Tuesday September 29, 2015

Ambulatory Surgery Centers: Infection Control Standards & Safe Injection Practices from CMS

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Objectives

- Explain the necessity for the ASC in-house policy on safe injection practices.
- Describe how to best communicate these mandatory infection control standards and safe injection practices to new-employees during their on-boarding/orientation training.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

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You Don't Want One of These

Introduction to the CMS CfCs on Infection Control

Conditions for Coverage (CFC)

- CMS published **Conditions For Coverage** (CfC) for Ambulatory Surgical Centers or ASC
- Similar to Conditions of Participation or CoPs published for hospitals
- ASC facilities that accept Medicare payment
  - Must follow the CfC regulations for all patients
  - Not just for Medicare or Medicaid patients
  - Don't forget the Infection Control Worksheet

ASC Interpretive Guidelines

- CMS posted many revisions since May 15, 2009
- Current manual is dated April 1, 2015
  - First publishes in Federal Register
  - Next publishes the interpretive guidelines
  - Some standards have a survey procedures which are like the test questions to the test
- Renumbered the tag numbers and 151 pages (Q tag numbers 001-267)
  - Infection control worksheet (Exhibit 351) not attached to interpretive guidelines but form is available off the CMS website and periodically updated
- Available on CMS website[1]

[1]www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

2 Policy memos at www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

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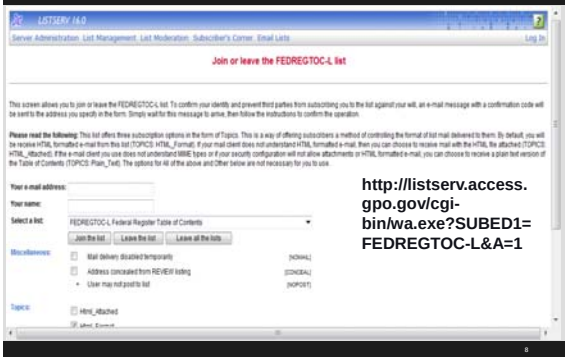
Subscribe to the Federal Register Free



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

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CMS ASC CFC Manual

State Operations Manual
Appendix L - Guidance for Surveyors: Ambulatory Surgical Centers

Table of Contents
(Rev. 137, 04-01-15)

Transmittals for Appendix L

Part I - Ambulatory Surgical Center Survey Protocol

Introduction

Regulatory and Policy References

Tasks in the Survey Protocol

Task 1 – Off-Site Survey Preparation
Task 2 – Entrance Activities
Task 3 – Information Gathering/Investigation
Task 4 – Preliminary Decision Making and Analysis of Findings
Task 5 – Exit Conference
Task 6 – Post-Survey Activities

www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_Appendixtoc.pdf

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CMS Rewrites ASC Manual in 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 02-12-25
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_37.pdf

Center for Medicaid and State Operations/Survey and Certification Group

DATE: May 15, 2009

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: State Operations Manual (SOM) Appendix L, Ambulatory Surgical Centers (ASC) Comprehensive Revision

Memorandum Summary

- New ASC Conditions for Coverage (CfCs) take effect on May 18, 2009.
- SOM Appendix L has been revised:
  - Part 1, Survey Protocol has been added.
  - The Interpretive Guidelines have been extensively updated to reflect the new and revised CfCs, as well as to provide more detailed guidance for existing CfCs. Feedback on this guidance is welcome; as needed, further refinements will be made in the future.
- ASPEN Tags for ASC surveys have been revised and renumbered. ASPEN surveyor kits with the new tags and regulatory text will be available shortly after May 18th.

On November 18, 2008 the Centers for Medicare & Medicaid Services (CMS) adopted the Hospital Outpatient Prospective Payment System final rule (73 FR 68502). The final rule included revisions to the ASC CfCs in 42 CFR 416.2 – 416.52 that take effect on May 18, 2009.

Original ASC Infection Control Worksheet

Attachment 2

Exhibit 351

INFECTION CONTROL SURVEYOR WORKSHEET

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (e.g., the staff person responsible for sterilization should answer the sterilization questions).

A minimum of one surgical procedure must be observed during the site visit, unless the ASC is a low volume ASC with no procedures scheduled during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases.

When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS 2567 when deficient practices are observed.

PART 1 - ASC CHARACTERISTICS

1) ASC name: _____

2) Address: _____

_____

State: _____

3) 10-digit CMS Certification Number: _____

4) What year did the ASC open for operation? _____

5) Please list date(s) of site visit: _____ (mm/dd/yyyy) to _____ (mm/dd/yyyy)

6) What was the date of the most recent previous federal (CMS) survey: _____ (mm/dd/yyyy)

7) Does the ASC participate in Medicare via accredited "deemed" status? 1 ☐ YES 2 ☐ NO

7a) If YES, by which CMS-recognized accreditation organization? (Check only ONE):

1 ☐ Accreditation Association for Ambulatory Health Care (AAAHC)
2 ☐ American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)

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Conditions for Coverage (CFC)

- All CMS manuals found at website[1]
- Appendix **L** in the State Operations Manual Section 1832 of SSA ASC must meet quality and safety standards
- They are **Q** standards and Infection Control section starts at Q-0240
- Every ASC should have a copy of this
- Consider placing it on your intranet or making it available on all units

[1] http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf

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Location of CMS Hospital CoP Manuals

Medicare State Operations Manual
Appendix

- 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

CMS Hospital CoP Manuals new address
www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

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

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I	Life Safety Code	140 KB
J	Intermediate Care Facilities for Persons With Mental Retardation	1,810 KB
K	Comprehensive Outpatient Rehabilitation Facilities	202 KB
L	Ambulatory Surgical Services Interpretive Guidelines and Survey Procedures	263 KB
M	Hospice	720 KB
N	Pharmaceutical Service Requirements in Long-Term Care Facilities	Deleted
P	Survey Protocol for Long-Term Care Facilities	929 KB
PP	Interpretive Guidelines for Long-Term Care Facilities	1,440 KB
Q	Determining Immediate Jeopardy	326 KB
R	Resident Assessment Instrument for Long-Term Care Facilities	38 KB

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Sample Page from ASC CfC Manual

Q-0240
(Rev. 56, Issued: 12-30-09, Effective/Implementation: 12-30-09)

§416.51 Condition for Coverage – Infection control

The ASC must maintain an infection control program that seeks to minimize infections and communicable diseases.

Interpretive Guidelines: §416.51

This regulation requires the ASC to maintain an active program for the minimization of infections and communicable diseases. The National Institute of Allergy and Infectious Diseases (NIAID) 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. (See NIAID website glossary)

The ASC's infection control program must:

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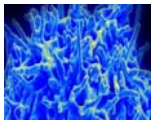
CMS ASC Infection Control Worksheet



Updated Infection Control Worksheet

- CMS issued survey memo on June 26, 2015
- Announced revisions to the infection control worksheet
- Revised to bring the worksheet into compliance with accepted standards of practices
- Also to reflect currently released guidance
- Also to clarify questions that were being asked of the past worksheet

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CMS Memo Revising IC Worksheet

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: 15-43-ASC

DATE: June 26, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)

Memorandum Summary

- *ASC Infection Control Surveyor Worksheet Revisions*: The Centers for Medicare & Medicaid Services (CMS) has made minor revisions to the Infection Control Surveyor Worksheet, Exhibit 351 of the State Operations Manual (SOM) for assessing compliance with the Medicare ASC Infection Control Condition for Coverage (CfC).
- *Change:* Revisions were made to bring the worksheet into alignment with current accepted standards of practice; reflect recently released guidance; and improve the clarity of certain questions. The worksheet is used by State and Federal surveyors on all survey activity in ASCs when assessing compliance with the infection control CfC.

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Revised IC Worksheet 17 Pages

Exhibit 351

Ambulatory Surgical Center (ASC) **INFECTION CONTROL SURVEYOR WORKSHEET**

(Rev: 142, Issued: 07-17-15, Effective: 07-17-15, Implementation: 07-17-15)

Name of State Agency or AO (please specify) _____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest (*e.g.*, the staff person responsible for sterilization should answer the sterilization questions). A minimum of one surgical procedure must be observed during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases. When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.

PART 1 – ASC CHARACTERISTICS

1. ASC Name _____

2. Address, State and Zip Code _____ Address

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CMS ASC Infection Control Worksheet

The following are sections discussed in the worksheet:

- Infection control program requirements
  - Must follow nationally recognized standards
- Qualified infection preventionist
  - Enough hours to direct program
- System to identify infections related to procedures
- Reporting system to state health agency
- Training of staff in orientation and annually

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CMS ASC Infection Control Worksheet

- Hand hygiene requirements
  - Direct care givers do not wear artificial fingernails
- Safe injection practices
- Single use devices, sterilization and high level disinfection
  - Chemical indicator in every load and weekly biological indicator for each sterilizer and every load of implantable items
- Immediate use steam sterilization (IUSS)
- Environmental infection control

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The CMS Infection Control Pilot

- When CMS first piloted the IC worksheet in 2008 in 67 ASFs and current version 7-17-15
- 68% had lapses in at least one IC category
- 18% has lapses in three or more of the five categories
  - Handling of blood glucose monitoring equipment, safe injection practices, equipment reprocessing and handling, hand hygiene, and environmental cleaning

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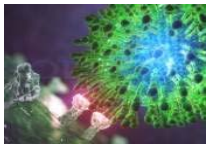
CMS Survey Memos on Infection Control



CMS Policy and Memo Website

- Check the CMS website for updates
  - Consider doing this every month especially the survey and certification memos
  - Assign responsibility to one person
  - Check below website once a month
- Website includes information on CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices

Source: http://www.cms.hhs.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

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CMS Policy & Memo to States

Policy & Memos to States and Regions

CMS Survey and Certification memoranda, guidance, clarifications and instructions to State Survey Agencies and CMS Regional Offices. www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

Show entries: 10

Filter On:

Title	Memo #	Posting Date	Fiscal Year
Final Rule: SNF Medicare FY 2016 Payments, Quality Reporting, Value-Based Purchasing and Staffing Data Collection Requirements – Informational Only	15-49-NH	2015-08-07	2015
Publication of Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities; Proposed Rule (CMS-3260-P) – Informational Only	15-46-NHs	2015-07-17	2015
Medication-Related Adverse Events in Nursing Homes	15-47-NH	2015-07-17	2015
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) Appendix J, Part II - Clarifications to the Interpretive Guidance at Tag W167 for §483.430(d)(3)	15-48-ICF/IID	2015-07-17	2015
Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)	15-43-ASC	2015-06-26	2015
Use of Portable Reverse Osmosis (RO) Units and Block Carbon	15-44-ESRD	2015-06-26	2015

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Example of a Survey Memo Informed Consent

Ref: S&C-11-21-ASC

DATE: **April 8, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarifications to the Ambulatory Surgical Center (ASC) Interpretive Guidelines, State Operations Manual Appendix L – Obtaining consent before observing surgical procedures

Memorandum Summary

ASCs may not limit surveyor ability to observe patient care and surveyors are not required to:

- Sign documents or provide proof of vaccinations in order to observe a surgical procedure.
- Obtain the consent of the operating physician prior to observing a surgical procedure.

Surveyors will:

- Obtain patient's consent.
- Conduct themselves in a manner that protects patient safety and that does not interfere with the operating physician or procedure.

It has come to our attention that some ASCs are attempting to require surveyors satisfy certain

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CRE and ERCP 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

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.

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SAFE Injections in ASCs

Survey & Certification - General Information

- Overview
- Spotlight
- CLIA
- Contact Information
- Background Check Pilot Program
- Revisit User Fee Program
- Accreditation
- Policy & Memos to States and Regions

Policy & Memos to States and Regions

Details for Safe Injection Practices in Ambulatory Surgical Centers (ASCs)

Return to List

Shown below are the details for the item you selected from the list.

Title	Safe Injection Practices in Ambulatory Surgical Centers (ASCs)
Memo #	08-20
Posting Date	05/16/2008
Fiscal Year	2008
Summary	Recently the State of Nevada and federal epidemiologists identified a cluster of hepatitis C infections where the infected individuals all had procedures in the same ASC. Subsequent survey of that ASC identified unsafe injection practices. The Centers for Disease Control and Prevention (CDC) has developed pertinent information on safe injection practices. State Agencies (SAs) should disseminate this information to certified ASCs in their States, and should also ensure that all surveyors who conduct ASC surveys are familiar with this material.

Survey and Cert Letter 08-20 (PDF, 1.4 MB)

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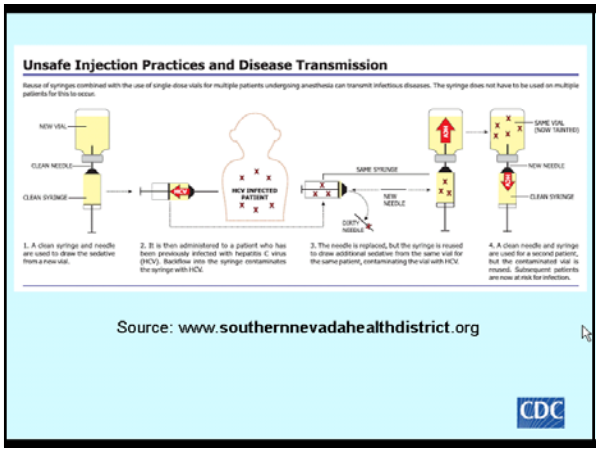

Source: www.southernnevadahealthdistrict.org

CDC

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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Safe Injection Practices 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: 12-35-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 "SDV's") 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 drugs 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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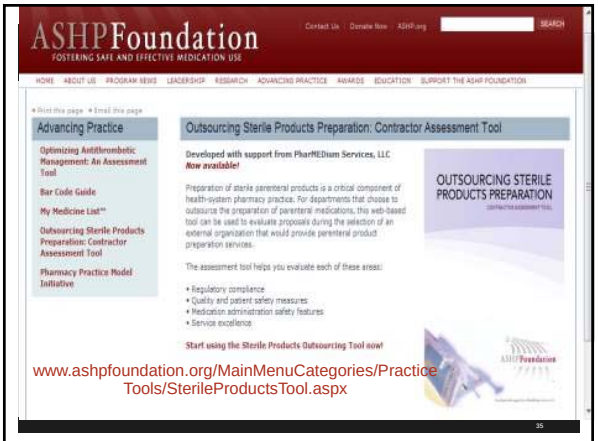

www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx

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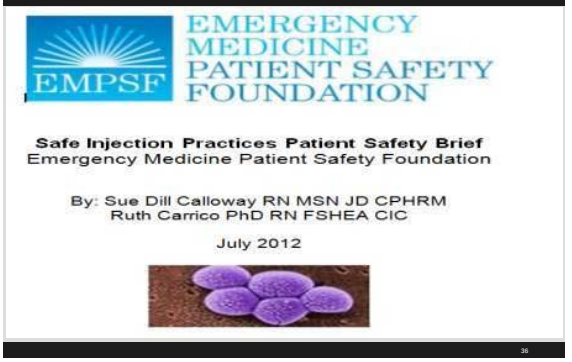
Safe Injection Practices



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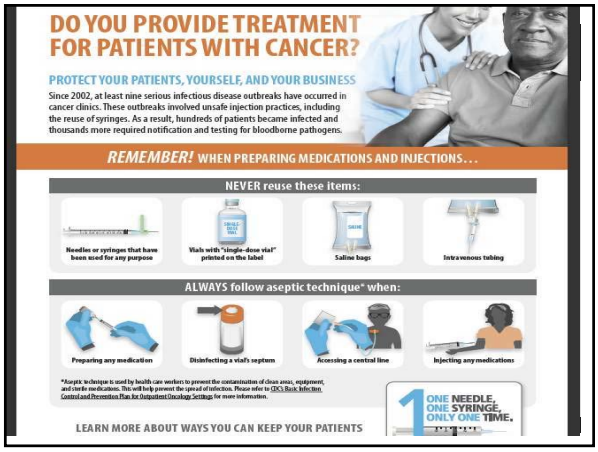
Not All Vials Are Created Equal



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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CMS Memo May 30, 2014

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

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Infection Control Breaches

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: 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

- If any of the listed breaches are observed, then will take appropriate enforcement action
- And will make the public health authority aware
  - Includes LTC, ASCs, hospice, hospitals, home health agencies, CAH, rural health clinics and dialysis facilities
- CDC is working closely with SA on HAI prevention
- List of breaches to be referred include:
- Using the same needle for more than one individual;

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CMS Memo Infection Control Breaches

- Using the same (pre-filled/manufactured/insulin or any other) syringe, pen or injection device for more than one individual
- Re-using a needle or syringe which has already been used to administer medication to an individual to subsequently enter a medication container (e.g., vial, bag), and then using contents from that medication container for another individual
- Using the same lancing/fingerstick device for more than one individual, even if the lancet is changed

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CMS Memo on Insulin Pens

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

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Insulin Pens

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

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html

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

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CDC Has Flier on Insulin Pens

CDC CLINICAL REMINDER

Insulin Pens
Must Never Be Used for More than One Person

Summary

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

Background

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

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

Recommendations

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Insulin Pen Posters and Brochures Available

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

About the Campaign | Safe Injection Practices | Healthcare Provider Information | Patient Information | Campaign Resources | News | Contact Us

Insulin Pen Safety – One Insulin Pen, One Person

BE AWARE
DON'T SHARE

ONE INSULIN PEN, ONLY ONE PERSON

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

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

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

- Poster
- Brochure

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

Additional Resources

- VA Patient Safety Alert: Multi-Dose Pen Injection (Department of Veterans Affairs, January 2013).

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CMS Memo Humidity in the OR

- CMS issues memo related to the relative humidity (RH) on April 19, 2013
  - 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
  - Tag 60 and 101 in ASC manual
- 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

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Humidity in Anesthetizing Areas

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: 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:***
  - When 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, L, 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

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: 15-27-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=1331564405&message_id=8653272&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 periOperative 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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HHS Action Plan

- HHS estimated that HAIs incur nearly $20 billion in excess healthcare cost each year
  - Many are preventable
- Top priority of HHS now and CMS is under HHS
- Develop HHS Action Plan to Prevent HAIs
- Every infection preventionist (IP) should have a copy of this document
- HHS get a billion dollars to enforce IC and has a video every healthcare practitioner should see
  - Partnering to heal video at http://www.hhs.gov/partneringtoheal

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

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Video on Preventing HAI

State Specific ASC Regulations

- Many states have state specific regulations on freestanding ASCs
- Every ASC should be familiar with their state specific law
  - For example, Ohio has OAC 3701-83, amended 6/8/09[1]
  - Most all states have their ASC rules accessible on the internet
  - Provide citation to all your policies to both the CFC and state law provision

[1] http://www.odh.ohio.gov/rules/final/finalRules.aspx

CMS Resources

- CMS has website on Ambulatory Surgical Center[1]
- CMS has other resources on ASC
  - Medicare Learning Network (MLN) Spotlights
  - ASC Transmittals
  - Join ASC Mailing list
  - Join the Open door forum
  - ASC Internet only manuals
  - ASC Payment website[2]

[1] http://www.cms.hhs.gov/center/asc.asp
[2] http://www.cms.hhs.gov/ASCPayment/

Conditions for Coverage (CFC)

- Sign up for ASC Open Door Forums to stay informed on changes to ASC
- This is a free service by CMS
- Consider taping it and then administrator can listen and direct relevant sections to the appropriate staff
- Generally CMS does not have an outline of what is discussed in the open door forum
- CMS has an ASC website with resources

Source: http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html

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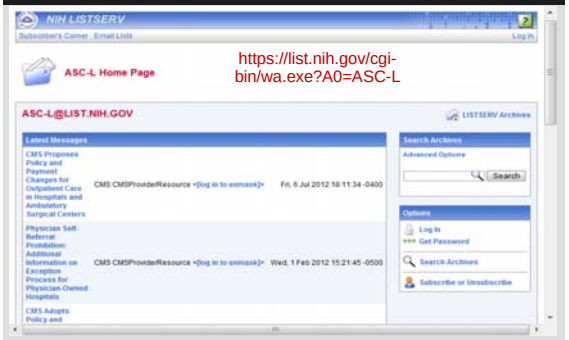
Join ASC Listserv Policies and Information



https://list.nih.gov/cgi-bin/wa.exe?A0=ASC-L

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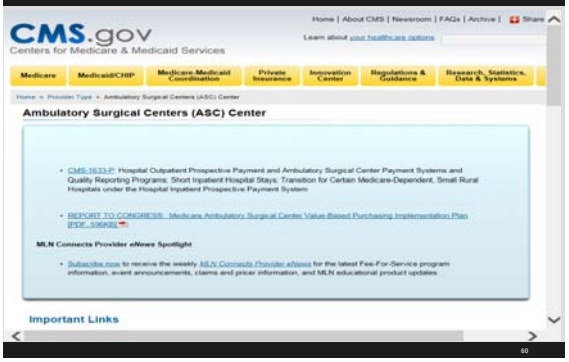
CMS Ambulatory Surgical Center



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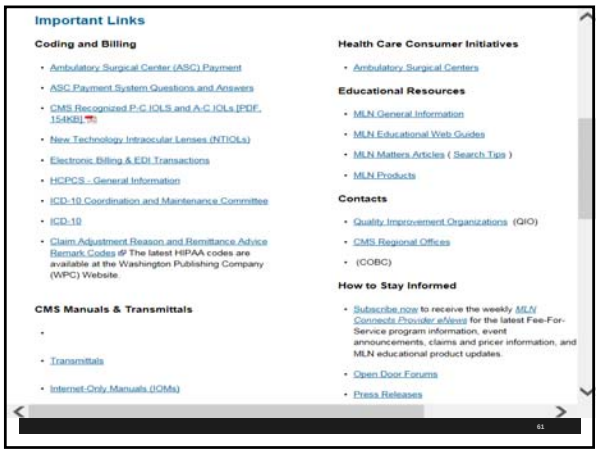
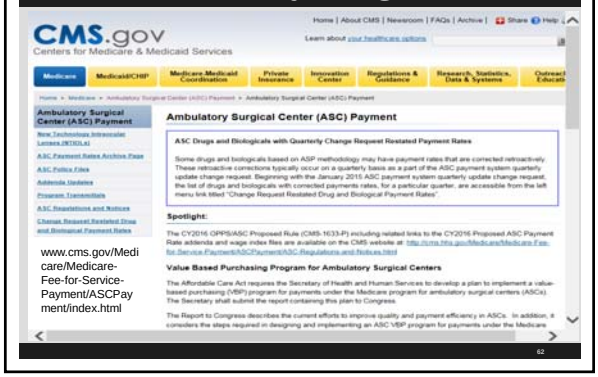
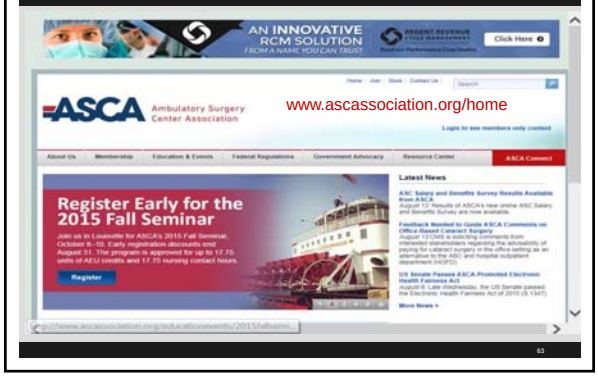


CMS Ambulatory Surgical Center



www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/index.html

National ASCA Association



www.ascassociation.org/home

CDC's Ebola Website

Approved Accreditation Agencies

- There are four Medicare approved accreditation agencies for ASCs for deemed status
  - The Joint Commission (TJC)
  - American Association for Accreditation of Ambulatory Surgical Facilities (AAAASF)
  - Accreditation Association for Ambulatory Health Care (AAAHC)
  - American Osteopathic Association (AOA) or Healthcare Facility Accreditation program (HFAP)

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CFC or the CoPs?

- Hospital elects for ASC to operate as a department of the hospital (CoPs) or decides to be paid as a ASC (CFC)
- Hospitals that operate a freestanding ASC as a department of the hospital follows the CMS CoPs
  - 510 pages long with tag numbers from 0001 to 1164
  - Radiology section changed in 2013 and no longer the same in CoP and CFC

[1] http://edocket.access.gpo.gov/2008/pdf/E8-26212.pdf

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CMS Oversight of Infection Control

- CMS pilot show poor infection control standards
- This is why CMS gets a $50 million dollar grant and $10 million for ASCs so surveyors more knowledgeable
- Part 2 of the infection control worksheet is to provide detailed guidelines for assessing if the ASC has a sanitary environment
- CMS had mandatory training for ASC surveyors and heavy focus on the infection control standards and work sheet
  - Focus on instrument reprocessing also

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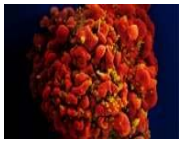
Best Practices HAIs in Ambulatory Surgery



Best Practices HAIs in Ambulatory Surgery

- CMS requires ASCs to follow national standards of care and practice
- This is why best practices and evidenced based practice is important to implement in the ASC
- PPSA publishes use of evidence-based practices for prevention of HAIs in ambulatory surgery in 2013
- Infection control plan should be updated annually
- A structured education and competency program is implemented to integrate knowledge at the bedside
- Process and outcome measures are evaluated

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Top Five Surgical Site Infections

Table 1. Top Five Infection Sites for Surgical Site Infections (SSIs), as Reported to the Pennsylvania Patient Safety Authority, March 2004 through July 2012

SURGICAL SITE	NO. OF SSIs	PROCEDURE WITH HIGHEST NO. OF SSIs (n)
Knee or shoulder joint	86	Arthroscopy/rotator cuff repair (41)
Ankle or foot	83	Bunionectomy (28)
Eye	79	Cataract surgery (40)
Abdomen	52	Hernia repairs (22)
Hand or wrist	49	Carpal tunnel surgery (15)

Pennsylvania Patient Safety Advisory Page 1

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Best Practices HAIs in Ambulatory Surgery

SAFETY

Monitoring the Use of Evidence-Based Best Practices for Prevention of Healthcare-Associated Infections (HAIs) in Ambulatory Surgery

Monitoring compliance with best practices aimed at preventing HAIs is fundamental to improvement. This sample tool is designed to assess facility best-practice strategies and compliance in five categories: surveillance techniques, standardized educational programs, safe injections and point-of-care devices, sterilization and high-level disinfection, and environmental infection control. This tool provides assessment questions consistent with current infection control guidelines and may be adapted or revised as per facility policy. This tool can also be used to identify barriers to implementation of best practices at the bedside and to identify gaps in the effectiveness of the infection control program.

This tool can be used to assist an ambulatory surgical facility with assessment and process monitoring of the level of implementation of current evidence-based best practices. Questions in each category are assessed based on their consistency with the guidelines and on the following elements:

- Infection control goals are consistent with the infection control plan and are updated at least annually.
- Policies and procedures are up to date and reviewed annually.
- A structured educational/competency program is implemented to integrate knowledge into practice at the bedside.
- Sufficient resources are provided to enable staff compliance with policies.
- Process and outcome measures are evaluated and reviewed by the quality assurance and process improvement committee.
- Accountability is assigned for administrative support, resources, and implementation of best-practice strategies.

Application Considerations

- Facility self-assessment: This tool can be used by the facility to evaluate the current level of best-practice implementation.
- Clinical observation: Multiple items can be evaluated by clinical observation or simulation.
- Staff interview: Questions can be answered verbally, prior to clinical observation of actual practice.
- Record review: Ensure documentation of each category in the medical record, policy manual, and education records.

Sources

- A complete list of current guidelines for each category is located on the last page of the assessment tool.

Directions for Use

- In the implementation category cells next to each of the individual practices listed, enter the score for level of implementation (2, 1, or 2).
- In the remediation plan column, describe the action to improve scores less than 100%.

http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/Documents/2013_prepubtool_assessment.pdf

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SAFETY

Ambulatory Surgical Facility Infection Control Practice Assessment

Scoring: 2 = 100% implemented; 1 = Partially implemented; 0 = Not implemented

	BEST PRACTICES	IMPLEMENTATION CATEGORIES: Infection control plan and goals	Policies and Procedures	Education/competency program	Resources	Accountability assigned	Monitoring of processes and outcomes assigned	REMEDIATION PLAN
	I. SURVEILLANCE							
1	Postoperative surgical site infections (SSIs) are actively identified and tracked.	•	•	•	•	•	•	
2	There is written documentation confirming tracking of SSIs.	•	•	•	•	•	•	
3	The facility complies with state notifiable disease reporting requirements.	•	•	•	•	•	•	
4	SSI tracking information is shared with facility clinicians.	•	•	•	•	•	•	
	II. STANDARDIZED EDUCATION							
1	A designated, licensed healthcare professional directs the infection control program.	•	•	•	•	•	•	
2	The healthcare professional directing infection control has received formal training in infection control and prevention.	•	•	•	•	•	•	
3	All facility staff receive ongoing, job-specific infection control education.	•	•	•	•	•	•	
4	The infection control education includes all licensed medical							

Safe Injections and Point of Care Devices

	BEST PRACTICES	IMPLEMENTATION CATEGORIES: Infection control plan and goals	Policies and Procedures	Education/competency program	Resources	Accountability assigned	Monitoring of processes and outcomes assigned	REMEDIATION PLAN
2	The rubber septum is scrubbed with alcohol and dried prior to puncture.	-	-	-	-	-	-	
3	Injections are prepared in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment.	-	-	-	-	-	-	
4	Needles, syringes, prefilled syringes, and insulin pen cartridges are used for only one patient.	-	-	-	-	-	-	
5	Single-dose and multidose dose vials are always entered with a new needle and a new syringe, even for the same patient.	-	-	-	-	-	-	
6	Manufactured prefilled syringes, single-dose vials, ampoules, and intravenous solutions are used for only one time, for one dose, and for one patient.	-	-	-	-	-	-	
7	Medication administration tubing and connectors are used for only one patient.	-	-	-	-	-	-	
8	Multidose vials are dated when opened or punctured and discarded within 28 days or per manufacturer's instructions for an expiration date after opening, whichever is first.	-	-	-	-	-	-	
9	Multidose vials used on multiple patients are kept in a centralized, clean medication area and do not enter the immediate patient treatment area.	-	-	-	-	-	-	
10	Single-dose vials are discarded within one hour of opening or puncturing.	-	-	-	-	-	-	
11	Glucose meters are cleaned and disinfected after each patient.	-	-	-	-	-	-	

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	BEST PRACTICES	IMPLEMENTATION CATEGORIES: Infection control plan and goals	Policies and Procedures	Education/competency program	Resources	Accountability assigned	Monitoring of processes and outcomes assigned	REMEDIATION PLAN
IV.	STERILIZATION AND HIGH-LEVEL DISINFECTION***							
1	Items are precleaned according to manufacturer's directions or evidence-based guidelines.	-	-	-	-	-	-	
2	Semicritical equipment, such as laryngoscope blades and respiratory therapy equipment, that contacts nonintact skin or mucosa is high-level disinfected.	-	-	-	-	-	-	
3	Critical equipment that enters sterile tissue or the vascular system, such as surgical instruments or implants, is sterilized.	-	-	-	-	-	-	
4	Medical devices and instruments are visually inspected for residual soil and recleaned if necessary before packaging and sterilization.	-	-	-	-	-	-	
5	Documentation of chemical, biological, and mechanical indicators is completed.	-	-	-	-	-	-	
6	Items are contained, handled, and stored in a manner to avoid compromised sterility.	-	-	-	-	-	-	
7	Sterile packages are inspected for integrity.	-	-	-	-	-	-	
8	Documentation is in place that chemicals for high-level disinfection are prepared, tested, and replaced according to manufacturer's instructions.	-	-	-	-	-	-	
9	Instruments undergoing high-level disinfection are disinfected for the appropriate length of time and at the appropriate temperature and allowed to dry as specified by manufacturer or evidence-based guidelines.	-	-	-	-	-	-	

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Best Practices HAIs in Ambulatory Surgery

- PPSA had 733 events related to HAI surgical site infections and sterilization issues
  - From March 2004 to July 2012
  - Looked at adverse events classified as infections due to procedural complications, breaks in sterile technique, and sterilization problems due to equipment, supplies, or devices
  - 84% of the 733 infection control related events
  - Positive cultures in 43% of the 613 SSI event reports with Staph accounting for 59%
  - 16% due to sterilization problems with equipment, devices, surgical supplies or breaks in sterile technique

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FOCUS ON INFECTION PREVENTION

Ambulatory Surgical Facilities: Strategies to Integrate Basic Infection Control Concepts into Clinical Practice

Sharon Bradley, RN, CIC
Senior Infection Prevention Analyst
Pennsylvania Patient Safety Authority

ABSTRACT

In the last decade, the Centers for Medicare and Medicaid Services and the Centers for Disease Control and Prevention conducted investigations of national outbreaks of viral and bacterial infections and assessments of infection control practices in ambulatory surgical facilities (ASFs) across the country. Lax infection control practices were found to be widespread in ASFs, mostly due to clinicians misunderstanding or disregarding the standards of care. From March 2004 through July 2012, Pennsylvania ASFs reported 733 events related to healthcare-associated surgical site infections (SSI) and sterilization errors through the Pennsylvania Patient

BACKGROUND

Since 2001, more than 150,000 patients in the United States have been exposed to viral and bacterial pathogens as a result of unsafe infection control and injection practices in ambulatory surgical facilities (ASFs), resulting in infectious outbreaks of meningitis, hepatitis, rectal abscesses, and joint infections.[1] These numbers may represent only a fraction of actual cases. Many outbreaks and sporadic transmissions associated with ASFs go unrecognized because patients may be treated for the infection in a physician office or a hospital, and some diseases (e.g., hepatitis) have long incubation periods.[1,2] Outbreaks have been identified in hospital and nursing home settings; however, outbreaks with the most widespread impact have occurred in outpatient settings.[2] Results of outbreak investigations by the Centers for Disease Control and Prevention (CDC)[3,4] and, more recently, national surveys by departments of health[5,6] point to lax infection control practices in ASFs, mostly due to clinicians' misunderstanding or disregarding the standards of care.[7]

In response to these outbreaks, in 2008, the Centers for Medicare and Medicaid Services (CMS) developed and piloted the Infection Control Surveyor Worksheet in ASFs in three states, assessing compliance with five categories of infection control.[8] Of the 68 ASFs inspected, 68% (n = 46) had lapses in at least one infection control category. Surveyors found that 18% (n = 12) had lapses in three or more of the following five categories: handling of blood glucose monitoring equipment, safe injection practices, equipment reprocessing and handling, hand hygiene, and environmental cleaning.[8]

In Pennsylvania, ASFs are required to report to the Pennsylvania Patient Safety Authority through its Pennsylvania Patient Safety Reporting System (PA PSRS) adverse events classified as infections due to procedural complications, breaks in sterile technique, and sterilization problems due to equipment, supplies, or devices.[9,10] From March 2004

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What They Found

- The flush step in the sterilization process of cleaning colonoscopes was omitted. All staff were reeducated to the endoscopy cleaning process.
- The nurse noticed 20 minutes into a case that the indicator in the arthroscopy instruments had not changed color to indicate that sterilization had occurred.
- It was noted that the antireflux valve was missing from the 24-hour tubing.
- At the end of the day the tech collecting autoclave sheets discovered that the set of instruction had been put in the autoclave and not run so unsterilized instruments were used on the patient.

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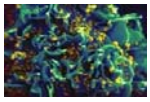
The CMS CfCs for Infection Control



Infection Control Q-0240

- There are many sections on infection control in the CFC manual
- Infection control is a very important section and is being hit hard in the surveys
  - CMS got a $50 million dollar grant to enforce infection control standards and HHS 1 billion so surveyors are better educated
- Issue receiving interest after ASCs in Nevada were found to have multiple problems
  - 40,000 patients had to be tested who were seen over 4 yr period
  - The reuse of syringes having colonoscopies caused patients to get HIV, Hepatitis B and C

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MMWR Weekly

May 16, 2008 / 57(19);513-517

Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic --- Nevada, 2007

On January 2, 2008, the Nevada State Health Division (NSHD) contacted CDC concerning surveillance reports received by the Southern Nevada Health District (SNHD) regarding two persons recently diagnosed with acute hepatitis C. A third person with acute hepatitis C was reported the following day. This raised concerns about an outbreak because SNHD typically confirms four or fewer cases of acute hepatitis C per year. Initial inquiries found that all three persons with acute hepatitis C underwent procedures at the same endoscopy clinic (clinic A) within 35--90 days of illness onset. A joint investigation by SNHD, NSHD, and CDC was initiated on January 9, 2008. The epidemiologic and laboratory investigation revealed that hepatitis C virus (HCV) transmission likely resulted from reuse of syringes on individual patients and use of single-use medication vials on multiple patients at the clinic. Health officials advised clinic A to stop unsafe injection practices immediately, and approximately 40,000 patients of the clinic were notified about their potential risk for exposure to HCV and other bloodborne pathogens. This report focuses on the six cases of acute hepatitis C identified during the initial investigation, which is ongoing; additional cases of acute hepatitis C associated with exposures at clinic A might be identified. Comprehensive measures involving viral hepatitis surveillance, health-care provider education, public awareness, professional oversight, licensing, and improvements in medical devices can help detect and prevent transmission of HCV and other bloodborne pathogens in health-care settings.

MRSA Safe Injection Practices July 13, 2012

www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm?s_cid=mm6127a1_w

Centers for Disease Control and Prevention MMWR Morbidity and Mortality Weekly Report

Weekly / Vol. 61 / No. 27 July 13, 2012

Invasive *Staphylococcus aureus* Infections Associated with Pain Injections and Reuse of Single-Dose Vials — Arizona and Delaware, 2012

Transmission of life-threatening bacterial infections can occur when health-care personnel do not adhere to Standard Precautions and instead use medication in containers labeled as single-dose or single-use for more than one patient (*1*). This report summarizes the investigation of two outbreaks of invasive *Staphylococcus aureus* infection confirmed in 10 patients being treated for pain in outpatient clinics. In each outbreak, the use of single-dose or single-use vials (SDVs) for more than one patient was associated with infection transmission. In both investigations, clinicians reported difficulty obtaining the medication type or vial size that best fit their procedural needs. These outbreaks are a reminder of the serious consequences that can result when SDVs are used for more than one patient. Clinician adherence to safe injection practices, particularly when appropriately sized SDVs are unavailable, is important to prevent infection transmission. If SDVs must be used for more than one patient, full adherence to *U.S. Pharmacopeia* standards is critical to minimize the risks of multipatient use.

Pain Management Clinic — Arizona

On April 8, 2012, the Arizona Department of Health Services was notified of a patient with acute mediastinitis with blood and pleural fluid cultures positive for methicillin-resistant *Staphylococcus aureus* (MRSA). The report indicated this patient and two other patients with culture-confirmed invasive MRSA infections had undergone procedures recently patients: two new syringes were used to withdraw 5 mL each from a 10 mL SDV of contrast medium (300 mgI/mL) and a 10 mL SDV of saline solution. The contents from each syringe then were transferred to the alternate vial, resulting in two 10 mL vials of diluted contrast solution, one for use in the morning and one reserved for the afternoon. Among patients receiving contrast on the day of the outbreak, six received injections from the morning vial and four from the afternoon vial. All of the patients with MRSA infections received diluted contrast from the afternoon vial.

The three patients with MRSA infections went to a local hospital 4–8 days after their outpatient pain remediation procedures. They required inpatient care for severe infections, including acute mediastinitis, bacterial meningitis, epidural abscess, and sepsis. Hospitalization ranged from 9 to 41 days, with additional long-term acute care required for one patient. The fourth recipient of diluted contrast from the afternoon vial was found deceased at home, 6 days after treatment at the clinic. The cause of death was reported as multiple-drug overdose; however, invasive MRSA infection could not be ruled out.

Samples from six unopened vials of contrast medium from the lot in use by the facility at the time of the outbreak were sent to CDC for analysis. No intrinsic contamination was identified using standard bacterial culture methods. Unopened vials of saline were not cultured because the lot in use at the time of the outbreak was not available and saline was routinely used

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Unsafe Injection Practices Outbreaks

Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic — Nevada, 2007

Outbreak of *Burkholderia cepacia* Bloodstream Infection at an Outpatient Hematology and Oncology Practice

Transmission of Hepatitis B and C Viruses in Outpatient Settings — New York, Oklahoma, and Nebraska, 2000–2002

Outbreak of *Serratia marcescens* Bloodstream and Central Nervous System Infections After Interventional Pain Management Procedures

75% of ASCs Cited in Infection Control

- July 2010 article states 75% of ASCs in one state received infection control citations
  - Reusing single use devices
  - Improper surgical attire
  - No infection control training (including training physicians)
  - OR nurse wearing ring
  - Doctor whose mask was not tied
  - Nurse picks up something off the OR floor and doesn't reglove
  - Instrument in OR on mayo stand after room cleaned

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Outpatient Surgery

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Oct. 27 - 29, 2010

Home > News > July, 2010

More Than 75% of Ill. Surgery Centers Cited in Infection Control Inspections

Dropped instruments and contaminated hands are among the lapses cited in state reports.

An OR nurse picks something off the floor mid-procedure, discards it, and then returns to work without washing her hands. A dropped surgical instrument is picked up, placed on a clean table and left there -- even after the case is over and the room is cleaned. A surgeon enters the OR with his mask untied and dangling from his face.

These are just some of the infection control lapses discovered at more than three-quarter of Illinois surgery centers inspected over the past year, according to state reports obtained by the Associated Press.

In 22 out of 29 centers surveyed, inspectors found clinics cleaning and reusing single-

Safe Injection Practices

- The surveyors will hit safe injection practices hard during the survey
- CMS has an infection control worksheet that everyone should be familiar with
- CDC has guidelines on single dose and multidose vials
  - Available at http://www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html
- Every ASC should have a safe injection practice P&P

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CDC Injection Safety Website

www.cdc.gov/injectionsafety/

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CDC 10 Standards on Safe Injection Practices

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Face Masks and Spinal Injections

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

Injection Safety
- CDC's Role
- CDC Statement
- Information for Providers
- Information for Patients
- Preventing Unsafe Injection Practices
- Safe Injection Practices
- ▸CDC Clinical Reminder: Spinal Injection Procedures
- Infection Prevention during Blood Glucose Monitoring and Insulin Administration
- 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

Injection Safety > Preventing Unsafe Injection Practices

Recommend 6 Tweet 1 Share

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

Available for download Clinical Reminder [PDF - 343 KB]

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

Summary

The Centers for Disease Control and Prevention (CDC) is concerned about the occurrence of bacterial meningitis among patients undergoing spinal injection procedures that require injection of material or insertion of a catheter into epidural or subdural spaces (e.g., myelogram, administration of spinal or epidural anesthesia, or intrathecal chemotherapy). Outbreaks of bacterial meningitis following these spinal injection procedures continue to be identified among patients whose procedures were performed by a healthcare provider who did not wear a facemask (e.g., may be labeled as surgical, medical procedure, or isolation mask).[1] with the most recent occurrence in October 2010 (CDC unpublished data). This notice serves as a reminder that facemasks should always be worn by healthcare providers when performing these spinal injection procedures.[2]

Email page
Print page

Contact Us:
Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333
800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348
New Hours of Operation
8am-8pm ET/Monday-Friday
Closed Holidays
cdcinfo@cdc.gov

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Revised IC Worksheet 17 Pages

Exhibit 351

Ambulatory Surgical Center /ASC/ INFECTION CONTROL SURVEYOR WORKSHEET

(Rev: 142, Issued: 07-17-15, Effective: 07-17-15, Implementation: 07-17-15)

Name of State Agency or AO (please specify) _____

Instructions: The following is a list of items that must be assessed during the on-site survey, in order to determine compliance with the infection control Condition for Coverage. Items are to be assessed primarily by surveyor observation, with interviews used to provide additional confirming evidence of observations. In some cases information gained from interviews may provide sufficient evidence to support a deficiency citation.

The interviews and observations should be performed with the most appropriate staff person(s) for the items of interest [*e.g.*, the staff person responsible for sterilization should answer the sterilization questions]. A minimum of one surgical procedure must be observed during the site visit. The surveyor(s) must identify at least one patient and follow that case from registration to discharge to observe pertinent practices. For facilities that perform brief procedures, e.g., colonoscopies, it is preferable to follow at least two cases. When performing interviews and observations, any single instance of a breach in infection control would constitute a breach for that practice.

Citation instructions are provided throughout this instrument, indicating the applicable regulatory provision to be cited on the Form CMS-2567 when deficient practices are observed.

PART 1 – ASC CHARACTERISTICS

1. ASC Name _____

2. Address, State and Zip Code _____
Address

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Safe Injection Practices

II. Injection Practices (injectable medications, saline, other infusates)
Observations are to be made of staff *preparing* and *administering* medications and *performing* injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).
Unless otherwise indicated, a "No" response to any question below must be cited as a deficient practice in relation to 42 CFR 416.51(a).

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. Needles are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Syringes are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
C. The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	*○ Yes ○ No ○ N/A*	*○ Observation ○ Interview ○ Both*

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Safe Injection Practices IC Worksheet

II. Injection Practices (injectable medications, saline, other infusates)
Observations are to be made of staff preparing and administering medications and performing injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).
Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).
If unable to observe is selected, please clarify in the surveyor notes box why it was not observed and attempt to assess by means of interview or documentation review.

NOTE: Some types of infection control breaches, including some specific to medication administration practices, pose a risk of bloodborne pathogen transmission that warrant engagement of public health authorities. When management review confirms that a survey has identified evidence of one or more of the breaches described in S&C: 14-36-All, in addition to taking appropriate enforcement action to ensure the deficient Medicare practices are corrected, the SA should also make the responsible State public health authority aware of the identified breach.

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
A. Needles are used for only one patient.	○ Yes ○ No ○ *Unable to observe*	

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Safe Injection Practices IC Worksheet

- One needle and one syringe for only one patient
- Disinfect rubber septum with alcohol even if new
- Enter medication vial only with new needle
- Pre-drawn medication are labeled with date and time drawn, initial of person, name, strength, time, and BUD
- Bag of IV, tubing, and connectors used for only one patient
- Voluntary P&P that multi-dose vials are used for one patient only

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Safe Injection Practices IC Worksheet

- Date multi-dose vials to expire in 28 days unless sooner by the manufacturer which is different from BUD
- Do not take multi-dose vials into patient care areas including the OR and anesthesia cart unless used on that patient then discarded
- Sharps are disposed of in puncture resistant containers
- Replace sharps containers when fill line is reached

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CDC Resources Safe Injection Practices

CDC 10 Safe Injection Practices

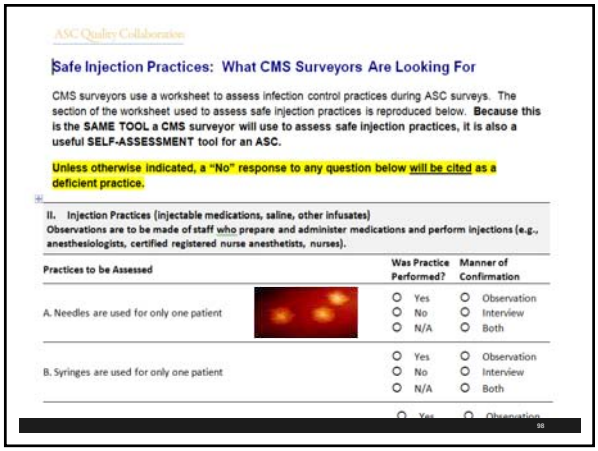
www.cdc.gov/injectionsafety/IP07_standardPrecaution.html

Advancing ASC Quality

- ASC Quality Collaboration has ASC tool kit for infection prevention
- Includes one on hand hygiene and safe injection practices
  - Excellent resources on safe injection practices
- Includes a basic and expanded version of the toolkit
  - These are available at http://www.ascquality.org/advancing_asc_quality.cfm

ASC Quality Collaboration Toolkits

http://ascquality.org/advancing_asc_quality.cfm



ASC Quality Collaboration

Safe Injection Practices: What CMS Surveyors Are Looking For

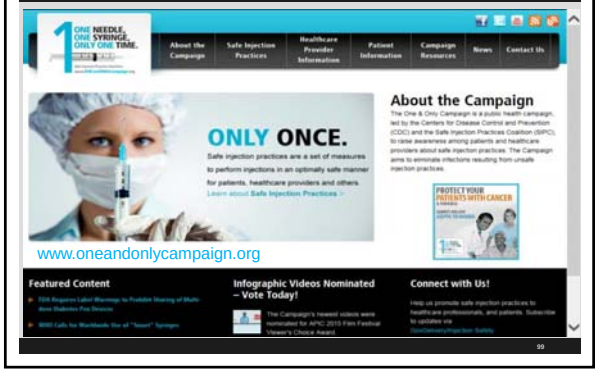
CMS surveyors use a worksheet to assess infection control practices during ASC surveys. The section of the worksheet used to assess safe injection practices is reproduced below. **Because this is the SAME TOOL a CMS surveyor will use to assess safe injection practices, it is also a useful SELF-ASSESSMENT tool for an ASC.**

Unless otherwise indicated, a "No" response to any question below will be cited as a deficient practice.

II. Injection Practices (injectable medications, saline, other infusates)
Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. Needles are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both
B. Syringes are used for only one patient	○ Yes ○ No ○ N/A	○ Observation ○ Interview ○ Both

CDC One & Only Campaign



www.oneandonlycampaign.org

Injection Safety Checklist

INJECTION SAFETY CHECKLIST

The following Injection Safety checklist items are a subset of items that can be found in the *CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care*.

The checklist, which is appropriate for both inpatient and outpatient settings, should be used to systematically assess adherence of healthcare providers to safe injection practices. Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.

Injection Safety	Practice Performed?	If answer is No, document plan for remediation
Proper hand hygiene, using alcohol-based hand rub or soap and water, is performed prior to preparing and administering medications.	Yes No	
Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment.	Yes No	
Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).	Yes No	
The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	Yes No	
Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for	Yes No	

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Infection Control Q-0240

- The infection control section starts at Tag number 240
- **Standard** states that the ASC must maintain an infection control program that seeks to minimize infections and communicable diseases
- The ASC must have an active program to minimize infections and communicable diseases
- CMS has a definition of what is an infectious disease and infectious agent
  - Definition from The National Institute of Allergy and Infectious Diseases (NIAID)

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Infection Control Q 240

- An **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 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

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Infection Control Q 240

- An infection control program must;
  - Provide a functional and sanitary environment for surgical services, to avoid sources and transmission of infections and communicable diseases
  - What constitutes a functional and sanitary environment is discussed in detail under tag 241
  - Be based on nationally recognized infection control guidelines
  - These organizations have many great resources

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Requirements of an Infection Control Program

- Nationally recognized organizations include:
  - CDC or the Center for Disease Control
  - SHEA or The Society for Healthcare Epidemiology of American
  - APIC or Association for Professionals in Infection Control and Epidemiology
  - American Association of PeriOperative Registered Nurses or AORN
  - Institute for Healthcare Improvement or IHI
  - IDSA or the Infectious Diseases Society of America
  - Pa Patient Safety Authority or PaPSA

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APIC Website

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AORN

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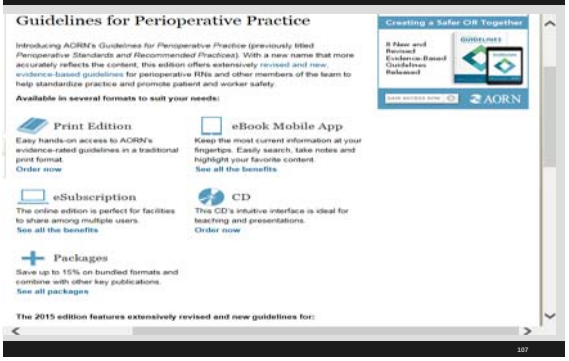
AORN Guidelines for Perioperative Practice



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Institute for Healthcare Improvement IHI

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SHEA Website

CDC Website

Requirements of an Infection Control Program

- Be directed by a designated health care professional with training in infection control
  - Infection preventionist should be qualified through education, training, experience, or certification
  - Certification is not required
- Be integrated into the ASC's QAPI program
- Be ongoing
- Include actions to prevent, identify and manage infections and communicable diseases; and

Infection Control Q 240

- Include a mechanism to immediately implement corrective actions and preventive measures that improve the control of infection within the ASC
  - Administrators need to listen to IP if they identify a problem
- The ambulatory care setting presents unique challenges for infection control
- Patients remain in common areas for a prolonged period of time such as the lobby
  - Some newer ASCs have lobbies with hepa filtration devices and lights that kill bacteria and viruses in the air

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Infection Control Q 240

- Surgery and recovery rooms are turned around quickly
- May be hard to identify patients with infectious or communicable diseases
- Patients are in the ASC a short time which makes it hard sometimes to identify infections associated with the ASC
- Information has to be obtained after discharge and not directly linked if the patient was in the hospital

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Infection Control Q 240

- Want to have physicians report back when postoperative infections are seen in the office
- The ASC can send an email to the primary care physician after discharge (See tag 245)
- Be sure to add this to the NPP (HIPAA Notice of Privacy Practice) and to the form the patient is signing so they are aware of this
- Considering asking the patient for their email address so you can send a follow up email
  - Send a follow up email asking if they have any problems including any postoperative infections

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Infection Control 240

- ASCs must have a comprehensive infection control program
- In the past, poor infection control programs related to injections of medications, saline or other infusates in some ASCs have resulted in the transmission of communicable diseases
- Thousand of patients had to be tested for communicable diseases
  - This include hepatitis B and C and HIV

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Infection Control 240

- The survey procedure discusses that one of the surveyors must complete the infection control worksheet
  - Remember every nurse, department director, and pharmacists should be familiar with the sections covered in the revised infection control worksheet
  - Infection preventionist should do training to physicians and staff
- However, each member of the survey team is to assess compliance with the ASC CfC requirements
  - Surveyors of ASC training session had heavy focus on infection control

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Infection Control Sanitary Environment Q 241

- **Standard:** The ASC must provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice (SOP).
- Necessary to avoid transmission of infections and communicable diseases
- All areas must be clean and sanitary
  - Include surgical prep area, PACU, and OR
- ASC must monitor environmental services (housekeeping) and maintenance activities

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Policies for Sanitary Environment

- Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external construction/renovation
- Maintaining safe air handling systems in areas of special ventilation, such as the OR
- Techniques for food sanitation if employee food storage and eating areas are provided

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Policies for Sanitary Environment

- Techniques for cleaning and disinfecting environmental surfaces, carpeting, and furniture
- Techniques for disposal of regulated and non-regulated waste and
- Techniques for pest control
- These policies should be consistent with SOC such as CDC, AORN, APIC, SHEA etc.
  - CMS does not prescribe guidelines but ASC should document choices

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CDC Guidelines for Environmental IC

Guidelines for Environmental Infection Control in Health-Care Facilities

Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC)

Prepared by
Lynne Sehulster, Ph.D.[1]
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National Center for Infectious Diseases
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Sharp Memorial Hospital
San Diego, California

The material in this report originated in the National Center for Infectious Diseases, James M. Hughes, M.D., Director, and the Division of Healthcare Quality Promotion, Steven L. Solomon, M.D., Acting Director

www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm

Summary

The health-care facility environment is rarely implicated in disease transmission, except among patients who are immunocompromised. Nonetheless, inadvertent exposures to environmental pathogens (e.g., Aspergillus spp. and Legionella spp.) or airborne pathogens (e.g., Mycobacterium tuberculosis and varicella-zoster virus) can result in adverse patient outcomes and cause illness among health-care workers. Environmental infection-control strategies and engineering controls can effectively prevent these infections. The incidence of health-care–associated infections and pseudo-outbreaks can be minimized by 1) appropriate use of cleaners and disinfectants; 2) appropriate maintenance of medical equipment (e.g., automated endoscope reprocessors or hydrotherapy equipment); 3) adherence to water-quality standards for hemodialysis, and to ventilation standards for specialized care environments (e.g., airborne infection isolation rooms, protective environments, or operating rooms); and 4) prompt management of water intrusion into the facility. Routine environmental sampling is not usually advised, except for water quality determinations in hemodialysis settings and other situations

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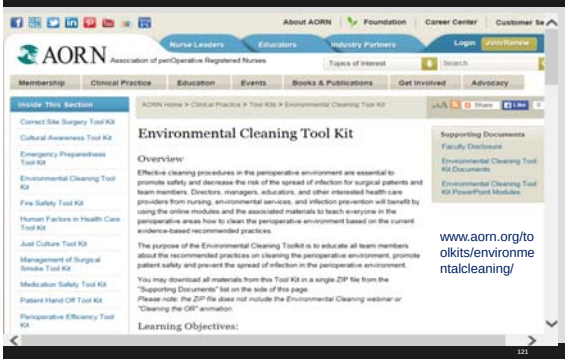
AORN Toolkit Environmental Cleaning



www.aorn.org/toolkits/environmentalcleaning/

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Survey Procedure Q 241

- Surveyor is instructed to use the specific questions on the infection control worksheet related to environmental infection control
- Instructed to observe how clean the ASC is including PACU, floors, horizontal surfaces, patient equipment, air inlets, supply, storage areas etc.
- Interview staff to determine whether cleaning and disinfection takes place and using appropriate materials

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Survey Procedure Q 241

- Determine if has procedure for decontamination after gross spills of blood or other body fluids
- Determine whether sharps are disposed of properly
  - Needlestick Safety and Prevention Act
  - Part of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030)
  - Have sharps containers at the bedside in all rooms
- Determine if the ASC re-uses devices that are marketed for single use

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CMS IC Worksheet Part IV

- Tool for assessing compliance with Standard that the ASC provides a functional and sanitary environment by adhering to professionally acceptable standards of practice
- Observations are made of staff performing environmental cleaning including surgical technicians
- CMS also added the citation instructions
  - Unless otherwise indicated in the body of the worksheet , a "No" response to any question must be cited as a deficient practice

Environmental Infection Control

IV. Environmental Infection Control

Observations are to be made of staff performing **environmental cleaning (e.g., surgical technicians, cleaning staff, etc.)**

If unable to observe is selected, please clarify in the surveyor notes box why it was not observed and attempt to assess by means of interview or documentation review.

*Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).*

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Operating rooms are cleaned and disinfected after each surgical or invasive procedure with an EPA-registered disinfectant	○ Yes ○ No ○ *Unable to observe*	
B. Operating rooms are terminally cleaned daily	○ Yes ○ No ○ *Unable to observe*	
C. *Environmental surfaces in patient care areas are cleaned and disinfected, using an EPA-registered disinfectant on a regular basis (e.g., daily), when spills occur and when*	○ Yes ○ No ○ *Unable to observe*	

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Environmental Infection Control

- OR disinfected after each surgical or invasive procedure with an EPA registered disinfectant
- OR terminally cleaned daily
- Surfaces in patient care area cleaned and disinfected on a regular basis
  - And when spills occur or surfaces are visibly contaminated
- Have P&P to decontaminate gross spills of blood
- Will observe nurse doing finger stick for blood sugar
  - Hand hygiene done before and after with gloves

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Environmental Infection Control

- Finger stick device must be totally disposable including lancet holding device
- Point-of-care device, like glucose meter, is disinfected after every use and according to manufacturer's instructions
- If manufacturer does not have cleaning instructions then must be limited to one patient use

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Infection Control Program Q 242

- **Standard**: The ASC must maintain an ongoing program designed to prevent, control, and investigate infections and communicable diseases.
- In addition, the infection control and prevention program must include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines.

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Infection Control Program Q 242

- Program must be ongoing
- Must prevent, control, and investigate infections and communicable diseases
- Must have an active surveillance program
  - Must cover patients and staff
  - Must include detection through collecting and analyzing the data
  - CDC has good surveillance resources
- Program must be based on national standards
  - Specify CDC, AORN, SHEA, APIC, in P&P, IC plan etc.

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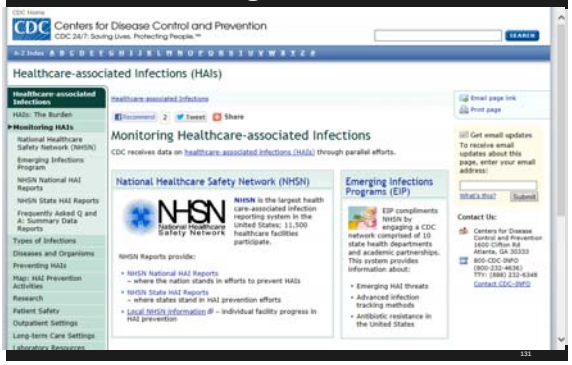
CDC Surveillance

CDC Monitoring HAI



I. Essential Elements of Surveillance[1, 2, 3]

A. Assess the population and identify those at greatest risk for the outcome or process of interest

1. Healthcare-associated infections (HAI) (outcomes)
2. Patient care practices aimed at preventing HAI (processes)

B. Select the outcome or process for surveillance

1. Examples of outcomes: HAI, infection or colonization with a specific organism, pyrogenic reaction or vascular access infection in hemodialysis patients, sharps injuries, etc.
2. Examples of processes: Central line insertion practices (CLIPs), surgical care processes (e.g., preoperative antimicrobial prophylaxis), medication errors, influenza vaccination rates, hepatitis B immunity rates, personnel compliance with protocols, etc.
3. Examples of other events: Occurrence of reportable diseases and conditions, communicable diseases in personnel, organisms or syndromes indicative of bioterrorist events, etc.

C. Determine observation time period

D. Choose the surveillance methodology (See Section II)

E. Monitor for the outcome or process using standardized definitions for all data

Elements of Effective State-Based Surveillance for Multidrug-Resistant Organisms Related to Healthcare-Associated Infections: Summary of Discussions from a Council of State and Territorial Epidemiologists and Centers for Disease Control and Prevention Experts Meeting

Jonathan Duffy, MD, MPH[a]; Dawn Sievert, PhD, MS[a]; Catherine Rebmann, MPH[a]; Marion Kainer, MD, MPH[b,c]; Ruth Lynfield, MD[b,d]; Perry Smith, MD[b,e]; Scott Fridkin, MD[a]

[a]Centers for Disease Control and Prevention
[b]Council of State and Territorial Epidemiologists
[c]Tennessee Department of Health
[d]Minnesota Department of Health
[e]New York State Department of Health

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So 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 Physicians, 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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PRIORITY AREA	ACTION REQUIRED	MEASUREMENT OF SUCCESS	LEAD	PRIORITY	COMPLETION DATE
Management and Communication of Critical Data and Information	1. Establish a process for thorough review and appropriate action steps related to the following: • Hospital X deaths or serious harm associated with infections, including mechanism to share action plans and findings Hospital X-wide to prevent reoccurrence • Notification & inclusion of ICP leaders in renovation or new construction design • Incidences of infection control breakdown	Established review process and action plan drafted	Patient Safety Center with assistance of multidisciplinary ICP workgroup	HIGH	March 09
	2. Evaluate available ICP alert and reporting software to maximize ICP efficiency, documentation, screening and surveillance	Completed evaluation with recommendation of ICP alert and reporting software	Patient Safety Center with assistance of multidisciplinary ICP workgroup	HIGH	September 09
	3. Define metrics for: • Appropriate use of targeted antibiotics • MRSA • SSI • VAP • CLBSI • CA-UTI	Monthly report of metrics	Hospital X Pharmacy & Therapeutics Committee, Quality Management Department and Patient Safety Center	HIGH	July 09

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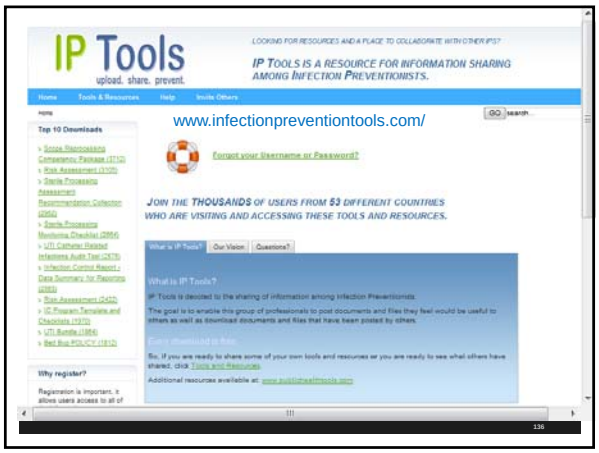

Infection Control Program Q 242

- ASC needs to select one or more sets of guidelines for the following key functions:
  - Maintain sanitary environment
  - Develop and implement IC activities for MS, employees, contract workers including nurses who are employed by the physician, housekeeping etc
  - Mitigate the risks associated with HAI
    - Correct name is healthcare-association infections

5 Key Functions of Infection Control

- Identifying infections
- Monitoring compliance with all policies, procedures, protocols and other infection control program requirements
  - Need to make sure all P&P are followed
  - Make sure staff are aware of all IC P&P
- Program evaluation and revision of the program, when indicated
  - ASC should consider doing this once a year and documenting when it is done

Infection Control Activities Q 242

- Evaluate staff immunization status for designated infectious diseases
  - Follow the recommendation of the CDC ACIP or Advisory committee on Immunization Practices
  - Recommendations at www.cdc.gov/vaccines/recs/acip/default.htm
  - See also www.flu.gov
- Need a policy regarding when the ASC is going to screen staff for infections likely to cause significant infectious diseases
  - Must include when staff are restricted from providing direct care to patients

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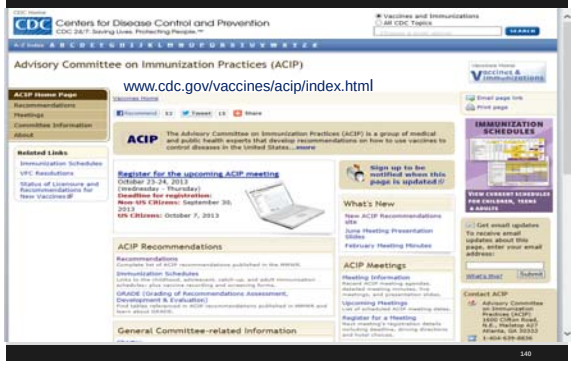
Advisory Committee on Immunization Practices



www.cdc.gov/vaccines/acip/index.html

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CDC Flu and Vaccination Information

www.cdc.gov/flu/index.htm

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Infection Control Activities Q 242

- P&P must also include when staff must remain away from the ASC all together
- Need P&P for reportable disease under state law
  - Every state has a list of communicable diseases that must be reported to the state department of health like MRSA or VRE
- New employees need orientation and regular update training in preventing and controlling HAI
  - Do not forget to provide infection control training to the physicians and LIPs also

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Infection Control Activities 242

- Infection preventionist should also provide training on methods to prevent exposure and transmission of infections and communicable diseases
  - Hand hygiene is one of the most important ways to prevent infection
  - Studies show that compliance rates could be improved
- ASC needs methods to evaluate staff exposure to patients with infectious and communicable diseases
  - Nurse has needle stick injury and patient is HIV positive
  - Nurse exposed to patient who is diagnosed with TB

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Mitigation of Risks Contributing to HAI

- The CDC defines an HAI as a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent or its toxin for purposes of surveillance
- There must be no evidence that the infection was present or incubating at the time of admission to the ASC
- HAI can be from an endogenous
  - Such as from skin, nose, mouth, GI trach, or vagina that are normally inhibited by microorganisms
  - Note the Jan 7, 2010 edition of NEJM

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Mitigation of Risks Contributing to HAI 242

- This article found that one out of every seven patients have staph aureus in their nose
  - If culture positive can irrigate and add nasal drops and reduce surgical site infections
  - Recent study found one in four patient have positive nasal culture for staph
  - Jan 2010 NEJM also found that using chlorahexidine instead of betadine could reduce surgical site infections dramatically
- HAI can be from an exogenous source which means outside the body

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Surgery Risk Mitigation Measures

- Examples of exogenous sources would include visitors, patient care staff, patient equipment, medical devices, or the health care environment
- Surgery related infection risk mitigation
  - Implement prophylaxis (antibiotics) to prevent surgical site infection
  - Must be given at the appropriate time (usually within one hour of the incision)
  - Must be discontinued appropriately after surgery
  - Do not forget if long case to look to see if patient needs rebolusing of the antibiotic

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Surgery Risk Mitigation Measures 242

- Need to address aseptic techniques used in surgery including sterilization or high level disinfection of instruments
  - Sterilization of scopes and other equipment is very important and recent problems have made this an area that is hit hard during the survey
  - CMS issues memo on sterilization of equipment including flash sterilization (immediate use steam is new name)
  - AORN Perioperative Standards and Recommended Practices has standards on this now called Guidelines for PeriOperative Practices
  - Need to clean instruments with lap sponge, soak in enzymatic solution and then sterilize so no bioburden

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IUSS Question in IC Worksheet

Practices to be Assessed	Was Practice Performed?
H. Is immediate-use steam sterilization (IUSS) performed on-site? **If NO, skip to "High Level Disinfection Section"** **If YES, you must also assess the practices at questions "I - K":** (A "No" answer does not result in a citation)	○ Yes ○ No
I. If IUSS is performed, all of the following criteria are met: • Work practices ensure proper cleaning and decontamination, inspection, and arrangement of the instruments into the recommended sterilizing trays or other containment devices before sterilization. • Once clean, the item is placed within a container intended for immediate use. The sterilizer cycle and parameters used are selected according to the manufacturers' instructions for use for the device, container, and sterilizer.	○ Yes ○ No ○ Unable to observe ○ N/A

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IUSS Question in IC Worksheet

- If IUSS used, must ensure proper cleaning, decontamination, inspection, and arrangement of instruments in sterilizing trays
- One clean, item is placed in container for immediate use and placed on field in aseptic manner
- Must follow manufacturer instructions
- Sterilizer function is monitored such as mechanical, biologic, and chemical
  - Not a routine or frequent practice
- Not performed on implants, CJ instruments, etc.

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Immediate Use Sterilization

- CMS issues a memo on immediate use sterilization or IUSS
  - 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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Immediate Use Steam Sterilization IUSS

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: 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.

Introduction

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Immediate-Use Steam Sterilization

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

AAMI

ACCREDITATION ASSOCIATION FOR AMBULATORY HEALTH CARE, INC.

AORN
Association of Perioperative Registered Nurses

APIC
Spreading Knowledge. Preventing Infection.®

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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Single Use, High Level Disinfection, Sterilization

III. Single Use Devices, Sterilization, and High Level Disinfection

Pre-cleaning must always be performed prior to sterilization and high-level disinfection

Sterilization must be performed for critical equipment (i.e., instruments and equipment that enter normally sterile tissue or the vascular system, such as surgical instruments)

High-level disinfection must be performed for semi-critical equipment (i.e., items that come into contact with non-intact skin or mucous membranes such as reusable flexible endoscopes, laryngoscope blades)

Observations are to be made of staff *performing* equipment reprocessing (e.g., surgical techs), unless these activities are performed under contract or arrangement off-site from the ASC.

Unless otherwise indicated, a "No" response to any question below **must** be cited as a deficient practice in relation to 42 CFR 416.51(a).

SINGLE-USE DEVICES

(Choose N/A if single-use devices are never reprocessed and used again) (Surveyor to confirm there is a contract or other documentation of an arrangement with a reprocessing facility by viewing it)

Practices to be Assessed	Was Practice Performed?	*Surveyor Notes*
A. a. If single-use devices are reprocessed, they are devices that are approved by the FDA for reprocessing	○ Yes ○ No ○ N/A	

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Surgery Risk Mitigation Measures 242

- Need to promote hand hygiene among staff
  - Follow CDC guidelines or the WHO hand hygiene guidelines
  - TJC has great document on how to measure hand hygiene adherence
- Need measures specific to prevention of organizations that are antibiotic resistant
  - Concerns because of MRSA and VRE and other super bugs
  - We need new antibiotics to fight there emerging infections

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CDC Hand Hygiene Guidelines

www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

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CDC Posters

www.cdc.gov/handhygiene/Resources.html

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World Health Organization | Patient Safety

http://whqlibdoc.who.int/publications/2009/9789241597906_eng.pdf

WHO Guidelines on Hand Hygiene in Health Care

First Global Patient Safety Challenge
Clean Care is Safer Care

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CDC Hand Hygiene Recommendations

- CDC published guidelines Oct 25, 2002 at www.cdc.gov/handhygiene/
- In CDC MMWR Recommendations and Reports,
- Report available at www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm or go to www.cdc.gov,
- TJC published document in 2009 on Measuring Hand Hygiene Adherence: Overcoming the Challenges and this is an important document,
- Monitored during infection control tracer,

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HAND HYGIENE ADHERENCE: OVERCOMING THE CHALLENGES

http://www.jointcommission.org/assets/1/18/hh_monograph.pdf

This monograph was authored by The Joint Commission in collaboration with the following organizations:

- The Association for Professionals in Infection Control and Epidemiology, Inc.
- The Centers for Disease Control and Prevention
- The Institute for Healthcare Improvement
- The National Foundation for Infectious Diseases
- The Society for Healthcare Epidemiology of America
- The World Health Organization World Alliance for Patient Safety

This monograph was supported in part by an unrestricted educational grant provided by GOJO Industries, Inc., Akron, Ohio

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Surgery Risk Mitigation Measures 242

- ASC must measure specific safe practices for injecting medications and saline and other infusates
  - Recommend policy on safe injection practices with 10 CDC recommendation
  - Include single and multi-dose vials recommendations
- Germicides and disinfectants must be used in accordance with manufacturers instructions
- Appropriate use of facility and medical equipment
  - Includes hepa air filtration, UV lights, and other equipment to control the spread of infectious agents

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AJIC special article

www.apic.org/AM/Template.cfm?Section=Position_Statements&Template=/CM/ContentDisplay.cfm&ContentID=15088

APIC position paper: Safe injection, infusion, and medication vial practices in health care

Susan A. Dolan, RN, MS, CIC,[a] Gwenda Felizardo, RN, BSN, CIC,[b] Sue Barnes, RN, BSN, CIC,[c] Tracy R. Cox, RN, CIC,[d] Marcia Patrick, RN, MSN, CIC,[e] Katherine S. Ward, RN, BSN, MPH, CIC,[f] and Kathleen Meehan Arias, MS, CIC[g]
Washington, DC

Outbreaks involving the transmission of bloodborne pathogens or other microbial pathogens to patients in various types of health care settings due to unsafe injection, infusion, and medication vial practices are unacceptable. Each of the outbreaks could have been prevented by the use of proper aseptic technique in conjunction with basic infection prevention practices for handling parenteral medications, administration of injections, and procurement and sampling of blood. This document provides practice guidance for health care facilities on essential safe injection, infusion, and vial practices that should be consistently implemented in such settings.

Key Words: Bloodborne pathogens; injection; infusion; medication vial practices; aseptic technique; parenteral medications; administration of injections; procurement of blood.

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The transmission of bloodborne viruses and other microbial pathogens to patients during routine health care procedures continues to occur because of the use of unsafe and improper injection, infusion, and medication vial practices by health care professionals in the exposure of >100,000 individuals to viral hepatitis and the transmission of either hepatitis B virus (HBV) or hepatitis C virus (HCV) to more than 500 patients.[1-3] The unsafe practices used by health care per-

Surgery Risk Mitigation Measures 242

- Educate patients, visitors and staff about infections and communicable diseases and methods to reduce transmission in the ASC and in the community
  - APIC has a number of free educational brochures
  - CDC has MRSA education both for staff and community MRSA
  - TJC has the speak up brochure series including five things you can do to reduce infections
  - CDC has a video on hand hygiene and standard precautions at www.cdc.gov/handhygiene/training/interactiveEducation/

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Educational Brochures

http://www.apic.org/AM/Template.cfm?Section=Education_Resources&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=91&ContentID=8738

APIC works to provide information to both the general public and healthcare professionals. The brochures on this page are regularly reviewed and updated as needed to insure that the information provided is current. These materials are available for you to download, copy and distribute free of charge. These pamphlets are intended to provide a general reference to each topic. No brochure can adequately diagnose a medical condition. If in doubt regarding your symptoms, please contact a healthcare professional.

- 10 tips for preventing the spread of infection
- Antibiotic Safety
- Chlamydia
- Companion Animals and Your Health
- Food Safety in Your Home
- Hand Hygiene for Consumers
- Hand Hygiene for Healthcare Workers
- Healthy Skin - An Ounce of Prevention
- Hepatitis A (HAV)
- Hepatitis B (HBV)
- Hepatitis C
- Hepatitis C (HCV)
- How to Dine Out Safely
- Los Hechos Sobre Chlamydia
- Meningococcal Meningitis
- Mold in Your Home
- Patient Safety - Protecting Yourself from Medical Errors
- Pneumonoccal Disease - Are You at Risk?
- Prevent Needlesticks
- Preventing Infection During Your Chemotherapy Treatment
- Preventing Ventilator Associated Pneumonia
- Respiratory Etiquette - An Important Cultural Change
- Respiratory Syncytial Virus
- Scarlet Fever
- Speak Up: Five Things You Can Do To Prevent Infection
- Traveling Overseas - Tips on How to Avoid Infection

www.cdc.gov/mrsa/mrsa_initiative/skin_infection/index.html

CDC Home

Centers for Disease Control and Prevention

Your Online Source for Credible Health Information

SEARCH

A-Z Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z #

National MRSA Education Initiative: Preventing MRSA Skin Infections

National MRSA Education Initiative

- About MRSA Skin Infections
- Consumer Educational Materials
- MRSA Photos
- Information for Healthcare Professionals
- Materials for Healthcare Professionals
- Treatment Algorithm
- Public Service Announcements
- Press Room

The goal of the National MRSA Education Initiative is to help Americans better recognize and prevent MRSA skin infections.

Why is this important? Recent data show that Americans visit the doctor approximately 12 million times each year to get checked for suspected Staph or MRSA skin infection.

The good news is that a few simple steps can prevent and reduce the spread of MRSA.

Text size: S M L XL

Email page

Print page

Bookmark and share

Contact Us:

Centers for Disease Control and Prevention
National MRSA Education Initiative
1600 Clifton Rd.
MS A35
Atlanta, GA 30333
800-CDC-INFO (800-232-4636)
TTY: (888) 232-6348
24 Hours/Every Day
cdcinfo@cdc.gov

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SpeakUP™

Five Things You Can Do To Prevent Infection is supported by

American Hospital Association
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Centers for Disease Control and Prevention
www.cdc.gov

Infectious Diseases Society of America
www.idsociety.org

The Joint Commission
www.jointcommission.org

Society for Healthcare Epidemiology of America
www.shea-online.org

The Joint Commission is the largest health care accrediting body in the United States that promotes quality and safety.

Helping health care organizations help patients

The Joint Commission

5 Five Things You Can Do To Prevent Infection

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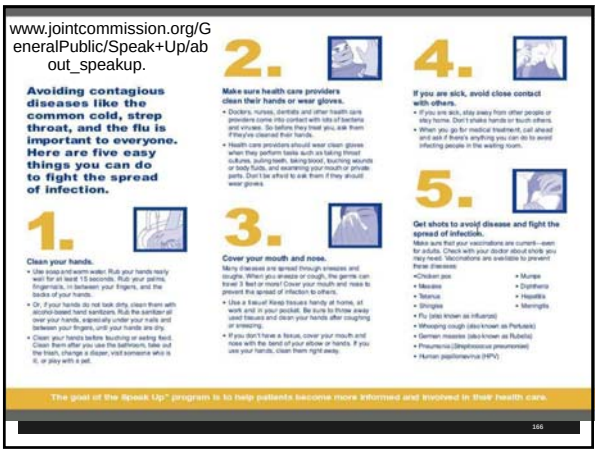
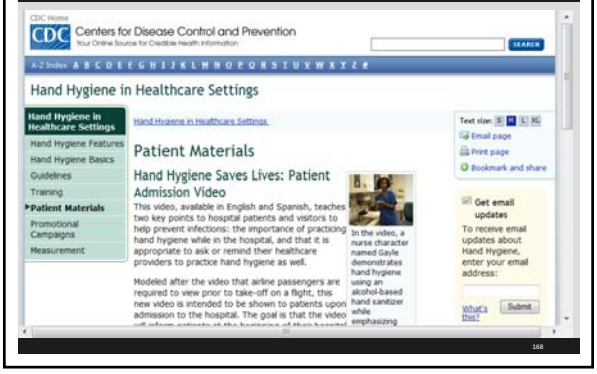
www.jointcommission.org/GeneralPublic/Speak+Up/about_speakup.



CDC Hand Hygiene Resources and Video

www.cdc.gov/handhygiene/Patient_materials.html



Identifying Infections 242

- ASC must monitor activities through out the entire facility to identify infection risks and communicable disease problems
  - Need to document the monitoring and tracking activities
- Surveillance should be done in accordance with recognized infection control surveillance activities such as the CDC National Healthcare Safety Network
- Need to monitor follow up of patients after discharge to gather information to see if they got an infection

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National Healthcare Safety Network NHSN

- CDC has great resources
- Includes an internet surveillance system that is secure
- Can monitor adverse reactions and incidents related to blood or blood products
- There is no cost
- Has a resource library
- Has many training resources with webcast training lectures on device associated module, catheter associated UTI, MRDO surveillance etc.

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Identifying Infections 242

- ASC must develop and implement interventions to address issues identified through the detection activities
- ASC must then monitor the effectiveness of the intervention to make sure it worked
  - Can collect data and analysis to show it worked
- Must not only have policies but must make sure they are being followed
  - Do staff use hand hygiene before providing care to patients
  - Is the equipment sterilized and disinfected properly

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CDC Guidelines for Environmental IC

- Chapters on;
- Air and water including dialysis water control
- Laundry and bedding
- Cleaning spills of blood
- Carpeting and pest control
- Regulated medical waste etc.
- See also Guidelines for the Disinfection and Sterilization in Healthcare Facilities
  - Cleaning equipment and scopes

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Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

www.cdc.gov/hicpac/Disinfection_Sterilization/toc.html

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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University of North Carolina Health Care System
Chapel Hill, NC 27514

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University of North Carolina School of Medicine
Chapel Hill, NC 27599-7030

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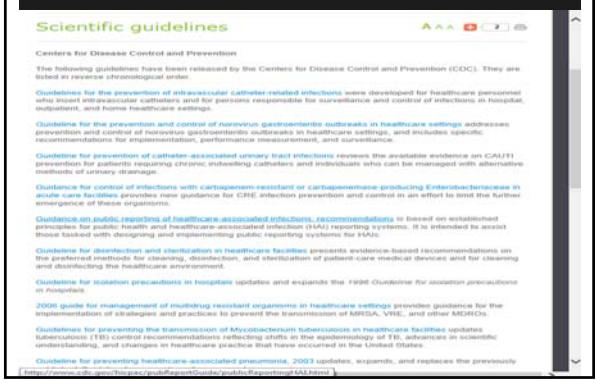
APIC Guidelines


Scientific guidelines

Centers for Disease Control and Prevention

The following guidelines have been released by the Centers for Disease Control and Prevention (CDC). They are listed in reverse chronological order.

Guidelines for the prevention of intravascular catheter-related infections were developed for healthcare personnel who insert intravascular catheters and for persons responsible for surveillance and control of infections in hospital, outpatient, and home healthcare settings.

Guideline for the prevention and control of norovirus gastroenteritis outbreaks in healthcare settings addresses prevention and control of norovirus gastroenteritis outbreaks in healthcare settings, and includes specific recommendations for implementation, performance measurement, and surveillance.

Guideline for prevention of catheter-associated urinary tract infections reviews the available evidence on CAUTI prevention for patients requiring chronic indwelling catheters and individuals who can be managed with alternative methods of urinary drainage.

Guidance for control of infections with carbapenem-resistant or carbapenemase-producing Enterobacteriaceae in acute care facilities provides new guidance for CRE infection prevention and control in an effort to limit the further emergence of these organisms.

Guidance on public reporting of healthcare-associated infections: recommendations is based on established principles for public health and healthcare-associated infection (HAI) reporting systems. It is intended to assist those tasked with designing and implementing public reporting systems for HAIs.

Guideline for disinfection and sterilization in healthcare facilities presents evidence-based recommendations on the preferred methods for cleaning, disinfection, and sterilization of patient-care medical devices and for cleaning and disinfecting the healthcare environment.

Guideline for isolation precautions in hospitals updates and expands the 1996 Guideline for isolation precautions in hospitals.

2006 guide for management of multidrug resistant organisms in healthcare settings provides guidance for the implementation of strategies and practices to prevent the transmission of MRSA, VRE, and other MDROs.

Guidelines for preventing the transmission of Mycobacterium tuberculosis in healthcare facilities updates tuberculosis (TB) control recommendations reflecting shifts in the epidemiology of TB, advances in scientific understanding, and changes in healthcare practice that have occurred in the United States.

Guideline for preventing healthcare-associated pneumonia, 2003 updates, expands, and replaces the previously

http://www.cdc.gov/hicpac/pubRegistGuide/publicReporting.html

Program Evaluation 242

- IC program must be part of the PI program
- ASC are performing more invasive procedures increasing the risk for developing and transmitting infections
- Patients have varying degrees of wellness which makes this IC challenging in the ASC
  - May include elderly or patients with immuno-compromised state
- ASC should design their infection control program with this in mind

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Program Evaluation 242

- Need to take precautions for patients who present with risk of transmission by airborne or droplet route
  - Would include prompt separation
  - Implement respiratory hygiene/ cough etiquette protocols
  - Cover your cough campaign
- Appropriate isolation precautions based on the routes of transmission of the suspected infection
  - CDC has isolation guidelines for hospitals that can be helpful for the ASC infection preventionist
  - www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html

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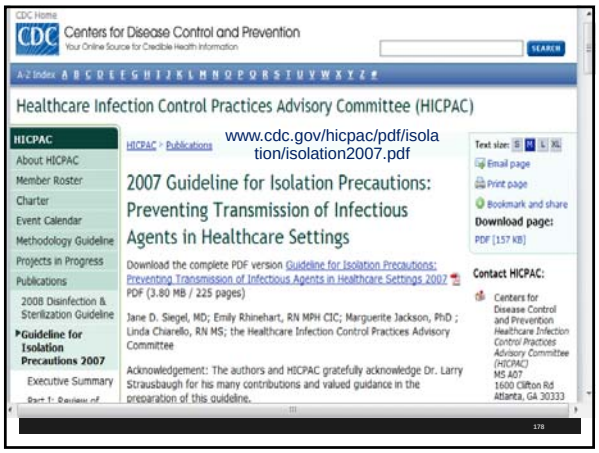

www.cdc.gov/hicpac/pdf/isolation/isolation2007.pdf

Cover Your Cough Posters

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

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Survey Procedures 242

- Surveyor is told to use the IC tool to assess compliance with this standard
- Determine if there is an ongoing program to prevent, control, and investigate diseases among all staff, contract workers, and volunteers
- Make sure P&P are implemented correctly and consistent with national standards of care
- Make sure ASC mitigates risk that attribute to HAIs like hand hygiene
- Make sure ASC is tracking and monitoring all activities

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Infection Control Program 243

- **Standard:** The program must be under the direction of a designated and qualified professional with training in infection control
- Called an infection preventionist (IP) now by APIC
- Must designate in writing who this is

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Infection Control Program 243

- ASC must make sure this person has training in the principles and methods of infection control
- Certification in IC is desirable but not required
- Must maintain qualifications through education and training (will look at personnel file of IP)
  - Recommend national and local meetings such as APIC and SHEA
- Does not specify how many FTEs this is but need to have adequate resources to get the job done
  - APIC and SHEA publish studies and recommendations on resource allocation

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Infection Control Program 244

- **Standard:** IC program is an integral part of the PI program
  - IC program must be integrated into the PI program
  - Data and program activities are a part of PI
- The program measures indicators and activities related to IC on an ongoing basis
- Surveyor to make sure IC activities result in specific actions to improve IC
- Two of the common things measured are geared at reducing infections

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What do you Measure for PI?

- Patient Burns and Patient Fall in the ASC
- Prophylactic IV Antibiotic on Time
- Hospital Transfer/Admission
- Wrong Site, Side, Patient, Procedure or Implant
- Appropriate Surgical Site Hair Removal
- Normothermia Outcome
- Unplanned Anterior Vitrectomy
- Safe surgery checklist and volume data on selected surgical procedures, Flu vaccine rates among personnel, endoscopy surveillance and follow up and surveillance of patients with adenomatous polyps, cataract improvement in 90 days

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ASC Quality Collaboration

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Infection Control Program 245 12-12-2013

- **Standard**: The IC program must provide a plan of action for preventing, identifying, and managing infections and communicable disease
- IC program must implement the corrective and preventive measures that result in improvement
- ASC must have a comprehensive plan
  - Consider electronic surveillance
  - Could include hand hygiene, infectious waste management, bloodborne pathogens, bioterrorism readiness, patient outcomes, duties of the IP, surveillance strategies, environmental monitoring, antibiotic utilization studies, outbreak management, communicable disease reporting, education, P&P required and followed, etc.

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CMS ASC Quality Reporting

www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting/index.html

ASC Quality Reporting

Overview

The Ambulatory Surgical Center Quality Reporting (ASCQR) Program is a pay-for-reporting, quality data program finalized by the Centers for Medicare & Medicaid Services (CMS). Under this program, ASCs report quality of care data for standardized measures to receive the full annual update to their ASC annual payment rate, beginning with Calendar Year (CY) 2014 payments.

Program Requirements

Initial program requirements were included in the CY 2012 Outpatient Prospective Payment System (OPPS)/ASC final rule, CMS-1525-FC, and the FY 2013 Inpatient Prospective Payment System (IPPS) rule.

Read more about the Ambulatory Surgical Center (ASC) Quality Reporting Program in the CY 2012 OPPS/ASC final rule. Our section begins on page 371 of the PDF document (also noted as Federal Register page 74492).

Measures for CY 2014 Payment Determination

- ASC-1 Patient Burn
- ASC-2 Patient Fall
- ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4 Hospital Transfer/Admission
- ASC-5 Prophylactic Intravenous (IV) Antibiotic Timing

Measures for CY 2015 Payment Determination

- ASC-1 Patient Burn
- ASC-2 Patient Fall
- ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4 Hospital Transfer/Admission
- ASC-5 Prophylactic Intravenous (IV) Antibiotic Timing
- ASC-6 Safe Surgery Checklist Use

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CMS ASC Measures Flu in 2016

Measures for CY 2015 Payment Determination

- ASC-1 Patient Burn
- ASC-2 Patient Fall
- ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4 Hospital Transfer/Admission
- ASC-5 Prophylactic Intravenous (IV) Antibiotic Timing
- ASC-6 Safe Surgery Checklist Use
- ASC-7 ASC Facility Volume Data on Selected ASC Surgical Procedures

Measures for CY 2016 Payment Determination

- ASC-1 Patient Burn
- ASC-2 Patient Fall
- ASC-3 Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4 Hospital Transfer/Admission
- ASC-5 Prophylactic Intravenous (IV) Antibiotic Timing
- ASC-6 Safe Surgery Checklist Use
- ASC-7 ASC Facility Volume Data on Selected ASC Surgical Procedures
- ASC-8 Influenza Vaccination Coverage among Healthcare Personnel

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Infection Control Plan 245

- IC plan must result in improvements in outcomes
- Plan must include the following:
  - Maintenance of a sanitary environment
  - Development and implementation of infection control measures related to ASC personnel
  - Mitigation of risks associated with patient infections present upon admission
  - Mitigation of risks contributing to healthcare-associated infections

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Infection Control Plan 245

- Active surveillance
- Monitoring compliance with all P&P, protocols, and other IC program requirements
- Plan evaluation and revision of the plan when indicated
- Coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable and infectious disease threats and outbreaks
- Compliance with reportable disease requirements of the local health authority

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Infection Control Plan 245

- ASCs are required to have a process to follow up each patient after discharge
- This is done to identify and track infections associated with the ASC visit
- If ASCs learns of an infection in the post-operative period from the physician or the patient
  - ASC may consider inquiring if there a lab confirmation of an infectious disease
  - Are there indications the infection was associated with the stay
  - Can delegate part of follow-up to physicians on staff if information is reported back to ASC and documented in the medical record

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Infection Control Plan 245

- Surveyor is suppose to make sure plan has all the required elements of IC
- Suppose to ask for documentation of actual examples of how issues were identified and corrected
- Make sure those actions resulted in improvement
- IP to go over IC plan with surveyor and explain how it addresses the fundamental elements of an IC program

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Infection Control Plan 245

- Surveyor procedure
  - Surveyor is suppose to ask leadership how it tracks infections among both patients and staff
  - Surveyor is to ask for documentation that infections are tracked for all patients
  - Surveyor is suppose to ask the leadership what diseases are reported to the staff to verify that the ASC is aware of the state department of health reporting requirements
  - Surveyor will ask if the ASC has ever reported a reportable disease to the state
    - If yes, will review documentation of the case

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ASC Infection Control Plan

OUTCOME AND PROCESS MEASURES

Process	Goal	Opportunities to Reduce Risk	Assessment	Measure of Success	Responsible Party
Hand Hygiene	Staff will perform hand hygiene at every opportunity following CDC guidelines with an observation rate > 80%.	Staff will perform hand hygiene with Alcohol Hand Rub or Soap & Water before & after patient contact. After removing gloves and after contact with blood, body fluids or contaminated surfaces. Gloves changed between patients/activities. Gloves are worn when coming in contact with a potentially infectious patients or blood/body fluids or contaminated surfaces.	Observation	All opportunities for hand hygiene were taken. Observation rate is > 80%.	All staff and visitors

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ASC Infection Control Plan

SSI	The rate of SSI's will be < 1% with a target of 0%.	Hand Hygiene/Scrub Patient preparation. Surgical attire procedures are followed. Sterile Field requirements are met. All per AORN guidelines. Environmental cleaning is done per CDC requirements.	Observation Reported breaches of surgical asepsis.	The ASC rate of SSI's is < 1%. All opportunities to reduce the risk of SSI's are being practiced.	All Staff

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ASC Infection Control Plan

Outcome and Process Measures

Process	Goal	Opportunities to Reduce Risk	Assessment	Measure of Success	Responsible Party
Endoscope Reprocessing	Prevent HAIs' due to improper processing of endoscopes which can result in cross contamination or outbreaks. Rate will be < 1% with a target rate of 0%.	Limiting operating room traffic. Continuing education. Endoscopes will be processed per manufacturer's directions. Staff will wear appropriate PPE during reprocessing. Continuing education & competency assessment will be done at least annually.	Reprocessing logs are monitored. Observation of cleaning.	No cross-contamination or outbreaks are reported.	Staff
Injection Practices	Reduction/elimination of exposure to blood borne pathogens. Rate will be < 0.5% with a target rate of 0%.	Follow APIC's/CDC's guidelines for safe injection practices which include: Never use medication in a syringe for more than one patient even if the needle is changed between patients. Utilize sharps safety devices whenever possible.	Observe staffs injection practices. Vials are labeled with expiration date. Safety devices are activated when available.	Employee health nurse reports a rate of 0% exposure to BBP through unsafe injection practices.	All Staff

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ASC Infection Control Plan

Outcome and Process Measures

Process	Goal	Opportunities to Reduce Risk	Assessment	Measure of Success	Responsible Party
Sterilization	Medical and surgical instruments do not transmit infectious pathogens to patients or staff. The ASC is sterilizing equipment using standard methods per guidelines of APIC, AAMI, AORN & CDC.	Sterilized equipment is cleaned and visually inspected prior to sterilization. All parameters of steam sterilization are met i.e. time, temperature level, pressure and moisture. Chemical indicators are placed in each load and inspected for integrity and reprocessed if there is any doubt of improper sterilization. Biological indicator, on days	Packages pass visual inspection and chemical parameters. Flash sterilization is <1% of loads.	No cases of transmission of pathogens to patient or staff.	All staff

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So What Are the CDC 10 Recommendations?

- The CDC has a page on Injection Safety that contains the excerpts from the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- Summarizes their 10 recommendations
- CMS expects hospitals to follow the CDC guidelines
- Available at http://www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html

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CDC Safe Injection Recommendations

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

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CDC Safe Injection Recommendations

- Use fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use
- Consider a syringe, needle, or cannula contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set

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CDC Safe Injection Recommendations

- Use single-dose vials for parenteral medications whenever possible
- Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use
- If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile

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CDC Safe Injection Recommendations

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

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CDC Safe Injection Recommendations

- Worker safety; Adhere to federal (OSHA) and state requirements for protection of healthcare personnel from exposure to blood borne pathogens
- Wear a mask when placing a catheter or injecting material into the spinal canal or subdural space
  - Example, during myelograms, lumbar puncture and spinal or epidural anesthesia.

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The End! Questions???

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Resources

- There are many places in the rest of the ASC manual that reference infection control
- Information is provided on those sections
- References to the national standards of care and practice are also included such as APIC, SHEA, etc.

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Infection Control Other Sections

- Board section (states that surveyor is suppose to ask who performs infection control
  - APIC now calls them a infection preventionist
- Surgical Services section states that surgical procedures must be performed in a safe manner
- Safe manner is defined and states must follow acceptable standards of practice including the APIC standards
  - APIC stands for Association of Professionals in Infection Control and Epidemiology

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Infection Control

- Surgical services also states that infection control includes the following
  - The conformance to aseptic and sterile technique by all individuals in the surgical area
  - That there is appropriate cleaning between surgical cases and appropriate terminal cleaning applied
    - AORN has section on how to clean the OR and between cases
  - That operating room attire is suitable for the kind of surgical case performed, that persons working in the operating suite must wear only clean surgical costumes, that surgical costumes are designed for maximum skin and hair coverage

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Infection Control

- AORN has section on what is suitable attire in the OR in their Perioperative Standards and Recommended Practices
- Surgical services also states that infection control includes the following
  - That equipment is available for rapid “emergency” high-level disinfection/ sterilization of operating room materials
  - This is an important issue with both TJC (the Joint Commission) and CMS
  - CMS issues a memo on this for ASCs

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Infection Control

- That sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture- and dust-controlled environment, and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice.
- That temperature and humidity are monitored and maintained within accepted standards of practice
  - AORN in the Perioperative Standards and Recommended Practices state what the temperature and humidity should be in the OR and PACU

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Infection Control

- ASC that identifies problems with IC thru the PI program should take action to reduce the potential for transmission (p
- Tag 81 discusses that the ASC must measure, analyze, and track quality indicators, adverse events and infection control performance
- ASC should have outcome indicators and focus on complication rates and HAI rates
- ASC should look at surgical site infection rate and make sure antibiotic prophylaxis meets the SOC such as the CDC guidelines

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Infection Control

- The location of the OR within the ASC and the access to it must conform to accepted standards of practice, particularly for infection control, with respect to the movement of people, equipment and supplies in and out of the OR
- Discuss rapid emergency sterilization of OR equipment and says should not be routinely used since intended for emergency use
- Can allow individuals to accompany patients in the PACU as long as consistent with SOP and infection control guidelines

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Infection Control

- Tag 103 on the physical environment has many sections on infection control including
  - The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities
  - Must have program to follow up every patient after discharge to identify and track if they had an infection associated with the stay in the ASC
  - If find out about an infection from the surgeon then needs to investigate to see if from the ASC
- Surveyor to ask LD how it tracks infections among staff and patients

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Infection Control

- Tag 122 discusses that ASC needs to track infection rate when evaluating whether to recredential the physicians
- Tag 181 on administration of drugs discusses using standard infection control practices when using injectible medications
- Radiology standards require enforcing infection control standards
- Tag 232 on patient rights says staff should follow all current infection control standards

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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) www.cdc.gov/ncidod/dhqp/hicpac_pubs.html
  - Infection control plan for ambulatory care
  - Guidelines for Disinfection and Sterilization in Healthcare Facilities 2008
  - Guidelines for Isolation Precautions 2007
  - Management of Multidrug-Resistant Organisms 2006
  - Influenza Vaccination of Healthcare Personnel 2006 and CDC has flu website at www.flu.gov with information on universal flu vaccine(all strains of the flu for decades)

www.infectioncontroltoday.com/

Bioterrorism

- ASC should be knowledgeable about emergency preparedness, including bioterrorism
- Terrorists could use bioterrorism
- There is a long list of bioterrorism agents
  - Anthrax, arena viruses, 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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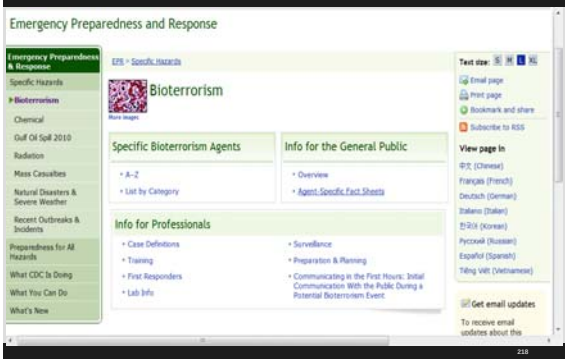
http://emergency.cdc.gov/bioterrorism/



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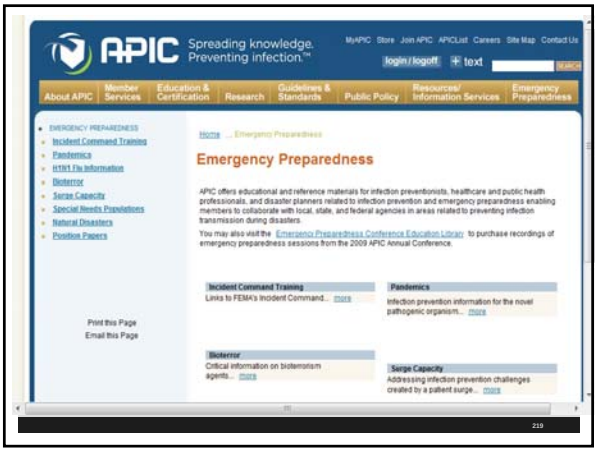

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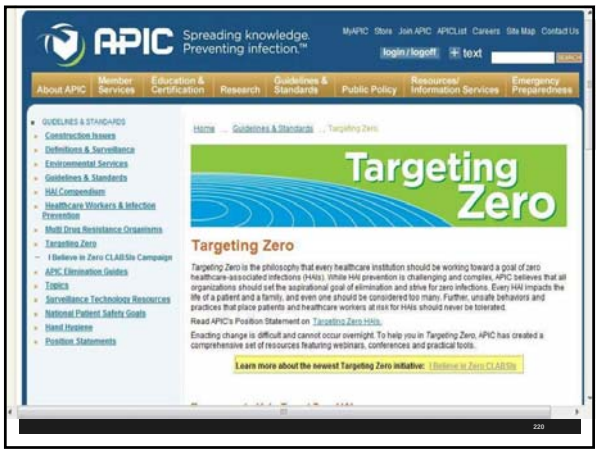
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Multi Drug Resistance Organisms
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I Believe in Zero CLABSIs Campaign
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Surveillance Technology Resources
National Patient Safety Goals
Hand Hygiene
Position Statements
Home ... Guidelines & Standards ... Targeting Zero
Targeting Zero
Targeting Zero
Targeting Zero is the philosophy that every healthcare institution should be working toward a goal of zero healthcare-associated infections (HAIs). While HAI prevention is challenging and complex, APIC believes that all organizations should set the aspirational goal of elimination and strive for zero infections. Every HAI impacts the life of a patient and a family, and even one should be considered too many. Further, unsafe behaviors and practices that place patients and healthcare workers at risk for HAIs should never be tolerated.
Read APIC's Position Statement on Targeting Zero HAIs.
Enacting change is difficult and cannot occur overnight. To help you in Targeting Zero, APIC has created a comprehensive set of resources featuring webinars, conferences and practical tools.
Learn more about the newest Targeting Zero initiative: I Believe in Zero CLABSIs
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APIC
Spreading knowledge. Preventing infection.™
Contact: Liz Garman, 202/454-2604
egarman@apic.org
APIC INTRODUCES "GUIDE TO ELIMINATION OF INFECTIONS IN HEMODIALYSIS"
Washington, June16, 2010 – In an effort to establish universally accepted best practices for protecting patients undergoing hemodialysis, the Association for Professionals in Infection Control and Epidemiology (APIC) has published a Guide to the Elimination of Infections in Hemodialysis. Following cardiovascular disease, infection is the second largest cause of death for hemodialysis patients.
The Guide was developed by healthcare professionals responsible for infection prevention in acute care, ambulatory and home hemodialysis settings. With input from infection preventionists, dialysis technicians and dialysis nurses, the Guide presents effective and actionable steps to reduce the risk of infection and protect patients.
Hemodialysis technologies have greatly improved the health and quality of life for millions of people across the globe suffering from kidney disease and kidney failure. However, patients receiving these treatments are particularly vulnerable to healthcare-associated infections (HAIs) due to their weakened immune systems and the invasive nature of hemodialysis devices. For the majority of hemodialysis patients, treatments are administered three times weekly, further increasing the risk of being infected by pathogens present in healthcare settings. Hospitalizations due to infections in hemodialysis patients rose 34% between 1993 and 2006.
"The morbidity, mortality and cost of these infections are significant and increasing, yet preventable," said APIC CEO Kathy Warye. "APIC's new Guide to the Elimination of Infections in Hemodialysis provides evidence-based strategies to help protect this particularly vulnerable patient population from an increasingly prevalent problem. The new Guide will also prepare our members to meet future priorities from the federal government, which will focus on infection control in dialysis and ambulatory surgical
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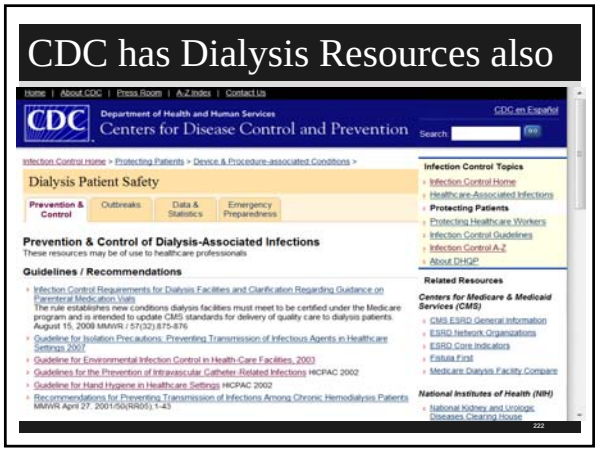
CDC has Dialysis Resources also
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Infection Control Home > Protecting Patients > Device & Procedure-associated Conditions >
Dialysis Patient Safety
Prevention & Control
Outbreaks
Data & Statistics
Emergency Preparedness
Prevention & Control of Dialysis-Associated Infections
These resources may be of use to healthcare professionals
Guidelines / Recommendations
Infection Control Requirements for Dialysis Facilities and Clarification Regarding Guidance on Parenteral Medication Vials
The rule establishes new conditions dialysis facilities must meet to be certified under the Medicare program and is intended to update CMS standards for delivery of quality care to dialysis patients. August 15, 2008 MMWR / 57(32);875-876
Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007
Guideline for Environmental Infection Control in Health-Care Facilities, 2003
Guidelines for the Prevention of Intravascular Catheter-Related Infections HICPAC 2002
Guideline for Hand Hygiene in Healthcare Settings HICPAC 2002
Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients MMWR April 27, 2001/50(RR05);1-43
Infection Control Topics
Infection Control Home
Healthcare-Associated Infections
Protecting Patients
Protecting Healthcare Workers
Infection Control Guidelines
Infection Control A-Z
About DHQP
Related Resources
Centers for Medicare & Medicaid Services (CMS)
CMS ESRD General Information
ESRD Network Organizations
ESRD Core Indicators
Fistula First
Medicare Dialysis Facility Compare
National Institutes of Health (NIH)
National Kidney and Urologic Diseases Clearing House
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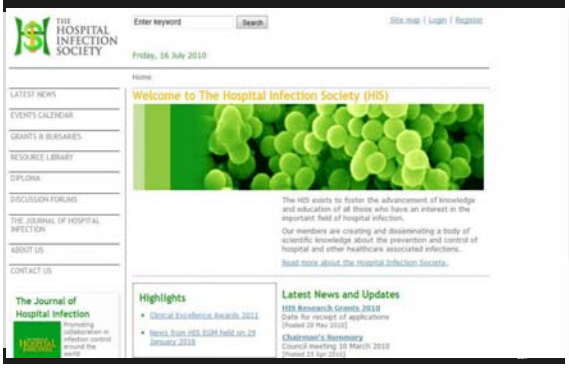
www.apic.org/Content/NavigationMenu/PracticeGuidance/APICEliminationGuides/Hemodialysis_Resourc.htm

www.who.int/en/

http://www.his.org.uk/



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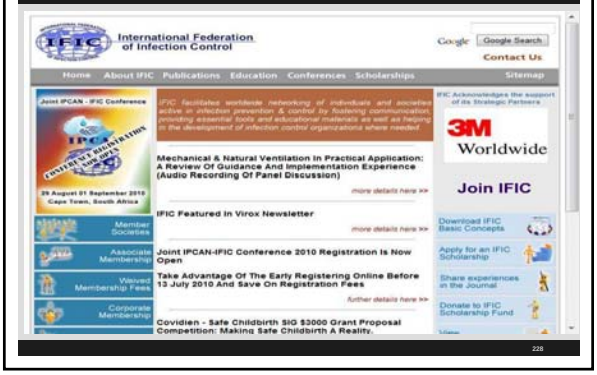

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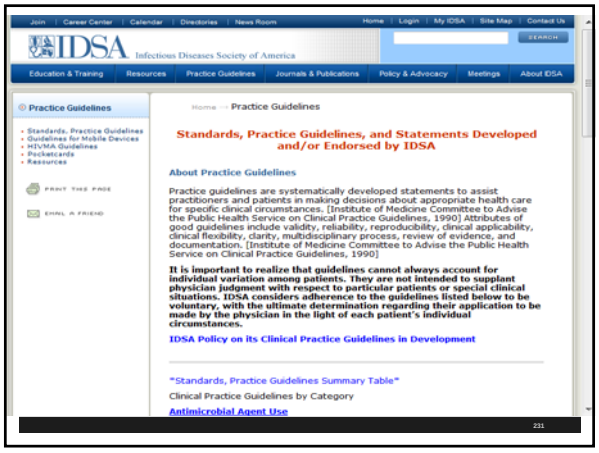

PA Patient Safety Authority

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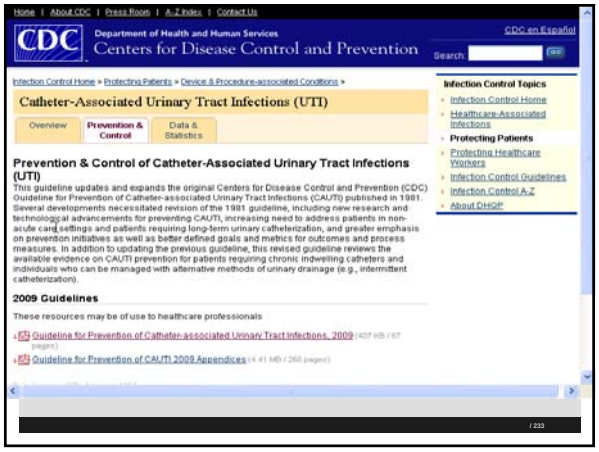
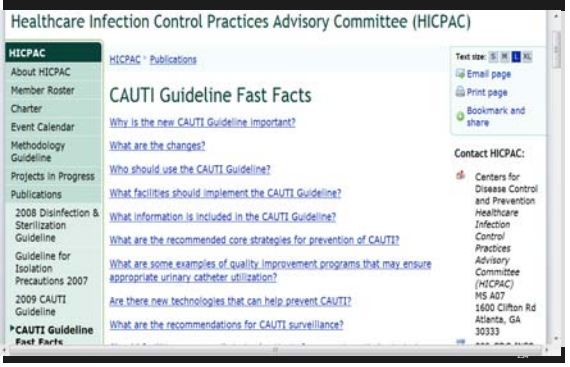


www.cdc.gov/hicpac/CAUTI_fastFacts.html



www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html

Healthcare Infection Control Practices Advisory Committee (HICPAC)

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Charter
Event Calendar
Methodology Guideline
Projects in Progress
Publications
2008 Disinfection & Sterilization Guideline
Table of Contents
Executive Summary
Approach to Disinfection and Sterilization
Factors Affecting

HICPAC > Publications

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

The complete Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 is available for download in PDF format (948 kB / 158 pages).

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http://www.cdc.gov/hicpac/pubs.html

Fast Facts
Podcast: Dr. Sanjay Saint discusses CAUTIs
Management of MDRO's in Healthcare Settings
Guidance on Public Reporting of HAIs 2003
Proceedings & Presentations
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2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings This document is intended for use by infection control staff, healthcare epidemiologists, healthcare administrators, nurses, other healthcare providers, and persons responsible for developing, implementing, and evaluating infection control programs for healthcare settings across the continuum of care.
Complete PDF version available for download Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007 PDF (3.80 MB / 225 pages)

Guidelines for Environmental Infection Control in Health-Care Facilities June 6, 2003 / 52(RR10);1-42 The *Guidelines for Environmental Infection Control in Health-Care Facilities* is a compilation of recommendations for the prevention and control of infectious diseases that are associated with healthcare environments.
Available for download [PDF - 1.4 MB]

Guidelines for Hand Hygiene in Healthcare Settings Published 2002 October 25, 2002 / Vol. 51 / No. RR-16 (PDF 496 KB / 56 pages)
Recent developments in the field have stimulated a review of the scientific data regarding hand hygiene and the development of new guidelines designed to improve hand-hygiene practices in

800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 24 Hours/Every Day
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Thanks for Attending!

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