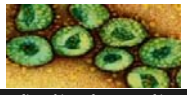
AHC Media

December 6, 2016

CMS Hospital Infection Control Standards & Antibiotic Stewardship



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Speaker

- Sue Dill Calloway RN, Esq. CPHRM, CCMSCP
- AD, BA, BSN, MSN, JD
- President of Patient Safety and Education Consulting
- 5447 Fawnbrook Lane
- Dublin, Ohio 43017
- 614 791-1468 (Call with questions, No emails)
- sdill1@columbus.rr.com

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Objectives

- Review details of tracers included in the CMS infection control worksheet.
- Describe CMS requirements for safe injection practices and sharps safety.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

3

Introduction into the CMS Infection Control Standards

INFECTION PREVENTION is everyone's business

4

Hospitals Do Not Want One of These

5

The Conditions of Participation (CoPs)

- The manual is known as the conditions of participation or the CoPs for short
- The CoP sections are called tag numbers
- They go from Tag 0001 to 1164
  - All the sections contain a tag number so it is easy to go back and look up that section if you want to read more about it
  - Infection control starts at tag number **747 to 756**
  - The CMS infection control worksheet also has the tag number specified
- There are currently 525 pages in the current manual

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The Conditions of Participation (CoPs)

- Regulations first published in 1986
  - Manual updated more frequently now
  - **Questions** to CMS at **hospitalscg@cms.hhs.gov**
  - CAH have a separate manual and these are provided at the end and questions to CAHscg@cms.hhs.gov
- First regulations are published in the **Federal Register** then CMS publishes the **Interpretive Guidelines** and some have **Survey Procedures** [2]
  - Hospitals should check this website once a month for changes

[1]www.gpoaccess.gov/fr/index.html [2]www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp

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How to Keep Up with Changes

- First, periodically check to see you have the most current CoP manual[1]
- Once a month go out and check the survey and certification website as discussed previously [2]
- Once a month check the CMS transmittal page [3]
  - CMS reserves right to tinker with the language in survey memo and when final will publish it as a transmittal and then placed in manual
  - Have one person in your facility who has this responsibility

- [1] http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf
- 2 http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage
- 3 http://www.cms.gov/Transmittals

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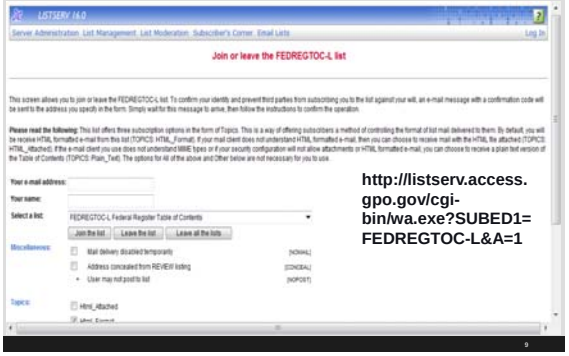
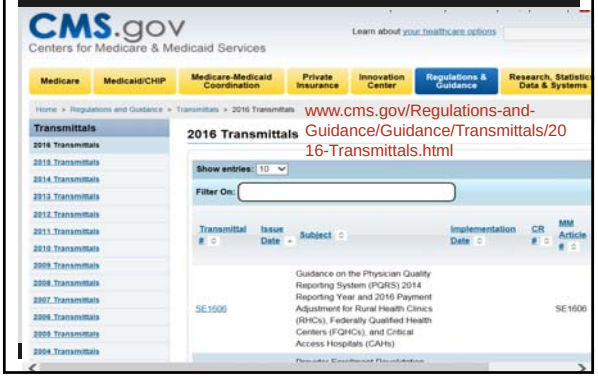
Subscribe to the Federal Register Free



http://listserv.access.gpo.gov/cgi-bin/wa.exe?SUBED1=FEDREGTOC-L&A=1

9

Transmittals



www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2016-Transmittals.html

Medicare State Operations Manual

Appendix

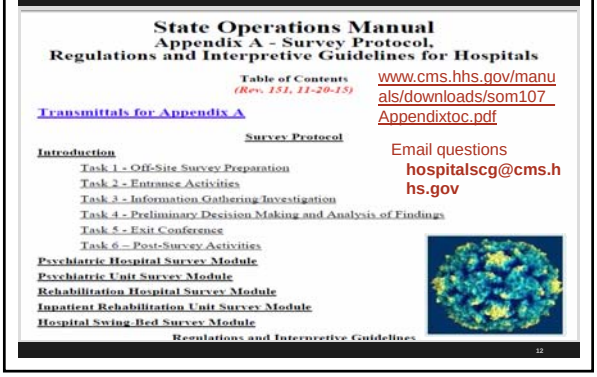
Email questions to CMS hospitalscg@cms.hhs.gov

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the 'Download' column to see any available file in PDF.
- To return to this page after opening a PDF file on your desktop, use the browser "back" button. This is because closing the file usually will also close most browsers

New website at www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

App. No.	Description	PDF File
A	Hospitals	2,185 KB
AA	Psychiatric Hospitals	606 KB

CoP Manual Also Called SOM



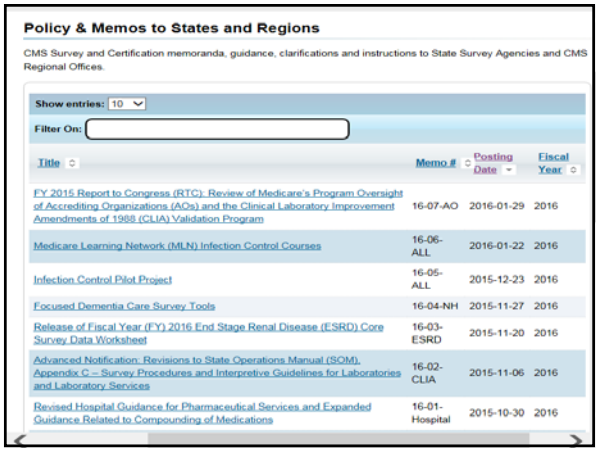
www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

Email questions **hospitalscg@cms.hhs.gov**

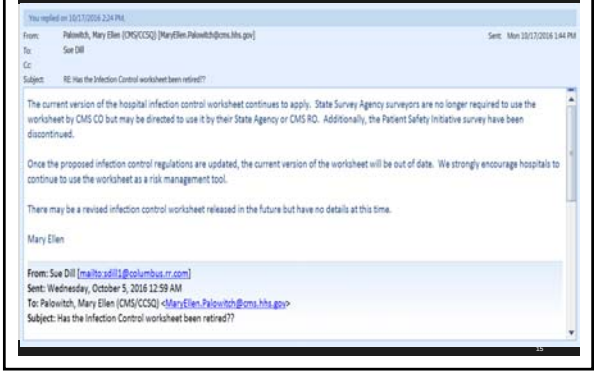
CMS Survey and Certification Website

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

Click on policy & memos to states



Continue to Use the IC Worksheet



Proposed CMS Infection Control Changes

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CMS Proposes New Changes

- CMS proposes new changes to the hospital CoPs which address infection control
  - Called the Improvement in Patient Care Act
- Published in the Federal Register on June 16, 2016
- Every infection preventionist should read this
- Would require every hospital to have an antimicrobial stewardship program
- Change title to Infection Prevention & Control and Antibiotic Stewardship
- IP must be qualified and appointed by board

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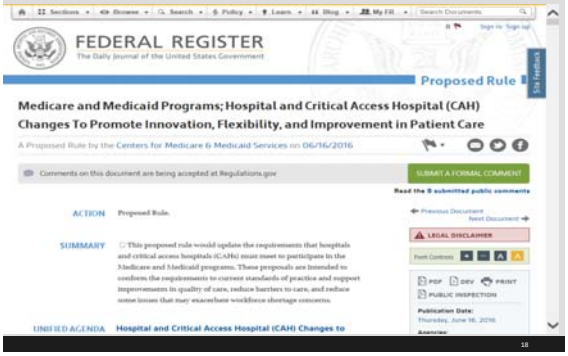
Antibiotic Stewardship Program



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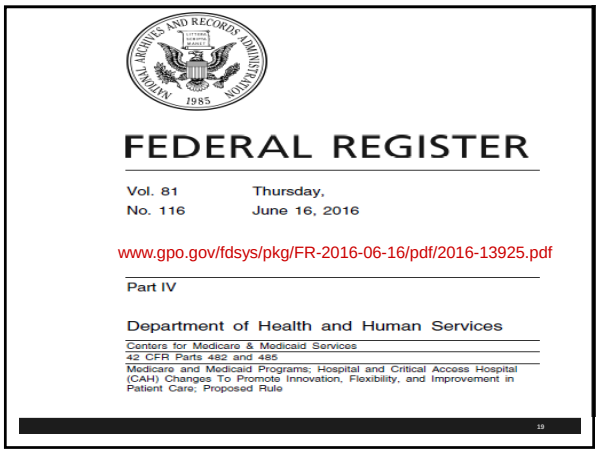

FEDERAL REGISTER

Vol. 81 Thursday,
No. 116 June 16, 2016

www.gpo.gov/fdsys/pkg/FR-2016-06-16/pdf/2016-13925.pdf

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services
42 CFR Parts 482 and 485
Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care; Proposed Rule

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CMS Proposes New Changes

- Must have an active IC program and hospital wide for surveillance
- Need to prevent and control HAI and other infectious diseases
- Must optimize antibiotic use through an antibiotic stewardship program and to reduce C-diff
- Program must demonstrate adherence to nationally recognized IC guidelines and best practices
- Must follow CDC National Healthcare Safety Network

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CMS Proposes New Changes

- IP must be appointed by the board
- Expect hospitals to look at the Guidelines for Outpatients on Infection Control from the CDC
- Review HHS action plan to prevent HAI
- Expand focus and awareness of the sources of HAI in the infection control program
- Need P&P on an active antibiotic stewardship programs
  - Includes many requirements that must be in the hospital's antimicrobial stewardship program

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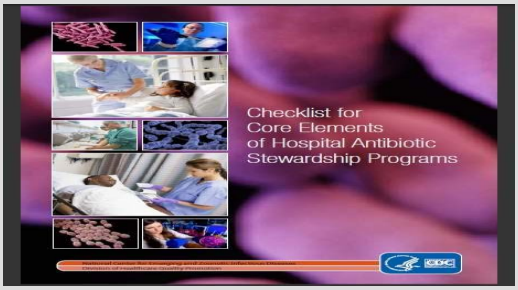
CDC Toolkit Hosp Core Elements



www.ahaphysicianforum.org/resources/appropriate-use/antimicrobial/content%20files%20pdf/CDC%20checklist.pdf

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CDC Outpatient Core Elements

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 65 / No. 6
November 11, 2016

http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6506.pdf

Core Elements of
Outpatient Antibiotic Stewardship

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CMS Deficiency Reports on Infection Control

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Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on March 22, 2013 regarding access to hospital complaint data
- Includes acute care and CAH hospitals
  - Does not include the plan of correction but can request
  - Can count up number of deficiencies
- This is the CMS 2567 deficiency data and lists the tag numbers
- Updating quarterly
  - Available under downloads on the hospital website at www.cms.gov

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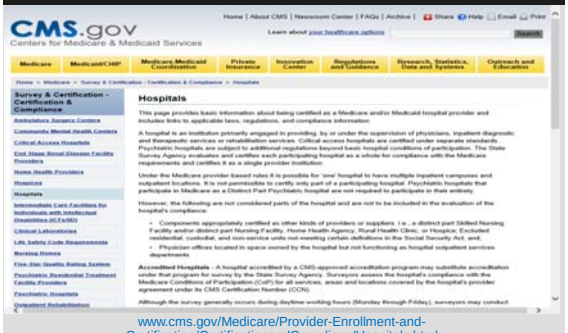
Updated Deficiency Data Reports



www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html

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Infection Control Deficiencies May 13, 2016

Section	Tag Number	Number
Infection Control	747	118
Infection Control Officer	748	103
Infection Control Program	749	474
Infection Control LD Responsibilities	756	44 Total 732

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CMS Deficiencies

- Failed to wash hands when removing gloves when putting on sterile gloves next
- Stored colostomy bags when patient went home in clean utility room
- Many related to infection control issues in dietary
- Failure to have PI on infection control issues
- Failure to immunize staff regarding flu vaccine
- Failure to ensure staff had immunity to infectious diseases

40 28

CMS Deficiencies

- Failure to have an ongoing IC program
- Not cleaning glucometers between uses
- No policy for cleaning nebulizer between uses
- Failure to dispose of hazardous waste in the right container
- Clean linen on floor
- Expired medication and equipment
- Inappropriate dressing change
- Dirty keyboard

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CMS Deficiencies

- Failure to enforce hand hygiene guidelines
- Card board packing boxes in nursing units
- Housekeeping carts not cleaned after each use
- Did not presoak dirty surgical instruments
- Did not throw sharps in sharps container
- Sharps container over the line
- Failure to have all the required policies
- Failure to make sure isolation procedures followed

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CMS Deficiencies

- Did not follow TB plan and place patient in isolation who had classic symptoms
- Not using single dose vials
- Using multidose vials inappropriately and expired ones
- Allowing sales representative into OR after it started without proper scrubs
- Using insulin pens inappropriately
- Cardiac cath floor had blood and debris on it

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CMS Survey Memos on Infection Control

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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

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CMS Memo on Safe Injection Practices

- June 15, 2012 CMS issues a 7 page memo on safe injection practices and section in IC worksheet
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- 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
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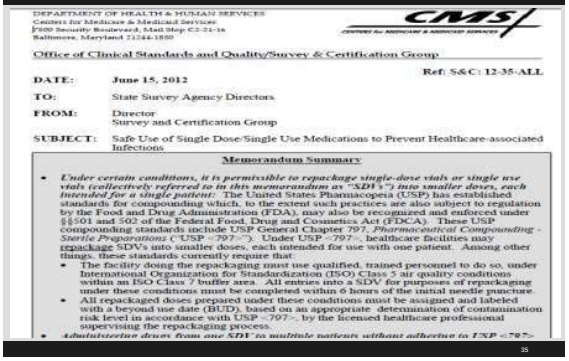
Single Dose Memo



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

CMS

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-35-ALL

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 Pharmacopeia (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.
- ***Administering doses from one SDV to multiple patients without adhering to USP <797>***

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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.

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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

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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

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CMS Memo on Safe Injection Practices

- So if make it in a single dose vial then you need to buy it in a single dose vial
  - If they only make it in a multi-dose vial then try and use it as a single dose vial
  - If not then try and use it only on one patient
- Do not take multi-dose vial into patient room or into OR
  - Unless in OR you treat it as a single dose vial and discard
  - Mark multi-dose vial expires in 28 days unless sooner by manufacturer
- Clean off lid even if new vial for 10-15 seconds and let dry

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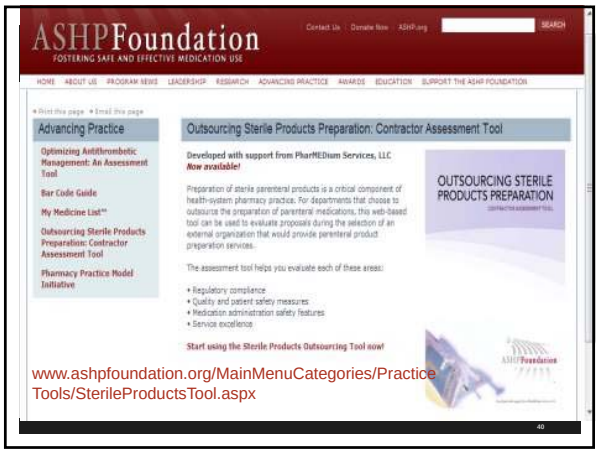
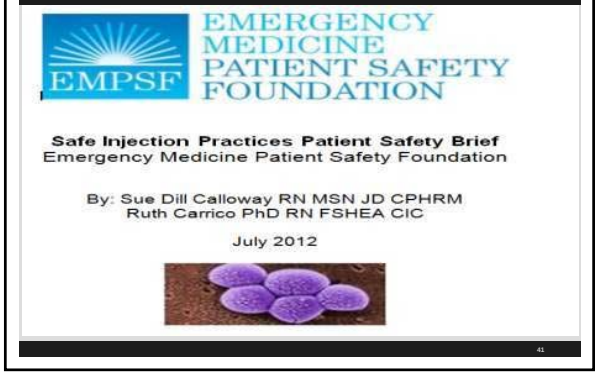
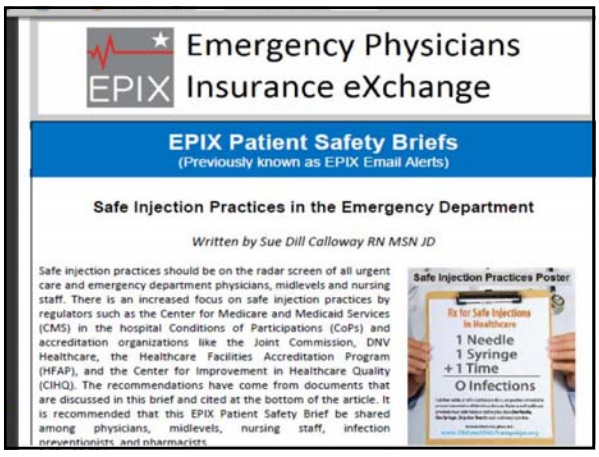
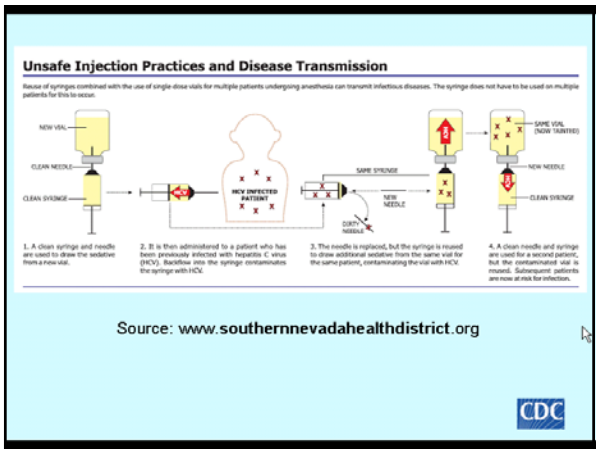


www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx

Safe Injection Practices



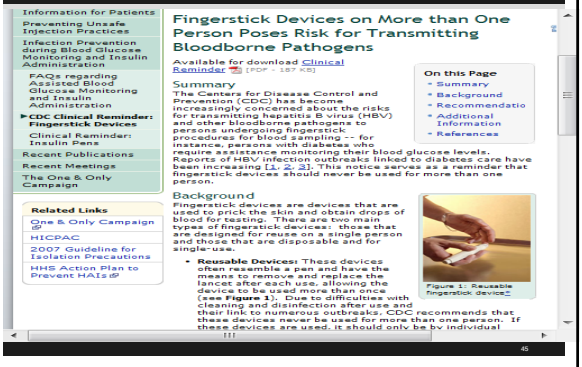




CDC One and Only Campaign

http://oneandonlycampaign.org

Fingerstick Devices



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)

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Not All Vials Are Created Equal

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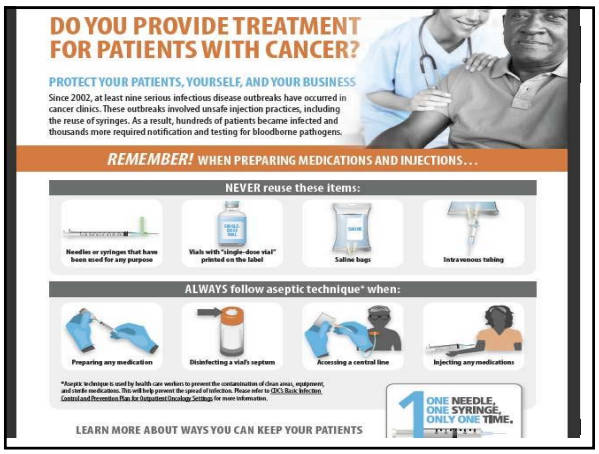

Watch Award Winning Video

Safe Injection Practices - How to Do It Right

www.youtube.com/watch?v=6D0stMoz80k&feature=youtu.b

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FDA Cleaning of Glucose Monitors

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

Guidance for Industry and Food and Drug Administration Staff

Document issued on: October 11, 2016.

The draft of this document was issued on January 7, 2014.

www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380325.pdf

For questions regarding this document, contact Leslie Landree at leslie.landree@fda.hhs.gov, or at 301-796-6147.

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CMS Memo on Insulin Pens

- CMS issues memo on insulin pens
- 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

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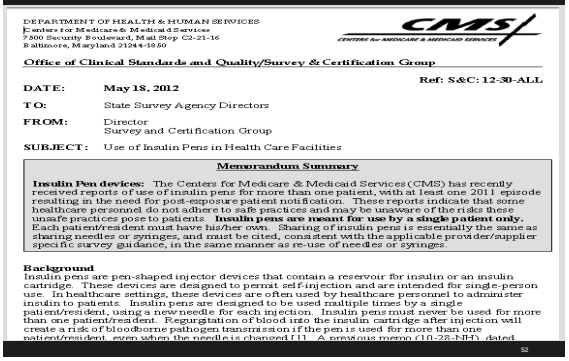
Insulin Pens Survey Memo



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

CMS — CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 12-30-ALL

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 (10-28-NH), dated

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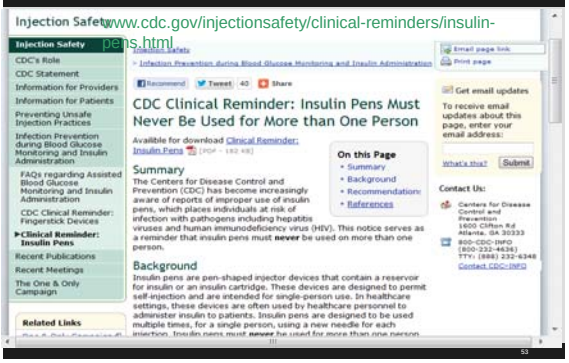
CDC Reminder on Insulin Pens



Injection Safety www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html

Injection Safety
- CDC's Role
- CDC Statement
- Information for Providers
- Information for Patients
- Preventing Unsafe Injection Practices
- Infection Prevention during Blood Glucose Monitoring and Insulin Administration
- FAQs regarding Assisted Blood Glucose Monitoring and Insulin Administration
- CDC Clinical Reminder: Fingerstick Devices
- ▸Clinical Reminder: Insulin Pens
- Recent Publications
- Recent Meetings
- The One & Only Campaign

Related Links

Injection Safety
» Infection Prevention during Blood Glucose Monitoring and Insulin Administration

Recommend Tweet 40 Share

CDC Clinical Reminder: Insulin Pens Must Never Be Used for More than One Person

Availible for download Clinical Reminder: Insulin Pens (PDF - 192 KB)

On this Page
- Summary
- Background
- Recommendation:
- References

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.

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Print page

Get email updates
To receive email updates about this page, enter your email address:
What's this? Submit

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

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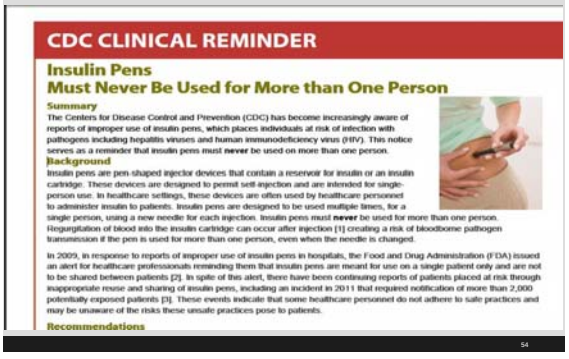
CDC Has Flier for Hospitals on Insulin Pens



CDC CLINICAL REMINDER

Insulin Pens
Must Never Be Used for More than One Person

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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

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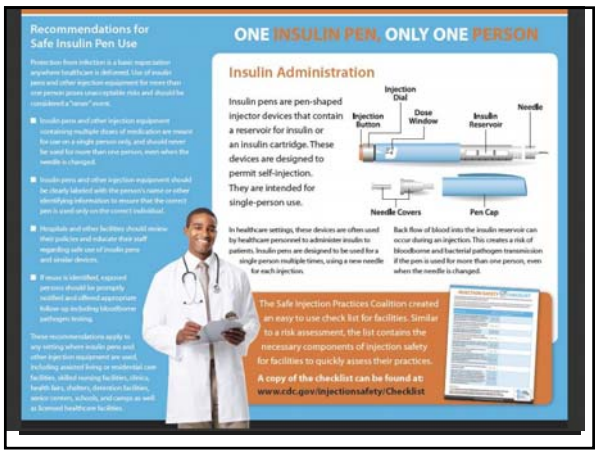
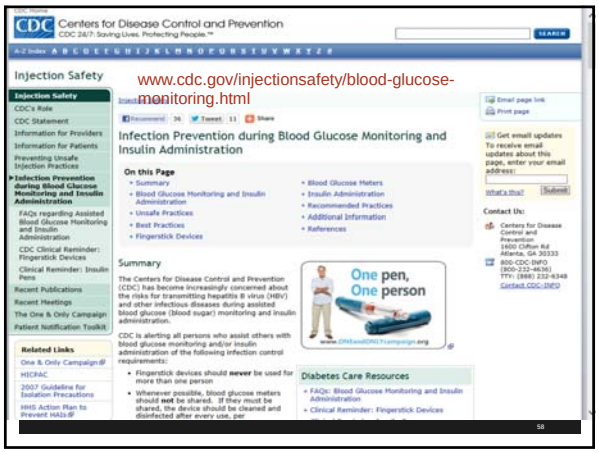
Insulin Pen Posters and Brochures Available

www.oneandonlycampaign.org /content/insulin-pen-safety

Brochure

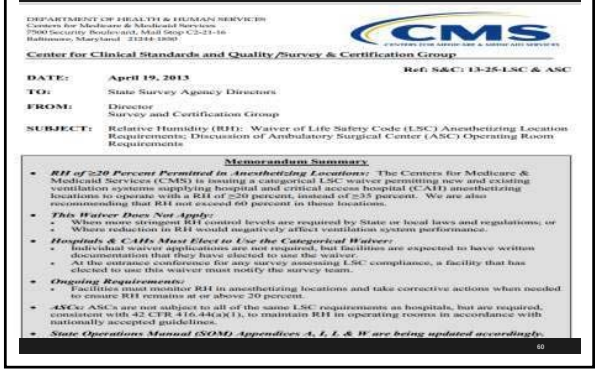




CMS Memo April 19, 2013

- CMS issues two memos related to the relative humidity (RH) and humidity not in IC section
- AORN use to say temperature maintained between 68-73 degrees and humidity between 30-60% in OR, PACU, cath lab, endoscopy rooms and instrument processing areas
- CMS says if no state law can write policy or procedure or process to implement the waiver
- Waiver allows RH between 20-60%
- In anesthetizing locations- see definition in memo

Humidity in Anesthetizing Areas



Impact of Lowering the Humidity

- Lowering humidity can impact some equipment and supplies
- Can affect shelf life and product integrity of some sterile supplies including EKG electrodes
- Some electro-medical equipment may be affected by electrostatic discharge especially older equipment
  - Can cause erratic behavior of software and premature failure of the equipment
  - It can affect calibration of the equipment
- Follow the manufacturers instructions for use that explains any RH requirements

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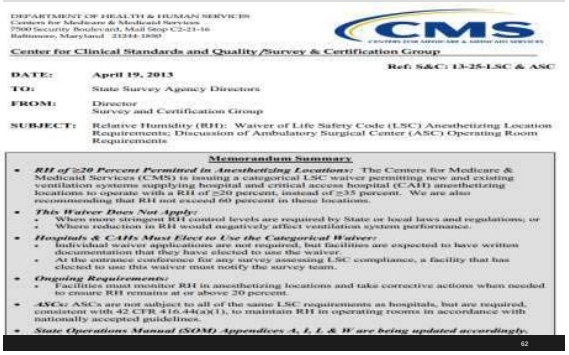
Humidity in Anesthetizing Areas



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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-25-LSC & ASC

DATE: April 19, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Relative Humidity (RH): Waiver of Life Safety Code (LSC) Anesthetizing Location Requirements; Discussion of Ambulatory Surgical Center (ASC) Operating Room Requirements

Memorandum Summary

- ***RH of ≥20 Percent Permitted in Anesthetizing Locations:*** The Centers for Medicare & Medicaid Services (CMS) is issuing a categorical LSC waiver permitting new and existing ventilation systems supplying hospital and critical access hospital (CAH) anesthetizing locations to operate with a RH of ≥20 percent, instead of ≥35 percent. We are also recommending that RH not exceed 60 percent in these locations.
- ***This Waiver Does Not Apply:***
  - Where more stringent RH control levels are required by State or local laws and regulations; or
  - Where reduction in RH would negatively affect ventilation system performance.
- ***Hospitals & CAHs Must Elect to Use the Categorical Waiver:***
  - Individual waiver applications are not required, but facilities are expected to have written documentation that they have elected to use the waiver.
  - At the entrance conference for any survey assessing LSC compliance, a facility that has elected to use this waiver must notify the survey team.
- ***Ongoing Requirements:***
  - Facilities must monitor RH in anesthetizing locations and take corrective actions when needed to ensure RH remains at or above 20 percent.
- ***ASCs:*** ASCs are not subject to all of the same LSC requirements as hospitals, but are required, consistent with 42 CFR 416.44(a)(1), to maintain RH in operating rooms in accordance with nationally accepted guidelines.
- ***State Operations Manual (SOM) Appendices A, I, L & W are being updated accordingly.***

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Impact of Lowering the Humidity

- Lowering humidity can impact some equipment and supplies
- Can affect shelf life and product integrity of some sterile supplies including EKG electrodes
- Some electro-medical equipment may be affected by electrostatic discharge especially older equipment
  - Can cause erratic behavior of software and premature failure of the equipment
  - It can affect calibration of the equipment
- Follow the manufacturers instructions for use that explains any RH requirements

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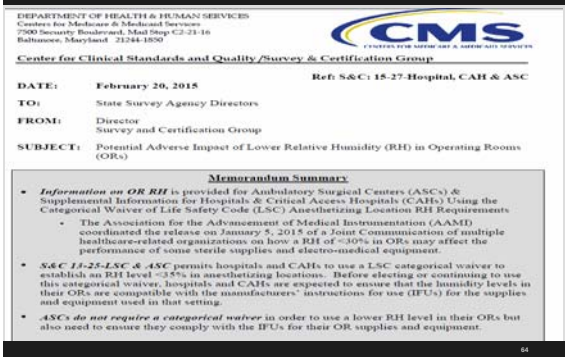
CMS Memo on Low Relative Humidity



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Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 15-27-Hospital, CAH & ASC

DATE: February 20, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Potential Adverse Impact of Lower Relative Humidity (RH) in Operating Rooms (ORs)

Memorandum Summary

- ***Information on OR RH*** is provided for Ambulatory Surgical Centers (ASCs) & Supplemental Information for Hospitals & Critical Access Hospitals (CAHs) Using the Categorical Waiver of Life Safety Code (LSC) Anesthetizing Location RH Requirements
  - The Association for the Advancement of Medical Instrumentation (AAMI) coordinated the release on January 5, 2015 of a Joint Communication of multiple healthcare-related organizations on how a RH of <30% in ORs may affect the performance of some sterile supplies and electro-medical equipment.
- ***S&C 13-25-LSC & ASC*** permits hospitals and CAHs to use a LSC categorical waiver to establish an RH level <35% in anesthetizing locations. Before electing or continuing to use this categorical waiver, hospitals and CAHs are expected to ensure that the humidity levels in their ORs are compatible with the manufacturers' instructions for use (IFUs) for the supplies and equipment used in that setting.
- ***ASCs do not require a categorical waiver*** in order to use a lower RH level in their ORs but also need to ensure they comply with the IFUs for their OR supplies and equipment.

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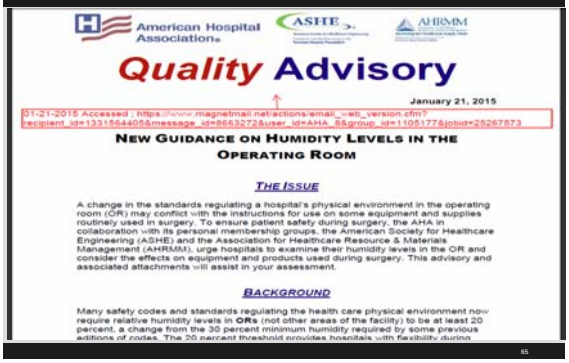
Impact of Lowering the Humidity



American Hospital Association · ASHE · AHRMM

Quality Advisory

January 21, 2015

01-21-2015 Accessed : https://www.magnetmail.net/actions/email_web_version.cfm?recipient_id=133156440S5message_id=8663272&user_id=AHA_8&group_id=1105177&jobid=25267573

NEW GUIDANCE ON HUMIDITY LEVELS IN THE OPERATING ROOM

THE ISSUE

A change in the standards regulating a hospital's physical environment in the operating room (OR) may conflict with the instructions for use on some equipment and supplies routinely used in surgery. To ensure patient safety during surgery, the AHA in collaboration with its personal membership groups, the American Society for Healthcare Engineering (ASHE) and the Association for Healthcare Resource & Materials Management (AHRMM), urge hospitals to examine their humidity levels in the OR and consider the effects on equipment and products used during surgery. This advisory and associated attachments will assist in your assessment.

BACKGROUND

Many safety codes and standards regulating the health care physical environment now require relative humidity levels in **ORs** (not other areas of the facility) to be at least 20 percent, a change from the 30 percent minimum humidity required by some previous editions of codes. The 20 percent threshold provides hospitals with flexibility during

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Lowering Humidity Can Have Other Effects

RELATIVE HUMIDITY LEVELS IN THE OPERATING ROOM
JOINT COMMUNICATION TO HEALTHCARE DELIVERY ORGANIZATIONS
January 2015

ASCA · ACCE · American Hospital Association · ASHE · American Society of Anesthesiologists · AHRMM · AAMI · AORN · AST · HIDA · IAHCSMM

This is an important communication to the multiple stakeholders in healthcare whose work touches sterile supplies and electro-medical equipment used in delivering care to patients. The subject is about how relative humidity (RH) levels lower than 30% can impact the integrity and functionality of some of these products, with a special emphasis on RH levels in the operating room (OR). The following professional organizations have collaborated in the development of this communication: Ambulatory Surgery Center Association (ASCA), American College of Clinical Engineering (ACCE), American Hospital Association (AHA), American Society for Healthcare Engineering (ASHE), American Society of Anesthesiologists (ASA), American Society of Heating, Refrigeration and Air Conditioning Engineers (ASHRAE), Association for Healthcare Resource & Materials Management (AHRMM), Association for the Advancement of Medical Instrumentation (AAMI), Association of perriOperative Registered Nurses (AORN), Association of Surgical Technologists (AST), Health Industry Distributors Association (HIDA), and the International Association of Healthcare Central Service Materials Management (IAHCSMM).[1]

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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 injures and to save 60,000 lives

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Watch this Video on Preventing HAI

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CMS 4 IC Breaches Memo

- CMS publishes 4 page memo on infection control breaches and when they warrant referral to the public health authorities on May 30, 2014
- 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

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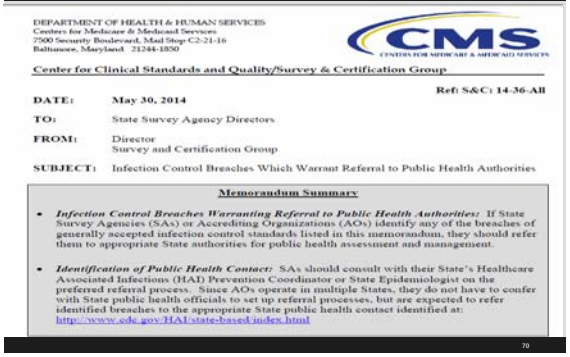
Infection Control Breaches



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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-36-All

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

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CMS Memo Infection Control Breaches

- Using the same needle for more than one individual
- 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/fingerstick device for more than one individual, even if the lancet is changed

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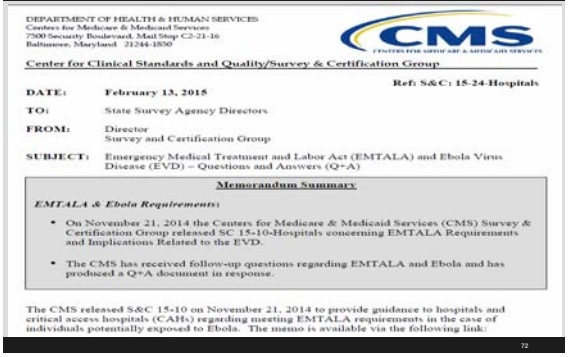
CMS Issues 3rd Ebola Memo



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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-24-Hospitals

DATE: February 13, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Emergency Medical Treatment and Labor Act (EMTALA) and Ebola Virus Disease (EVD) – Questions and Answers (Q+A)

Memorandum Summary

EMTALA & Ebola Requirements:

- On November 21, 2014 the Centers for Medicare & Medicaid Services (CMS) Survey & Certification Group released SC 15-10-Hospitals concerning EMTALA Requirements and Implications Related to the EVD.
- The CMS has received follow-up questions regarding EMTALA and Ebola and has produced a Q+A document in response.

The CMS released S&C 15-10 on November 21, 2014 to provide guidance to hospitals and critical access hospitals (CAHs) regarding meeting EMTALA requirements in the case of individuals potentially exposed to Ebola. The memo is available via the following link:

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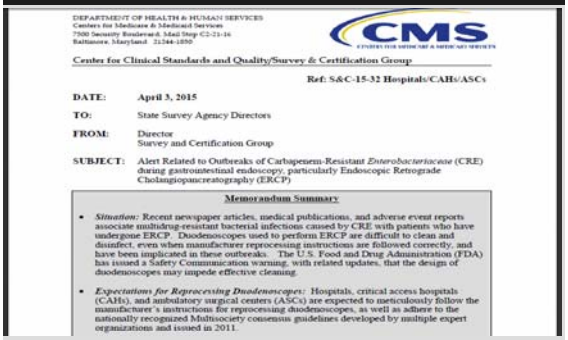
CRE and ERCP's



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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-15-32 Hospitals/CAHs/ASCs

DATE: April 3, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Alert Related to Outbreaks of Carbapenem-Resistant *Enterobacteriaceae* (CRE) during gastrointestinal endoscopy, particularly Endoscopic Retrograde Cholangiopancreatography (ERCP)

Memorandum Summary

- *Situation:* Recent newspaper articles, medical publications, and adverse event reports associate multidrug-resistant bacterial infections caused by CRE with patients who have undergone ERCP. Duodenoscopes used to perform ERCP are difficult to clean and disinfect, even when manufacturer reprocessing instructions are followed correctly, and have been implicated in these outbreaks. The U.S. Food and Drug Administration (FDA) has issued a Safety Communication warning, with related updates, that the design of duodenoscopes may impede effective cleaning.
- *Expectations for Reprocessing Duodenoscopes:* Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs) are expected to meticulously follow the manufacturer's instructions for reprocessing duodenoscopes, as well as adhere to the nationally recognized Multisociety consensus guidelines developed by multiple expert organizations and issued in 2011.

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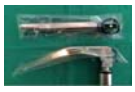
CDC Health Update
Review Procedures for Cleaning, Disinfecting and Sterilizing Reusable Medical Devices



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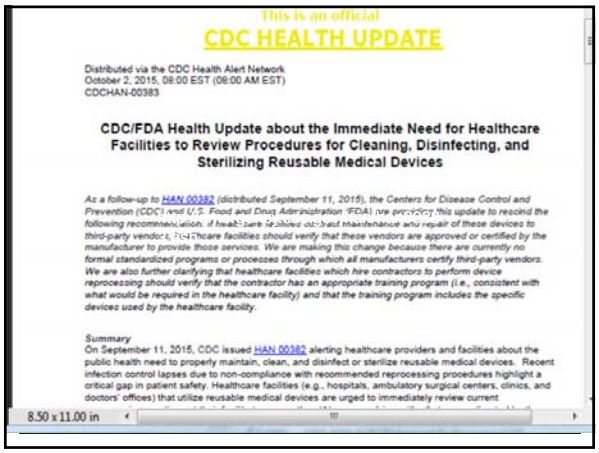
CDC FDA Health Update

- CDC and FDA issue a health update on October 2, 2015
- Hospitals need to maintain, clean, and disinfect or sterilize reusable medical devices
- Must have P&Ps that are consistent with current standards and guidelines
- Must comply with the steps set out by the device manufacturer
- Clarified earlier memo and if hospital outsources contract maintenance and repair do not have to use only a certified vendor since no one is doing this

75



This is an official

CDC HEALTH UPDATE

Distributed via the CDC Health Alert Network
October 2, 2015, 08:00 EST (08:00 AM EST)
CDCHAN-00383

CDC/FDA Health Update about the Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

As a follow-up to HAN 00382 (distributed September 11, 2015), the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are providing this update to rescind the following recommendation: If healthcare facilities outsource maintenance and repair of these devices to third-party vendors, healthcare facilities should verify that these vendors are approved or certified by the manufacturer to provide those services. We are making this change because there are currently no formal standardized programs or processes through which all manufacturers certify third-party vendors. We are also further clarifying that healthcare facilities which hire contractors to perform device reprocessing should verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices used by the healthcare facility.

Summary
On September 11, 2015, CDC issued HAN 00382 alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices. Recent infection control lapses due to non-compliance with recommended reprocessing procedures highlight a critical gap in patient safety. Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current

8.50 x 11.00 in

CDC FDA Health Update

- Articles in news lately that patients are being notified that they are at increased risk of infection due to lapses in basic cleaning and disinfection and sterilization of medical devices
- Due to failure to follow manufactures' instruction for critical and semi-critical items
  - Critical items (e.g., surgical instruments) are objects used to enter sterile tissue or the vascular system and must be cleaned and sterilized prior to reuse
  - Semi-critical items (e.g., endoscopes for upper endoscopy and colonoscopy, laryngoscope blades) are objects that contact mucous membranes or non-intact skin and require, at a minimum, cleaning and high-level disinfection prior to reuse

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CDC FDA Health Update

- Healthcare facilities should arrange for a professional with expertise in device processing to immediately assess their reprocessing procedures
- Has a list of training requirements that include in orientation and once a year
- Need to document competency and training
- Trainer should observe before allowed to do independently
- Need to have copies of manufacturers instructions
  - Available at http://emergency.cdc.gov/han/han00383.asp

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Training Requirements

Training

- Healthcare facilities should provide training to all personnel who reprocess medical devices.
  - Training should be required and provided:
    - Upon hire or prior to provision of services at the facility
    - At least once a year
    - When new devices or protocols are introduced, including changes in the manufacturer's instructions for use during the device's life cycle
  - Personnel should be required to demonstrate competency with device reprocessing (i.e., trainer observes correct technique) prior to being allowed to perform reprocessing independently.
  - Healthcare facilities should maintain current documentation of trainings and competencies.
  - If the healthcare facility hires a contractor for device reprocessing, the facility should verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices the healthcare facility uses.
  - Copies of manufacturers' instructions for operating and reprocessing each type of reusable device should be readily available to staff and inspectors. This file should include instructions for use of chemical disinfectants.

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P&P and Audit and Feedback

- Has a section on audit and feedback
  - Should regularly audit adherence to cleaning, disinfecting, sterilization, and device storage procedures
  - Provide feedback to personnel
- Has a section on policies and procedures
  - Make sure adequate time to clean and follow all of the steps of the manufacturer
  - Have process to tell when ready for patient use such as tagging system or storage in designated area
  - P&P on what to do if there is a reprocessing error

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Infection Control Policies and Procedures

- Healthcare facilities should allow adequate time for reprocessing to ensure adherence to all steps recommended by the device manufacturer, including drying, proper storage, and transport of reprocessed devices.
  - Considerations should be made regarding scheduling of procedures and supply of devices to ensure adequate time is allotted for reprocessing.
- Healthcare facilities should have protocols to ensure that healthcare personnel can readily identify devices that have been properly reprocessed and are ready for patient use (e.g., tagging system, storage in a designated area).
- Healthcare facilities should have policies and procedures outlining facility response in the event of a recognized reprocessing error or failure. Healthcare personnel should assess the cause of the error or failure and the exposure event in order to determine the potential risk of infection. The procedure should include how patients who might have been exposed to an improperly reprocessed medical device would be identified, notified, and followed.
- Individuals responsible for infection prevention and reprocessing at the healthcare facility should be consulted whenever new devices will be purchased or introduced to ensure that infection control considerations are included in the purchasing decision as well as subsequent implementation of appropriate reprocessing policies and procedures and to ensure that the recommended reprocessing equipment is available at the healthcare facility.
- Healthcare facilities should maintain documentation of reprocessing activities, including maintenance records for reprocessing equipment (e.g., autoclaves, automated endoscope reprocessors, medical washers and washer-disinfectors, water treatment systems), sterilization records (physical, chemical, and biological indicator results), and records verifying high-level disinfectants were tested and replaced appropriately.
- Healthcare facilities should follow manufacturer recommendations for maintenance and repair of medical devices that are used to perform reprocessing functions as well as medical devices that are reprocessed.

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Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

William A. Rutala, Ph.D., M.P.H.[1,2], David J. Weber, M.D., M.P.H.[1,2], and the Healthcare Infection Control Practices Advisory Committee (HICPAC)[3]

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Mentions AAMI Standards

Sterilization, Part 1: Sterilization in Health Care Facilities: This is AAMI's all-time, best-selling standards collection for hospitals and healthcare facilities.

Buy Online | Product Details

www.aami.org/productspublications/ProductList.aspx?metadataid=149

Sterilization, Part 2: Equipment Design and Use, 2015 Edition

The 2015 edition of this sterilization collection for manufacturers and users of sterilization equipment includes 25 AAMI standards and guidance documents.

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Sterilization, Part 3: Industrial Process Control

Whether using in-house or contract facilities, manufacturers that ship their products sterile should not be without this book.

Buy Online | Product Details

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CDC Vaccine Storage and Handling

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CDC Vaccine Storage and Handling Toolkit

- Make sure you have a copy of this 82 page document
- Published June 2016 and maintain the cold chain
- Do not store vaccines in dorm like refrigerators
- Temperature revised to range between 36 and 46 degrees (previously 35-46 degrees F)
  - State may also have specific requirements
- Use a medical (biological) refrigerator that monitors temperature and set at mid range (40 degrees)
- E-mail specific questions to CDC: NIPInfo@cdc.gov

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Vaccine Storage & Handling Toolkit

June 2016

www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

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CDC Vaccine Storage and Handling Toolkit

- Make sure staff familiar with storage and handling P&Ps and document training
  - Train in orientation and annually
  - When new vaccines added to inventory
  - CDC has online training programs
- Keep standard operating procedures (SOP) for storage and handling near storage units
- Written storage and handling plan can help staff to ensure vaccines are properly managed

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Immunization: You Call the Shots-Module Ten-Storage and Handling--2016
WBT2596

PROGRAM DESCRIPTION:
This module is the tenth in a series titled Immunization: You Call the Shots and focuses on storage and handling requirements for vaccines.

The series has been available since the mid-nineties in various formats. Previously available as a CDrom, it is now presented in web-based format. The series is designed to provide key immunization knowledge in a very basic step-by-step manner. It presents practice-oriented content about immunization. It does not discuss the denser more complex material regarding epidemiology, disease transmission, etc.

It addresses an important audience for immunization training: the new provider or the medical or nursing student. It is also an excellent review for a seasoned healthcare provider. It has often been used by nursing schools to introduce their students to the comprehensive core knowledge about immunization.

Since it presents a simpler version of the core knowledge about immunization it is a needed alternative to the faster-paced denser core course that NCIRD provides. Titled Epidemiology and Prevention of Vaccine-Preventable Diseases. It is a multi-session course of 12 to 15 hours. Evaluation of that course revealed that immunization providers sought a primer or more basic course for newcomers to the immunization field. The You Call The Shots series directly responds to that evaluation feedback.

OBJECTIVES:
At the conclusion of the session, the participant will be able to:

1. Define and explain cold chain management.
2. Describe the components of routine and emergency plans for vaccine storage and handling.
3. Describe the roles of the primary and back-up coordinators and other staff in the storage and handling of vaccines.
4. Describe proper storage equipment use and monitoring.
5. Describe correct vaccine and diluent storage and handling for routinely recommended vaccines.
6. Describe correct vaccine storage, handling, and disposal of routinely recommended vaccines.
7. Identify actions that should be taken if vaccines have not been stored properly.
8. Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

FACULTY/CREDENTIALS:
Dale Babcock, BS, Technical Information Specialist, CDC/NCIRD
Melissa Barrett, MS, MCHES, Health Education Specialist, CDC, NCIRD
Jennifer Hambonsky, MPH, MCHES, Health Education Specialist, CDC/NCIRD
N. Suzanne Johnson-DeLeon MPH; Health Education and Information Specialist, CDC/NCIRD
Raymond Strikas, MD, MPH, Medical Officer, CDC/NCIRD
Donna Weaver, RN, MN, Nurse Educator, CDC/NCIRD

ORIGINATION DATE: 1/15/2016
EXPIRATION DATE: 1/15/2017

URL http://www.cdc.gov/vaccines/ed/youcalltheshots.htm
HARDWARE/SOFTWARE: Computer Hardware; Internet connection; Browser
MATERIALS: Internet connection and computer

TARGET AUDIENCE: Administrators, CHES certified health educators, Physicians, Epidemiologists, LPNs, LVNs, Medical assistants, medical students, NPs, nurse technicians, other health educators

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www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp

CDC Vaccine Storage and Handling Toolkit

- Vaccine cold chain is temperature controlled environment to maintain and distribute vaccine in optimal condition
  - Too much exposure to heat, cold, or light can damage vaccine
- Designate person to be primary vaccine coordinator
- Has a document called at a glance resource guide
- http://www.cdc.gov/vaccines/hcp/admin/downloads/vacc-admin-storage-guide.pdf

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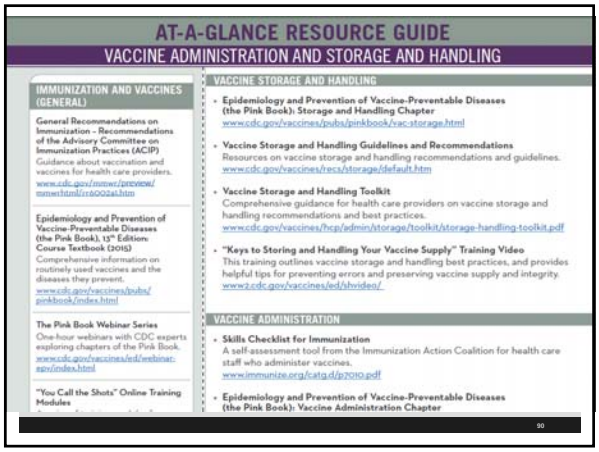

AT-A-GLANCE RESOURCE GUIDE
VACCINE ADMINISTRATION AND STORAGE AND HANDLING

IMMUNIZATION AND VACCINES (GENERAL)

General Recommendations on Immunization – Recommendations of the Advisory Committee on Immunization Practices (ACIP)
Guidance about vaccination and vaccines for health care providers.
www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm

Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book), 13th Edition: Course Textbook (2015)
Comprehensive information on routinely used vaccines and the diseases they prevent.
www.cdc.gov/vaccines/pubs/pinkbook/index.html

The Pink Book Webinar Series
One-hour webinars with CDC experts exploring chapters of the Pink Book.
www.cdc.gov/vaccines/ed/webinar-epv/index.html

"You Call the Shots" Online Training Modules

VACCINE STORAGE AND HANDLING

- **Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book): Storage and Handling Chapter**
  www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html
- **Vaccine Storage and Handling Guidelines and Recommendations**
  Resources on vaccine storage and handling recommendations and guidelines.
  www.cdc.gov/vaccines/recs/storage/default.htm
- **Vaccine Storage and Handling Toolkit**
  Comprehensive guidance for health care providers on vaccine storage and handling recommendations and best practices.
  www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
- **"Keys to Storing and Handling Your Vaccine Supply" Training Video**
  This training outlines vaccine storage and handling best practices, and provides helpful tips for preventing errors and preserving vaccine supply and integrity.
  www2.cdc.gov/vaccines/ed/shvideo/

VACCINE ADMINISTRATION

- **Skills Checklist for Immunization**
  A self-assessment tool from the Immunization Action Coalition for health care staff who administer vaccines.
  www.immunize.org/catg.d/p7010.pdf
- **Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book): Vaccine Administration Chapter**

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CDC Vaccine Storage and Handling Toolkit

- Use stand alone refrigerator or freezer with enough space to accommodate without crowding
- Use digital data logger with current and valid certificate of calibration testing
  - Have back up in case one breaks or malfunctions
- Pharmacy grade units are designed to store biologics and have fan forced air circulation that promote uniform temperatures
  - Have microprocessors with digital temperature sensor
  - Don't use dormitory style refrigerators but not all small storage units are dormitory units

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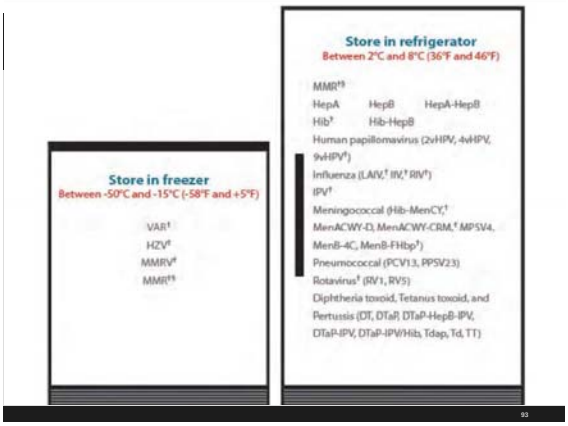
CDC makes the following recommendations for vaccine storage units:

- Use purpose-built units designed to either refrigerate or freeze (can be compact, under-the counter-style or large units).
- If a purpose-built unit is not available, use a stand-alone household unit.
- If you must use a household-grade combination refrigerator/freezer unit, only use the refrigerator compartment for storing vaccines. These units have cold spots and temperature fluctuations, and air circulating from the freezer could expose refrigerated vaccines to freezing temperatures. Use a separate stand-alone freezer to store frozen vaccines.
- **Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.** These units have a single exterior door and an evaporator plate/cooling coil, usually located in

Household combination refrigerator/freezer

Do not store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.



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ISMP Guidelines on IV Push Medication

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ISMP IV Push Medications Guidelines

- ISMP has published a 26 page document called "ISMP Safe Practice Guidelines for Adult IV Push Medications
- The document is organized into factors that increase the risk of IV push medications in adults,
  - Current practices with IV injectible medications
  - Developing consensus guidelines for adult IV push medication and
  - Safe practice guidelines
  - About 90% of all hospitalized patients have some form of infusion therapy

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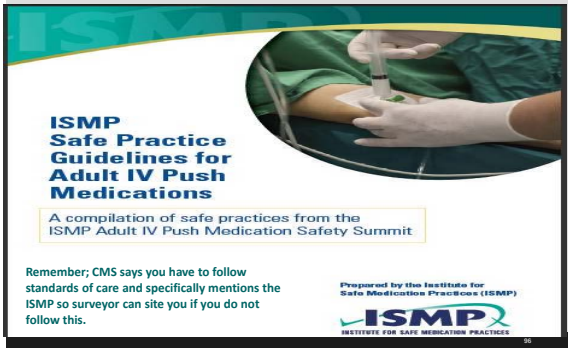
IV Push Medicine Guidelines



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IV Push Medications Guidelines

- Provide IV push medications in a ready to administer form
- Use only commercially available or pharmacy prepared prefilled syringes of IV solutions to flush and lock vascular access devices
- If available in a single dose vial then need to buy in single dose vial
- Aseptic technique should be used when preparing and administering IV medication
  - This includes hand hygiene before and after administration

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IV Push Medications Guidelines

- The diaphragm on the vial should be disinfected even if newly opened
  - The top should be cleaned using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab for at least ten seconds to it dr
- Medication from a glass vial should be with a filter needle unless the specific drug precludes this
- Medication should only be diluted when recommended by the manufacturer or in accordance with evidence based practice or approved hospital policies

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IV Push Medications Guidelines

- If IV push medication needs to be diluted or reconstituted these should be performed in a clean, uncluttered, and separate location
- Medication should not be withdrawn from a commercially available, cartridge type syringe into another syringe for administration
- It is also important that medication not be drawn up into the commercially prepared and prefilled 0.9% saline flushes
  - This are to flush an IV line and are not approved to use to dilute medication

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3.6 Do NOT dilute or reconstitute IV push medications by drawing up the contents into a commercially-available, prefilled flush syringe of 0.9% sodium chloride.

Discussion: Commercially available prefilled syringes of saline and heparin are regulated by the US Food and Drug Administration as *devices*, not as medications. These devices have been approved for the flushing of vascular access devices, but have NOT been approved for the reconstitution, dilution, and/or subsequent administration of IV push medications. Such use would be considered "off label" and not how manufacturers intended these products to be used, nor have prefilled flush syringes been tested for product safety when used in this manner.

Warnings intended to limit the use of prefilled syringes for medication preparation and administration appear on some syringe barrels, clearly stating "IV flush only." Some manufacturers have also limited or removed the gradation markings on the prefilled flush syringes in order to prevent measurement of a secondary medication in the flush syringe. When prefilled syringes are used in an off-label manner, the practitioner and employer bear the legal liability for any adverse events occurring from this practice.[21]

The mislabeling that occurs when medications are added to a prefilled syringe and a secondary label is not applied creates significant risk for errors. In many cases, the manufacturer's label is permanently affixed to the syringe barrel and contains product codes and a barcode as well as specific information about the fluid and its volume. When another medication is added to this syringe, there is no adequate method to amend the manufacturer's label, without covering the current information.[21] Thus, the syringe frequently remains labeled as 0.9% sodium chloride, when it also contains the diluted or reconstituted medication.

Although this unsafe practice is widespread, and many who use it mistakenly believe the risk of an error is insignificant—a belief clearly reinforced during public comment regarding this guidance statement—summit participants arrived at a consensus that the practice must be eliminated.

3.7 When necessary to prepare more than one medication in a single syringe for IV push administration

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IV Push Medications Guidelines

- Combination of more than one medication is a single syringe is seldom necessary and could result in unwanted changes in the medication
- Never use IV solution or mini bags as a common source to flush an IV as to dilute for more than one patient
- Label syringes of IVP medication unless prepared and immediately given with no break
- Administer IV push medication at rate recommended by manufacturer or supported by evidenced based practices and often given too fast

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CMS Hospital Worksheet on Infection Control

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CMS Hospital Worksheets History

- CMS has three final worksheets
- Addresses discharge planning, infection control (IC), and QAPI (performance improvement)
- Final ones issued November 26, 2014
- Has a section on **safe injection practices** and **antibiotic stewardship**
- Every hospital should review this and be familiar with its content and use as a self assessment tool

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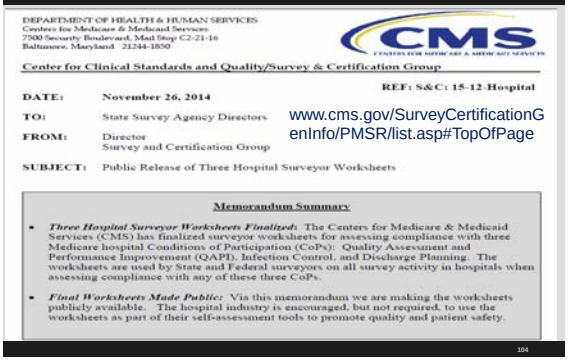
Final 3 Worksheets Infection Control



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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

REF: S&C: 15-12-Hospital

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.

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

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CMS Hospital Worksheets

- Hospitals should be familiar with the three worksheets and IC one is 49 pages
- Will use whenever a validation survey or certification survey is done at a hospital by CMS
- CMS says worksheets are used by State and federal surveyors on all survey activity in assessing compliance with any of the three CoPs
- Hospitals are encouraged by CMS to use the worksheet as part of their self assessment tools which can help promote quality and patient safety

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CMS Hospital Worksheets

- And of course completing the forms helps the hospital to comply with those three CoPs
- Citation instructions are provided on each of the worksheets
- The surveyors will follow standard procedures when non-compliance is identified in hospitals
- This includes documentation on the Form CMS 2567
- Not used in CAH but good tool for CAH to use
- **Questions** to: **hospitalscg@cms.hhs.gov**

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CMS Hospital Worksheets

- This would impress the surveyor when they came to the hospital
- The worksheet is used in new hospitals undergoing an initial review and hospitals that are not accredited who are suppose to have a CMS survey every three or so years
  - The Joint Commission (TJC), American Osteopathic Association (AOA) Healthcare Facility Accreditation Program, CIHQ, (Center for Improvement in Healthcare Quality) or DNV Healthcare are the 4 AOs with deemed status
- It would also be used for hospitals undergoing a validation survey by CMS

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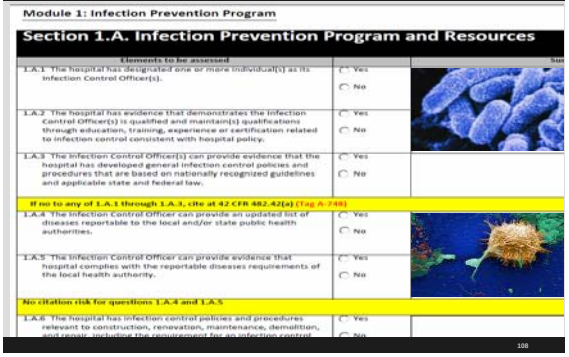
Infection Control Program and Resources



Module 1: Infection Prevention Program

Section 1.A. Infection Prevention Program and Resources

Elements to be assessed		Sur
1.A.1 The hospital has designated one or more individual(s) as its Infection Control Officer(s).	○ Yes ○ No	
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.	○ Yes ○ No	
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.	○ Yes ○ No	
If no to any of 1.A.1 through 1.A.3, cite at 42 CFR 482.42(a) (Tag A-748)		
1.A.4 The Infection Control Officer can provide an updated list of diseases reportable to the local and/or state public health authorities.	○ Yes ○ No	
1.A.5 The Infection Control Officer can provide evidence that hospital complies with the reportable diseases requirements of the local health authority.	○ Yes ○ No	
No citation risk for questions 1.A.4 and 1.A.5		
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	○ Yes ○ No	

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CMS Infection Control Standards

What Hospitals Need to Know.

Mandatory Compliance

- Hospitals that participate in Medicare or Medicaid must meet the Conditions of Participation (COPs)
  - For **all patients** in the facilities
  - Not just those who are Medicare or Medicaid
- Hospitals accredited by TJC, DNV Healthcare, CIHQ, and HCFA have what is called deemed status
  - This means hospitals can be reimbursed for M/M patients without going through a state department of health survey
  - CMS must now report deficiencies to the accreditation organizations (AO)
  - CMS announces unannounced surveys related to IC control

CMS Hospital CoPs

- Interpretative guidelines on CMS website under state operations manual[1]
  - Consider placing copy on intranet
  - Can go back and look up tag number to read more and infection control starts at tag 747
  - Make sure you are familiar with the CMS infection control worksheet and can read the IC standards and not figure out what they are going to ask you
  - Because you must follow **standards of care and practice**
- Manuals found at website

[1]http://www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf (new)

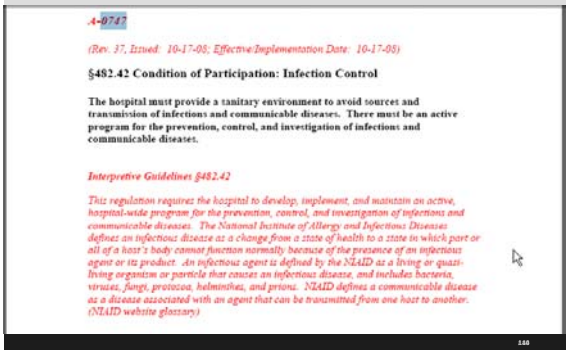
Infection Control

- There were 12 pages of infection control interpretive guidelines
- CAH follow Appendix W but Infection Control standards are very closely cross walked now
- Reflected tag numbers, **A-0747 thru 756**
- Updated to reflect changing infectious and communicable disease threats
- Includes current knowledge and best practices
- Must follow national standards of care and practice

Infection Control

- Included four major sections
  - Active infection control program
  - Investigations and control of infections
  - Infection control log (no longer mandatory)
  - CEO, CNO, and MS must ensure hospital-wide training program and correction plan for problem areas
- Note that CMS has announced infection control inspections of hospitals so need to do this right

CMS Infection Control



A-0747

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.42 Condition of Participation: Infection Control

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

Interpretive Guidelines §482.42

This regulation requires the hospital to develop, implement, and maintain an active, hospital-wide program for the prevention, control, and investigation of infections and communicable diseases. The National Institute of Allergy and Infectious Diseases defines an infectious disease as a change from a state of health to a state in which part or all of a host's body cannot function normally because of the presence of an infectious agent or its product. An infectious agent is defined by the NIAID as a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminthes, and prions. NIAID defines a communicable disease as a disease associated with an agent that can be transmitted from one host to another. (NIAID website glossary)

TJC Infection Prevention and Control

- TJC has a chapter on Infection Prevention and Control that is 8 pages long
- Organized into planning, implementation and evaluation
- Also 5 important ones in NPSGs on reducing the risk of HAIs (Goal 7), hand hygiene, prevent surgical site infections, MDROs, and central line infections and CaUTI
- Need to be aware of both and most stringent applies

HHS Action Plan

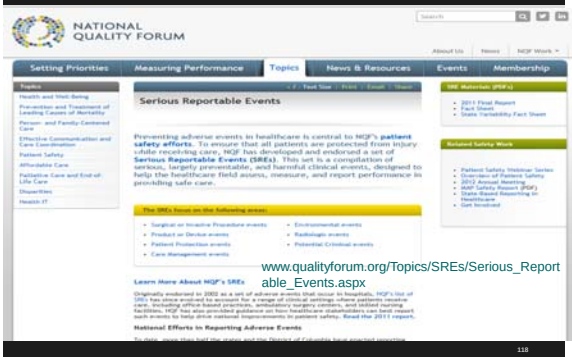
- Estimated that HAIs incur nearly $20 billion in excess healthcare cost each year
  - Many are preventable
- Top priority of HHS now
- Develop HHS Action Plan to Prevent HAIs
- Every infection preventionist (IP) should have a copy of this document

[1] http://hhs.gov/ophs/initiatives/hai/index.html

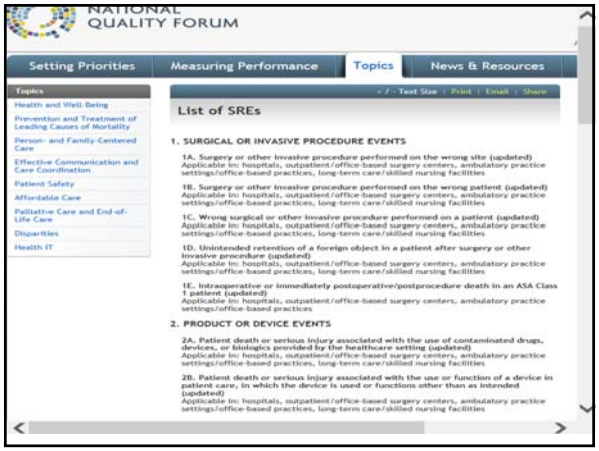
Infection Control Follow the Money!

- This area is very important now
- Now if you do not do this right it could cost the hospital money
- CMS has hospital acquired condition (HAC) in which no additional payment is made for Medicare patients and CMS will do this for Medicaid patients
- Many states agree not to bill for some or all of the 29 never events or serious reportable events (revised list in 2011)
- Insurance companies are putting it into their contracts that hospitals will not bill for any of the never events

NQF Serious Reportable Events



www.qualityforum.org/Topics/SREs/Serious_Reportable_Events.aspx



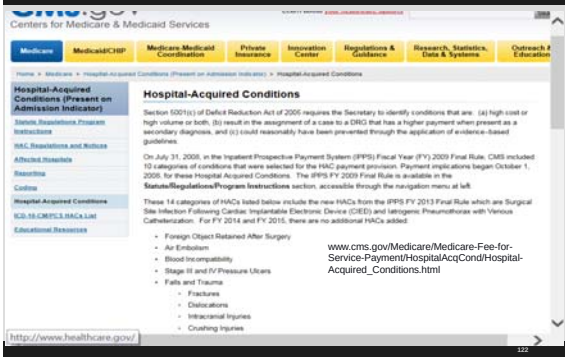
Infection Control

- Make sure you have a qualified infection control coordinator, nurse, or epidemiologist
  - Now called infection preventionist or IP by APIC & CMS
- There will be no additional payment if a Medicare patient gets a hospital acquired conditions
- Do you have enough FTEs devoted to the area of infection control or is your facility woefully underfunded and understaffed??

CMS Hospital Acquired Conditions

- CMS has no additional payment for these HACs or never events
- Studies show hugh cost to hospitals
- Vascular catheter-associated infection
- Surgical site infection such as mediastinitis after coronary artery bypass graft surgery
- Catheter-associated urinary tract infections
- Surgical-site infections following certain orthopedic procedures (repair, replacement or fusion of joints)

CMS Hospital Acquired Conditions



Infection Control (IC) 747

- **Standard:** Hospital must have sanitary environment to avoid sources and transmission of infection and communicable diseases
  - Maintain an active IC program for prevention, control, and investigation of infections and communicable diseases
  - Standards apply to **all** departments of hospitals both on and off campus
- All areas must be clean and sanitary
  - No dried blood on the floor, side of stretchers or on the ceiling tile

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CMS Hospital CoP Definition of Infection

- The guidelines include a **definition** of infectious disease, infectious agent, and communicable diseases
- Hospitals may want to include these definitions in their policies and procedures
- Definitions developed by the National Institute of Allergy and Infectious Diseases (NIAID)
- **Communicable disease** is defined as a disease associated with an agent that can be transmitted from one host to another

Definition of Infection

- **Infectious disease** is defined as a change from a state of health to a state in which part or all of a host's body cannot function normally because of the presence of an infectious agent or its product.
- An **infectious agent** is defined as a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminths (parasitic worms), and prions.

Sanitary Environment 747

- Infection prevention must include monitoring of housekeeping (Environmental Services) and maintenance including construction activities
- Areas to monitor include food storage preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage and equipment cleaning

Construction and Renovation Manual

- Infection control starts when the hospital itself is built or renovated
- APIC has its Infection Prevention Manual for Construction and Renovation 2015
- Offers tips for infection preventionists during construction
  - Has 11 chapters and helps education hospital administration on the importance of infection control during construction
  - APIC does charge a fee for the manual

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Infection Control Standards of Care 0747

- Include all standards of care and practice
  - State and federal laws
- Look at national organization recommendations
  - **APIC** (Association for Professionals in Infection Control and Epidemiology), **CDC** (Center for Disease Control), **SHEA** (Society for Healthcare Epidemiology of America), **OSHA** (Occupational Health and Safety Administration), **AORN,** IDSA, etc.
- Investigate infections and communicable diseases for **inpatients** and **personnel** working in hospitals including volunteers

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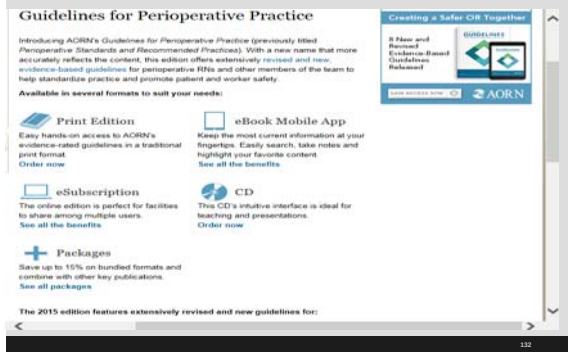
APIC Website

SHEA Website

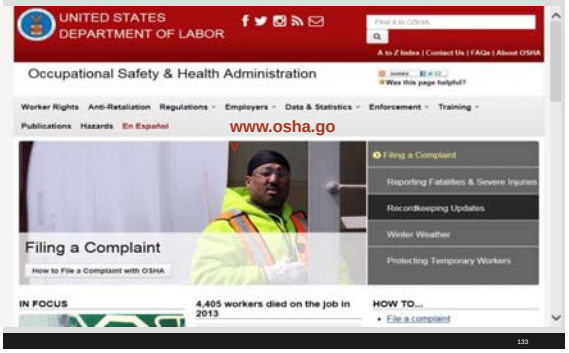
www.shea-online.org

AORN

AORN Guidelines for Perioperative Practice



OSHA Website



OSHA Worker Safety in Hospitals

CDC Website

AAMI Standards

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APIC's Targeting Zero Campaign

- Targeting zero is the philosophy that every hospital should be working toward a goal of zero HAIs
- While not all HAIs are preventable, APIC believes we should strive for the goal of elimination and strive for zero infections as in their 2020 strategic plan
- Association for Professionals in Infection Control and Epidemiology (APIC) put together many resources to help hospitals to start to meet this goal
- Prompt investigation of HAIs of greatest concern to the hospital (like MRSA, C-Diff surgical site infections, catheter associated UTIs)
- Needed because of our declining arsenal of antibiotics to treat infections

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Active Surveillance Program 747

- Maintain active surveillance program
  - So what's in your IC plan and IC program?
  - Specific measures for infection detection, data collection, analysis monitoring, and evaluations of preventive interventions
  - Must be hospital wide and include staff and patients
- Document surveillance activities
- Must have reliable sampling or other mechanism in place to identify and monitor infections and communicable diseases

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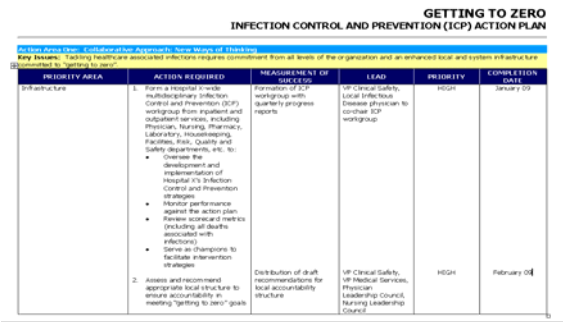
What's in Your Infection Control Plan?



GETTING TO ZERO
INFECTION CONTROL AND PREVENTION (ICP) ACTION PLAN

Action Area One: Collaborative Approach: New Ways of Thinking
Key Issues: Tackling healthcare associated infections requires commitment from all levels of the organization and an enhanced local and system infrastructure committed to "getting to zero"

PRIORITY AREA	ACTION REQUIRED	MEASUREMENT OF SUCCESS	LEAD	PRIORITY	COMPLETION DATE
Infrastructure	1. Form a Hospital X-wide multidisciplinary Infection Control and Prevention (ICP) workgroup from inpatient and outpatient services, including Physician, Nursing, Pharmacy, Laboratory, Housekeeping, Facilities, Risk, Quality and Safety departments, etc. to: • Oversee the development and implementation of Hospital X's Infection Control and Prevention strategies • Monitor performance against the action plan • Review scorecard metrics (including all deaths associated with infections) • Serve as champions to facilitate intervention strategies	Formation of ICP workgroup with quarterly progress reports	VP Clinical Safety, Local Infectious Disease physician to co-chair ICP workgroup	HIGH	January 09
	2. Assess and recommend appropriate local structure to ensure accountability in meeting "getting to zero" goals	Distribution of draft recommendations for local accountability structure	VP Clinical Safety, VP Medical Services, Physician Leadership Council, Nursing Leadership Council	HIGH	February 09

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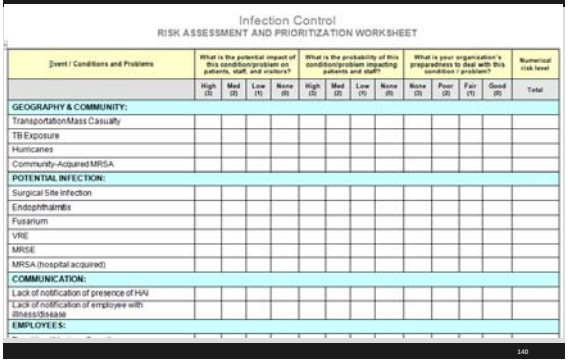
IC Risk Assessment & Prioritization



Infection Control
RISK ASSESSMENT AND PRIORITIZATION WORKSHEET

Event / Conditions and Problems	What is the potential impact of this condition/problem on patients, staff, and visitors?				What is the probability of this condition/problem impacting patients and staff?				What is your organization's preparedness to deal with this condition / problem?				Numerical risk level
	High (3)	Med (2)	Low (1)	None (0)	High (3)	Med (2)	Low (1)	None (0)	None (3)	Poor (2)	Fair (1)	Good (0)	Total
GEOGRAPHY & COMMUNITY:													
Transportation/Mass Casualty													
TB Exposure													
Hurricanes													
Community-Acquired MRSA													
POTENTIAL INFECTION:													
Surgical Site Infection													
Endophthalmitis													
Fusarium													
VRE													
MRSE													
MRSA (hospital acquired)													
COMMUNICATION:													
Lack of notification of presence of HAI													
Lack of notification of employee with illness/disease													
EMPLOYEES:													

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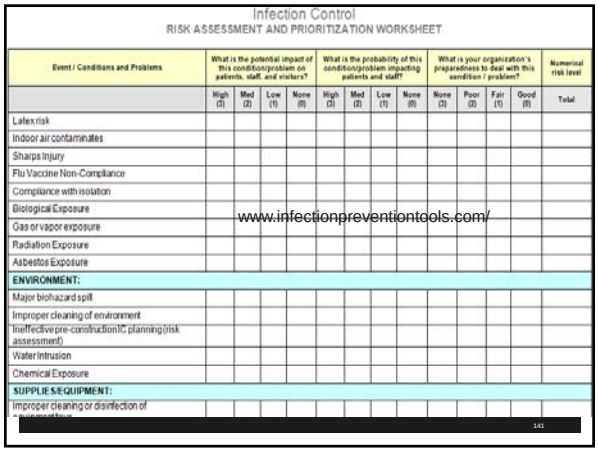

Infection Control
RISK ASSESSMENT AND PRIORITIZATION WORKSHEET

Event / Conditions and Problems	What is the potential impact of this condition/problem on patients, staff, and visitors?				What is the probability of this condition/problem impacting patients and staff?				What is your organization's preparedness to deal with this condition / problem?				Numerical risk level
	High (3)	Med (2)	Low (1)	None (0)	High (3)	Med (2)	Low (1)	None (0)	None (3)	Poor (2)	Fair (1)	Good (0)	Total
Latex risk													
Indoor air contaminates													
Sharps Injury													
Flu Vaccine Non-Compliance													
Compliance with isolation													
Biological Exposure													
Gas or vapor exposure													
Radiation Exposure													
Asbestos Exposure													
ENVIRONMENT:													
Major biohazard spill													
Improper cleaning of environment													
Ineffective pre-construction IC planning (risk assessment)													
Water intrusion													
Chemical Exposure													
SUPPLIES/EQUIPMENT:													
Improper cleaning or disinfection of													

www.infectionpreventiontools.com/

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Infection Control

- Infection control must be integrated in QAPI
- Surveillance activities should be conducted in accordance with recognized surveillance practices
  - CDC NHSN (National Healthcare Safety Net)
  - **NHSN** is internet-based surveillance system managed by the CDC
  - Hospitals now using to report ICU and NICU central line infections and CAUTIs
  - Available for hospitals at no charge and great resource
  - Provides multiple options for data analysis and more flexibility for sharing information within and outside the facility

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Infection Control

- NHSN replaces the CDCs National Nosocomial Infection Surveillance system (NNIS)
  - Was considered the gold standard for tracking HAI for more than 30 years
  - Designed to help hospitals better manage episodes of HAI such as MRSA and VRE
  - Used by the VA hospitals
  - Hospitals report selected central line infections and CAUTIs
- Enroll on-line for HAI surveillance and many other resources[1]

[1]http://www.cdc.gov/ncidod/dhqp/nhsn.html

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CDC Surveillance Resources

- Surveillance for:
- Antimicrobial use and resistance

- CLABSI or central line associated bloodstream infection and CLIP central line insertion practices
- CAUTI or catheter associated UTI
- MDRO/C-Diff, blood safety surveillance
- VAP or ventilator associated pneumonia
- SSI or surgical site infections
- Healthcare personnel exposure, vaccinations etc.

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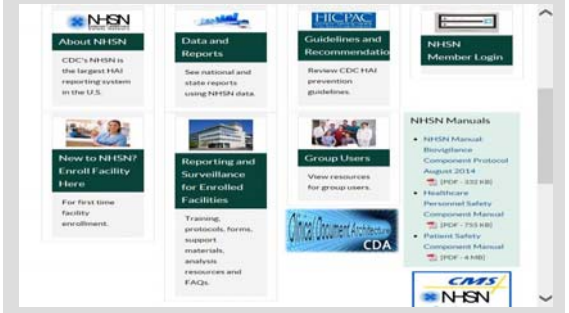
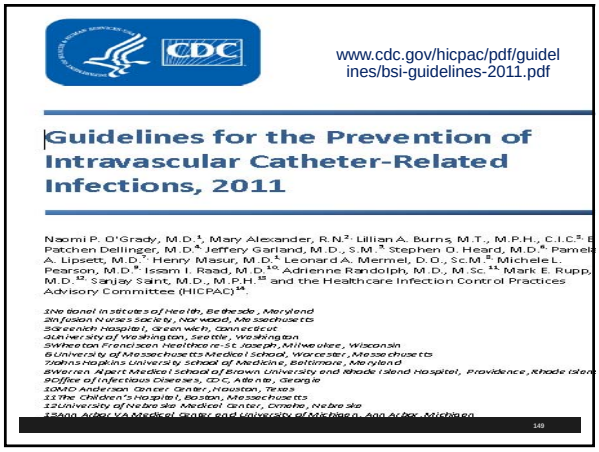
CDC National Healthcare Safety Network

Reporting and Surveillance



Reporting and Surveillance



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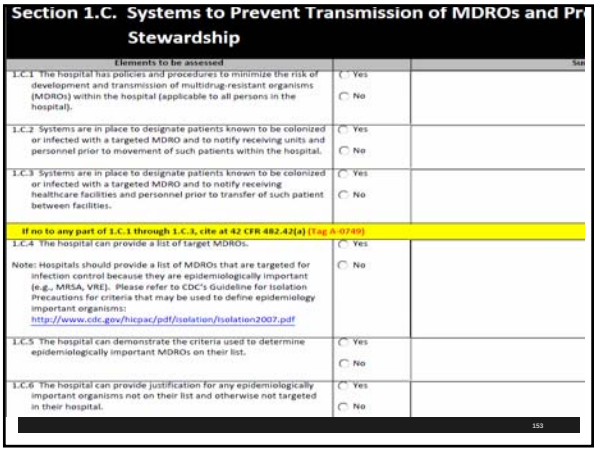
4 Challenges in Infection Control

- CMS said there are four special challenges in infection control (just four?)
  - Challenge 1: Multidrug-Resistant Organisms
  - Challenge 2: Infection Control in Ambulatory Care
  - Challenge 3: Communicable Disease Outbreaks
  - Challenge 4: Bioterrorism

Multidrug-Resistant Organisms

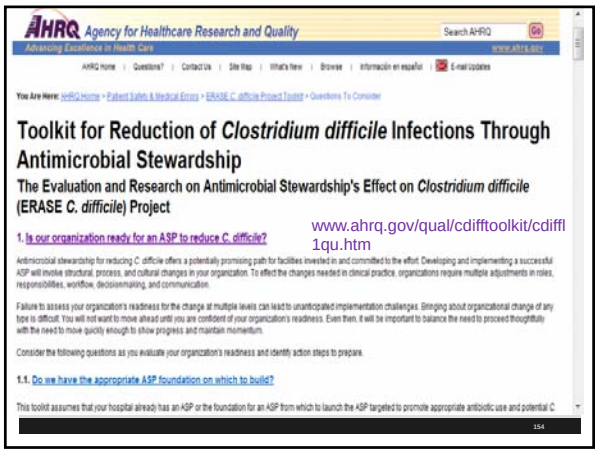
- Multidrug-resistant organisms (MDROs) are resistant to one or more antimicrobial agents
  - Treatment is more difficult
  - These bad bugs are more dangerous
- Have systems in place to identify and prevent transmission of these organisms.
- The CDC has a special publication on "Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006"[1]

[1]http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf



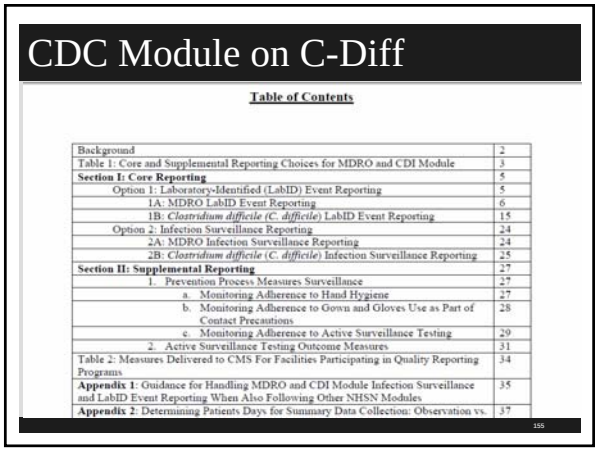
Section 1.C. Systems to Prevent Transmission of MDROs and Pr
Stewardship

Elements to be assessed		Su
1.C.1 The hospital has policies and procedures to minimize the risk of development and transmission of multidrug-resistant organisms (MDROs) within the hospital (applicable to all persons in the hospital).	○ Yes ○ No	
1.C.2 Systems are in place to designate patients known to be colonized or infected with a targeted MDRO and to notify receiving units and personnel prior to movement of such patients within the hospital.	○ Yes ○ No	
1.C.3 Systems are in place to designate patients known to be colonized or infected with a targeted MDRO and to notify receiving healthcare facilities and personnel prior to transfer of such patient between facilities.	○ Yes ○ No	
If no to any part of 1.C.1 through 1.C.3, cite at 42 CFR 482.42(a) (Tag A-0749)		
1.C.4 The hospital can provide a list of target MDROs. Note: Hospitals should provide a list of MDROs that are targeted for infection control because they are epidemiologically important (e.g., MRSA, VRE). Please refer to CDC's Guideline for Isolation Precautions for criteria that may be used to define epidemiology important organisms: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf	○ Yes ○ No	
1.C.5 The hospital can demonstrate the criteria used to determine epidemiologically important MDROs on their list.	○ Yes ○ No	
1.C.6 The hospital can provide justification for any epidemiologically important organisms not on their list and otherwise not targeted in their hospital.	○ Yes ○ No	



www.ahrq.gov/qual/cdifftoolkit/cdiffl1qu.htm

CDC Module on C-Diff



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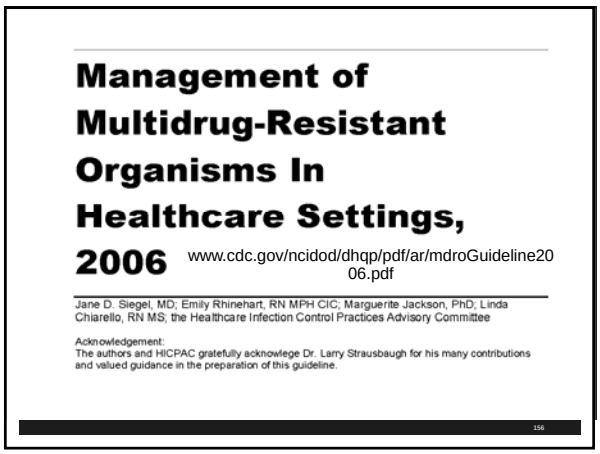

www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf

APIC C-Diff Guide

Guide to Preventing *Clostridium difficile* Infections

www.apic.org/Professional-Practice/Implementation-guides

APIC

About APIC
APIC's mission is to create a safer world through prevention of infection. The association's more than 14,000 members direct infection prevention programs that save lives and improve the bottom line for hospitals and other healthcare facilities. APIC advances its mission through patient safety, implementation science, competencies and certification, advocacy, and data standardization.

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SHEA C-Diff Guidelines

CHICAGO JOURNALS

www.shea-online.org/GuidelinesResources/Guidelines/Guideline/ArticleId/11/Clinical-Practice-Guidelines-for-Clostridium-difficile-Infection-in-Adults-2010.aspx

SHEA The Society for Healthcare Epidemiology of America

Clinical Practice Guidelines for Clostridium difficile Infection in Adults: 2010 Update by the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA)
Author(s): Stuart H. Cohen , MD, Dale N. Gerding , MD, Stuart Johnson , MD, Ciaran P. Kelly , MD, Vivian G. Loo , MD, L. Clifford McDonald , MD, Jacques Pepin , MD, Mark H. Wilcox , MD
Source: *Infection Control and Hospital Epidemiology*, Vol. 31, No. 5 (May 2010), pp. 431-455
Published by: The University of Chicago Press on behalf of The Society for Healthcare Epidemiology of America
Stable URL: http://www.jstor.org/stable/10.1086/651706
Accessed: 02/08/2011 23:02

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Compendium to Prevent HAI Infections

AHRQ Toolkit on KPC

- AHRQ has a free toolkit for hospitals to help control and prevent Klebsiella pneumoniae carbapenemase (KPC)
  - Called the Carbapenem-Resistant Enterobacteriaceae (CRE) Control and Prevention Toolkit
  - This is a highly dangerous, antibiotic-resistant germ
- Will help hospitals implement the CDC guidelines and is 56 page toolkit
  - available at www.ahrq.gov/cretoolkit

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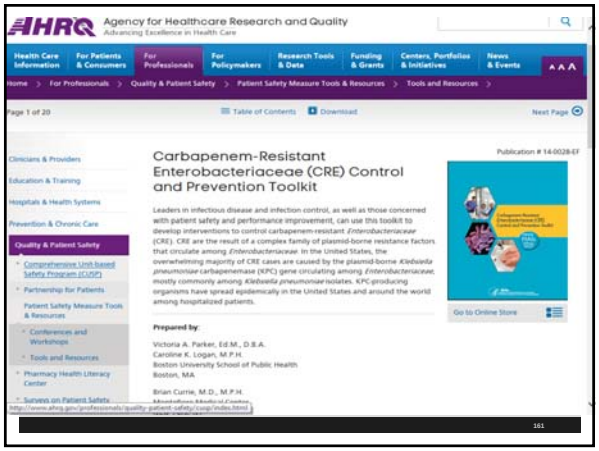

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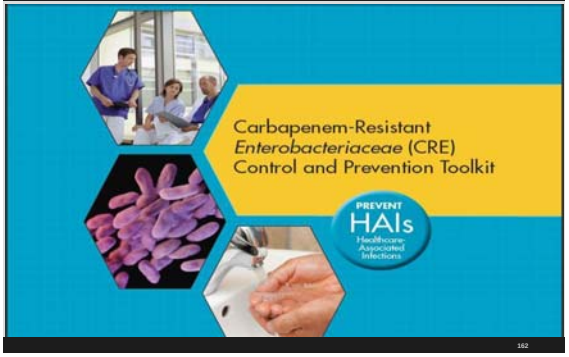
Free Toolkit for Hospitals



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Infection Control in Ambulatory Care

- Infection control in ambulatory care presents special problems
  - Patients remain in common areas such as the lobby and ED waiting areas
  - Patients are turned around quickly with minimal cleaning
  - Infectious patients may not be recognized immediately
  - Immuno-compromised patients can receive treatment in rooms with other patients who pose a risk of infection

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Infection Control in Ambulatory Care 747

- Use preventive measures when infectious individuals are identified
- This could include prompt separation
- Implement respiratory hygiene or cough etiquette protocols
- Use appropriate isolation precautions
- Worksheet has an entire section on isolation and also includes respiratory tracer

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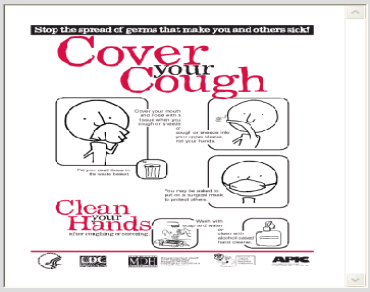
Cover Your Cough Posters



www.cdc.gov/flu/protect/covercough.htm

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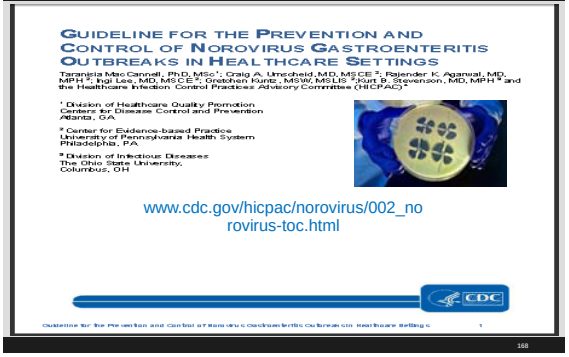
APIC Resources for Ambulatory Care

Infection Control in Ambulatory Care

- Guidelines have been developed by the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC)
  hwww.cdc.gov/hicpac/pubs.html
  - Infection control plan for ambulatory care
  - Norovirus gastroenteritis outbreaks 2011
  - Guidelines for Disinfection and Sterilization in Healthcare Facilities 2008
  - Guidelines for Isolation Precautions 2007
  - CDC Intravascular guidelines 2011
  - Management of Multidrug-Resistant Organisms 2006
  - Influenza Vaccination of Healthcare Personnel 2006

CDC Norovirus Guidelines



www.cdc.gov/hicpac/norovirus/002_norovirus-toc.html

CDC HICPAC

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Infection Control in Ambulatory Care

- CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) Guidelines (continued)
  - Guidance on Public Reporting of HAI 2005
  - Guidelines for Preventing Healthcare Associated Pneumonia 2004
  - Guidelines for Environmental Infection Control in Healthcare Facilities 2003, 2002 Hand hygiene guidelines, Prevention of Surgical Site Infections and more
  - HICPAC is a federal advisory committee made up of 14 external IC experts who provide guidance and advice to the CDC and HHS
    - Members from APIC, SHEA, AORN, CMS, FDA etc.

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Preventing Infections in the Outpatient Unit

- 2015 CDC has a guide and checklist for preventing infections in the outpatient setting
  - The Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care and
  - The Infection Prevention Checklist for Outpatient Settings; Minimum Expectations for Safe Care
- Free off the website at www.cdc.gov/hai/settings/outpatient/outpatient-settings.html?source=govdelivery

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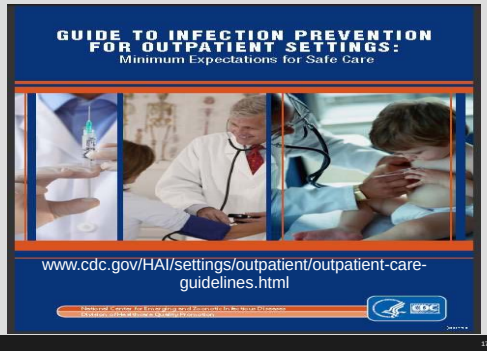
CDC Guide Infection Control Outpatients



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Communicable Disease Outbreaks

- Community-wide outbreaks of communicable diseases present many of the same types of issues as hospital infection disease threats
  - Understand the epidemiology
  - Such as measles, flu, EBOLA, MERS or SARS
  - Know how it is transmitted and the clinical course of the disease in order to manage the outbreak
- Pandemics, or widespread outbreaks of an infection require back up resources
  - Hospitals need to work with state, federal, and local health agencies

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Communicable Disease Outbreaks

- There are at a minimum four things that must be addressed:
  - Preventing transmission among patients, healthcare personnel, and visitors
  - Identifying persons who may be infected and exposed
  - Providing treatment or prophylaxis to large numbers of people
  - Logistical issues (staff, medical supplies, resupply, continued operations, and capacity)

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HOSPITAL POLICIES AND PROCEDURES

Department: Epidemiology — Subject No.: 35-36.1

Subject: Influx of People With Infectious Disease — Page 1 of 2; Revision: 7/2008; Effective: 4/2005

I. In addition to implementation of the general Emergency Management Policies, the following issues will be addressed for infectious diseases. Additional information is contained in policies for SARS, Bioterrorism preparedness, pandemic flu preparation.

II. Community Resources: Determine if this is a community-wide event and if other facilities, shelters, hotels, etc., are also accepting the infectious patients. If so, coordinate decision-making with community disaster agencies and local/state public health departments.

III. Type Of Infectious Disease/Mode Of Transmission: Determine what types of infectious disease the patients have and its mode of transmission. If the mode of transmission is any mode that requires precautions beyond standard precautions, make a decision regarding the following:

A. Are rooms needed with negative pressure for isolation?
   1. If yes, does the facility have adequate negative pressure rooms or can rooms be retrofitted for negative pressure?
   2. Can several patients fit into the available negative pressure rooms and thus accommodate the influx?
   3. Can a wing of the building that does not share an air system with the rest of the building be used for the infectious patients?
   4. Does the entire building need to be emptied of patients without the infectious disease so the building can be used for only patients with the infectious disease?
   5. Does an outdoor temporary shelter need to be implemented to house the infectious patients?

B. If negative pressure is not needed but contact or droplet precautions are,
   1. Does the facility have adequate rooms/spaces to cohort the patients with the infectious disease? Move patients to fifth floor if possible to vent out top of

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Bioterrorism

- Hospitals should be well versed in emergency preparedness, including bioterrorism
- Terrorists could use bioterrorism
- There is a long list of bioterrorism agents
  - Anthrax, arenaviruses, botulism, brucellosis, cholera, Ebola virus hemorrhagic fever, E. coli, Lassa fever, plague, ricin toxin, salmonella, and cryptosporidium
- For a comprehensive list go to website[1]

[1]http://www.emergency.cdc.gov/agent/agentlist.asp

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CDC Emergency Preparedness

www.bt.cdc.go

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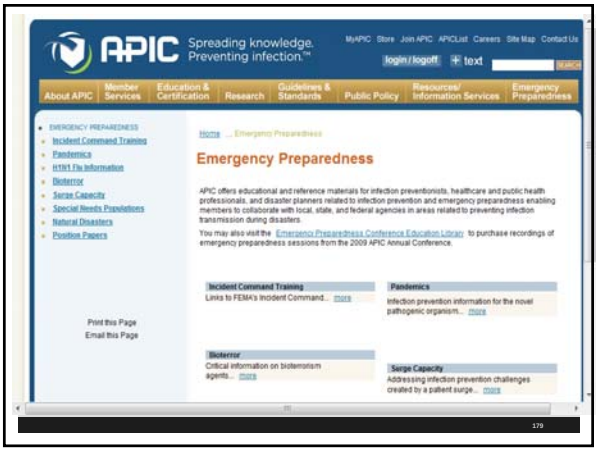
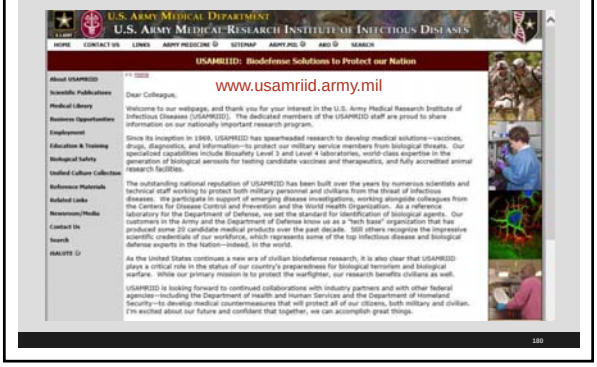
CDC Emergency Preparedness



Bio-defense Solutions by the Army



Bioterrorism

- The hospital must be in compliance with the Occupational Health and Safety Administration's Bloodborne Pathogens regulation
  - 29 CFR 1910.1030.[1] http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl
- The Code of Federal Regulations can be obtained free from the internet
- Regulations address PPE, safer needles, and use of universal precautions to prevent the spread of infection

Organizations and Policies 748

- **Standard:** A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases
- APIC and CMS call these professionals infection preventionists

IP Officer's Responsibilities

- Many have added these to their job descriptions
- Maintain sanitary hospital environment
  - Ventilation and water controls, construction- make sure safe environment, safe air handling in areas of special ventilations such as the OR and isolation rooms, techniques for food sanitation, cleaning and disinfecting surfaces, carpeting and furniture, how is pest control done, and disposal of trash along with non-regulated waste

Infection Control Officer 748

- Hospital infection control officers are often referred to as hospital epidemiologists (HEs), infection control professionals (ICPs) or IP
  - APIC and CMS calls them Infection Preventionist or IP
- CDC has defined "infection control professional" as "a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control"
- The hospital must designate in writing an individual as its infection control officer

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Infection Control Preventionist

- The person assigned to the job should be educated and competent in that area
  - Qualified through education, training, experience, or certification
- Certification offered by:
  - Certification Board of Infection Control and Epidemiology Inc. (CBIC)
  - Specialty boards in adult or pediatric infectious diseases
    - American Board of Internal Medicine (for internists)
    - American Board of Pediatrics (for pediatricians).

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APIC Competency in Infection Prevention

www.ajicjournal.org/article/S0196-6553(12)00165-4/fulltext

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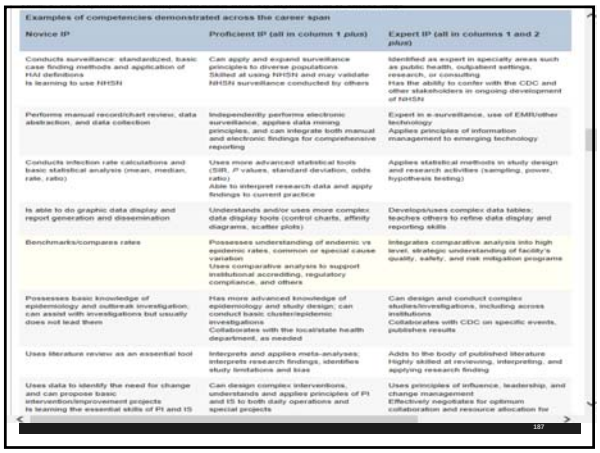

Examples of competencies demonstrated across the career span

Novice IP	Proficient IP (all in column 1 plus)	Expert IP (all in columns 1 and 2 plus)
Conducts surveillance: standardized, basic case finding methods and application of HAI definitions Is learning to use NHSN	Can apply and expand surveillance principles to diverse populations Skilled at using NHSN and may validate NHSN surveillance conducted by others	Identified as expert in specialty areas such as public health, outpatient settings, research, or consulting Has the ability to confer with the CDC and other stakeholders in ongoing development of NHSN
Performs manual record/chart review, data abstraction, and data collection	Independently performs electronic surveillance, applies data mining principles, and can integrate both manual and electronic findings for comprehensive reporting	Expert in e-surveillance, use of EMR/other technology Applies principles of information management to emerging technology
Conducts infection rate calculations and basic statistical analysis (mean, median, rate, ratio)	Uses more advanced statistical tools (SIR, P values, standard deviation, odds ratio) Able to interpret research data and apply findings to current practice	Applies statistical methods in study design and research activities (sampling, power, hypothesis testing)
Is able to do graphic data display and report generation and dissemination	Understands and/or uses more complex data display tools (control charts, affinity diagrams, scatter plots)	Develops/uses complex data tables; teaches others to refine data display and reporting skills
Benchmarks/compares rates	Possesses understanding of endemic vs epidemic rates, common or special cause variation Uses comparative analysis to support institutional accrediting, regulatory compliance, and others	Integrates comparative analysis into high level, strategic understanding of facility's quality, safety, and risk mitigation programs
Possesses basic knowledge of epidemiology and outbreak investigation; can assist with investigations but usually does not lead them	Has more advanced knowledge of epidemiology and study design; can conduct basic cluster/epidemic investigations Collaborates with the local/state health department, as needed	Can design and conduct complex studies/investigations, including across institutions Collaborates with CDC on specific events, publishes results
Uses literature review as an essential tool	Interprets and applies meta-analyses; interprets research findings, identifies study limitations and bias	Adds to the body of published literature Highly skilled at reviewing, interpreting, and applying research finding
Uses data to identify the need for change and can propose basic intervention/improvement projects Is learning the essential skills of PI and IS	Can design complex interventions, understands and applies principles of PI and IS to both daily operations and special projects	Uses principles of influence, leadership, and change management Effectively negotiates for optimum collaboration and resource allocation for

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Infection Control Preventionist (IPs)

- Infection control officers should maintain their qualifications
- This should be done through ongoing education and training
  - APIC has excellent educational conferences
  - This requirement can be demonstrated by participation in infection control courses, or in local and national meetings organized by recognized professional societies, such as APIC and SHEA
- Develop and implement IC measures (hospital staff, contract workers, volunteers)

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IP Duties Id, Report, Investigate 749

- **Standard:** The infection preventionist must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases
- This includes both patients and personnel
- Infection control should be specific to each department in addition to house wide
- It needs to be evaluated and revised when necessary
- There are many activities that the IP must ensure is done

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IPs Responsibilities 749

- Mitigate risks associated with
  - Patient infections present upon admission
  - Risks contributing to HAI
- Conduct active surveillance
  - Includes patients, staff, volunteers, and contract workers
  - Must identify and track infectious and communicable diseases
  - Including HAI selected by IC program based on targeted surveillance based on nationally recognized guidelines and periodic risk assessment

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IC Officer's Responsibilities 749

- Active surveillance (continued)
  - Culture of patient colonized with MDRO
  - Isolation patients
  - Patients or staff with reportable communicable diseases
  - Staff or patients with signs in which local, state, or feds request
  - Staff or patients infected with significant pathogens
  - Recommend use of automated surveillance technology
- Monitoring compliance with all P&Ps, protocols and other infection control program requirements

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IPs Responsibilities 749

- Evaluate and revise of the program, when indicated
- Coordinate with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks
  - As required by law
- Comply with the reportable disease requirements of the local health authority
- Integrate IC program into hospital-wide QAPI

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Infection Control P&P 749

- Long list of IC policies that hospitals must have
- The 22 policies and practices are now organized under 5 sections
- Maintain a sanitary physical environment which includes many things including:
  - Includes ventilation and water quality control issues including
  - Maintaining safe air handling in isolation rooms
  - Techniques for food sanitation

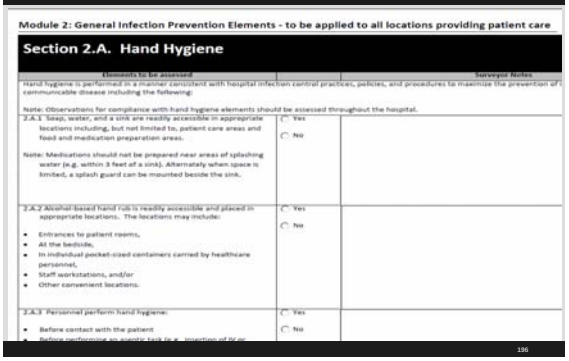
Infection Control P&P 749

- Maintain a sanitary physical environment which includes many things including (continued):
  - Techniques for cleaning and disinfecting environmental surfaces, carpeting and furniture
  - Techniques for textiles reprocessing, storage and distribution
  - Techniques for disposal of regulated and non-regulated waste and
  - Techniques for pest control

IC Policies

- New employee orientation (include hand hygiene)
- Mitigate risk that cause or contribute to HAI
  - SCIP measures, appropriate hair removal, timely antibiotics in OR, DC in 24 hours except 48 hours for cardiac patients, beta blockers during perioperative periods for select cardiac patients, proper sterilization of equipment, etc.
  - Promotion of hand hygiene among staff and employees including alcohol based hand sanitizers
  - Section on hand hygiene tracer in infection control worksheet

Hand Hygiene Tracer



Module 2: General Infection Prevention Elements - to be applied to all locations providing patient care

Section 2.A. Hand Hygiene

Elements to be assessed		Surveyor Notes
Hand hygiene is performed in a manner consistent with hospital infection control practices, policies, and procedures to maximize the prevention of communicable disease including the following:		
Note: Observations for compliance with hand hygiene elements should be assessed throughout the hospital.		
2.A.1 Soap, water, and a sink are readily accessible in appropriate locations including, but not limited to, patient care areas and food and medication preparation areas. Note: Medications should not be prepared near areas of splashing water (e.g. within 3 feet of a sink). Alternately when space is limited, a splash guard can be mounted beside the sink.	○ Yes ○ No	
2.A.2 Alcohol-based hand rub is readily accessible and placed in appropriate locations. The locations may include: • Entrances to patient rooms, • At the bedside, • In individual pocket-sized containers carried by healthcare personnel, • Staff workstations, and/or • Other convenient locations.	○ Yes ○ No	
2.A.3 Personnel perform hand hygiene: • Before contact with the patient	○ Yes ○ No	

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CDC Guidelines on Hand Hygiene

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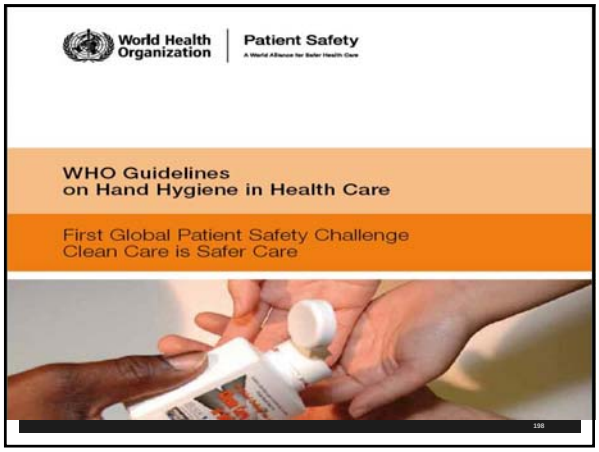

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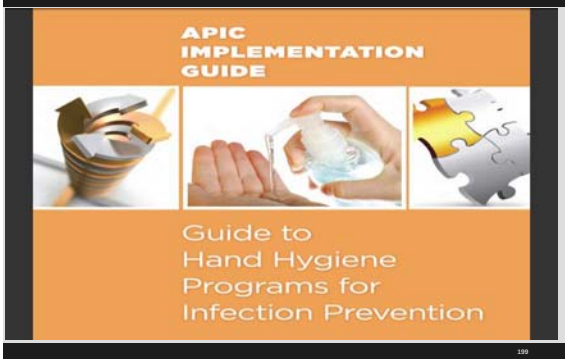
2015 APIC Guide to Hand Hygiene Program



This is Your Hand Unwashed Johns Hopkins

CDC Poster Clean Hands Save Lives!

Infection Control P&Ps 749

- **Hospital staff related measures**
  - Evaluate hospital staff immunization status for infectious diseases as per CDC and APIC (in IC worksheet)
  - How you screen hospital staff for infections likely to cause significant infectious disease to others,
  - Policy on when staff are restricted from working
  - New employee training and periodic continuing education to staff on how to prevent and control HAI and methods to prevent transmission
  - Measures to evaluate staff and volunteers exposed to patients with infectious or communicable diseases

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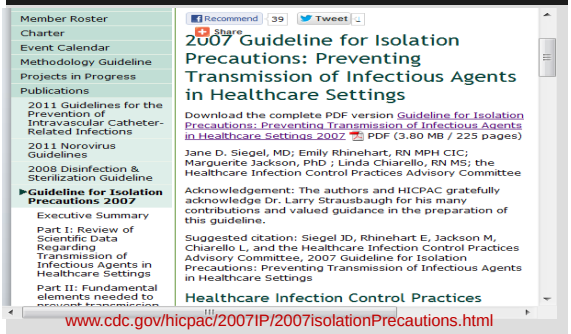
Infection Control P&Ps 749

- How to mitigate risk when patient admitted with infection
  - Must be consistent with the CDC isolation guidelines
  - Staff knowledge of PPE
  - Use and follow the CDC isolation guidelines
    - The isolation standards are where the CDC 10 safe injection practices are located which are hit hard during the survey

205

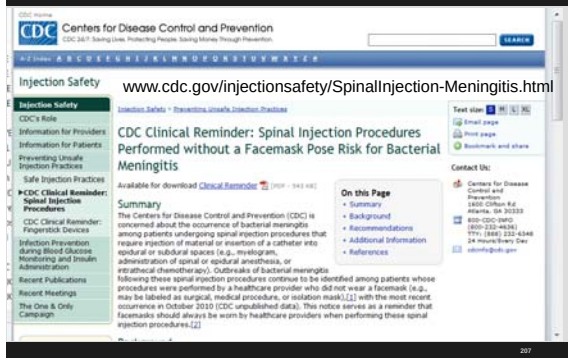
CDC Isolation Guidelines



www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html

206

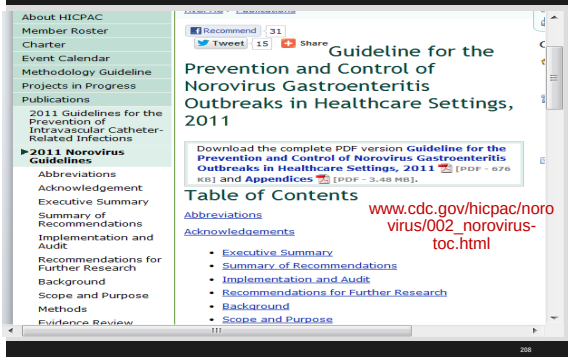
Wear a Mask Epidural Spinal or LP



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

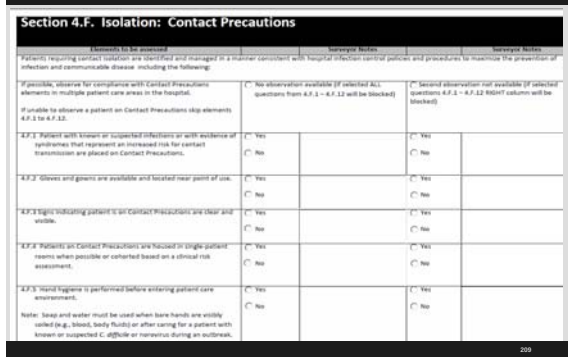
207

CMS Norovirus Guidelines



www.cdc.gov/hicpac/norovirus/002_norovirus-toc.html

Isolation Contact Precautions

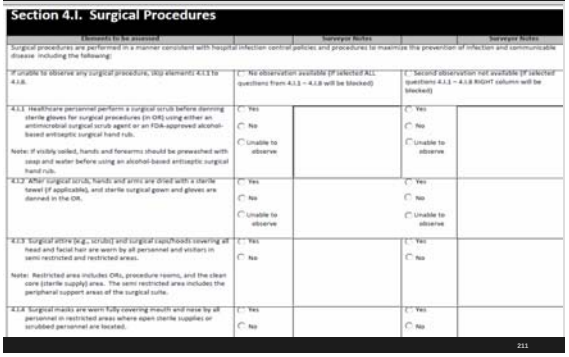


IC Policies 749

- HAI risk mitigation
  - Implement things to prevent SSI such as timely antibiotics during OR
  - Promotion of hand hygiene
  - Measures to prevent organisms that are antibiotic resistant such as MRSA and VRE
  - Aseptic technique in surgery and invasive procedures outside of OR including sterilization of instruments
    - Section on surgery tracer and sterilization of instruments in WS

/ 40

Surgical Procedures



Section 4.I. Surgical Procedures

Elements to be assessed		Surveyor Notes		Surveyor Notes
Surgical procedures are performed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:				
If unable to observe any surgical procedure, skip elements 4.I.1 to 4.I.8.	☐ No observation available (If selected ALL questions from 4.I.1 – 4.I.8 will be blocked)		☐ Second observation not available (If selected questions 4.I.1 – 4.I.8 RIGHT column will be blocked)	
4.I.1 Healthcare personnel perform a surgical scrub before donning sterile gloves for surgical procedures (in OR) using either an antimicrobial surgical scrub agent or an FDA-approved alcohol-based antiseptic surgical hand rub. Note: If visibly soiled, hands and forearms should be prewashed with soap and water before using an alcohol-based antiseptic surgical hand rub.	☐ Yes ☐ No ☐ Unable to observe		☐ Yes ☐ No ☐ Unable to observe	
4.I.2 After surgical scrub, hands and arms are dried with a sterile towel (if applicable), and sterile surgical gown and gloves are donned in the OR.	☐ Yes ☐ No ☐ Unable to observe		☐ Yes ☐ No ☐ Unable to observe	
4.I.3 Surgical attire (e.g., scrubs) and surgical caps/hoods covering all head and facial hair are worn by all personnel and visitors in semi-restricted and restricted areas. Note: Restricted area includes ORs, procedure rooms, and the clean core (sterile supply) area. The semi restricted area includes the peripheral support areas of the surgical suite.	☐ Yes ☐ No		☐ Yes ☐ No	
4.I.4 Surgical masks are worn fully covering mouth and nose by all personnel in restricted areas where open sterile supplies or scrubbed personnel are located.	☐ Yes ☐ No		☐ Yes ☐ No	

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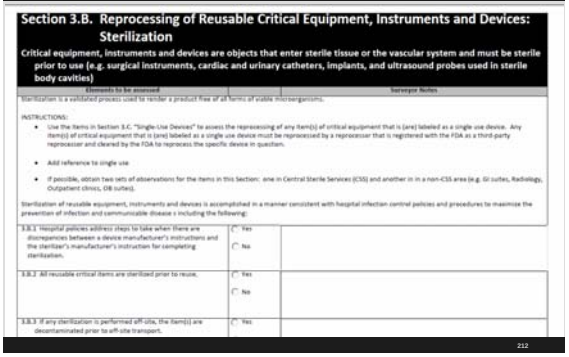
Reprocessing Reusable Critical Equipment



Section 3.B. Reprocessing of Reusable Critical Equipment, Instruments and Devices: Sterilization

Critical equipment, instruments and devices are objects that enter sterile tissue or the vascular system and must be sterile prior to use (e.g. surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities)

Elements to be assessed		Surveyor Notes
Sterilization is a validated process used to render a product free of all forms of viable microorganisms. INSTRUCTIONS: • Use the items in Section 3.C. "Single-Use Devices" to assess the reprocessing of any item(s) of critical equipment that is (are) labeled as a single use device. Any item(s) of critical equipment that is (are) labeled as a single use device must be reprocessed by a reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. • Add reference to single use • If possible, obtain two sets of observations for the items in this Section: one in Central Sterile Services (CSS) and another in in a non-CSS area (e.g. GI suites, Radiology, Outpatient clinics, OR suites). Sterilization of reusable equipment, instruments and devices is accomplished in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease s including the following:		
3.B.1 Hospital policies address steps to take when there are discrepancies between a device manufacturer's instructions and the sterilizer's manufacturer's instruction for completing sterilization.	☐ Yes ☐ No	
3.B.2 All reusable critical items are sterilized prior to reuse.	☐ Yes ☐ No	
3.B.3 If any sterilization is performed off-site, the item(s) are decontaminated prior to off-site transport.	☐ Yes	

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IC Policies 749

- Central line bundle, VAP bundle or sepsis bundle, prompt removal of foley catheter
- Use of disinfectants, antiseptics, and germicides in accordance with manufacturers instructions
- Isolation procedures for:
  - Highly immuno-suppressed patients (HIV or chemo patients)
  - Trach care, respiratory care, burns, and other similar situations

40 213

IP Tools www.infectionpreventiontools.com/

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IC Policies 749

- Appropriate use of facility and medical equipment (hepa filters, negative pressure room, UV lights and other equipment) to prevent the spread of infectious agents
- Education on infection and communicable diseases for patients, visitors, care givers, and staff
- Active surveillance system, method for getting data to determine if there is a problem
- Policy on getting cultures from patients, etc.

/ 40

Policies and Organization 749

- Need IC officer (now called IP or Infection Preventionist) and IC committee
- IC officer must develop and implement policies on control of infection and communicable diseases
- Person must be designated in writing who is qualified through education and experience
- Lists the responsibilities of this person- consider putting into job description

/ 40

Infection Control

- The IP must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel
- Applies to both healthcare-associated infections (HAI) and community-acquired infection

Infection Control Activities Tag 749

The following activities should be based on national guidelines:

- Maintenance of a sanitary hospital environment
- Development and implementation of infection control measures related to hospital personnel (hospital staff, for infection control purposes, includes all hospital staff, contract workers (e.g., agency nurses, housekeeping staff, etc.), and volunteers
- Mitigation of risks associated with patient infections present upon admission and risks contributing to HAI
- Active surveillance

Infection Control Activities 749

- Monitoring compliance with all policies, procedures, protocols and other infection control program requirements
- Program evaluation and revision of the program, when indicated
- Coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks
- Complying with the reportable disease requirements of the local health authority

Log of Incidents 750 Deleted 2013

- Must maintain a log related to infections and communicable diseases
  - CMS deleted the log requirement effective 7-16-2012
  - Log requirements use to require the following;
- Includes information from patients
- Includes employees, contract staff such as agency nurses, and volunteers
- Includes surgical site infections, patients or staff with MDRO, patients who meet isolation requirements

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CEO, DON, and MS 756

- The CEO, CNO, and MS must ensure that there is hospital-wide QAPI and training program that address problems identified by IC officer
  - QAPI now means Quality Assessment not Assurance
- Implement a successful corrective action plan in affected problem areas
- Train staff in problems identified
- Problems must be reported to nursing, MS, and administration

/ 40

The End! Questions???

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- CAH infection control standards follow

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What every CAH needs to know about the Conditions of Participation (CoPs)

Infection Control 278 2015

- Standard: Need a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel
  - Must be facility wide
- Provides definitions of infectious diseases and communicable disease that hospital can put in its P&P
- HAI or healthcare-associated infection is one that patient develops while in the hospital or other healthcare facility

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Infection Control 278 2015

- CDC found 1 in 25 hospital patients has a HAI
  - This is 772,000 every year
- 75,000 patients will die from HAI every year
- Must have sanitary environment
  - No dried blood on side rails or floor
- Need infection preventionist who is qualified by education and experience
- APIC has competency document

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Infection Control 278 2015

- Must follow nationally recognized infection control practices or guidelines
- Examples include: CDC, APIC, SHEA, AORN and OSHA
  - CDC is Center for Disease Control
  - AORN is the Association for periOperative Nurses
  - APIC is the Association for Professionals in Infection Control and Epidemiology
  - SHEA is the Society for Healthcare Epidemiology of America

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4 Challenges in Infection Control

- CMS said there are four special challenges in infection control (just four?)
  - Challenge 1: Multidrug-Resistant Organisms
  - Challenge 2: Infection Control in Ambulatory Care
  - Challenge 3: Communicable Disease Outbreaks

  - Challenge 4: Bioterrorism

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Multidrug-Resistant Organisms

- Multidrug-resistant organisms (MDROs) are resistant to one or more antimicrobial agents
  - Treatment is more difficult
  - These bad bugs are more dangerous such as C-diff, VRE, MRSA, CRE (E. coli, Enterobacter, Klebsiella) etc.
  - National priority
- Have systems in place to identify early and prevent transmission of these organisms.
- The CDC has a special publication on “Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006”[1]

[1]http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf

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CDC Module on C-Diff

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Multidrug-Resistant Organisms

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[1]http://www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf

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Infection Control Ambulatory Care

- Infection control in ambulatory care presents special problems
  - Patients remain in common areas such as the lobby and ED waiting areas
  - Patients are turned around quickly with minimal cleaning
  - Infectious patients may not be recognized immediately
  - Immuno-compromised patients can receive treatment in rooms with other patients who pose a risk of infection

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Infection Control Ambulatory Care

- Place in room and don't leave in lobby if can be contagious and implement cough etiquette protocol
- Guidelines have been developed by the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) hwww.cdc.gov/hicpac/pubs.html
  - Infection control plan for ambulatory care
  - Norovirus gastroenteritis outbreaks
  - Guidelines for Disinfection and Sterilization in Healthcare Facilities and Guidelines for Isolation Precautions
  - CDC Intravascular guidelines
  - MRDO and Influenza Vaccination of Healthcare Personnel

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Infection Control Ambulatory Care

- CDC's Guidelines (continued)
  - Guidance on Public Reporting of HAI 2005
  - Guidelines for Preventing Healthcare Associated Pneumonia 2004
  - Guidelines for Environmental Infection Control in Healthcare Facilities 2003, 2002 Hand hygiene guidelines, Prevention of Surgical Site Infections and more
  - HICPAC is a federal advisory committee made up of 14 external IC experts who provide guidance and advice to the CDC and HHS
    - Members from APIC, SHEA, AORN, CMS, FDA etc.

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Preventing Infections in the Outpatient Unit

- CDC has a guide and checklist for preventing infections in the outpatient setting
  - The Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care and
  - The Infection Prevention Checklist for Outpatient Settings; Minimum Expectations for Safe Care
- Free off the website at www.cdc.gov/hai/settings/outpatient/outpatient-settings.html?source=govdelivery

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Communicable Disease Outbreaks

- Community-wide outbreaks of communicable diseases present many of the same types of issues as hospital infection disease threats
  - Such as measles, SARS, or the flu
  - Understand the epidemiology
  - Know how it is transmitted and the clinical course of the disease in order to manage the outbreak

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Communicable Disease Outbreaks

- There are at a minimum four things that must be addressed:
  - Preventing transmission among patients, healthcare personnel, and visitors
  - Identifying persons who may be infected and exposed
  - Providing treatment or prophylaxis to large numbers of people
  - Logistical issues (staff, medical supplies, resupply, continued operations, and capacity)

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HOSPITAL POLICIES AND PROCEDURES

Department: Epidemiology — Subject No.: 35-36.1

Subject: Influx of People With Infectious Disease — Page 1 of 2
Revision: 7/2008
Effective: 4/2005

I. In addition to implementation of the general Emergency Management Policies, the following issues will be addressed for infectious diseases. Additional information is contained in policies for SARS, Bioterrorism preparedness, pandemic flu preparation.

II. Community Resources: Determine if this is a community-wide event and if other facilities, shelters, hotels, etc., are also accepting the infectious patients. If so, coordinate decision-making with community disaster agencies and local/state public health departments.

III. Type Of Infectious Disease/Mode Of Transmission: Determine what types of infectious disease the patients have and its mode of transmission. If the mode of transmission is any mode that requires precautions beyond standard precautions, make a decision regarding the following:

A. Are rooms needed with negative pressure for isolation?
   1. If yes, does the facility have adequate negative pressure rooms or can rooms be retrofitted for negative pressure?
   2. Can several patients fit into the available negative pressure rooms and thus accommodate the influx?
   3. Can a wing of the building that does not share an air system with the rest of the building be used for the infectious patients?
   4. Does the entire building need to be emptied of patients without the infectious disease so the building can be used for only patients with the infectious disease?
   5. Does an outdoor temporary shelter need to be implemented to house the infectious patients?

B. If negative pressure is not needed but contact or droplet precautions are,
   1. Does the facility have adequate rooms/spaces to cohort the patients with the infectious disease? Move patients to fifth floor if possible to vent out top of

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Bioterrorism

- Hospitals should be well versed in emergency preparedness, including bioterrorism
- The response will be different based on the agent
- Work with state and local agencies to develop a plan
- There is a long list of bioterrorism agents
  - Anthrax, arenaviruses, botulism, brucellosis, cholera, Ebola virus hemorrhagic fever, E. coli, Lassa fever, plague, ricin toxin, salmonella, and cryptosporidium
- For a comprehensive list go to website[1]

[1]http://www.emergency.cdc.gov/agent/agentlist.asp

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Infection Control 278 2015

- **Surveillance and corrective actions**
  - Need active surveillance program
  - Surveillance includes detection, data collection, analysis, monitoring and evaluation
  - Must have facility wide surveillance to monitor infections and communicable diseases in the CAH
  - Must be consistent with recognized surveillance activities like the CDC National Healthcare Safety Net (NHSN)
  - Must address interventions to address issues identified

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Infection Control

- NHSN replaces the CDCs National Nosocomial Infection Surveillance system (NNIS)
  - Was considered the gold standard for tracking HAI for more than 30 years
  - Designed to help hospitals better manage episodes of HAI such as MRSA and VRE
  - Used by the VA hospitals
  - Hospitals report central line infections in ICUs and NICUs and certain CaUTI
- Enroll on-line for HAI surveillance and many other resources[1]

[1]http://www.cdc.gov/ncidod/dhqp/nhsn.html

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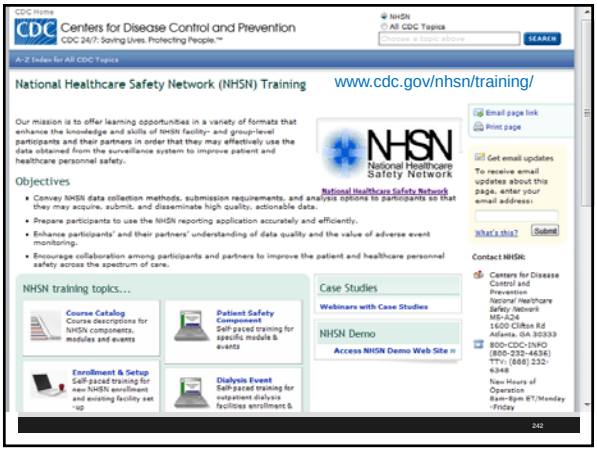
CDC National Healthcare Safety Network



Infection Control 278 2015

- **Sanitary environment**
  - Needed to avoid transmission of infection and communicable diseases
  - This includes all CAH units and off site locations
  - Need to monitor housekeeping
  - Must monitor maintenance including repair, renovation, and construction activity
  - Must monitor food storage, preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage, equipment cleaning, etc.

Infection Control 278 2015

- **Mitigation of risks**
  - Need P&P to mitigate risks associated with HAI
  - Must implement IC techniques and standard precautions
  - Must include but not be limited to:
  - Hand hygiene, cough etiquette, use of contact, droplet, and airborne precautions
    - See Infection Control Worksheet
  - Use of PPE such as gloves, masks, and gowns
  - Safe work practices to prevent bloodborne pathogen

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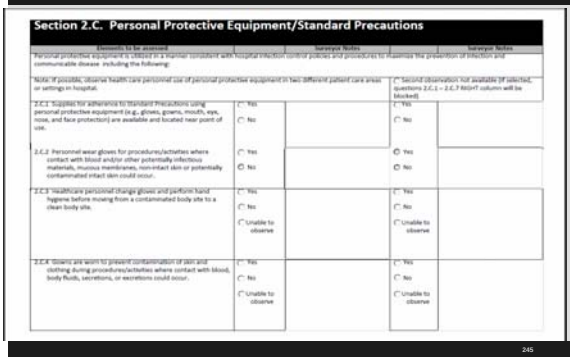
PPE Section in IC Worksheet



Section 2.C. Personal Protective Equipment/Standard Precautions

Elements to be assessed		Surveyor Notes		Surveyor Notes
Personal protective equipment is utilized in a manner consistent with hospital infection control policies and procedures to minimize the prevention of infection and communicable disease including the following:				
Note: If possible, observe health care personnel use of personal protective equipment in two different patient care areas or settings in hospital.			○ Second observation not available (if selected, questions 2.C.1 – 2.C.7 RIGHT column will be blocked)	
2.C.1 Supplies for adherence to Standard Precautions (using personal protective equipment (e.g., gloves, gowns, mouth, eye, nose, and face protection)) are available and located near point of use.	○ Yes ○ No		○ Yes ○ No	
2.C.2 Personnel wear gloves for procedures/activities where contact with blood and/or other potentially infectious materials, mucous membranes, non-intact skin or potentially contaminated intact skin could occur.	○ Yes ◉ No		◉ Yes ○ No	
2.C.3 Healthcare personnel change gloves and perform hand hygiene before moving from a contaminated body site to a clean body site.	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	
2.C.4 Gowns are worn to prevent contamination of skin and clothing during procedures/activities where contact with blood, body fluids, secretions, or excretions could occur.	○ Yes ○ No ○ Unable to observe		○ Yes ○ No ○ Unable to observe	

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OSHA Blood borne Pathogen Standard

Must implement UNIVERSAL PRECAUTIONS to prevent contact with blood such as:

- Hand washing (see CDC hand hygiene document at www.cdc.gov or WHO 2009 hand hygiene)
- No recapping needles
- Sharp containers in close proximity to use
- Not eating or drinking in work station
- No apply lip balm in work areas, if reasonable likelihood of occupational exposure)
- Not handling contact lens in work area
- Must wash your hands after gloves removed

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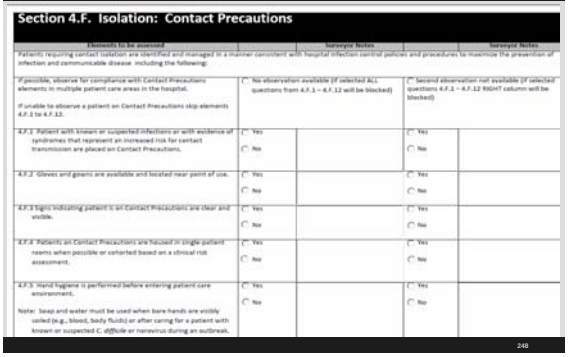
IP Tools www.infectionpreventiontools.com/

Isolation Contact Precautions



Safe Medication 278 2015

- Safe medication preparation and administration includes:
  - Prepare injectables in designated clean medication area not adjacent to contaminated areas
    - Such as medication room
  - Proper hand hygiene before handling medications
  - Always disinfect a rubber septum with alcohol before piercing it
    - 15 second and let dry

Safe Medication 278 2015

- **Safe medication preparation and administration includes:**
  - Always using aseptic technique when preparing and administering injections
  - Never entering a vial or IV with a used syringe or needle
  - Never administering medications from the same syringe to more than one patient, even if the needle is changed
  - Single dose vials can be used on only one patient
    - Unless prepared in pharmacy under USP 797 guidelines

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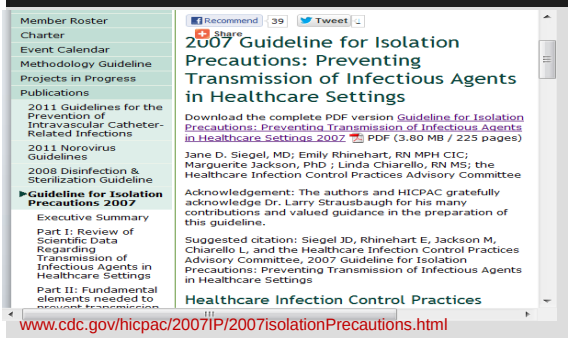
10 CDC Safe Injection Practices Standards



www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html

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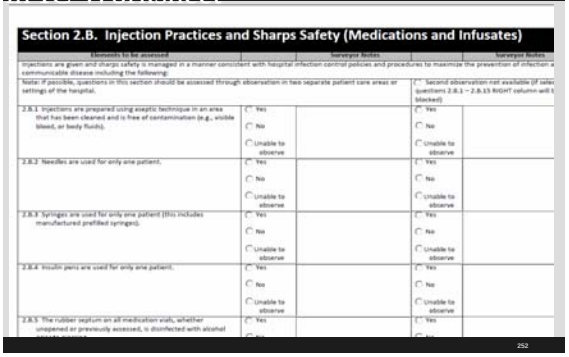
Safe Injection Practices and Sharps Safety in IC Worksheet



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Safe Medication 278 2015

- **Safe medication preparation and administration includes:**
  - IV bags can be used on one patient
  - If multi-dose vial try and use for one patient only and do not take into patient room
  - Mark multi-dose vial expires in 28 days unless sooner by manufacturer
  - Wear a mask when placing a catheter or injecting into epidural, spinal or subdural area
    - Like ED physician doing LP or anesthesiologist who puts in epidural for pain relief

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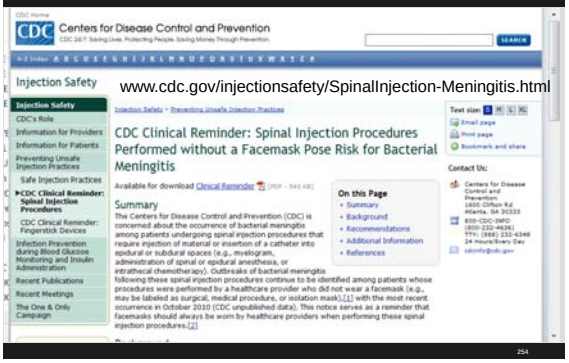
Wear a Mask Epidural Spinal or LP



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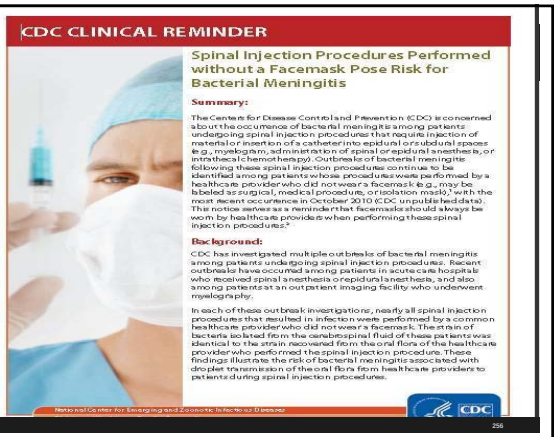

CDC CLINICAL REMINDER

Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis

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), 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.[1]

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.

National Center for Emerging and Zoonotic Infectious Diseases

CDC

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Safe Medication 278 2015

- **Safe medication preparation and administration includes:**
  - Never use same finger stick device for more than one patient
  - Never use insulin pens on more than one patient and CMS issues memo on this
  - Avoid sharing glucose meters
  - If must be done then clean after every use as recommended by manufacturer
  - P&P to make sure reusable patient care equipment is cleaned and reprocessed

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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

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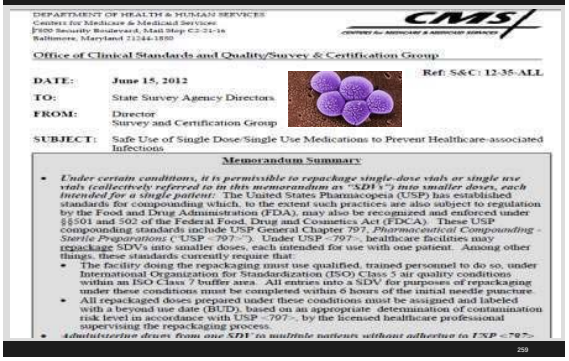
Single Dose Memo



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

CMS

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

Ref: S&C: 12-35-ALL

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 Pharmacopeia (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.
- *Administering doses from one SDV to multiple patients without adhering to USP <797>*

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Fingerstick Devices

Information for Patients
Preventing Unsafe Injection Practices
Infection Prevention during Blood Glucose Monitoring and Insulin Administration
FAQs regarding Assisted Blood Glucose Monitoring and Insulin Administration
CDC Clinical Reminder: Fingerstick Devices
Clinical Reminder: Insulin Pens
Recent Publications
Recent Meetings
The One & Only Campaign

Related Links
One & Only Campaign
HICPAC
2007 Guideline for Isolation Precautions
HHS Action Plan to Prevent HAIs

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

Available for download Clinical Reminder (PDF - 187 KB)

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

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

Figure 1: Reusable fingerstick device

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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)

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Safe Injection Practices Memo

EMERGENCY MEDICINE PATIENT SAFETY FOUNDATION

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

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ASC Quality Collaboration

http://ascquality.org/advancing_asc_quality.cfm

ASC Quality Collaboration | Quality Measures and Guide | Quality Report | Advancing ASC Quality: ASC TIPs

Advancing ASC Quality

To support the ASC industry's focus on high quality care, the ASC Quality Collaboration is assembling **ASC Tools for Infection Prevention**, or **ASC TIPs**. Our goal is to make infection prevention resources readily accessible to ASCs by bringing them together in one location.

The following **ASC TIPs** are now available:

- Hand Hygiene Toolkit
- Safe Injection Practices Toolkit
- Point of Care Devices Toolkit
- Environmental Infection Prevention Toolkit
- Single-Use Device Reprocessing Toolkit
- Endoscope Reprocessing Toolkit
- Sterilization and High-Level Disinfection Toolkit

Each toolkit is available in two versions, **BASIC** and **EXPANDED**:

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Safe Medication 278 2015

- **Safe medication preparation and administration includes:**
  - Must train staff on infection control P&P
  - Expected to provide role specific education on:
    - Proper hand hygiene, standard and transmission-based precautions, asepsis, sterilization, disinfection, food sanitation, housekeeping, linen care, medical and infectious waste disposal, injection safety, separation of clean from dirty, as well as other means for limiting the spread of infections

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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

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Safe Medication 278 2015

- **Safe medication preparation and administration includes:**
  - Must monitor compliance with all P&P and IC program requirements
  - Must do a program evaluation and make revisions when indicated
  - Need to provide education to patients and visitors about precautions to prevent infections

– CDC and APIC have many free resources

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APIC Brochures

- APIC has a number of educational brochures that hospitals can download and provide to staff and patient 1
- Includes 10 tips to prevent the spread of infection and hand hygiene for patients and one for healthcare workers
- Information to patients is on standard precautions (hand hygiene) and transmission precautions for patients with certain diseases (contact precautions)
- 1www.apic.org/AM/Template.cfm?Section=Education_Resources&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=91&ContentID=8738

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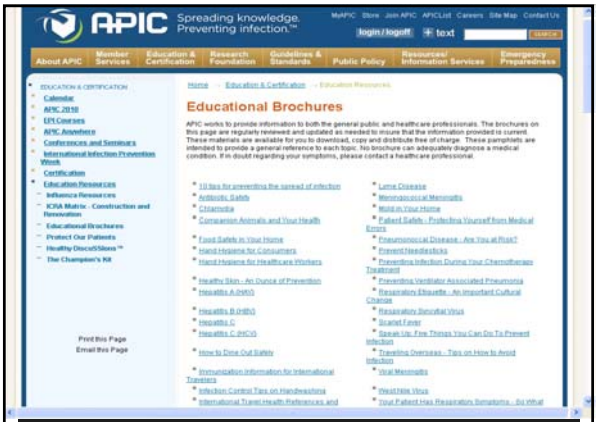
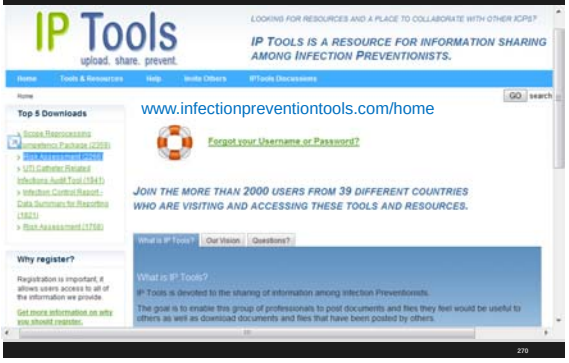


Survey Procedure 278

- Surveyor to make sure there is a qualified IP
- CAH must show how program follows national guidelines and standards
  - Recommend citing sources in P&P
- Will look to make sure hospital is sanitary and hospital performs active surveillance
- Will make sure staff follow standard precautions and have IC education
- Will make sure medications are prepared safely

Risk Assessment Tools from IP Tools



Risk Assessment Tools

Infection Control
RISK ASSESSMENT AND PRIORITIZATION WORKSHEET

Event / Conditions and Problems	What is the potential impact of this condition/problem on patients, staff, and visitors?				What is the probability of this condition/problem impacting patients and staff?				What is your organization's preparedness to deal with this condition / problem?				Numerical risk level
	High (3)	Med (2)	Low (1)	None (0)	High (3)	Med (2)	Low (1)	None (0)	None (3)	Poor (2)	Fair (1)	Good (0)	Total
GEOGRAPHY & COMMUNITY:													
Transportation Mass Casualty													
TB Exposure													
Hurricanes													
Community-Acquired MRSA													
POTENTIAL INFECTION:													
Surgical Site Infection													
Endophthalmitis													
Fusarium													
VRE													

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Risk Assessment Tools

Event / Conditions and Problems	What is the potential impact of this condition/problem on patients, staff, and visitors?				What is the probability of this condition/problem impacting patients and staff?				What is your organization's preparedness to deal with this condition / problem?				Numerical risk level
	High (3)	Med (2)	Low (1)	None (0)	High (3)	Med (2)	Low (1)	None (0)	None (3)	Poor (2)	Fair (1)	Good (0)	Total
Latex risk													
Indoor air contaminates													
Sharps Injury													
Flu Vaccine Non-Compliance													
Compliance with isolation													
Biological Exposure													
Gas or vapor exposure													
Radiation Exposure													
Asbestos Exposure													
ENVIRONMENT:													
Major biohazard spill													
Improper cleaning of environment													
Ineffective pre-construction IC planning (risk													

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Immediate Use Sterilization

- CMS issues a memo on flash sterilization which is now called immediate use sterilization
  - Multiple society went together and named immediate use sterilization; AORN, AAMI, APIC, AAAHC, etc.
- CMS instructs hospitals to follow manufactures recommendation
- Not intended to be used to process items used at a later date
- Intended for immediate use so used during a procedure for which it was sterilized and in manner that minimizes exposure to air and other contaminates

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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

Ref: S&C: 14-44-Hospital/CAH/ASC

DATE: August 29, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings

Memorandum Summary

- ***Change in Terminology: "Flash" Sterilization vs. IUSS:*** Nationally recognized organizations with expertise in infection prevention and control and instrument sterilization processes, and other professional organizations recommend abandoning the use of the term "flash" sterilization, which is now considered outmoded, and replacing it with the term "IUSS."
- ***Update of S&C Memorandum 09-55 Regarding Standards for Immediate Use Sterilization in Surgical Settings:*** This memo reiterates and updates information regarding nationally recognized infection prevention and control guidelines and professionally acceptable standards of practice with respect to immediate use sterilization and supersedes S&C Memorandum 09-55.

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Now Called Immediate-Use Steam

http://www.aorn.org/News/View/03A1334C-ADE2-CF8F-B329DD5F7E9B71B2

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Immediate-Use Steam Sterilization

www.aami.org/publication/standards/ST79_Immediate_Use_Statement.pdf

Immediate-Use Steam Sterilization

"Flash sterilization" has traditionally been used to describe steam sterilization cycles where unwrapped medical instruments are subjected to an abbreviated steam exposure time and then used promptly after cycle completion without being stored. This is in contrast to traditional "terminal sterilization" cycles, where instruments are sterilized within containers, wrappers, or primary packaging designed to maintain the instruments' sterility and allow the devices to be stored for later use. The term "flash" arose out of the abbreviated time of exposure of the unwrapped device.

Today, however, "flash sterilization" is an antiquated term that does not fully describe the various steam sterilization cycles now used to process items not intended to be stored for later use. Current guidelines may require longer exposure times and/or the use of single wrappers or containers designed to allow for aseptic transfer of an item to the point of use. The term "immediate-use steam sterilization" more accurately reflects the current use of these processes. The same critical reprocessing steps (such as cleaning, decontaminating, and transporting sterilized items) must be followed regardless of the specific sterilization cycle employed, a safe process does not include short-cuts or work-arounds.

"Immediate use" is broadly defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item

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Flash Sterilization (Immediate-Use)

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-09-55

DATE: September 4, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Flash Sterilization Clarification - FY 2010 Ambulatory Surgical Center (ASC) Surveys

Memorandum Summary

Flash Sterilization Clarification: State survey agencies (SAs) using the new survey process in FY 2009, including completing the Infection Control Surveyor Worksheet, have experienced challenges in evaluating use of "flash sterilization" by ASCs. Attachment 1 clarifies what this term means, and how to distinguish appropriate from inappropriate use of flash sterilization.

Background

We are clarifying the issue of the Infection Control Surveyor Worksheet and flash sterilization. This is an area in which technological changes require changes in the way surveyors assess compliance of sterilization practices in ASCs. Attachment 1 is a set of bullets the Centers for Medicare & Medicaid Services (CMS) has developed with assistance from the Centers for Disease Control & Prevention and the Food and Drug Administration. They have been informally distributed to FY 2009 ASC-HAI volunteer SAs, and will be reviewed at the October 20-22 surveyor training.

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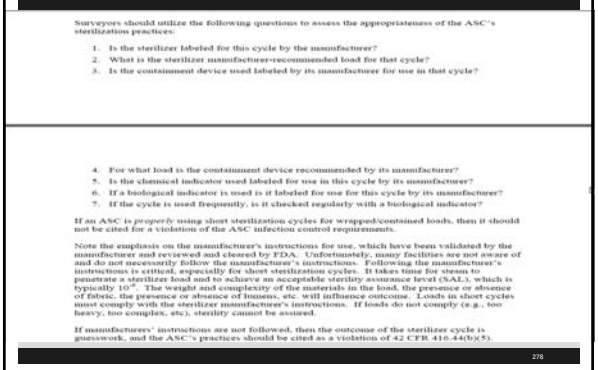
Follow Manufacturer Recommendations



Surveyors should utilize the following questions to assess the appropriateness of the ASC's sterilization practices:

1. Is the sterilizer labeled for this cycle by the manufacturer?
2. What is the sterilizer manufacturer-recommended load for that cycle?
3. Is the containment device used labeled by its manufacturer for use in that cycle?
4. For what load is the containment device recommended by its manufacturer?
5. Is the chemical indicator used labeled for use in this cycle by its manufacturer?
6. If a biological indicator is used is it labeled for use for this cycle by its manufacturer?
7. If the cycle is used frequently, is it checked regularly with a biological indicator?

If an ASC is *properly* using short sterilization cycles for wrapped/contained loads, then it should not be cited for a violation of the ASC infection control requirements.

Note the emphasis on the manufacturer's instructions for use, which have been validated by the manufacturer and reviewed and cleared by FDA. Unfortunately, many facilities are not aware of and do not necessarily follow the manufacturer's instructions. Following the manufacturer's instructions is critical, especially for short sterilization cycles. It takes time for steam to penetrate a sterilizer load and to achieve an acceptable sterility assurance level (SAL), which is typically 10^{-6}. The weight and complexity of the materials in the load, the presence or absence of fabric, the presence or absence of lumens, etc. will influence outcome. Loads in short cycles must comply with the sterilizer manufacturer's instructions. If loads do not comply (e.g., too heavy, too complex, etc), sterility cannot be assured.

If manufacturers' instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the ASC's practices should be cited as a violation of 42 CFR 416.44(b)(5).

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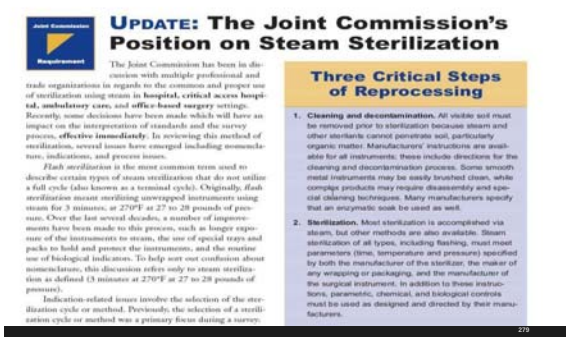
TJC Immediate Use (Steam Sterilization)



Joint Commission Requirement

UPDATE: The Joint Commission's Position on Steam Sterilization

The Joint Commission has been in discussion with multiple professional and trade organizations in regards to the common and proper use of sterilization using steam in **hospital, critical access hospital, ambulatory care,** and **office-based surgery** settings. Recently, some decisions have been made which will have an impact on the interpretation of standards and the survey process, **effective immediately**. In reviewing this method of sterilization, several issues have emerged including nomenclature, indications, and process issues.

Flash sterilization is the most common term used to describe certain types of steam sterilization that do not utilize a full cycle (also known as a terminal cycle). Originally, *flash* sterilization meant sterilizing unwrapped instruments using steam for 3 minutes, at 270°F at 27 to 28 pounds of pressure. Over the last several decades, a number of improvements have been made to this process, such as longer exposure of the instruments to steam, the use of special trays and packs to hold and protect the instruments, and the routine use of biological indicators. To help sort out confusion about nomenclature, this discussion refers only to steam sterilization as defined (3 minutes at 270°F at 27 to 28 pounds of pressure).

Indication-related issues involve the selection of the sterilization cycle or method. Previously, the selection of a sterilization cycle or method was a primary focus during a survey.

Three Critical Steps of Reprocessing

1. **Cleaning and decontamination.** All visible soil must be removed prior to sterilization because steam and other sterilants cannot penetrate soil, particularly organic matter. Manufacturers' instructions are available for all instruments; these include directions for the cleaning and decontamination process. Some smooth metal instruments may be easily brushed clean, while complex products may require disassembly and special cleaning techniques. Many manufacturers specify that an enzymatic soak be used as well.
2. **Sterilization.** Most sterilization is accomplished via steam, but other methods are also available. Steam sterilization of all types, including flashing, must meet parameters (time, temperature and pressure) specified by both the manufacturer of the sterilizer, the maker of any wrapping or packaging, and the manufacturer of the surgical instrument. In addition to these instructions, parametric, chemical, and biological controls must be used as designed and directed by their manufacturers.

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Preventing Surgical Site Infection

How to Use Rapid Cycle Sterilization of Surgical Instruments

"The Joint Commission has decided to refocus its survey efforts on all of the critical processes included in sterilization."

The Joint Commission updated its position on steam sterilization in June 2009. (See The Joint Commission Takes a Second Look at Rapid Cycle Sterilization, page 9, for details.)

National Patient Safety Goal NPSG.07.05.01 requires organizations to implement best practices to prevent surgical site infections (SSI). Sterilization of surgical instruments is a key part of SSI prevention. The most common way to

Joint Commission released a statement updating its position on this type of sterilization.

Rapid cycle sterilization involves a process that begin with physical cleaning and decontamination of the instruments. This process removes

specifically address steam sterilization, the goal states that organizations should implement policies and practices aimed at reducing the risk of surgical site infections that meet regulatory requirements and are aligned with evidence-based standards, such as Centers for Disease Control and Prevention guidelines, and guidelines of other professional organizations. Other Joint Commission standards address sterilization, such as Standard IC.02.02.01 which requires organizations to reduce the risk of infections associated with medical equipment, devices, supplies; and EC.02.04.03, which requires organizations to conduct performance testing and maintenance for all of its sterilizers.

Organizations should also ensure that the appropriate staff members understand its policies related to surgical site infections, including rapid cycle sterilization of surgical instruments.

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Thanks for attending!

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