr. Joseph Perz and others from CDC, NYC and Oregon concluded, “Healthcare exposures may represent an important source of new HBV and HCV infections among older adults.” In a case control study involving 48 cases of HBV and HCV and 159 controls, cases were more likely to report one or more behavioral risk exposures, including sexual or household contact with an HBV or HCV patient, >1 sex partner, illicit drug use, or incarceration, hemodialysis, injections in a healthcare setting and surgery. See Attachment 2, NJ’s investigation algorithm for “Investigation of Possible Healthcare Transmission of Blood borne pathogens (HBV & HCV).”

Guidance regarding medication and fluid use for anesthesia in the immediate patient area (e.g., patient rooms or bays, and operating rooms), or safe injection practices includes:

- Use appropriate aseptic technique and hand hygiene.
- All medications and fluids should be single-patient-use ONLY, including single-dose vials, multi-dose vials, ampules, syringes, bottles and bags, and controlled substances from pharmacy.
- When a medication or other solution vial is accessed, both the syringe and the needle/cannula must be sterile. Once the syringe has been used, it should not be refilled even for the same patient.
- If a medication or other solution is not available in the single-dose form and a multi-dose vial must be used, discard the multi-dose vial after single patient use.
- Syringes should be capped when not in use.
- Discard all used and/or opened medication/fluid containers (e.g., cap off, bag entered) no later than the end of the patient’s procedure (exception: bag/bottle in use with administration tubing connected to patient’s vascular access). The nurse anesthetist guidelines state that if the anesthesia circuit is FDA-approved and packaged as a single patient/single use device and the package is opened, the recommendation would be to discard at the end of the case even if unused.
• Discard used needles/syringes intact in a nearby sharps container after use, or at the latest, at the end of the patient’s procedure.

• Store unused syringes, needles and related items in a clean area to avoid cross-contamination from used items.

• Store medications and solutions in accordance with the manufacturer’s recommendations, and discard if sterility is compromised.

Additionally, when we discuss Injection Safety, there have always been questions related to how much time is needed to “scrub the hub.” SHEA News, September 6, 2012 states a 5 second rub with 70% isopropyl alcohol is enough to disinfect needleless connector valves. There was a significant difference between scrub vs no scrub, but not between the 5, 10, 15 and 20 second scrubs.

Single-dose containers do not contain preservatives and should be used promptly. According to US Pharmacopeia 797, “opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and compounding sterile preparations, shall be used within one hour if opened in worse than ISO class 5 air quality, and any remaining contents must be discarded.”

NOTE: The safest practice is for a syringe and needle to be used only once to administer a medication to a single patient, after which the syringe and needle should be discarded. This practice prevents inadvertent reuse of the syringe and protects healthcare personnel from harms such as needle stick injuries. However, when this is not feasible (e.g., when administration of incremental doses to a single patient from the same syringe is an integral part of the procedure), reuse of the same syringe and needle for the same patient should occur as part of a single procedure with strict adherence to aseptic technique. In such situations it is essential that the syringe never be left unattended and that it be discarded immediately at the end of the procedure. Additionally, Dr. Montana, NJDOH CDS Medical Director, recommends that medication never be carried in pockets, and since there is no preservative in the single dose vial there should not be long delays between incremental dose administrations.

An algorithm summarizing the “Investigation of Possible Healthcare Transmission of Bloodborne Pathogens (HBV & HCV)” can be found in Attachment 2, along with another presentation of the same information in a text and a table format (Attachments 3 and 4) which may be easier to understand for some.

Compounding Pharmacy Products (produced in free-standing, not associated with an acute-care facility)

Compounding pharmacies prepare customized medications that are not commercially available for individual patients with specialized medical needs. A prescription is required for a compounded product. Compounding pharmacies are regulated by the State Boards of Pharmacy. The FDA has a limited role. Compounding pharmacies are exempt from good manufacturing practice regulations that ensure quality of FDA-approved products, therefore compounded products are not regularly evaluated for clinical safety and efficacy. Products prepared at compounding pharmacies include
sterile ophthalmic solutions, irrigation solutions, cardioplegia solutions, dialysis solutions, and injections (i.e., anesthesia, antibiotics, parenteral nutrition, steroids).

Contamination of products produced by compounding pharmacies has led to several disease outbreaks and large product recalls. For example, in September 2012, the discovery of fungal contamination in a preservative-free methylprednisolone product led to the largest HAI outbreak investigation in United States history. There were over 730 cases of fungal meningitis, abscess, stroke, or joint infections, leading to over 50 deaths associated with this contamination.

In the past decade, there have been several outbreak investigations caused by product produced in free-standing compounding pharmacies. The Pew Charitable Trusts has identified 20 pharmacy compounding errors associated with 982 adverse events, including 67 deaths, since 2001.

<table>
<thead>
<tr>
<th>Year</th>
<th>States</th>
<th>Reported cases</th>
<th>Reported deaths</th>
<th>Adverse events</th>
<th>Compounding error</th>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>FL, GA, ID, IL, IN, MI, MN, NC, NH, NJ, NY, OH, PA, RI, SC, TN, TX, VA</td>
<td>690</td>
<td>45</td>
<td>Fungal meningitis and other infections</td>
<td>Contamination&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Spinal injections: preservative-free sterile methylprednisolone acetate</td>
</tr>
<tr>
<td>2012</td>
<td>CA and 6 other states</td>
<td>33</td>
<td></td>
<td>Fungal eye infections; 23 cases of partial to severe vision loss</td>
<td>Contamination&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Eye injections: Brilliant Blue-C (BBC) octadecyl and benzalkonium</td>
</tr>
<tr>
<td>2011</td>
<td>FL, TN</td>
<td>21</td>
<td></td>
<td>Bacterial eye infection; one case of neuroretinitis and ophthalmic, four cases of loss of eye sight; three patients had eye removals</td>
<td>Contamination&lt;sup&gt;c&lt;/sup&gt;</td>
<td>Eye injections: intravitreal bevacizumab (Avastin) injections</td>
</tr>
<tr>
<td>2011</td>
<td>CA</td>
<td>5</td>
<td></td>
<td>Blindness</td>
<td>Unintended presence of another medication&lt;sup&gt;d&lt;/sup&gt;</td>
<td>Eye injections: intravitreal bevacizumab (Avastin) injections</td>
</tr>
<tr>
<td>2011</td>
<td>AL</td>
<td>19</td>
<td>9</td>
<td>Bacterial bloodstream infection</td>
<td>Contamination&lt;sup&gt;e&lt;/sup&gt;</td>
<td>Parenteral nutrition solution</td>
</tr>
<tr>
<td>2010</td>
<td>IL</td>
<td>1</td>
<td>1</td>
<td>Fatal overdose</td>
<td>Dose of sodium 60 times stronger than ordered&lt;sup&gt;f&lt;/sup&gt;</td>
<td>IV solution: sodium chloride</td>
</tr>
<tr>
<td>2007</td>
<td>WA, OR</td>
<td>3</td>
<td>3</td>
<td>Fatol overdose</td>
<td>Dose of colchicine eight times stronger than labeled concentration&lt;sup&gt;g&lt;/sup&gt;</td>
<td>IV solution: colchicine</td>
</tr>
<tr>
<td>2007</td>
<td>MD, CA</td>
<td>8</td>
<td></td>
<td>Bacterial bloodstream infection</td>
<td>Contamination&lt;sup&gt;h&lt;/sup&gt;</td>
<td>IV solution: fentanyl</td>
</tr>
</tbody>
</table>

U.S. Illnesses and Deaths Associated with Compounded Medications (2001–Present)

The Pew Charitable Trusts has identified 20 pharmacy compounding errors associated with 982 adverse events, including 67 deaths, since 2001. Contamination of sterile products were the most common compounding errors, though some were the result of pharmacists’ and technicians’ miscalculations and mistakes in filling prescriptions.
An investigation involving a product produced in a compounding pharmacy should be reported and discussed with the CDS HAI team BEFORE an investigation begins.

### Single Dose Vials

Inappropriate use of single dose vials (SDVs) can lead to transmission of life-threatening bloodborne pathogens and bacterial infections. In the MMWR July 2012, CDC summarized two of these outbreaks in the article, “Invasive *Staphylococcus aureus* Infections Associated with Pain Injections and Reuse of Single-Dose Vials — Arizona and Delaware.” Ten patients in Arizona and Delaware contracted either MRSA or MSSA as a result of single dose vial misuse. Single dose vials are typically preservative free, therefore frequent access can lead to bacterial contamination. In addition, accessing a single dose vial multiple times increased the risk of patient-to-patient transmission of bloodborne pathogens such as HIV, HBV and HCV.

In each outbreak, the use of SDVs for more than one patient was associated with infection transmission. In both investigations, clinicians reported reusing SDVs because of difficulty obtaining the medication type or vial size that best fit their procedural needs. Clinician adherence to safe injection practices, even when appropriately sized SDVs are unavailable, is important to prevent infection transmission.
Please ensure that an investigation involving possible contamination of a SDV is reported and discussed with the CDS HAI team BEFORE an investigation begins.

**STEPS FOR EVALUATING AN INFECTION CONTROL BREACH, WITH NO IDENTIFIED DISEASE**

The NJDOH recommends that the investigation of a potential breach follow CDC’s guidance. This guidance is available at [www.cdc.gov/hai/state-resources/steps_for_eval_IC_breach.html](http://www.cdc.gov/hai/state-resources/steps_for_eval_IC_breach.html) and is excerpted below. See also the attached NJ’s algorithm titled “Management of Infection Control Breaches in Health Care Settings” (Attachment 5) for further information.

1. Identification of infection control breach:
   - Identify the nature of the breach, type of procedure, and biologic substances involved;
   - Review the recommended reprocessing methods or aseptic technique; and
   - Institute corrective action as early as possible.

2. Additional data gathering:
   - Determine the time frame of the breach and number of patients who were exposed;
   - Identify exposed patients with evidence of HBV, HCV, or HIV infections through medical records and/or public health surveillance data; and
   - Conduct literature review and consult experts.

3. Notify and involve key stakeholders:
   - Infection control professionals;
   - Risk management;
   - Local and State health departments;
   - Affected healthcare providers; and
   - Licensing or other regulatory agencies, if appropriate.

4. Qualitative assessment of breach:
   - If possible, classify breach as Category A or B:
     - Category A involves a gross error or demonstrated high-risk practice; and
     - Category B involves a breach with lower likelihood of blood exposure.

5. Decision regarding patient notification and testing:
   - If Category A, Patient notification and testing is warranted;
   - If Category B, Consider the following factors in the decision:
     - Potential risk of transmission;
• Public concern; and
• Duty to warn vs. harm of notification.

6. Communications and logistical issues:

• Develop communication materials;
• Consider post-exposure prophylaxis if appropriate;
• Determine who will conduct testing, obtain consent, and/or perform counseling, if appropriate;
• Determine if follow-up testing needed;
• Facilitate public inquiry and communication; and
• Address media and legal issues,

**Breaches in Sterilization/disinfection**

If the initial assessment of an HAI outbreak suggests a site visit is needed, you may want to include staff with expertise in sterilization and disinfection of medical equipment, devices and equipment. This staff answers questions related to policies/procedures/and practice associated with cleaning instruments before sterilization or disinfection, separation of clean and dirty, record keeping, use of a biological, packaging, time, temperature, and accordance with manufacturer guidelines.

**Diabetes Care and Infection Control**

**INSULIN PENS MUST NEVER BE USED FOR MORE THAN ONE PERSON.** Numerous outbreaks of bloodborne pathogens have been associated with blood glucose monitoring using poor infection control procedures.

All persons who assist others with glucose monitoring and/or insulin administration must follow the following infection control guidelines:

• Whenever possible, blood glucose meters should not be shared. If they must be shared, the device should be cleaned and disinfected after every use, per manufacturer’s instructions. If the manufacturer does not specify how the device should be cleaned and disinfected then it should not be shared
• Insulin pens and other medication cartridges and syringes are for single-patient-use only and should never be used for more than one person
• Fingerstick devices should never be used for more than one person

These recommendations apply to all settings where blood glucose monitoring and insulin administration may occur including:

• Hospitals or clinics
• Long-term care such as nursing homes and assisted living facilities
• Pre-hospital settings such as ambulances
• Senior centers
• Health fairs
• Correctional facilities
• Schools or camps

Please review the document titled “Blood Glucose Monitoring and Insulin Administration Frequently Asked Questions (FAQs).” This document and other valuable information is available on the CDC Injection Safety website at www.cdc.gov/injectionsafety/.

**Antimicrobial Resistance**

Antimicrobial drug resistance occurs everywhere in the world and is not limited to industrialized nations. Hospitals and other healthcare settings are battling drug-resistant organisms that spread inside these institutions. Drug-resistant infections also spread in the community at large. Examples include drug-resistant pneumonias, sexually transmitted diseases (STDs), and skin and soft tissue infections.

Some trends in drug resistance documented at CDC include:

• Reports of methicillin-resistant *Staphylococcus aureus* (MRSA), a potentially dangerous type of staph bacteria that is resistant to certain antibiotics and may cause skin and other infections, in persons with no links to healthcare systems have been observed with increasing frequency in the United States and elsewhere around the globe.

• Multi-drug resistant Klebsiella species and Escherichia coli such as carbapenem-resistant Enterobacteriaceae (CRE) have been isolated in hospitals throughout the United States.

• Antibiotic-resistant Streptococcus pneumoniae infections have significantly declined, but remain a concern in some populations.

• Antimicrobial resistance is emerging among some fungi, particularly those fungi that cause infections in transplant patients with weakened immune systems.

• Antimicrobial resistance has also been noted with some of the drugs used to treat human immunodeficiency virus (HIV) infections and influenza.

• The development of antimicrobial resistance to the drugs used to treat malaria infections has been a continuing problem in many parts of the world for decades. Antimicrobial resistance has developed to a variety of other parasites that cause infection.

Reports of outbreaks of antimicrobial resistance in health care facilities, though rare, require significant investigation and collaboration between public health personnel, the health care provider(s) and the laboratory(ies). Not only does public health have to verify the outbreak and the susceptibility pattern, but also ensure that a robust antimicrobial stewardship program is operational.
Although not a resistant organism, *Clostridium difficile* (*C. difficile*) can present as a diarrheal illness as a result of antimicrobial use. *C. difficile* targets patients whose normal bacterial flora have been damaged due to prescribed antimicrobials and can be difficult to treat once acquired. Historically, *C. difficile* has been a growing problem for many healthcare facilities and proper sterilization of surfaces and medical devices is an integral part of prevention.

**HAI RESOURCES**

Evidence-based recommendations for prevention of healthcare-associated infections from CDC/HICPAC can be found at [www.cdc.gov/hicpac/pubs.html](http://www.cdc.gov/hicpac/pubs.html)

Additional information can be found at:

- CDC Website on Healthcare-associated infections: [www.cdc.gov/hai](http://www.cdc.gov/hai)
- CDC Website on Hand Hygiene in Healthcare facilities: [www.cdc.gov/handhygiene](http://www.cdc.gov/handhygiene)
- CDC Website on Injection Safety: [www.cdc.gov/injectionsafety](http://www.cdc.gov/injectionsafety)
- CDC Website on Influenza: [www.cdc.gov/flu](http://www.cdc.gov/flu)