CMS Hospital Infection Control Breaches: What Hospitals Need to Know.
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Emergency Medicine Foundation
www.empsf.org
614 791-1468
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Headlines We Don’t Want to See

5 deaths linked to infections tied to hospital linens
8 hepatitis cases linked to clinic

Hepatitis C outbreak among clinic patients

Brooklyn Bug

Clinic linked to 8 cases of hepatitis C; 2,200 at risk

MEDICAL MYSTERY

Hepatitis C outbreak

Strikes 8 endoscopy patients of B’klyn clinic
The Conditions of Participation (CoPs)

- Regulations first published in 1986
  - Many changes since regulations first published

- First regulations are published in the **Federal Register** then CMS publishes the **Interpretive Guidelines** and some have survey procedures

- Hospitals should check this website once a month for changes

1. www.gpoaccess.gov/fr/index.html
Location of CMS Hospital CoP Manuals

CMS Hospital CoP Manuals new address
State Operations Manual
Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

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(Rev. 122, 09-26-14)

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Survey Protocol

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Psychiatric Unit Survey Module
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Policy & Memos to States and Regions

CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices.

Select From The Following Options:
- Show all items

- Show only (select one or more options):
  - Show only items whose [select one or more options]
  - Show only items whose Fiscal Year is [select one or more options]
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Click on policy & memos to states

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CMS Infection Control Breach Memo
CMS Memo May 30, 2014

- CMS publishes 4 page memo on infection control breaches and when they warrant referral to the public health authorities
- This includes a finding by the state agency (SA), like the Department of Health, or an accreditation organization
  - TJC, DNV Healthcare, CIHQ, or AOA HFAP
- CMS has a list and any breaches should be referred
- Referral is to the state authority such as the state epidemiologist or State HAI Prevention Coordinator
Infection Control Breaches

Center for Clinical Standards and Quality/Survey & Certification Group

DATE: May 30, 2014
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

Memorandum Summary

- **Infection Control Breaches Warranting Referral to Public Health Authorities:** If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they should refer them to appropriate State authorities for public health assessment and management.

- **Identification of Public Health Contact:** SAs should consult with their State’s Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, they do not have to confer with State public health officials to set up referral processes, but are expected to refer identified breaches to the appropriate State public health contact identified at: http://www.cdc.gov/HAI/state-based/index.html
Memo says Medicare regulations require hospitals that accept M/M to follow their infection control standards.

Some types of infection control breaches, such as ones related to medication administration, pose a risk of bloodborne pathogen transmission that warrant public health authorities to conduct a risk assessment.

- And if necessary to contact the patient.

Outside the scope of CMS but within authority of the SA such as the state department of health.
- If any of the listed breaches are observed, then will take appropriate enforcement action

- And will make the public health authority aware
  - Includes LTC, ASCs, hospice, hospitals, home health agencies, CAH, rural health clinics and dialysis facilities

- CDC is working closely with SA (state agency) on HAI prevention (healthcare associated infections)

- List of breaches to be referred include:

- Using the same needle for more than one individual
CMS Memo Infection Control Breaches

- Using the same (pre-filled/manufactured/insulin or any other) syringe, pen or injection device for more than one individual

- Re-using a needle or syringe which has already been used to administer medication to an individual to subsequently enter a medication container (e.g., vial, bag), and then using contents from that medication container for another individual

- Using the same lancing or fingerstick device for more than one individual, even if the lancet is changed
Unsafe Injection Practices and Disease Transmission

Reuse of syringes combined with the use of single-dose vials for multiple patients undergoing anesthesia can transmit infectious diseases. The syringe does not have to be used on multiple patients for this to occur.

1. A clean syringe and needle are used to draw the sedative from a new vial.
2. It is then administered to a patient who has been previously infected with hepatitis C virus (HCV). Backflow into the syringe contaminates the syringe with HCV.
3. The needle is replaced, but the syringe is reused to draw additional sedative from the same vial for the same patient, contaminating the vial with HCV.
4. A clean needle and syringe are used for a second patient, but the contaminated vial is reused. Subsequent patients are now at risk for infection.

Source: www.southernnevadahealthdistrict.org
Fingerstick Devices & Glucose Meters

- Glucose meters must be cleaned and disinfected between each patient use.
- Do hand hygiene and wear gloves during fingerstick blood glucose monitoring and other procedures involving potential exposure to blood or body fluids.
- **Fingerstick devices** (including the lancing device or the lancet itself) should never be used on more than person.
- Items contaminated with blood may not be immediately visible.
Fingerstick Devices

Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens

Available for download Clinical Reminder [PDF - 187 KB]

Summary
The Centers for Disease Control and Prevention (CDC) has become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other bloodborne pathogens to persons undergoing fingerstick procedures for blood sampling -- for instance, persons with diabetes who require assistance monitoring their blood glucose levels. Reports of HBV infection outbreaks linked to diabetes care have been increasing [1, 2, 3]. This notice serves as a reminder that fingerstick devices should never be used for more than one person.

Background
Fingerstick devices are devices that are used to prick the skin and obtain drops of blood for testing. There are two main types of fingerstick devices: those that are designed for reuse on a single person and those that are disposable and for single-use.

- Reusable Devices: These devices often resemble a pen and have the means to remove and replace the lancet after each use, allowing the device to be used more than once (see Figure 1). Due to difficulties with cleaning and disinfection after use and their link to numerous outbreaks, CDC recommends that these devices never be used for more than one person. If these devices are used, it should only be by individual
Fingerstick Devices

- Anyone performing fingerstick procedures should ensure that a device is not used on more than one patient
- Use auto-disabling single-use disposable fingerstick devices
- Pen like devices should not be used on multiple patients due to difficulty with cleaning and disinfection (one patient use)
CMS Memo on Safe Injection Practices
June 15, 2012 CMS issues a 7 page memo on safe injection practices

- Discusses the safe use of single dose medication to prevent healthcare associated infections (HAI)
- Notes new exception which is important especially in medications shortages
- General rule is that single dose vial (SDV) can only be used on one patient
- Will allow SDV to be used on multiple patients if prepared by pharmacist under laminar hood following USP 797 guidelines
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Office of Clinical Standards and Quality/Survey & Certification Group

DATE: June 15, 2012
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

Memorandum Summary

- Under certain conditions, it is permissible to repackage single-dose vials or single use vials (collectively referred to in this memorandum as “SDVs”) into smaller doses, each intended for a single patient. The United States Pharmacopoeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, Pharmaceutical Compounding - Sterile Preparations (“USP <797>”). Under USP <797>, healthcare facilities may repackage SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
  - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
  - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.

Ref: S&C: 12-35-ALL

CMS Memo on Safe Injection Practices

- All entries into a SDV for purposes of repackaging must be completed with 6 hours of the initial puncture in pharmacy following USP guidelines.

- Only exception of when SDV can be used on multiple patients.

- Otherwise using a single dose vial on multiple patients is a violation of CDC standards.

- CMS will cite hospital under the hospital CoP infection control standards since must provide sanitary environment.
  - Also includes ASCs, hospice, LTC, home health, CAH, dialysis, etc.
CMS Memo on Safe Injection Practices

- Bottom line is you can not use a single dose vial on multiple patients
- CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines
- SDV typically lack an antimicrobial preservative
- Once the vial is entered the contents can support the growth of microorganisms
- The vials must have a beyond use date (BUD) and storage conditions on the label
CMS Memo on Safe Injection Practices

- Make sure pharmacist has a copy of this memo
- If medication is repackaged under an arrangement with an off site vendor or compounding facility ask for evidence they have adhered to 797 standards
- ASHP Foundation has a tool for assessing contractors who provide sterile products
- Go to www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx
- Click on starting using sterile products outsourcing tool now
Outsourcing Sterile Products Preparation: Contractor Assessment Tool

Developed with support from PharmMEDium Services, LLC
Now available!

Preparation of sterile parenteral products is a critical component of health-system pharmacy practice. For departments that choose to outsource the preparation of parenteral medications, this web-based tool can be used to evaluate proposals during the selection of an external organization that would provide parenteral product preparation services.

The assessment tool helps you evaluate each of these areas:

+ Regulatory compliance
+ Quality and patient safety measures
+ Medication administration safety features
+ Service excellence

Start using the Sterile Products Outsourcing Tool now!
Not All Vials Are Created Equal

SINGLE-DOSE OR MULTI-DOSE?

NOT ALL VIALS ARE CREATED EQUAL.
Dozens of recent outbreaks have been associated with reuse of single-dose vials and misuse of multiple-dose vials. As a result of these incidents, patients have suffered significant harms, including death. CDC and the One & Only Campaign urge healthcare providers to recognize the differences between single-dose and multiple-dose vials and to understand appropriate use of each container type.

This information can literally save a life.

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.
Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

ONEANDONLYCAMPAIGN.ORG
Safe Injection Practices Patient Safety Brief
Emergency Medicine Patient Safety Foundation

By: Sue Dill Calloway RN MSN JD CPHRM
Ruth Carrico PhD RN FSHEA CIC

July 2012

The Centers for Disease Control and Prevention (CDC) says there are 1.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 99,000 deaths occur as a result. Infection prevention and control is an important issue in today’s healthcare environment. It is important to accreditation organizations like the Joint Commission (TJC). The Joint Commission has eight pages of standards in the chapter on Infection Prevention and Control (IC).
CDC One and Only Campaign

http://oneandonlycampaign.org

http://oneandonlycampaign.org/safe_injection_practices
Watch Award Winning Video

Safe Injection Practices - How to Do It Right

www.youtube.com/watch?v=6D0stMoz80k&feature=youtu.b
CMS Memo on Insulin Pens
CMS Memo on Insulin Pens

- CMS issues memo on insulin pens on May 18, 2012
- Insulin pens are intended to be used on one patient only
- CMS notes that some healthcare providers are not aware of this
- Insulin pens were used on more than one patient which is like sharing needles
- Every patient must have their own insulin pen
- Insulin pens must be marked with the patient’s name
Insulin Pens May 18, 2012

Office of Clinical Standards and Quality/Survey & Certification Group

DATE: May 18, 2012
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Use of Insulin Pens in Health Care Facilities

Memorandum Summary

**Insulin Pen devices:** The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients. **Insulin pens are meant for use by a single patient only.** Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

**Background**
Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times by a single patient/resident, using a new needle for each injection. Insulin pens must never be used for more than one patient/resident. Regurgitation of blood into the insulin cartridge after injection will create a risk of bloodborne pathogen transmission if the pen is used for more than one patient/resident, even when the needle is changed [1]. A previous memo (11-28-NH) dated
CDC Clinical Reminder: Insulin Pens Must Never Be Used for More than One Person

Summary
The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must never be used on more than one person.

Background
Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin pens must never be used for more than one person.

On this Page
- Summary
- Background
- Recommendation
- References

Contact Us:
Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333
800-CDC-INFO (800-232-4636)
TTY: (888) 232-6348
Contact CDC-INFO
CDC Has Flier for Hospitals on Insulin Pens

CDC CLINICAL REMINDER

Insulin Pens Must Never Be Used for More than One Person

Summary
The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must never be used on more than one person.

Background
Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin pens must never be used for more than one person. Regurgitation of blood into the insulin cartridge can occur after injection [1] creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed.

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration (FDA) issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single patient only and are not to be shared between patients [2]. In spite of this alert, there have been continuing reports of patients placed at risk through inappropriate reuse and sharing of insulin pens, including an incident in 2011 that required notification of more than 2,000 potentially exposed patients [3]. These events indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients.

Recommendations
VA Alert on Insulin Pens

- Pharmacist found several insulin pens not labeled for individual use
- Found used multi-dose pen injectors used on multiple patients instead of one patient use
- New requirement that can only be stored in pharmacy and never ward stocked
- Instituted new education for staff on use
- Part of annual competency of staff
- Instituted new policy of safe use of pen injectors
VA Issues Alert in 2013

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL13-04* January 17, 2013

Item: Multi-Dose Pen Injectors

Specific Incident: While inspecting inpatient units of a VA facility, the Chief of Pharmacy discovered several insulin pen injectors that were not labeled for individual patients. It was determined that the pen injectors were used to administer insulin to multiple patients by changing the needle between patients. Multi-dose pen injectors are intended for use by one patient only, and the pen injector and cartridges within them should never be shared between patients. The sharing of pen injectors may expose patients to blood-borne pathogens (e.g., HBV, HCV, HIV) through cross contamination in the pen cartridge.

General Information: A similar incident occurred in a VA facility in 2008 involving the use of the same heparin syringe for intravenous line flushes on multiple patients. NCPS published Patient Safety Alert AL08-20 on August 8, 2008 (see references). This alert prohibited the use of the same syringe to administer medications to multiple patients, even if the needle is changed for each patient.

Actions:

1) By close of business (COB) February 04, 2013, the Facility Director (or designee), in consultation with the Chief of Pharmacy (or designee), shall prohibit the use of multi-dose pen injectors (see attachment 1) on all patient care units (i.e., any unit where a staff member is involved in the storage, preparation or administration of a multi-dose pen injector).

Exceptions to Action 1 include the following:

- Patients being educated prior to discharge to use a patient-specific multi-dose pen injector.
- Eligible patients participating in the VA medical center’s Self-Medication Program (SMP) as established by VHA Handbook 1108.03 (see references).
- Patients requiring treatment with a medication delivered in a multi-dose pen injector, and no alternative formulation is available from the manufacturer for
VA Alert on Insulin Pens

- Decided to prohibit multi-dose insulin pen injectors on all patient units except the following:
  - Patients being educated prior to discharge to use a insulin pen injector
  - Eligible patient is self medication program
  - Patient needing treatment and no alternative formulation is available
  - Patients participating in a research protocol requiring an insulin pen
  - Pen injectors dispensed directly to patients as an outpatient prescription
Information for Healthcare Professionals: Risk of Transmission of Blood-borne Pathogens from Shared Use of Insulin Pens

FDA ALERT [03/19/2009]: The FDA is issuing this alert to remind healthcare providers and patients that insulin pens and insulin cartridges* (see description below) are never to be shared among patients. Sharing of insulin pens may result in transmission of hepatitis viruses, HIV, or other blood-borne pathogens.

The FDA has received information that insulin pens may have been shared among numerous patients (two thousand or more) in one hospital in the United States from 2007-2009 (http://www.wbamc.amedd.army.mil/), and in a smaller number of patients in at least one other hospital. Although the disposable needles in the insulin pens were reportedly changed for each patient, there is still a risk of blood contamination of the pen reservoir or cartridge. Patients who were treated with insulin pens at the hospitals in question are being contacted by the hospitals, and are being offered testing for hepatitis and HIV. Some of the potentially exposed patients have reportedly tested positive for hepatitis C; however it is not known if the hepatitis infection occurred through insulin pen sharing, or if those who tested positive had previously undiagnosed hepatitis C.
Insulin Pen Safety – One Insulin Pen, One Person

BE AWARE
DON’T SHARE

ONE INSULIN PEN,
ONLY ONE PERSON

The Safe Injection Practices Coalition created an insulin pen poster and brochure for healthcare providers as a reminder that insulin pens and other injectable medications are meant for one person and should never be shared. PDFs of these educational materials are linked below.

Specific Materials for Safe Use of Insulin Pens – for Clinicians and Patients

- Poster
- Brochure

Click here to order free copies of these materials from the Centers for Disease Control and Prevention (CDC) (publication numbers 22-1501 and 22-1503).

Additional Resources

- VA Patient Safety Alert Multi-Dose Pen Injectors (Department of Veterans Affairs, January 2013)
BE AWARE
DON’T SHARE

Insulin pens that contain more than one dose of insulin are only meant for one person.

They should never be used for more than one person, even when the needle is changed.

ONE INSULIN PEN, ONLY ONE PERSON

The One & Only Campaign is a public health campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices.

For more information, please visit: www.ONEandONLYcampaign.org
DON'T DO IT
Sharing Insulin Pens and Other Injection Equipment Jeopardizes Patients

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single person only and are not to be shared. Unfortunately, there have been continuing reports of persons placed at risk of bloodborne and bacterial pathogen transmission through sharing of insulin pens.

A SIMPLE RULE
Injection equipment (e.g., insulin pens, needles and syringes) should never be used for more than one person.

BE AWARE
DON'T SHARE
ONE INSULIN PEN, ONLY ONE PERSON

About the Safe Injection Practices Coalition
The Safe Injection Practices Coalition (SIPC) is a partnership of healthcare-related organizations led by the Centers for Disease Control and Prevention that was formed to promote safe injection practices in all U.S. healthcare settings. The SIPC has developed the One & Only Campaign – a public health education and awareness campaign – aimed at both healthcare providers and patients to advance and promote safe injection practices.

For more information, please visit:
www.ONEandONLYcampaign.org

What Every Healthcare Professional Needs To Know
Infection Control Video
Everyone Should See
Infection Control Video

- HHS has published a training video that every nurse, physician, infection preventionist and healthcare staff should see
- This includes risk managers
- It is an interactive video
- Called Partnering to Heal: Teaming Up Against Healthcare-Associated Infections
- Go to http://www.hhs.gov/partneringtoheal
- HHS wants to decrease HAI by 40%, wanted 1.8 million fewer injuries and can save 60,000 lives
Watch this Video on Preventing HAI

www.hhs.gov/ash/initiatives/hai/training/

Partnering to Heal: 
TEAMING UP AGAINST HEALTHCARE-ASSOCIATED INFECTIONS

Partnering to Heal is a computer-based, video-simulation training program on infection control practices for clinicians, health professional students, and patient advocates.

The training highlights effective communication about infection control practices and ideas for creating a "culture of safety" in healthcare institutions to keep patients from getting sicker. Users assume the identity of the following five main characters and make decisions about preventing healthcare-associated infections (HAIs):

A Physician, Nathan Green, Director of a Hospital Post-op Unit, ready to start new prevention efforts in the unit;

A Registered Nurse, Dena Gray, working to learn effective communications skills that could make the difference for her patients;
CMS Worksheets

Infection Control
October 14, 2011 CMS issues a 137 page memo in the survey and certification section

Memo discusses surveyor worksheets for hospitals by CMS during a hospital survey

Addresses discharge planning, infection control, and QAPI

- It was pilot tested in hospitals in 11 states and on May 18, 2012 CMS published a second revised edition

November 9, 2012 CMS issued the third revised worksheet which is now 88 pages

Final one issued November 26, 2014
Final CMS CoP Worksheets

- The worksheets are finally FINAL
- They are to be used by state and federal surveyors on all survey activities in hospitals when assessing compliance with any of the three CoPs
- Hospitals are encouraged to use the worksheets as part of their self-assessment tools
- Not used in CAH but great tool and CAH should still review
- Questions can be submitted to hospitalscg@cms.hhs.gov and this email for any CMS CoP question
Final Infection Control Worksheet

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

DATE:   November 26, 2014
TO:     State Survey Agency Directors
FROM:   Director
         Survey and Certification Group
SUBJECT: Public Release of Three Hospital Surveyor Worksheets

Memorandum Summary

- Three Hospital Surveyor Worksheets Finalized: The Centers for Medicare & Medicaid Services (CMS) has finalized surveyor worksheets for assessing compliance with three Medicare hospital Conditions of Participation (CoPs): Quality Assessment and Performance Improvement (QAPI), Infection Control, and Discharge Planning. The worksheets are used by State and Federal surveyors on all survey activity in hospitals when assessing compliance with any of these three CoPs.

- Final Worksheets Made Public: Via this memorandum we are making the worksheets publicly available. The hospital industry is encouraged, but not required, to use the worksheets as part of their self-assessment tools to promote quality and patient safety.
Centers for Medicare & Medicaid Services

Hospital Infection Control Worksheet

Name of State Agency: __________

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the Infection Control Condition of Participation. Items are to be assessed by a combination of observation, interviews with hospital staff, patients and their family/support persons, review of medical records, and a review of any necessary infection control program documentation. During the survey, observations or concerns may prompt the surveyor to request and review specific hospital policies and procedures. Surveyors are expected to use their judgment and review only those documents necessary to investigate their concern(s) or to validate their observations.

The interviews should be performed with the most appropriate staff person(s) for the items of interest, as well as with patients, family members, and support persons.

Hospital Characteristics

1. Hospital name: __________

2. CMS Certification Number (CCN): __________

3. Date of site visit: __________ / __________ / __________ to __________ / __________ / __________
# Section 1.A. Infection Prevention Program and Resources

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<th>Surveyor Notes</th>
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<tr>
<td>1.A.1 The hospital has designated one or more individual(s) as its Infection Control Officer(s).</td>
<td>○ Yes  ○ No</td>
</tr>
<tr>
<td>1.A.2 The hospital has evidence that demonstrates the Infection Control Officer(s) is qualified and maintain(s) qualifications through education, training, experience or certification related to infection control consistent with hospital policy.</td>
<td>○ Yes  ○ No</td>
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<tr>
<td>1.A.3 The Infection Control Officer(s) can provide evidence that the hospital has developed general infection control policies and procedures that are based on nationally recognized guidelines and applicable state and federal law.</td>
<td>○ Yes  ○ No</td>
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If no to any of 1.A.1 through 1.A.3, cite at 42 CFR 482.42(a) (Tag A-748)

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<td>1.A.4 The Infection Control Officer can provide an updated list of diseases reportable to the local and/or state public health authorities.</td>
<td>○ Yes  ○ No</td>
</tr>
<tr>
<td>1.A.5 The Infection Control Officer can provide evidence that hospital complies with the reportable diseases requirements of the local health authority.</td>
<td>○ Yes  ○ No</td>
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No citation risk for questions 1.A.4 and 1.A.5

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<tbody>
<tr>
<td>1.A.6 The hospital has infection control policies and procedures relevant to construction, renovation, maintenance, demolition, and repair, including the requirement for an infection control risk assessment (ICRA) to define the scope of the project and</td>
<td>○ Yes  ○ No</td>
</tr>
</tbody>
</table>
Injection Practices & Sharps Safety

- Section is on injection practices and sharps safety
- This includes medications, saline, and other infusates
- Injections are given and sharps safety is managed in a manner consistent with IC P&P
- CDC has standards on self injection practices
- Injections are prepared using aseptic technique
- One needle, one syringe for every patient and includes insulin pens
## Section 2. B Injection Practices and Sharps Safety (Medications, Saline, Other Infusates)

<table>
<thead>
<tr>
<th>Elements to be assessed</th>
<th>Manner of Assessment Code (check all that apply) &amp; Surveyor Notes</th>
<th>Manner of Assessment Code (check all that apply) &amp; Surveyor Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. B.1 Injections are prepared using aseptic technique in an area that has been cleaned and free of visible blood, body fluids, or contaminated equipment.</td>
<td>□ Yes □ No □ N/A</td>
<td>□ Yes □ No □ N/A</td>
</tr>
<tr>
<td>2. B.2 Needles are used for only one patient.</td>
<td>□ Yes □ No □ N/A</td>
<td>□ Yes □ No □ N/A</td>
</tr>
<tr>
<td>2. B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes and insulin pens).</td>
<td>□ Yes □ No □ N/A</td>
<td>□ Yes □ No □ N/A</td>
</tr>
</tbody>
</table>

**Interview = 1**  **Observation = 2**  **Infection Control Document Review = 3**  **Medical Record Review = 4**  **Other Document Review = 5**
Injections prepared using aseptic technique in area cleaned and free of blood and bodily fluids

Is rubber septum disinfected with alcohol before piercing?

Are single dose vials, IV bags, IV tubing and connectors used on only one patient?

Are multidose vials dated when opened and discarded in 28 days unless shorter time by manufacturer?

Make sure expiration date is clear as per P&P

If multidose vial found in patient care area must be used on only one patient
Point of Care Devices  IE

- Section is on point of care devices
  - Glucose meters, INR monitor
- Hand hygiene is performed before and after the procedure
- Gloves are worn when doing a finger stick
- Finger stick devices are not used on more than one person
  - This includes both the lancet and the lancet holding device
### Section 4. E Point of Care Devices (e.g. Blood Glucose Meter, INR Monitor)

<table>
<thead>
<tr>
<th>Elements to be assessed</th>
<th>Manner of Assessment Code (check all that apply) &amp; Surveyor Notes</th>
<th>Manner of Assessment Code (check all that apply) &amp; Surveyor Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Point of care devices are used in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease, including the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. E.1 Hand hygiene is performed before and after the procedure.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Yes</td>
<td>□ 1</td>
<td>□ Yes</td>
</tr>
<tr>
<td>□ No</td>
<td>□ 2</td>
<td>□ No</td>
</tr>
<tr>
<td>□ N/A</td>
<td>□ 3</td>
<td>□ N/A</td>
</tr>
<tr>
<td></td>
<td>□ 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ 5</td>
<td></td>
</tr>
<tr>
<td>4. E.2 Gloves are worn by healthcare personnel when performing the finger stick procedure to obtain the sample of blood and are removed after the procedure (followed by hand hygiene).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Yes</td>
<td>□ 1</td>
<td>□ Yes</td>
</tr>
<tr>
<td>□ No</td>
<td>□ 2</td>
<td>□ No</td>
</tr>
<tr>
<td>□ N/A</td>
<td>□ 3</td>
<td>□ N/A</td>
</tr>
<tr>
<td></td>
<td>□ 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ 5</td>
<td></td>
</tr>
<tr>
<td>4. E.3 Finger stick devices are not used for more than one patient. Note: This includes both the lancet and the lancet holding device.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Yes</td>
<td>□ 1</td>
<td>□ Yes</td>
</tr>
<tr>
<td>□ No</td>
<td>□ 2</td>
<td>□ No</td>
</tr>
<tr>
<td>□ N/A</td>
<td>□ 3</td>
<td>□ N/A</td>
</tr>
<tr>
<td></td>
<td>□ 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ 5</td>
<td></td>
</tr>
<tr>
<td>4. E.4 If used for more than one patient, the point-of-care device is cleaned and disinfected after every use according to manufacturer’s instructions. Note: if manufacturer does not provide instructions for cleaning and disinfection, then the device should not be used for &gt;1 patient.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Yes</td>
<td>□ 1</td>
<td>□ Yes</td>
</tr>
<tr>
<td>□ No</td>
<td>□ 2</td>
<td>□ No</td>
</tr>
<tr>
<td>□ N/A</td>
<td>□ 3</td>
<td>□ N/A</td>
</tr>
<tr>
<td></td>
<td>□ 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ 5</td>
<td></td>
</tr>
</tbody>
</table>
Point of Care Devices

- Must be cleaned after each patient use according to manufacturer instructions
- If manufacturer does not provide instructions for cleaning and disinfection, then the device should not be used for more than 1 patient
- Insulin pens are used for only one patient
- Gloves and gowns are available and located near point of use
The CDC on Safe Injection Practices
Vegas clinic physician gets life sentence for HCV outbreak that killed two patients

October 27, 2013 – 10:03 pm | By Gary Evans | No comments yet

In lieu of patient safety signs and infection control reminders, every ambulatory clinic in the country should just post the scowling countenance of one Dipak Desai, defrocked MD, who will spend the rest of his life in prison for practicing in flagrant disregard of injection safety.

It may well give pause to those who are greedy or ignorant enough to reuse and misuse vials, needles and syringes. Maybe a single outbreak would be averted, perhaps many more, for to look upon that face is to see the “hubris” that a Desai colleague described or know the “chiding” an anesthesiologist faced for suggesting a patient needed more of the precious propophol.

Desai’s two endoscopy clinics were in Las Vegas, where patients may fairly expect the gambling to end when they seek health care. In this case – which came to harsh light in 2007 and 2008 – nine patients were infected with hepatitis C virus and two died. More than 100 cases of HCV were possibly acquired in the outbreak, which resulted in some 65,000 patients recommended for testing.

On Oct. 24 the 63-year-old Desai was sentenced to life in prison, having been found guilty of 27 criminal charges including second-degree murder, according to published reports. Prosecutors successfully argued that he oversaw a “penny-pinching” practice where patient safety was trumped by profit. The practices described included using single-dose vials on more than one patient, which can spread blood borne viruses from patient to patient.
Safe Injection Practices

- This issue should be on the radar screen of every infection preventionist and hospital.
- Do you know the **ten** requirements for safe injection practices by the CDC?
- Are you familiar with the provisions of the CMS hospital worksheet in infection control that includes questions that will be asked on safe injection practices by the surveyors?
Safe Injection Practices

- Does your hospital have a policy on safe injection practices?
- Are all staff educated on safe injection practices including your physicians?
- Are all nurses educated in orientation and periodically on safe injection practices?
- We do not want to see headlines that discuss unsafe practices that result in patient injury and death
CDC Injection Safety Website

- The CDC has an injection safety website
- Contains information for providers
- Injection Safety FAQs
- Safe Injection Practices to Prevent Transmissions of Infections to Patients
- CDC’s Position on the Improper use of single dose vials
- Section from Guidelines for the Isolation Precautions to Prevent Transmission and more
  - www.cdc.gov/ncidod/dhqp/injectionsafety.html
Protect Patients Against Preventable Harm from Improper Use of Single-Dose/Single-Use Vials

In an effort to ensure clinicians are clear about CDC guidelines, the Agency is restating its position on the use of single-dose/single-use vials and also seeks to dispel inaccuracies being disseminated to healthcare providers.
CDC Guidelines

- CDC has a publication called 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- Has a section on Safe Injection Practices (III.A.1.b. and starts on page 68)
- Discusses four large outbreaks of HBV and HCV among patients in ambulatory facilities
- Identified a need to define and reinforce safe injection practices

Safe Injection Practices to Prevent Transmission of Infections to Patients

Download the complete 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings [PDF - 3.80 MB]

III.A.1.b. Safe Injection Practices

The investigation of four large outbreaks of HBV and HCV among patients in ambulatory care facilities in the United States identified a need to define and reinforce safe injection practices 453. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients. In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor. 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 453, 454. These include the use of a sterile, single-use, disposable needle and syringe for each injection given and prevention of contamination of injection equipment and medication.
CDC 10 Recommendations

- The CDC has a page on Injection Safety that contains the excerpts from the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- Summarizes their 10 recommendations
- CMS expects hospitals to follow the CDC guidelines
CDC Safe Injection Recommendations

- Use aseptic technique to avoid contamination of sterile injection equipment.
- Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed.
- Needles, cannula and syringes are sterile, single-use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient.
CDC Safe Injection Recommendations

- Use fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use.

- Consider a syringe, needle, or cannula contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set.
CDC Safe Injection Recommendations

- Use single-dose vials for parenteral medications whenever possible

- Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use

- If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile
CDC Safe Injection Recommendations

- Do not keep multidose vials in the immediate patient treatment area and store in accordance with the manufacturer's recommendations;
  - Discard if sterility is compromised or questionable
- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients
CDC Safe Injection Recommendations

- Worker safety; Adhere to federal (OSHA) and state requirements for protection of healthcare personnel from exposure to blood borne pathogens 1B

- Wear a mask when placing a catheter or injecting material into the spinal canal or subdural space

  - Example, during myelograms, lumbar puncture and spinal or epidural anesthesia. 1B
Wear a Mask Epidural Spinal or LP

CDC Clinical Reminder: Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis

Available for download Clinical Reminder [PDF - 543 KB]

Summary
The Centers for Disease Control and Prevention (CDC) is concerned about the occurrence of bacterial meningitis among patients undergoing spinal injection procedures that require injection of material or insertion of a catheter into epidural or subdural spaces (e.g., myelogram, administration of spinal or epidural anesthesia, or intrathecal chemotherapy). Outbreaks of bacterial meningitis following these spinal injection procedures continue to be identified among patients whose procedures were performed by a healthcare provider who did not wear a facemask (e.g., may be labeled as surgical, medical procedure, or isolation mask).[1] with the most recent occurrence in October 2010 (CDC unpublished data). This notice serves as a reminder that facemasks should always be worn by healthcare providers when performing these spinal injection procedures.[2]
Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis

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Background:
CDC has investigated multiple outbreaks of bacterial meningitis among patients undergoing spinal injection procedures. Recent outbreaks have occurred among patients in acute care hospitals who received spinal anesthesia or epidural anesthesia, and also among patients at an outpatient imaging facility who underwent myelography.

In each of these outbreak investigations, nearly all spinal injection procedures that resulted in infection were performed by a common healthcare provider who did not wear a facemask. The strain of bacteria isolated from the cerebrospinal fluid of these patients was identical to the strain recovered from the oral flora of the healthcare provider who performed the spinal injection procedure. These findings illustrate the risk of bacterial meningitis associated with droplet transmission of the oral flora from healthcare providers to patients during spinal injection procedures.
Wear a Mask Epidural Spinal or LP

www.cdc.gov/injectionsafety/SpinalInjection-Meningitis.html

CDC Clinical Reminder: Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis

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On this Page
- Summary
- Background
- Recommendations
- Additional Information
- References

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CDC Resources on Ebola

www.cdc.gov/vhf/ebola

Signs and Symptoms
Symptoms may appear anywhere from 2 to 21 days after exposure to ebolavirus...

Transmission
Spread through bodily fluids of a person who is sick with or has died from Ebola...

Risk of Exposure
During outbreaks of Ebola, those at highest risk include health care workers and family...

For Healthcare Workers
Updated guidance for managing or preparing for Ebola in the U.S. and abroad...

Prevention
Those at highest risk include health care workers and the family and friends of an infected individual...

Diagnosis
Diagnosing Ebola in an individual who has been infected for only a few days is difficult...

2014 West Africa Outbreak
The 2014 Ebola epidemic is the largest in history, affecting multiple countries in West Africa. Two imported cases, including one death, and two locally acquired cases in healthcare workers have been reported in the United States. CDC and partners are taking precautions to prevent the further spread of Ebola within the United States.

Latest CDC Outbreak Information
Updated November 24, 2014

What's New
November 25, 2014: Video & Slides: What You REALLY Need to Know about Ebola
November 24, 2014: Updated Case Counts
November 21, 2014: Information on the Survivability of the Ebola Virus in Medical Waste

Most Popular Materials
- Outbreak Distribution Map, West Africa
- About Ebola: Questions and Answers
- West Africa Outbreak – Infographic: [PDF - 1 page]
- Top 10 Things You Really Need to Know about Ebola: [PDF - 1 page]
**Guidance and Recommendations**

- Infection Prevention and Control Recommendations for Hospitalized Patients with Known or Suspected Ebola Virus Disease in U.S. Hospitals
- Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus

**Laboratory (specimen collection, transport, testing, submission)**

- Interim Guidance for Specimen Collection, Transport, Testing, and Submission for Persons Under Investigation for Ebola Virus Disease in the United States

**Protecting Healthcare Workers**

- Guidance for Personal Protective Equipment (PPE)

**Diagnosis**

- Case Definition for Ebola Virus Disease (EVD)

**General Information**

- Ebola Virus Disease Information for Clinicians in U.S. Healthcare Settings
- Safe Management of Patients with Ebola Virus Disease (EVD) in U.S. Hospitals

**Patient Transportation/Monitoring/Movement**

- Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure
- Guidance on Air Medical Transport for Patients with Ebola Virus Disease
- Interim Guidance for Emergency Medical Services (EMS) Systems and 9-1-1 Public Safety Answering Points (PSAPs) for Management of Patients with Known or Suspected Ebola Virus Disease in the United States

**Communication Resources**

- Radio PSAs
- Videos
- Infographics
- Factsheets
- Banners
- Posters
- Brochures/Tri-Folds

**Information for Specific Groups**

- Travelers
- Healthcare Workers
- Airlines, Airports, and Ports of Entry
- Parents, Schools, and Pediatric Healthcare Professionals
- Communication Resources for West African Audiences
- CDC Partners and Partner Organizations

**Useful Links**

- World Health Organization Global Alert and Response (GAR) Situation Report
24 Apply face shield (over surgical cap and N95 straps).
25 Perform hand hygiene.

27 Apply long cuff KC500 Purple Nitrile gloves over the standard patient care gloves. Make sure that the glove cuff covers the gown sleeve adequately to prevent exposure when providing patient care.
28 If activities performed in the room are likely to dislodge the cuff, it is acceptable to tape the gown sleeve and glove cuff to one another.

If the patient’s condition warrants, additional personal protective equipment may be added to these guidelines. This may include items such as Tyvek suits, powered air-purifying respirators, and aprons.
Ebola (Ebola Virus Disease)

What You Need to Know about Ebola

2014 West Africa Outbreak
The 2014 Ebola epidemic is the largest in history, affecting multiple countries in West Africa. One imported case from Liberia and associated locally acquired cases in healthcare workers have been reported in the United States. CDC and partners are taking precautions to prevent the further spread of Ebola within the United States.

Latest CDC Outbreak Information
Updated October 16, 2014

What’s New
October 20, 2014: Factsheet: Chlorine Poisoning
[PDF - 1 page]
October 20, 2014: Factsheet: Drinking Chlorine Can Make You Sick or Kill You
[PDF - 1 page]
October 19, 2014: Caring for Suspect or Confirmed Patients with Ebola
October 17, 2014: Frequently Asked Questions about Dallas and Ohio Flights

Most Popular Materials
- Q & A on 2014 West Africa Outbreak

SIGNS AND SYMPTOMS
Symptoms may appear anywhere from 2 to 21 days after exposure to ebolavirus...

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Spread through bodily fluids of a person who is sick with or has died from Ebola...

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Those at highest risk include health care workers and the family and friends of an infected individual...

RISK OF EXPOSURE
During outbreaks of Ebola, those at highest risk include health care workers and family...

DIAGNOSIS
Diagnosing Ebola in an individual who has been infected for only a few days is difficult...
Ebola Facts

- A person infected with Ebola can’t spread the disease until symptoms are present.
- The incubation period is 2 to 21 days but the average time is 8 to 10 days.
- Ebola is spread by direct contact with blood and body fluids.
  - Urine, feces, saliva, vomit, sweat, and semen.
- Ebola is one of 30 viruses that cause viral hemorrhagic fever syndrome.
- Also EVD or Ebola virus disease.
Ebola Facts

- Symptoms may include fever, myalgia, severe headache, abdominal pain, vomiting, diarrhea, or unexplained bleeding or bruising
- Can also have pharyngitis, maculopapular rash and bilateral conjunctival injection
- CDC website includes information on how to treat, late findings, how to diagnosis, and management of the patient with Ebola
- Important to ask patients if recent travel to Sierra Leone, Guinea, and Liberia
Ebola (Ebola Virus Disease)

Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus


Ebola viruses are transmitted through direct contact with blood or body fluids/substances (e.g., urine, feces, vomit) of an infected person with symptoms or through exposure to objects (such as needles) that have been contaminated with infected blood or body fluids. The role of the environment in transmission has not been established. Limited laboratory studies under favorable conditions indicate that Ebolavirus can remain viable on solid surfaces, with concentrations falling slowly over several days. In the only study to assess contamination of the patient care environment during an outbreak, virus was not detected in any of 33 samples collected from sites that were not visibly bloody. However, virus
Free Video on Donning and Doffing

CDC Expert Commentary
Ebola: Donning and Doffing of Personal Protective Equipment (PPE)

Video Instructions From the CDC
Arjun Srinivasan, MD (CAPT, USPHS), Bryan Christensen, PhD, Barbara A. Smith, BSN, MPA
October 29, 2014

Barbara Smith, RN, BSN, MPA, CIC

Ebola Resources

- Screening for Ebola virus disease:
  http://MedED.ahcmedia.com/e/27452/reening-criteria-hospitals-pdf/3gmmjy/833125713

- CDC case definition of Ebola:
  http://MedED.ahcmedia.com/e/27452/ebola-hcp-case-definition-html/3gmmyn/833125713

- Checklist for patients being evaluated for Ebola in the United States:
  http://MedED.ahcmedia.com/e/27452/-patients-evaluated-us-evd-pdf/3gmmys/833125713

- Algorithm for evaluation of returned travelers:
Ebola Resources

- Interim Guidance for Environmental Infection Control in Hospitals for Ebola Virus:

Infection prevention and control recommendations for hospitalized patients with known or suspected Ebola virus disease in U.S. hospitals:

Ebola virus disease information for clinicians in U.S. healthcare settings:
http://MedED.ahcmedia.com/e/27452/on-us-healthcare-settings-html/3gmmzb/833125713
Ebola Resources


- ENA has extensive list of resources at www.ena.org/about/media/ebola/Pages/default.aspx?utm_source=iContact&utm_medium=email&utm_campaign=Emergency%20Nurses%20Association&utm_content=10-16-14+Ebola
Tightened Guidance for U.S. Healthcare Workers on Personal Protective Equipment for Ebola

The Centers for Disease Control and Prevention is tightening previous infection control guidance for healthcare workers caring for patients with Ebola, to ensure there is no ambiguity. The guidance focuses on specific personal protective equipment (PPE) health care workers should use and offers detailed step by step instructions for how to put the equipment on and take it off safely.

Recent experience from safely treating patients with Ebola at Emory University Hospital, Nebraska Medical Center and National Institutes of Health Clinical Center are reflected in the guidance.

The enhanced guidance is centered on three principles:

- All healthcare workers undergo rigorous training and are practiced and competent with PPE, including taking it on and off in a systematic manner
- No skin exposure when PPE is worn
- All workers are supervised by a trained monitor who watches each worker taking PPE on and off.

All patients treated at Emory University Hospital, Nebraska Medical Center and the NIH Clinical Center have followed the three principles. None of the workers at these facilities have contracted the illness.

**Principle #1: Rigorous and repeated training**

Focusing only on PPE gives a false sense of security of safe care and worker safety. Training is a
Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing)

This guidance is current as of October 20, 2014

The following procedures provide detailed guidance on the types of personal protective equipment (PPE) to be used and on the processes for donning and doffing (i.e., putting on and removing) PPE for all healthcare workers entering the room of a patient hospitalized with Ebola virus disease (Ebola). The guidance in this document reflects lessons learned from the recent experiences of U.S. hospitals caring for Ebola patients and emphasizes the importance of training, practice, competence, and observation of healthcare workers in correct donning and doffing of PPE selected by the facility.
Enhanced Guidelines Oct 20, 2014

- Zero skin exposure when wearing personal protective equipment (PPE)

- Extensive training to ensure all healthcare workers demonstrate competency that they can safely wear, put on and remove PPE
  - Double gloves (Nebraska used triple gloves), boot covers, respirators, surgical hoods, disposable face shield and apron if patient has vomiting or diarrhea
  - Must be trained and demonstrated competency before taking care of patients

- Supervision by a trained monitor when healthcare workers put on and remove PPE at all times
DONNING BIOLOGICAL PPE - EBOLA PATIENTS

EQUIPMENT: 1 SURGICAL GOWN, 2 SURGICAL CAP/HAIR COVER, 3 FACE SHIELD, 4 STANDARD PATIENT GLOVES, 5 DOFFING PAD (LARGE FLUID REPELLENT FABRIC OR PLASTIC DRAPE), 6, 7, 8, 9, 10, 11

www.unmcheroes.org
PATIENT GLOVES, 5 DOPPING PAD (LARGE FLUID REPELLENT FABRIC OR PLASTIC DRAPE), 6 SURGICAL BOOT COVERS, 7 N95 RESPIRATOR, 8 LONG CUFF KC500 PURPLE NITRILE GLOVES, 9 TRASH RECEPTACLE, 10 DUCT TAPE, 11 APRON.

12 Perform hand hygiene. 13 Apply scrubs and plastic washable footwear (such as Crocs). 14 Remove all jewelry. 15 Take and record vital signs. 16 Hydrate.

Healthcare and Emergency Responder Organization
Education through Simulation

www.unmcheroes.org

http://app1.unmc.edu/nursing/heroes/pdf/vhfpe/donningBiologicalPPE-EbolaPatients-8.5x11-CC-v1.02.pdf
17 Apply boot covers, 18 surgical cap, and 19 surgical gown. NOTE: ALL TIES should be properly secured with a SIMPLE BOW. Ensure all fit well and cover the intended areas.
20 Perform hand hygiene.

21 Apply N95 respirator. 22 Seal mask to the face ensuring straps are not crossed and properly located at the crown of the head and base of the neck. 23 Perform a fit check of the respirator, breathing deeply in and out, feeling with your hands for any air leakage.
1. Bleach wipe the long cuff KC500 Purple Nitrile Gloves before opening the door to the patient room.
2. Step out of room onto the doffing pad with trash receptacle nearby.

DOFFING BIOLOGICAL PPE - EBOLA PATIENTS
Detailed Hospital Checklist for Ebola Preparedness

The U.S. Department of Health and Human Services (DHHS), Centers for Disease Control and Prevention (CDC), and Office of the Assistant Secretary for Preparedness and Response (ASPR), in addition to other federal, state, and local partners, aim to increase understanding of Ebola Virus Disease (EVD) and encourage U.S. hospitals to prepare for managing patients with Ebola and other infectious diseases. Every hospital should ensure that it can detect a patient with Ebola, protect healthcare workers so they can safely care for the patient, and respond in a coordinated fashion. Many of the signs and symptoms of Ebola are non-specific and similar to those of many common infectious diseases, as well as other infectious diseases with high mortality rates. Transmission can be prevented with appropriate infection control measures.

In order to enhance our collective preparedness and response efforts, this checklist highlights key areas for hospital staff -- especially hospital emergency management officers, infection control practitioners, and clinical practitioners -- to review in preparation for a person with Ebola arriving at a hospital for medical care. The checklist provides practical and specific suggestions to ensure your hospital is able to detect possible Ebola cases, protect your employees, and respond appropriately.

While we are not aware of any domestic Ebola cases, now is the time to prepare, as it is possible that individuals with Ebola in West Africa may travel to the United States, exhibit signs and symptoms of Ebola, and present to facilities.

Hospitals should review infection control policies and procedures and incorporate plans for administrative, environmental, and communication measures, as well as personal protective equipment (PPE) and training and education. Hospitals should also define the individual work practices that will be required to detect the introduction of a patient with Ebola or other emerging infectious diseases, prevent spread, and manage the impact on patients, the hospital, and staff.

The checklist format is not intended to set forth mandatory requirements or establish national standards. In this checklist, healthcare personnel refers to all persons, paid and unpaid, working
## PREPARE TO DETECT

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<tr>
<td>Review <strong>risks and signs and symptoms</strong> of Ebola, and train all front-line clinical staff on how to identify signs and symptoms of Ebola.</td>
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<td>Review CDC <strong>Ebola case definition</strong> for guidance on who meets the criteria for a person under investigation for Ebola and proper specimen collection and shipment guidelines for testing.</td>
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<td>Ensure EMS Crews at hospitals and other agencies are aware of <strong>current guidance</strong>.</td>
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<td>Review Emergency Department (ED) triage procedures, including patient placement, and develop or adopt screening criteria (e.g. relevant questions: exposure to case, travel within 21 days from affected West African country) for use by healthcare personnel in the ED to ask patients during the triage process for patients arriving with compatible illnesses.</td>
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<td>Post screening criteria in conspicuous placements at ED triage stations, clinics, and other acute care locations (see suggested screening criteria in Attachment A).</td>
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<td>Designate points of contact within your hospital responsible for communicating with state and local public health officials. <strong>Remember</strong>: Ebola is a nationally notifiable disease and must be reported to local, state, and federal public health authorities.</td>
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<td>Ensure that all triage staff, nursing leadership, and clinical leaders are familiar with the protocols and procedures for notifying the designated points of contacts to inform 1) hospital leadership (infection prevention and control, infectious disease, administration, laboratory, others as applicable), and 2) state and local public health authorities regarding a person under investigation (PUI).</td>
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<td>Conduct spot checks and inspections of triage staff to determine if they are incorporating screening procedures and are able to initiate notification, isolation, and PPE procedures for your hospital.</td>
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<td>Communicate with state and/or local health department on procedures for notification and consultation for Ebola testing requests.</td>
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<td>Ensure that laboratory personnel are aware of current guidelines for specimen collection, transport, testing, and submission for PUI.</td>
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## PREPARE TO PROTECT

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<td>Review and distribute the <strong>Guidelines for Environmental Infection Control in Health-Care Facilities</strong>.</td>
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<td>Treat all symptomatic travelers returning from affected West African countries.</td>
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Preparing for Ebola: What U.S. Hospitals Can Learn From Emory Healthcare and Nebraska Medical Center

Clinician Outreach and Communication Activity (COCA)
Webinar
October 14, 2014

CDC Has Many Free Presentations

www.cdc.gov/vhf/ebola/resources/videos.html
EMTALA and Ebola

Center for Clinical Standards and Quality/Survey and Certification Group

DATE: November 21, 2014
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Ebola Virus Disease (Ebola)

Memorandum Summary

- **Ebola and EMTALA requirements**: This Memorandum conveys information useful in responding to inquiries from hospitals concerning implications of Ebola for their compliance with EMTALA.

- **EMTALA Screening Obligation**: Every hospital or critical access hospital (CAH) with a dedicated emergency department (ED) is required to conduct an appropriate medical screening examination (MSE) of all individuals who come to the ED, including individuals who are suspected of having been exposed to Ebola, and regardless of whether they arrive by ambulance or are walk-ins. Every ED is expected to have the capability to apply appropriate Ebola screening criteria when applicable, to immediately isolate individuals who meet the screening criteria to be a potential Ebola case, to contact their state or local public health officials to determine if Ebola testing is needed, and, when a decision to test is made, to provide treatment to the individual, using appropriate isolation precautions, until a determination is made whether the individual has Ebola.

- **EMTALA Stabilization, Transfer & Recipient Hospital Obligations**: In the case of individuals who have Ebola, hospitals and CAHs are expected to consider current guidance of public health officials in determining whether they have the capability to provide appropriate isolation required for Ebola cases. Additionally, hospitals may have an obligation to transfer such patients to an institution with the capability to provide isolation required for Ebola cases.
EMTALA and Ebola

- CMS issues 4 page survey memo on November 21, 2014 and questions at hospitalSCG@cms.hhs.gov
- Every hospital, including CAHs, with a DED, must conduct an appropriate MSE on all patients coming to the ED
- This includes patients suspected of having been exposed to Ebola
- All EDs are expected to be able to apply appropriate Ebola screening
- And if necessary to isolate and notify state agency
EMTALA and Ebola

- If patient has Ebola then must follow current guidelines

- If any complaints, CMS will take into consideration the public health guidance in effect at the time

- Hospitals are encouraged to monitor the CDC’s website for the current guidance and information

- CMS has received a number of inquiries from hospitals regarding their EMTALA obligations

- EMS or public health protocols may develop community wide protocols for bringing patients only to specified hospitals if suspected of having Ebola
ENA and Ebola

- ENA has many resources available
- Discusses how we triage patients
  - Determine if the patient has a fever
  - Ask patients about travel to Ebola effected area in the last 21 days
  - If yes isolate until further screening is done
- Discusses how to don and doff PPE
  - Use a buddy system to make sure equipment is put on and taken off correctly
- Guidelines on how to transport patients
ENA Website on Ebola Resources

Ebola News and Resources

As the Ebola story continues to evolve, ENA would like to keep you informed with current and accurate information of the management of this health issue in the US. The current CDC guidelines on restricted movement, current as of October 29th, 2014 has been posted to the ENA Ebola resource website under Preparedness. The supportive evidence to assist you to write guidance and corresponding protocols is being developed on a daily basis. ENA recommends that emergency nurses remain informed, review information from recognized sources, and to assure appropriate communication and reassurances in your various clinical settings on how to meet this health emergency. Emergency nurses are masters of FACT not FEAR. We salute you and everything you do every day.

Get Started with our FAQs

www.ena.org/about/media/ebola/Pages/default.aspx?utm_source=iContact&utm_medium=email&utm_campaign=Emergency%20Nurses%20Association&utm_content=10-16-14+Ebola
British Nurse returns to Sierra Leone after recovery (11-19-14)
Enhanced Airport Entry Screening to Begin for Travelers to the United States from Mali (11-16-14)
Doctor Being Treated for Ebola in Omaha Dies (11-17-14)
Nebraska hospital prepares for new Ebola patient (11-13-14)
Ebola outbreak: MSF to start West Africa clinical trials (11-13-14)
U.S. emergency physician free of Ebola (11-11-14)
Identify, Isolate, Inform: Emergency Department Evaluation and Management for Patients Who Present with Possible Ebola Virus Disease, developed in collaboration with CDC, ACEP and ENA (10-27-14)

General Information and Disease Transmission

ENA Topic Brief: Ebola Virus Disease
The purpose of this topic brief is to examine EVD, discuss transmission, review prevention and containment measures, and consider future preparation strategies.

CDC: Key Messages: Ebola Virus Disease, West Africa (11-05-14)
CDC: About Ebola (10-03-14)
CDC: Questions and Answers about CDC's Ebola Monitoring & Movement Guidance (11-08-14)
CDC: Q&As on Ebola (11-09-14)
CDC: Q&As on Disease Transmission (11-13-14)
CDC: Review of Human-Human Transmission of Ebola Virus (10-29-14)
CDC: 2014 Ebola Outbreak in West Africa - Case Counts and Outbreak Distribution Map (11-14-14)
Healthcare Resources for Suspected Ebola Cases

The U.S. Department of Health and Human Services’ Centers for Disease Control and Prevention (CDC) and Office of the Assistant Secretary for Preparedness and Response (ASPR) aim to increase understanding and promote preparedness of emergency departments and emergency staff concerning the Ebola hemorrhagic fever, also known as Ebola virus disease (EVD).

While countries from around the world join forces to support African communities in combating this outbreak and its spread, we want to be sure our own nation is prepared. Although ASPR, NIH, CDC and other federal agencies are working with private industry to move experimental therapies and vaccine into the earliest clinical trials, standard treatment for EVD remains supportive therapy. Early identification and appropriate isolation of Ebola cases is critical to mounting an effective response.

ACEP Ebola Expert Panel Members

Click here to learn more about the panel members

Chair:
Stephen V. Cantrill, MD, FACEP

Panel Members:
Deena Brecher, MSN, RN, APRN, ACNS-BC, CEN, CPEN
Edward Etzen, MD, MPH, FACEP

Board Liaison:
James J. Augustine, MD, FACEP

ACEP Staff:
Marilyn Bromley, RN
Margaret Montgomery, RN, MSN

[+] Feedback
Identify, Isolate, Inform

News & Updates

- Key Messages: Ebola Virus Disease - Nov. 19, 2014
- ACEP at the White House - Nov. 13, 2014
  Video of ACEP President Dr. Mike Gerardi’s visit to discuss Ebola preparedness
  From NEJM Journal Watch
  From ACEP Now

Ebola Background & Diagnosis

- Case Definition for Ebola Virus Disease (EVD) - updated Nov. 16, 2014
- Ebola (Ebola Virus Disease) Signs and Symptoms - updated Nov. 14, 2014
- Safe Management of Patients with Ebola Virus Disease (EVD) in U.S. Hospitals - updated Nov. 16, 2014

ED Triage

- Identify, Isolate, Inform: Emergency Department Evaluation and Management for Patients Who Present with
Identify, Isolate, Inform: Emergency Department Evaluation and Management for Patients Who Present with Possible Ebola Virus Disease

**Background:** Procedures in the accompanying algorithm provide guidance on the Emergency Department (ED) evaluation and management of patients who present with possible Ebola virus disease (EVD). Guidance in this document reflects lessons learned from the recent experiences of U.S. hospitals caring for Ebola patients.

The risk of transmission of Ebola virus from a patient to a healthcare worker depends upon the likelihood the patient will have confirmed EVD combined with the likelihood and degree of exposure to infectious blood or body fluids. That risk depends on the severity of disease. Severe illness is strongly associated with high levels of virus production. In addition, close contact with the patient and invasive medical care can increase opportunities for transmission.

In general, the majority of febrile patients presenting to the ED do not have EVD, and the risk posed by patients with early, limited symptoms is lower than that from a patient hospitalized with severe EVD. Nevertheless, because early
The End!  Questions???

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