# Infection Prevention in Your Outpatient Care Facility

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## Objectives

- Shifting our Infection Prevention perspective
- Statistics on Outpatient Care in the US
- (Un)Safe Injections
- Review outbreaks
- Review two main problems with instrument processing in outpatient care
- Recent FDA/CDC Recommendations r/t scope processing and manufacturing
- TJC citations, UNC Health Care, August, 2016

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We are out there observing, teaching and translating our vast body of research into practice.

We cannot always make it perfect or even consistent with regulations and guidelines.

We can ALWAYS make it better and safer for our patients and our staffs.

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## Outpatient Care in the US

- More patients obtain healthcare in specialty clinics and physicians' offices in the United States than in hospitals.
- 1.2 billion ambulatory care visits in US: physician offices, outpatient hospital and ED (2008).
- 60.5% of those visits are to primary care physicians' offices.
- University of North Carolina Health Care outpatient sites had 1.7 million visits in 2015.

CDC: 2010

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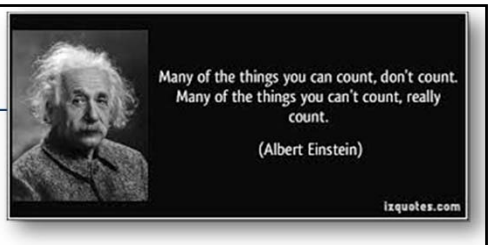
## Defining Surveillance




"The continued watchfulness over the distribution and trends of incidence through the systematic collection, consolidation, and evaluation of morbidity and mortality reports and other relevant data, together with dissemination to those who need to know." Langmuir, 1963

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## University of North Carolina Hospital's Infection Prevention Outpatient Surveillance Perspective

***Outcomes (data, infections, etc.)*** **-- historically inpatient infection prevention in contrast with**
***Performance/process measures*** **-- outpatient infection prevention**

**Outpatient Surveillance Definition:**

In UNCH's ambulatory surgery centers, physician practices, and specialty clinics outpatient surveillance is defined as bridging gaps between guidelines, standards, regulations and the actual practice of assessing infection prevention performance by applying a standard survey tool, gathering and analyzing the data collected with that tool, reporting that data back to facilities, and requiring action planning to improve performance if score is less than 100%.

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Outpatient facilities often exhibit

**Magnified**

physical plant challenges.

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Double Sinks: Both clean or both dirty.

Infection Prevention helped them figure this out.

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- No sink at all
- Storage of endocavitary probes in processing room

Infection Prevention helped them make it safer: switched to accelerated hydrogen peroxide HLD chemical that only requires one rinse…

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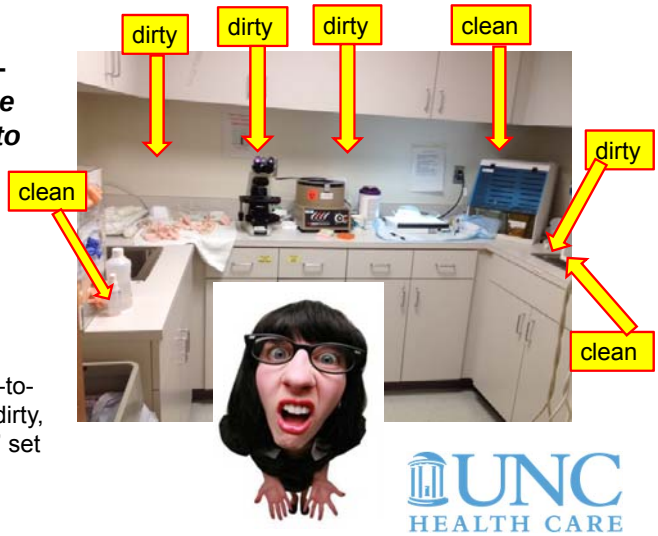
## Before Infection Prevention Assistance…a Hot Mess!

**Critical: rooms must have a dirty-to-clean flow *to the best of our ability to make it so*.**

(This is a "clean-to-dirty-to-clean-to-dirty-to-dirty-to-dirty, dirty, dirty, dirty-to-clean" set up.)

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## After Infection Prevention Assistance – it's all rainbows and unicorns!

They decluttered and established a "dirty-to-clean" flow (mostly).

Infection Prevention helped them figure this out.

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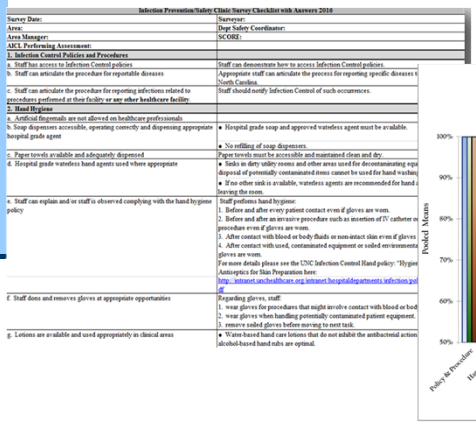
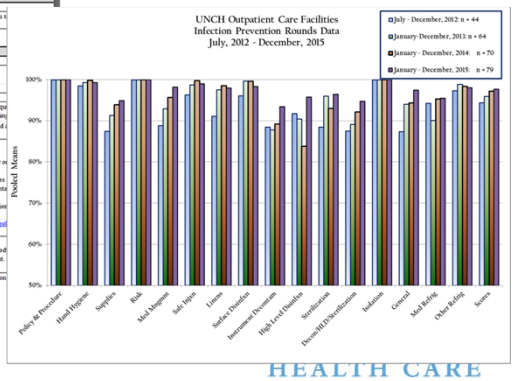
## UNCH's outpatient survey tool

- Compresses guidelines, standards, regulations and UNCH policy
- A usable, 17-section comprehensive instrument
- Provides a survey score to the facility
- Facilitates data gathering, analysis and correction of deficiencies



| Infection Prevention/Safety Clinic Survey Checklist with Answers 2016 | |
|---|---|
| Survey Date: | Surveyor: |
| Area: | Dept Safety Coordinator: |
| Area Manager: | SCORE: |
| AICL Performing Assessment: | |
| 1. Infection Control Policies and Procedures | |
| a. Staff has access to Infection Control policies | Staff can demonstrate how to access Infection Control policies. |
| b. Staff can articulate the procedure for reportable diseases | Appropriate staff can articulate the process for reporting specific diseases to the state of North Carolina. |
| c. Staff can articulate the procedure for reporting infections related to procedures performed at their facility or any other healthcare facility. | Staff should notify Infection Control of such occurrences. |
| 2. Hand Hygiene | |
| a. Artificial fingernails are not allowed on healthcare professionals | |
| b. Soap dispensers accessible, operating correctly and dispensing appropriate hospital grade agent | • Hospital grade soap and approved waterless agent must be available.<br>• No refilling of soap dispensers. |
| c. Paper towels available and adequately dispensed | Paper towels must be accessible and maintained clean and dry. |
| d. Hospital grade waterless hand agents used where appropriate | • Sinks in dirty utility rooms and other areas used for decontaminating equipment or disposal of potentially contaminated items cannot be used for hand washing.<br>• If no other sink is available, waterless agents are recommended for hand antisepsis before leaving the room. |
| e. Staff can explain and/or staff is observed complying with the hand hygiene policy | Staff performs hand hygiene:<br>1. Before and after every patient contact even if gloves are worn.<br>2. Before and after an invasive procedure such as insertion of IV catheter or surgical procedure even if gloves are worn.<br>3. After contact with blood or body fluids or non-intact skin even if gloves are worn.<br>4. After contact with used, contaminated equipment or soiled environmental surfaces even if gloves are worn.<br>For more details please see the UNC Infection Control Hand policy: "Hygiene and Use of Antiseptics for Skin Preparation here:<br>http://intranet.unchealthcare.org/intranet/hospitaldepartments/infection/policies/handwash.pdf |
| f. Staff dons and removes gloves at appropriate opportunities | Regarding gloves, staff:<br>1. wear gloves for procedures that might involve contact with blood or body fluids.<br>2. wear gloves when handling potentially contaminated patient equipment.<br>3. remove soiled gloves before moving to next task. |
| g. Lotions are available and used appropriately in clinical areas | • Water-based hand care lotions that do not inhibit the antibacterial action of soaps and alcohol-based hand rubs are optimal. |

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| **3. Storage and Use of Supplies** | |
| a. Clean and sterile supplies and equipment are stored appropriately | · Clean and sterile supplies must be stored in a manner to prevent contamination.<br>Bins used to store items must be clean upon inspection.<br>Sterile supplies and instruments that are set-up ahead of time should be protected from contamination and tampering. |
| b. Patient care supplies stored at least 36" from a sink or there is a protective barrier (splash guard) to prevent splash contamination; storage under sinks is discouraged except for the following allowed items: clean sharps containers, clean trash bags, detergents, and cleaning agents (NO hand soaps). | · To prevent water damage and/or contamination, only chemicals and reagents that do not react with each other or with water can be stored under sinks.<br>On the counter top, all items should be an adequate distance from sink or there must be a splash guard installed next to sink. |
| c. Supplies stored on shelves and off floors | · Must be 8" off floor.<br>· Must be 18" below sprinkler heads and 5" from ceiling if no sprinklers.<br>· Items should be removed from shipping cartons before storage to prevent contamination with soil/debris that might be on the cartons.<br>· Outer shipping boxes should not be left in clinical areas due to risk of environmental contamination.<br>· Supplies should be stored in plastic, washable containers; storage in cardboard is discouraged. |
| d. Supplies are within expiration date | · Sterile items must be clean, within date and properly stored. There should be no open steri-strips or opened packing strip bottles. These items are for single patient use.<br>· Supplies should be stocked and rotated "first in, first out" so oldest items are used first. |
| e. There is clear separation of clean and dirty activities | · Clean items/areas are clearly separated from dirty items.<br>· Need either separate clean/dirty rooms or the designated utility room must flow from clean to dirty. |
| f. Items labeled as "single use only" (SUDs) are not reused | The policy follows the FDA labeled guidelines that prohibit the reuse of Single Use Devices (SUDs). If single use devices are reprocessed, they are sent to the appropriate FDA-approved reprocessing facility. If reprocessed, must have contract available for viewing. |

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| 34 | **4. Risk Analysis** | |
| 35 | a. Types of procedures performed and services provided are appropriate for the physical space of the site as well as for the skill level and competency of staff | · New procedures and equipment are commissioned pursuant to Infection Control consultation where appropriate. |
| 36 | | · New construction or renovations are conducted in compliance with Infection Control standards as set forth in the facility's IC plan. |

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|---|---|---|
| 37 | **5. Medication Management** | |
| 38 | a. Medications must be separated by type and dosage | Recommended that all medications be stored separated by type and dosage in labeled, plastic, washable bins. |
| 39 | b. Requirements for storage and use of NC state supplied vaccines are met | See the NC State immunization web for details: http://www.immunize.nc.gov/ |
| 40 | c. Irrigation solutions are single patient use | · Irrigation solutions (bottles of sterile water, acetic acid, saline, etc.) must be discarded after use. |
| 41 | | · Betadine or other solutions poured into smaller containers must be labeled appropriately and discarded between patients if possible contamination has occurred. |
| 42 | d. Medications are within date | · No expired medications. |
| 43 | | · Multi-dose vials of **injectable** medications expire according to most recent UNC Adminstrative policy: Medication Management: Use Of Multi-Dose Vials/Pens Of Parenteral Medications In Acute Care And Ambulatory Care Environments. |
| 44 | e. Medications are stored appropriately | · Topical and internal medications are to be stored in a manner to prevent possible cross contamination and medication errors. |
| 45 | | · Chemicals are not to be stored adjacent to medications (e.g. nail polish remover, betadine). |
| 46 | f. Medications requiring special care after initial use are stored/labeled appropriately | · Special care meds would include those requiring refrigeration or those not kept at room temp for longer than manufacturer's recommendation, those with a shorter usage period as stated on the vial label by pharmacy or manufacturer (e.g. specific ophthalmic solutions, insulin-varies by manufacturer and type). |
| 47 | g. Medications are prepared safely | · Maintaining clean, uncluttered, and functionally separate areas for product preparation minimizes the possibility of contamination.<br>Injections are prepared in a clean area that is free from contamination with blood, body fluids, other visible contamination or used contaminated equipment.<br>NEVER dismantle dirty needles or syringes where medications are prepared.<br>Maintain separation of clean and dirty activities. |

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## (Un)Safe Injections

A safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community.

OneandOnlyCampaign.org

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## Overview

- **1998 – 2008**
  - 33 outbreaks in nonhospital health care settings
  - 12 in outpatient clinics
  - 6 in hemodialysis centers
  - 15 in long-term care facilities
  - 448 persons acquired HBV or HCV infection
  - The mechanism of infection was patient-to-patient transmission through failure of health care personnel to adhere to fundamental principles of infection control and aseptic technique
- **2008 – 2013**
  - 38 outbreaks of viral hepatitis related to healthcare reported to CDC during 2008-2013;
  - 94% occurred in non-hospital settings.

http://www.cdc.gov/hepatitis/Outbreaks/PDFs/HealthcareInvestigationTable.pdf

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## CDC: Outbreaks and Patient Notifications in Outpatient Settings, Selected Examples, 2010-2014

Outbreaks and Patient Notifications in Outpatient Settings, Selected Examples, 2010-2014

http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html

| Setting | Year Investigated | Pathogen(s) | Infection(s) | Patient Notification Performed (# notified) | Infection Control Breaches |
|---|---|---|---|---|---|
| Surgical Center [1] | 2014 | N/A* | N/A* | Yes (1,100) | 1) Reuse of syringes to access medication vials used for >1 patient?<br>2) Failure to properly reprocess reusable medical equipment |
| Orthopedic Clinic [2] | 2013 | *Staphylococcus aureus* | Septic Arthritis | No | 1) Complex preparation/compounding of injection materials involved extensive manipulations in the procedure room, with opportunities for contamination |
| Plastic Surgery Center [3] | 2013 | N/A* | N/A* | Yes (415) | 1) Reuse of syringes to access medication vials that may have been used for >1 patient? |
| Pain Management Clinic [4] | 2013 | Hepatitis B Virus | Hepatitis | Yes 534) | 1) Multiple procedural and infection control breaches were identified |
| Oral Surgery Clinic [5] | 2013 | Hepatitis C Virus | Hepatitis | Yes (5,810) | 1) Mishandling of injectable medications including reuse of single-dose vials of propofol<br>2) Improper reprocessing of dental instruments |
| Plastic Surgery Center [6] | 2013 | Nontuberculous mycobacteria, Other | Surgical Site Infection | No | 1) Off-label use of lubricating gel directly on sterile tissues<br>2) Reuse of single-use breast implants as sizers |
| | | | | | |

**2010 – 2014**

- **Total patients notified: 22,593**
- **86% (19,466) directly related to unsafe injections**

http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

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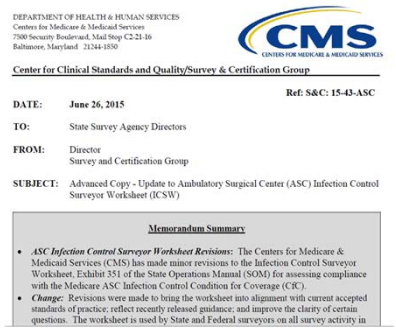
## CMS: Infection Control Worksheet

Two multi-page documents specifically for inspecting infection prevention practices in acute care and ambulatory surgical facilities.

Approximately 15 elements in worksheets dedicated to safe injections.



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

**Section 2.B. Injection Practices and Sharps Safety (Medications and Infusates)**

| Elements to be assessed | Surveyor Notes | Surveyor Notes |
|---|---|---|
| Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following: | | |
| Note: If possible, questions in this section should be assessed through observation in two separate patient care areas or settings of the hospital. | | Second observation not available (If checked, questions 2.B.1 – 2.B.15 RIGHT column will be blocked) |
| 2.B.1 Injections are prepared using aseptic technique in an area that has been cleaned and is free of contamination (e.g., visible blood, or body fluids). | ☐ Yes ☐ No ☐ Unable to observe | ☐ Yes ☐ No ☐ Unable to observe |
| 2.B.2 Needles are used for only one patient. | ☐ Yes ☐ No ☐ Unable to observe | ☐ Yes ☐ No ☐ Unable to observe |
| 2.B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes). | ☐ Yes ☐ No ☐ Unable to observe | ☐ Yes ☐ No ☐ Unable to observe |
| 2.B.4 Insulin pens are used for only one patient. | ☐ Yes ☐ No ☐ Unable to observe | ☐ Yes ☐ No ☐ Unable to observe |
| 2.B.5 The rubber septum on all medication vials, whether unopened or previously accessed, is disinfected with alcohol prior to piercing. | ☐ Yes ☐ No ☐ Unable to observe | ☐ Yes ☐ No ☐ Unable to observe |

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http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

| Standard | Element of Performance |
|---|---|
| **6. Safe Injection Practices** | |
| **ONE NEEDLE: ONE SYRINGE: ONE PATIENT: ONE TIME** | |
| a. Single dose vials are never used as multidose vials. | Single dose vials should be used whenever possible and discarded immediately after use. |
| b. Fluid infusion and administration sets (IV bags, tubing, and connectors) are used for one patient only and discarded after use. | Bags of IV fluids are ALWAYS single use. |
| c. IV fluids spiked at time of use. | IV fluids are spiked and tubing is primed immediately prior to use. |
| d. Patient's skin is prepped with an approved prep before IV placement . | Approved skin prep agents are alcohol or chlorhexidine gluconate (CHG). |
| e. Single dose medications or infusates are used for only one patient and not collected or combined (bags of IV fluids are ALWAYS single use). | No combining of "left-overs" from single dose vials. No flushes drawn from bulk sources such as liter bags of IV fluids. |
| f. Medication vials used for more than one (1) patient are always entered with a new needle and new syringe. | Medication vials used for more than one patient must be labeled as "multi-dose" by the drug manufacturer. |
| g. The rubber septum on a medication/infusate vial is disinfected with alcohol prior to piercing. | Enter or re-enter medication vials only after a robust wipe of the rubber septum with alcohol. |
| h. Needles and syringes are used for only one patient. | NEVER NEVER NEVER re-use needles or syringes. |
| i. Medications or infusates that are packaged as prefilled syringes are used for only one patient. | Pre-filled syringes are ALWAYS single doses. |
| j. Hand hygiene is performed before preparing medications. | |
| k. Medications or infusates are drawn up at start of each procedure. | • Compliance with USP 797 prohibits "pre-drawing" injectable medications from a single dose vial unless done under a hood which meets ISO class 5 conditions. Any injectable medication drawn from a single dose vial must be injected within an hour of drawing up. |
| l. Needles and syringes are discarded intact in an appropriate sharps container after use. | Safety devices are deployed; needles should not be removed from syringes. |
| m. Flushes are not drawn from a bulk container. | Bags of IV fluids are ALWAYS single use. |
| n. Appropriate safety devices are in use. Exceptions have an approval from Hospital Epidemiology. | OSHA regulation requires sharps safety devices to be used unless medically contraindicated. |

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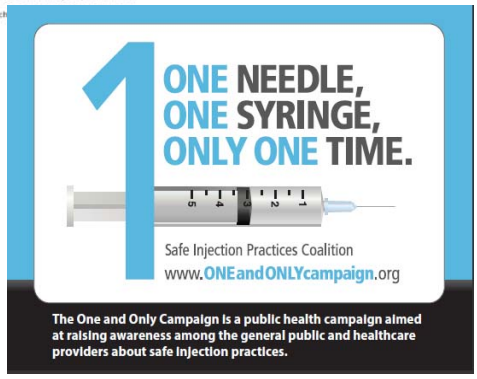
AJIC special article

**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; administration of injections; procurement of blood.




## A problem and its solution…


- *Multi*dose lidocaine
- Buffered with *single* dose bicarbonate
- Spike left in all day
- Solution: clinic has lidocaine and bicarbonate prefilled syringes prepared at compounding pharmacy, approved by our pharmacists, and per CMS and CDC advisory

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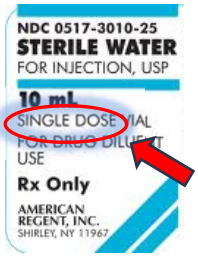
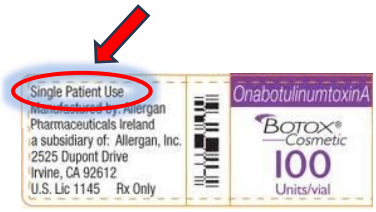
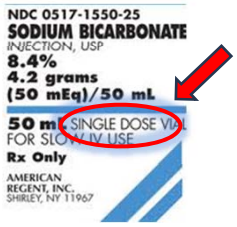
## Single Dose Medication Vials

Injectable medications labeled by the manufacturer as "single dose" or "single patient use" may be used for only ONE dose for ONE patient and the remainder discarded immediately.




- Injectable medications should be drawn up as needed – not ahead of time.
- Administer medications drawn from a single dose vial as soon as feasible.

Back to the assessment tool…

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|---|---|---|
| 64 | **7. Linens** | |
| 65 | a. Linens are stored appropriately | · Clean linen must be stored in designated area to prevent contamination from traffic and to reduce risk of linen falling on floor. |
| 66 | | · Clean linen must be kept covered if not in a closet, drawer, or cabinet. |
| 67 | b. Linens are laundered according to UNC Infection Control's Laundry and Linen Service policy | |

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| | | |
|---|---|---|
| 68 | **8. Surface Disinfection** | |
| 69 | a. Toys are disinfected per clinic specific policy | · Used washable toys/sand tables are cleaned with soap and water and rinsed with tap water or wiped with 70% alcohol on a routine basis (e.g. weekly) and when visibly soiled. |
| 70 | | · Toys must be non-porous and cleanable; plush toys are to be new and given to the individual patient. |
| 71 | | · Toys should be rinsed with tap water after cleaning to remove any disinfectant residue. |
| 72 | | · Toys should be restricted to only those that can be easily cleaned. |
| 73 | b. Non-critical items are cleaned per policy | · Non-critical items are those that come into contact with intact skin. Non-critical items should not contact blood or body fluids. |
| 74 | | · Single use disposable BP cuffs are to be used for one patient and discarded after use. |
| 75 | c. Patient care equipment (e.g., blood pressure cuffs, wall mounted otoscopes, etc.) should be cleaned with an EPA registered disinfectant detergent (e.g., MetriGuard®, Super Sani Cloths®) or 70% alcohol once a week, when obviously soiled, and after use for patients requiring Contact Precautions. | • Cleaning supplies are in their proper place. |
| 76 | | • Only hospital grade approved germicidals are to be used for cleaning surfaces in the healthcare environment. |
| 77 | | • Exam tables, recliners and short-term use beds should be cleaned weekly, when visibly soiled, and after use for patients requiring Contact Precautions. |
| 78 | d. Areas identified as nursing responsibility are cleaned appropriately | Some examples include medication storage areas, electrical equipment. |
| 79 | e. Point-of-care devices are cleaned according to policy | Medical equipment that involves blood testing, such as glucometers, must be cleaned between every patient with a hospital grade approved disinfectant. |

UNC HEALTH CARE 30

| | | |
|---|---|---|
| 80 | **9. Instrument Decontamination/pre-cleaning** | |
| 81 | a. Items are thoroughly pre-cleaned and decontaminated with enzymatic detergent according to manufacturer instructions and/or evidence-based guidelines prior to high level disinfection or sterilization. | Staff can demonstrate understanding of manufacturer's instructions for use. |
| 82 | b. Items are managed consistent with OSHA regulations and UNCH policy. | Example: dirty instruments must be transported from point-of-use to instrument processing area in a leak-proof container marked "biohazard." |

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| | | |
|---|---|---|
| 83 | **10. High Level Disinfection** | |
| 84 | a. Medical instrument and devices are visually inspected for residual soil and recleaned as needed before high level disinfection | |
| 85 | b. HLD equipment (e.g., AER) is maintained according to manufacturer instructions and/or evidence-based guidelines | AERs are maintained and logs kept of maintenance |
| 86 | c. Chemicals used for HLD are prepared according to manufacturer instructions, UNC infection control policy, and evidence-based guidelines | Infection Control-approved HLDs such as Cidex, Cidex OPA, Wavicide, etc. |
| 87 | d. Chemicals used for HLD are tested for minimum effective concentration (MEC) according to manufacturer instructions and/or evidence-based guidelines and are replaced before they expire | • Logs are kept for all HLD processes, including test strip QC.<br>• Containers must be covered and labeled with chemical name, hazard information and expiration date. |
| 88 | e. Chemicals used for HLD are documented to have been prepared and replaced according to manufacturer instructions and/or evidence-based guidelines | |
| 89 | f. Equipment is high-level disinfected according to manufacturer's instructions and/or evidence-based guidelines and according to UNC Cleaning, Disinfection, and Sterilization of Patient-Care Items policy | |
| 90 | g. Items that undergo HLD are dried before re-use | |
| 91 | h. HLD logs are in order | Logs must be kept on all HLD processes. |
| 92 | i. Test strips are properly dated | |

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| | | |
|---|---|---|
| 93 | **11. Sterilization** | |
| 94 | a. Autoclaves: chemical and biological indicators are used appropriately | Internal chemical indicators must be used in each package to be sterilized; the chemical indicator must be examined before the contents are used. |
| 95 | b. Biological indicators run at least weekly | Biological indicators are to be run at least weekly and must be used with each load containing implantable devices. |
| 96 | c. Sterilization logs accurate and up to date | Written records of each load should be kept. |
| 97 | d. Sterile packages are inspected for integrity and compromised packages are reprocessed | Instruments in torn, wet, or damaged sterilization pouches must be re-sterilized. |

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| | | |
|---|---|---|
| 98 | **12. General Decontamination/HLD/Sterilization** | |
| 99 | a. Proper PPE is worn when processing dirty equipment | Water-proof or water-resistant gown, disposable gloves (nitrile if performing HLD activities), and full face protection must be worn when processing dirty instruments. |
| 100 | b. Competencies are maintained for cleaning, disinfection and sterilization processes | Records of staff training must be documented. HLD competency is evaluated at commencement of employment and at least yearly thereafter. |
| 101 | c. HLD, decontamination, and /or sterilization is performed in appropriate environment | HLD, decontamination and/or sterilization may not be performed in a patient care area. If using glutaraldehyde proper ventilation is in place. |
| 102 | d. Areas used for cleaning or disinfection flow from dirty to clean | The area must have a definite work flow from dirty to clean to prevent contamination of equipment. |
| 103 | e. There is a procedure in place for identification and recall of inadequately sterilized or high level disinfected instruments | UNC Infection Prevention department must be notified immediately: 966-1638. |
| 104 | f. After sterilization or high level disinfection, devices and instruments are stored in a designated clean area so sterility is not compromised | Sterilized and high-level-disinfected items should not be stored in instrument processing areas whenever possible. |

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## Instrument Processing in Outpatient Care Facilities

Access to complex and invasive procedures in healthcare facilities other than hospitals:

1. Saves time and money

2. Brings heightened risk of infection to patients and staff

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## Spaulding Classification Scheme

**All major societies and healthcare advisory institutions subscribe:**

- AAMI: Association for the Advancement of Medical Instrumentation
- ASGE: American Society of Gastroenterologists
- SGNA: Society of Gastroenterology Nurses and Associates
- CDC: Centers for Disease Control and Epidemiology

**Clear, logical approach to disinfection and sterilization**

**Three categories:**

1. non-critical
2. semi-critical
3. critical

**Items categorized on the basis of the degree of risk of infection involved in their *use***

- Example: scissors vs. scissors

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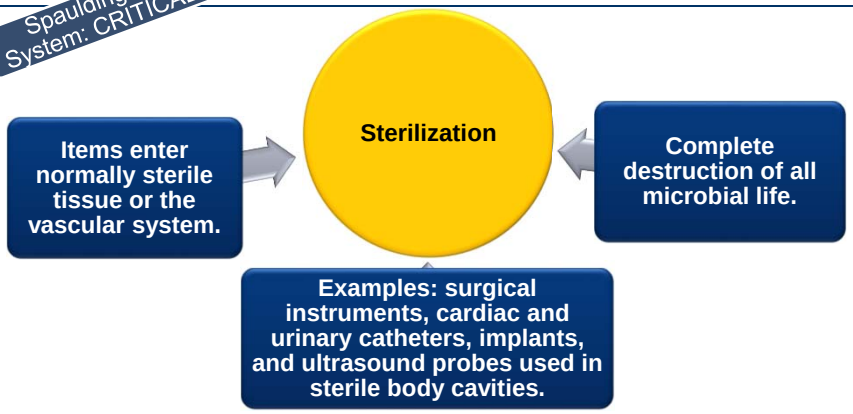
Spaulding Classification System: CRITICAL DEVICES




Critical items confer a high risk for infection if they are contaminated with any microorganism.

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HICPAC. Guideline for disinfection and sterilization in healthcare facilities, 2008. Centers for Disease Control and Prevention; 2008

## Steam Sterilization: Enormous Margin of Safety

- 100 quadrillion ($10^{-17}$) margin of safety
- Sterilization kills 1 trillion spores *in addition to* the washer/disinfector which removes or inactivates 10-100 million microbes.

There is a 1:100 quadrillion chance of the item NOT being sterile

(that's a "1" with 17 zeros after it)

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**Generally speaking, and particularly compared to HLD, I don't worry about steam sterilization practices – well, I don't lose sleep over steam sterilization.**


InspecAPedia.com

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Spaulding Classification System:
Semi-CRITICAL DEVICES

**High Level Disinfection**

**Items contact mucous membranes or nonintact skin.**

**Complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores.**

**Examples: some endoscopes, laryngoscope blades, cystoscopes, ultrasound probes.**

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HICPAC. Guideline for disinfection and sterilization in healthcare facilities, 2008. Centers for Disease Control and Prevention; 2008

## High-Level Disinfection: **No** Margin of Safety for GI Endoscopes

- Margin of safety with endoscope reprocessing minimal or non-existent for two reasons:
- Microbial load
  - GI endoscopes contain $10^{7\text{-}10}$
  - Cleaning results in 2-6 $\log_{10}$ reduction
  - High-level disinfection results in 4-6 $\log_{10}$ reduction
  - Results in a total 6-12 $\log_{10}$ reduction of microbes
- Complexity of endoscope
- Humans

Rutala WA, Weber DA. Infect Control Hosp Epidemiol 2015

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## I do worry about high-level disinfection practices.


123nspecAPedia.com

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## First: HLD and Sterilization Education for all IPs!

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CDC

## Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

William A. Rutala, Ph.D., David Weber, M.D., M.P.H., and the Healthcare Infection Control Practices Advisory Committee (HICPAC)

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

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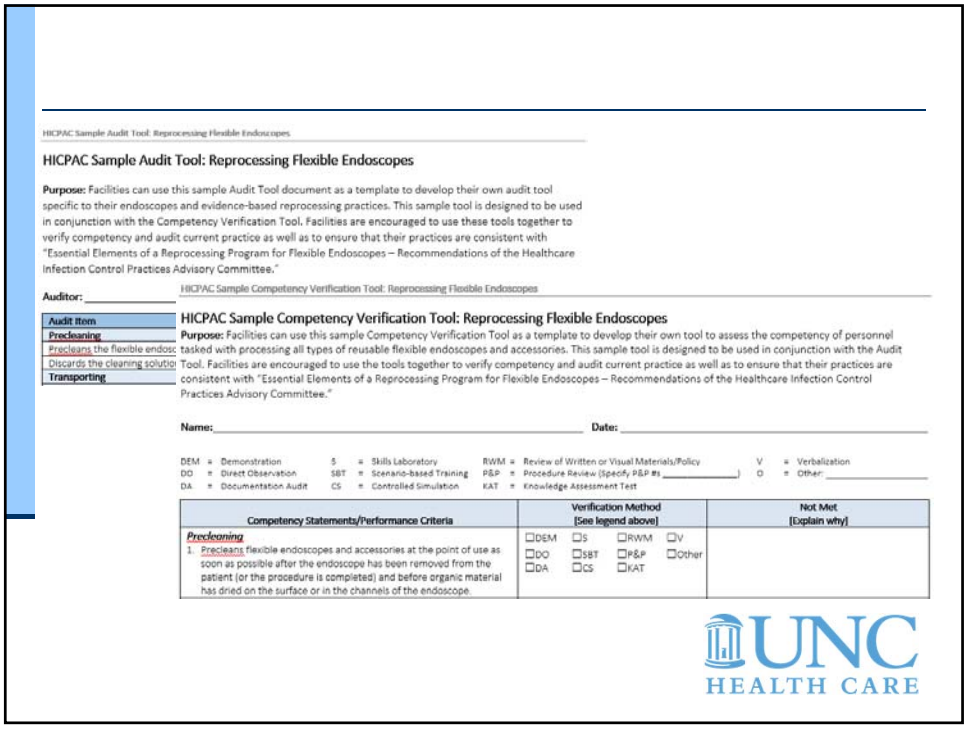

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

## HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

**Purpose:** Facilities can use this sample Audit Tool document as a template to develop their own audit tool specific to their endoscopes and evidence-based reprocessing practices. This sample tool is designed to be used in conjunction with the Competency Verification Tool. Facilities are encouraged to use these tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee."

**Auditor:** _____

| Audit Item |
|---|
| Precleaning |
| Precleans the flexible endosc |
| Discards the cleaning solutio |
| Transporting |

HICPAC Sample Competency Verification Tool: Reprocessing Flexible Endoscopes

## HICPAC Sample Competency Verification Tool: Reprocessing Flexible Endoscopes

**Purpose:** Facilities can use this sample Competency Verification Tool as a template to develop their own tool to assess the competency of personnel tasked with processing all types of reusable flexible endoscopes and accessories. This sample tool is designed to be used in conjunction with the Audit Tool. Facilities are encouraged to use the tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with "Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee."

**Name:** _____ **Date:** _____

DEM = Demonstration; DO = Direct Observation; DA = Documentation Audit; S = Skills Laboratory; SBT = Scenario-based Training; CS = Controlled Simulation; RWM = Review of Written or Visual Materials/Policy; P&P = Procedure Review (Specify P&P #s _____); KAT = Knowledge Assessment Test; V = Verbalization; O = Other: _____

| Competency Statements/Performance Criteria | Verification Method (See legend above) | Not Met (Explain why) |
|---|---|---|
| *Precleaning*<br>1. Precleans flexible endoscopes and accessories at the point of use as soon as possible after the endoscope has been removed from the patient (or the procedure is completed) and before organic material has dried on the surface or in the channels of the endoscope. | ☐DEM ☐S ☐RWM ☐V<br>☐DO ☐SBT ☐P&P ☐Other<br>☐DA ☐CS ☐KAT | |

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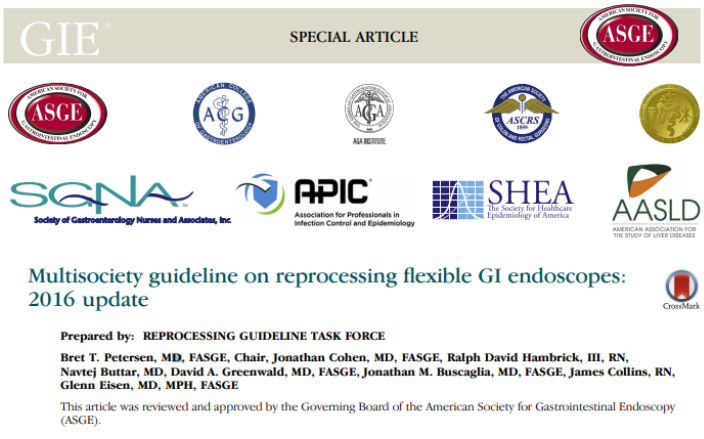
**Disinfection and Sterilization in Health Care Facilities: What Clinicians Need to Know**

- Rutala and Weber, Clinical Infectious Diseases 2004; 39:702–9

**Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2016 update**



GIE SPECIAL ARTICLE

Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

**Prepared by: REPROCESSING GUIDELINE TASK FORCE**

**Bret T. Petersen, MD, FASGE, Chair, Jonathan Cohen, MD, FASGE, Ralph David Hambrick, III, RN, Navtej Buttar, MD, David A. Greenwald, MD, FASGE, Jonathan M. Buscaglia, MD, FASGE, James Collins, RN, Glenn Eisen, MD, MPH, FASGE**

This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

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American National Standard

- Manufacturer's IFUs
- AAMI ST91
- AAMI ST79

AAMI
Advancing Safety in Healthcare Technology

ANSI/AAMI ST91:2015
Flexible and semi-rigid endoscope processing in health care facilities

**ANSI/AAMI ST79:2017**
*Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

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**Switch to disposables wherever possible.**

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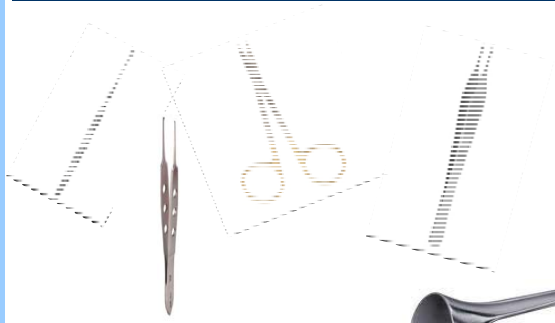
## Instruments



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## The Sterilizers


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## Sterilizers

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## Steam Sterilization

- Highly, highly, highly effective
- Nontoxic to patients and staff
- Cycle is easy to control and monitor
- Rapid cycle time
- Penetrates medical packing and device lumens
- Least affected by organic/inorganic soils

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## Class 5

## Integrating indicator

- One in every package

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## Biological Indicators (BIs)




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Biological indicators should be used at least weekly, with each load that contains implants, and, ideally, daily.

*BIs must be intended specifically for the type of sterilizer in use.*

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## Monitoring the Sterilization Cycle

**Mechanical (physical) parameters**

- Time
- Temperature
- Pressure

**Chemical parameters**

- Chemical indicators

Sterilizers that do not have recording devices should not be used

**Biological parameters**

- Biological indicators
  - Bacillus spores that directly measure sterilization

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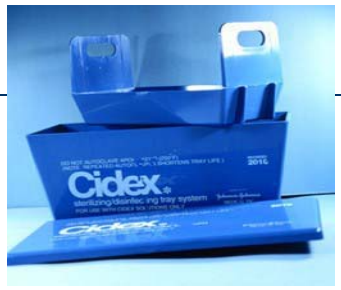
Your clinics may process semi-critical devices manually…




Or in an automated endoscope reprocessor

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Back to the assessment tool…

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| | | |
|---|---|---|
| 105 | **13. Isolation** | |
| 106 | a. Staff is able to articulate standard precaution and isolation policies (such as | • Personnel must be able to articulate and locate pertinent policies. |
| 107 | for TB, chickenpox, "Respiratory Etiquette") | • Use appropriate signage. |
| 108 | b. Staff are able to state how patients would be managed that have a known resistant organism (e.g. MRSA, VRE, C. difficile, draining wound or rash) | Per UNC Ambulatory Care policy: Wear appropriate PPE; meticulous hand hygiene. Clean and disinfect exam table and any other surfaces which contacted patient with an appropriate disinfectant. |
| 109 | c. Personal protective equipment (PPE) is available | Clinic must have sufficient stock of gowns, gloves, masks, and eye protection. |

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| | | |
|---|---|---|
| 110 | **14. General Issues** | |
| 111 | a. Areas free of dust, dirt, soil, trash, odors, clutter and hazards (fixtures, walls, ceilings, floors) | Ceiling tiles all intact, clean, dry and no stains. |
| 112 | b. Areas and furnishings are in good repair | Paint intact, cabinet doors functioning properly, no rips, holes, or cracks in vinyl upholstery. |
| 113 | c. Staff food and drinks are placed in appropriate areas | Stored away from patient care areas and in compliance with NC OSHA blood borne pathogen regulations. |

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| 15. Medication Refrigerators and Freezers | | | |
|---|---|---|---|
| a. Medication refrigerators and freezers are large enough to properly store medications. | Refrigerators and freezers must be large enough to store the year's largest inventory of medications. | | |
| b. Refrigerators and freezers well maintained and clean | Clean and well maintained. No expired food or medications. Store patient food, medications, and specimens in separate labeled refrigerators. | | |
| c. Medication refrigerator temperatures maintained between 36-46 degrees F (between 2-8 degrees Celsius)<br>Note: Clinics with state-supplied vaccines should use the NC state refrigerator and freezer logs available at http://www.immunize.nc.gov/providers/index.htm | | **Fahrenheit** | **Celsius** |
| | Food Freezer | Below 0° | Below -17° |
| | Food Refrigerator | 41° or less (2016) | 7° or less (2016) |
| | Medication Freezer | 5° to -13° | -15° to -25° |
| | Medication Refrigerator | 36° to 46° | 2° to 8° |
| | Specimen Freezer | 5° to -4° | -15° to -20° |
| d. Medication freezer maintained below 5 degrees F (below -15 degrees Celsius) | Specimen Refrigerator | 36° to 46° | 2° to 8° |
| e. An appropriate means to check medication in event of a power outage is in place | • All sites without emergency back-up power will have a reliable method of monitoring temperatures in all medication refrigerators and freezers. | | |
| | • Minimum and maximum temperatures shall be routinely checked and action taken for out-of range temperatures. | | |
| | • For power outages of less than two hours, leave doors to refrigerators and freezers closed. Proper storage temperatures will be maintained for at least 2 hours if doors are not opened. | | |
| | • In the event of a power outage lasting longer than two hours, call the Pharmacy Support Service at 919-966-1367 during normal working hours and pager 919-216-2903 after normal working hours to request help with drug storage. If no answer, call the Inpatient Pharmacy at 919-966-2376. | | |

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| 16. Food Refrigerators, Lab refrigerators, Ice Machines, Ice Chests | |
|---|---|
| a. Food and medications are stored separately | Patient nourishments are to be single-serving, individually sealed portions. Patient food refrigerator temperatures must monitored and documented routinely on the appropriate refrigerator log. |
| b. Food and/or medications are within date | Expiration date should be visible on all food/medication. |
| c. Specimens and culture media are stored separately from food and medications | Medications and food must be stored in separate refrigerators with all items within date and not stored with specimens. |
| d. Specimens and lab reagents are stored appropriately | Laboratory reagents must be stored separately from medications. |
| e. Ice chests and ice machines are maintained according to national and North Carolina state guidelines | 1. DO NOT handle ice directly by hand – use a scoop; wash hands before obtaining ice. |
| | 2. Store the ice scoop on a clean hard surface when not in use. DO NOT store in the ice bin. |
| | 3. Machines that automatically dispense ice are preferred to those that require ice to be removed from bins or chests with a scoop. |
| | 4. Weekly cleaning of ice storage chests, scoops, and ice chute extenders should be performed with fresh soap or detergent solution. After cleaning, rinse all surfaces of the ice storage chest with fresh tap water, wipe dry with clean materials, rinse again with a 10- to 100-ppm bleach solution (1 to 8 ml of sodium hypochlorite household bleach per gallon of water), and allow all surfaces to dry before returning the items to service. |
| | 5. Weekly cleaning as described above should be documented. |
| | 6. Limit access to ice storage chest and keep doors closed. |
| | 7. Follow manufacturer's instructions for periodic maintenance and cleaning/disinfecting ice machines. |
| | 8. Ice machines that dispense ice automatically are preferred for public access. |

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| 17. Safety | |
|---|---|
| a. Site Specific Fire Emergency Response Plan (SSFERP) | The SSFERPs must be current and accurate. Staff must know what it is and where it is located: http://intranet.unchealthcare.org/hospitaldepartments/safetynet/programs/dsc/handbook/SiteSpecificFirePlanProcedures.pdf |
| b. Fire extinguishers, emergency lights and pull stations | Do recessed extinguishers have signs posted above the extinguisher? Are extinguishers checked monthly and documented? Are all extinguishers and pull stations clear and unobstructed? Are emergency lights tested monthly and documented? The documentation form may be found here: http://intranet.unchealthcare.org/hospitaldepartments/safetynet/programs/dsc/forms/lightsextinguisherlog.docx |
| c. Fire suppression sprinklers | Is there an 18 inch clearance around sprinkler heads? |
| d. Doors | Doors should not be wedged open. |
| e. Small electrical appliances | • Space heaters are not allowed in UNCH facilities.<br>• Only commercial grade coffee makers are approved. See policy: http://intranet.unchealthcare.org/policies/unc-hcs-policies-pdf-new-format/ADMIN0233.pdf.<br>• Microwaves have "do not leave unattended" stickers on them. |
| f. Electrical panels | There must be a 36 inch clearance in front of electrical panels. |
| g. Mechanical rooms | Rooms housing data equipment, water heaters, air handlers, etc., must be clear of all other items. |
| h. Hallways | Are corridors and stairwells free of clutter and obstructions? |
| i. Oxygen tanks, liquid nitrogen tanks | • Oxygen tanks must secured in racks or by chains attached to the wall. Empty and full cylinders must be stored separately with clear signage indicating "full" or "empty."<br>• Non-pressurized liquid nitrogen tanks do not require securement devices. Full-face shield, safety glasses/goggles, and cryogenic gloves must be worn when working with liquid nitrogen. |
| j. Safety Data Sheets (SDSs) (formerly "MSDSs") | Staff should know how to access SDSs. |
| k. Eyewashes | Checked monthly and documented on the log which may be found here: http://intranet.unchealthcare.org/hospitaldepartments/safetynet/programs/dsc/handbook/Monthly%20Eyewash%20Activation%20Log.pdf |
| l. Medical equipment | Medical equipment is appropriately tagged and tags are not expired. |
| m. Spill kits are in place for relevant chemicals. | Contact Environmental Health and Safety for more information. |

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**This report is also submitted to the UNC Healthcare Hospital Infection Control Committee**

| | | | | | |
|---|---|---|---|---|---|
| **Survey Date:** | | | | | **Infection Preventionist: Judie Bringhurst** |
| **Area:** | | | | | **Departmental Safety Coordinator:** |
| **Area Manager:** | | | | | **Total Compliance:** 81% |

| Standard | Met | Not Met | N/A | Not Assessed | Notes |
|---|---|---|---|---|---|
| **1. Infection Control Policies and Procedures** | | | | | |
| a. Staff has access to Infection Control policies | 1 | | | | |
| b. Staff can articulate the procedure for reportable diseases | 1 | | | | |
| c. Staff can articulate the procedure for reporting infections related to procedures performed at their facility or at any other facility. | 1 | | | | |
| | **3** | **0** | | | |
| **Percent Met** | **100** | | | | |
| **2. Handwashing Facilities** | | | | | |
| a. Artificial fingernails are not allowed on healthcare professionals | | 1 | | | |
| b. Soap dispensers accessible, operating correctly and dispensing appropriate hospital grade agent | 1 | | | | |
| c. Paper towels available and adequately dispensed | | 1 | | | |
| d. Hospital grade waterless hand agents used where appropriate | 1 | | | | |
| e. Staff can explain and/or staff is observed complying with the hand hygiene policy | 1 | | | | |
| f. Staff dons and removes gloves at appropriate opportunities | 1 | | | | |
| g. Lotions are available and used appropriately in clinical areas | 1 | | | | |
| | **5** | **2** | | | |
| **Percent Met** | **71.43** | | | | |
| **3. Storage of Supplies** | | | | | |
| a. Clean and sterile supplies and equipment are stored appropriately | 1 | | | | |
| b. Patient care supplies stored at least 36" from a sink or there is a protective barrier (splash guard) to prevent splash contamination; storage under sinks is discouraged except for the following allowed items: clean sharps containers, clean trash bags, detergents, and cleaning agents (NO hand soaps). | | 1 | | | |
| c. Supplies stored on shelves and off floors | 1 | | | | |
| d. Supplies are within expiration date | 1 | | | | |
| e. There is clear separation of clean and dirty activities | 1 | | | | |
| f. Items labeled as "single use only" (SUDs) are not reused | 1 | | | | |
| | **5** | **1** | | | |
| **Percent Met** | **83.33** | | | | |

Where does all this data go?

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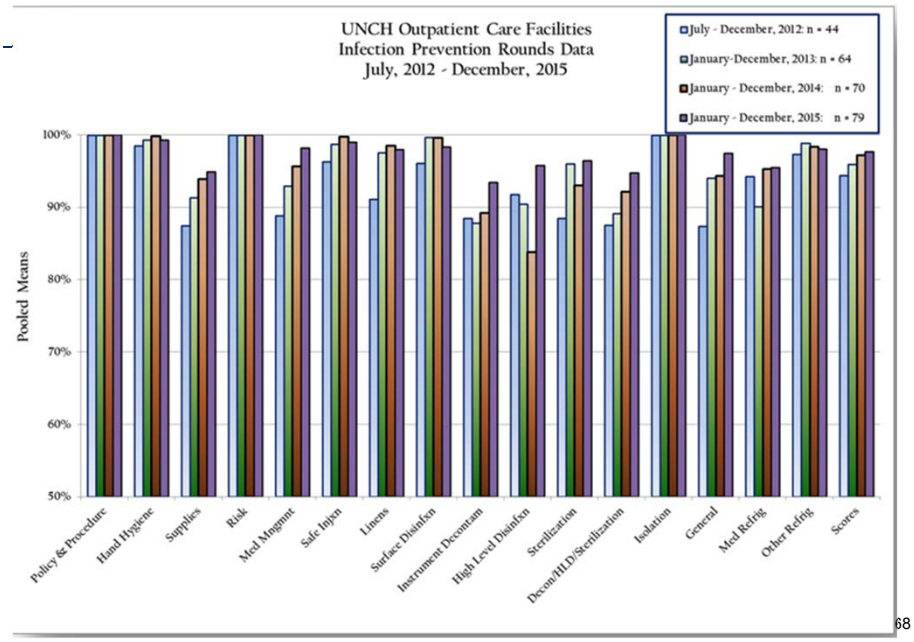


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## Step One…GEMBA: go to the place of the action:

Tuck *ANY* HLD Guideline under your arm and

**walk into your scope processing room, your instrument processing room, your instrument processing closet and start a conversation.**

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**It was a mistake for me to assume people who HLD *everyday* know the right way to do it.**

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## Guarantees

- We *CANNOT* always make it perfect or even consistent with regulations and guidelines.
- We *CAN* always make it better and safer for our patients and our staffs. I personally guarantee that.
- Just start your first visit…the rest will happen for you automatically.

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## Take a phased approach to correction.

- Take time to research your findings in the evidence-based literature and guidelines
- Document your researched findings with citations
- Plan your actions based on the evidence and national evidence-based guidelines
- Inform area leaders
- Assist your staff with fixing the most dangerous practices first
- Move forward with other fixes in order of priority
- Remember: one size DOES NOT fit all in outpatient facilities

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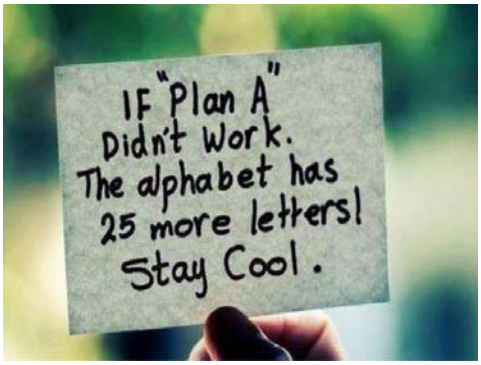


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**Once we, Infection Prevention, are fully engaged, the myriad elements and complexities of Outpatient Infection Prevention within our facilities will lead us where they need us to go.**

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# Thank you!

## Outpatients: The Nation's Largest Patient Population

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