

GUIDE TO INFECTION PREVENTION FOR OUTPATIENT SETTINGS:

Minimum Expectations for Safe Care



National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion



NOTE TO READERS

The following document is a summary guide of infection prevention recommendations for outpatient (ambulatory care) settings. The recommendations included in this document are not new but rather reflect existing evidence-based guidelines produced by the Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee. This summary guide is based primarily upon elements of Standard Precautions and represents the minimum infection prevention expectations for safe care in ambulatory care settings. Readers are urged to use the *Infection Prevention Checklist for Outpatient Settings* (Appendix A), a companion to the summary guide, and to consult the full guidelines for additional background, rationale, and evidence behind each recommendation.

All guidelines are available at:

http://www.cdc.gov/HAI/prevent/prevent_pubs.html

The transition of healthcare delivery from acute care hospitals to outpatient (ambulatory care) settings, along with ongoing outbreaks and patient notification events, have demonstrated the need for greater understanding and implementation of basic infection prevention guidance. *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care* distills existing infection prevention guidance from the Centers for Disease Control and Prevention (CDC) and the Healthcare Infection Control Practices Advisory Committee (HICPAC).

Over the past several decades, we have witnessed a significant shift in healthcare delivery from the acute, inpatient hospital setting to a variety of ambulatory and community-based settings. Ambulatory care is provided in hospital-based outpatient clinics, nonhospital-based clinics and physician offices, ambulatory surgical centers, and many other specialized settings. Americans have frequent encounters with ambulatory care. For example, more than three-quarters of all operations in the United States are performed in settings outside the hospital¹. In addition, between 1995 and 2007, the average person made three visits each year to physician offices². By 2007, the total number of physician offices visits approached one billion³. Vulnerable patient populations rely on frequent and intensive use of ambulatory care to maintain or improve their health. For example, each year more than one million cancer patients receive outpatient chemotherapy, radiation therapy, or both⁴. It is critical that all of this care be provided under conditions that minimize or eliminate risks of healthcare-associated infections (HAI).

Compared to inpatient acute care settings, ambulatory care settings have traditionally lacked infrastructure and resources to support infection

prevention and surveillance activities^{5,6,7}. While data describing risks for HAI are lacking for most ambulatory settings, numerous outbreak reports have described transmission of gram-negative and gram-positive bacteria, mycobacteria, viruses, and parasites^{8,9}. In many instances, outbreaks and other adverse events were associated with breakdowns in basic infection prevention procedures (e.g., reuse of syringes leading to transmission of bloodborne viruses).

All healthcare settings, regardless of the level of care provided, must make infection prevention a priority and must be equipped to observe Standard Precautions. The 2007 CDC and HICPAC Guideline for Isolation Precautions was a first attempt to provide recommendations that can be applied in all healthcare settings. The Guide presented here is based primarily upon elements of Standard Precautions from that guideline and represents the minimum infection prevention expectations for safe care in ambulatory care settings. It is intended for use by anyone needing information about general infection prevention measures in ambulatory care settings. To assist with conducting periodic assessments of infection prevention policies and practices, the reader is referred to the *Infection Prevention Checklist for Outpatient Settings*, which appears at the end of this document as Appendix A.

For the purposes of this document, ambulatory care is defined as care provided in facilities where patients do not remain overnight (e.g., hospital-based outpatient clinics, non-hospital based clinics and physician offices, urgent care centers, ambulatory surgical centers, public health clinics, imaging centers, oncology clinics, ambulatory behavioral health and substance abuse clinics, physical therapy and rehabilitation centers). Healthcare personnel (HCP) are defined as all

persons, paid and unpaid, working in ambulatory care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. This includes persons not directly involved in patient care (e.g., clerical, house-keeping, and volunteers) but potentially exposed to infectious agents that can be transmitted to and from HCP and patients.

This document does not replace existing, more-detailed guidance for hemodialysis centers or dental practices. Further, the reader is referred to other CDC and HICPAC guidelines and websites for more detailed information and for recommendations concerning specialized infection prevention issues (e.g., sterilization and disinfection of equipment, multi-drug resistant organisms).

OBJECTIVES

By highlighting existing CDC and HICPAC recommendations, this summary guide: 1) provides basic infection prevention recommendations for outpatient (ambulatory care) settings; 2) reaffirms Standard Precautions as the foundation for preventing transmission of infectious agents during patient care in all healthcare settings; 3) provides links to full guidelines and source documents, which readers can reference for more detailed background and recommendations.

FUNDAMENTAL ELEMENTS NEEDED TO PREVENT TRANSMISSION OF INFECTIOUS AGENTS IN AMBULATORY CARE SETTINGS

Dedicate Resources to Infection Prevention (Administrative Measures)

Infection prevention must be made a priority in any setting where healthcare is delivered. Those with primary administrative oversight of the ambulatory care facility/setting must ensure that sufficient fiscal and human resources are available to develop and maintain infection prevention and occupational health programs. This includes the availability of sufficient and appropriate equipment and supplies necessary for the consistent observation of Standard Precautions, including hand hygiene products, injection equipment, and personal protective equipment (e.g., gloves, gowns, face and eye protection).

Infection prevention programs must extend beyond Occupational Safety and Health Administration (OSHA) bloodborne pathogen training to address patient protection. Facilities should assure that at least one individual with training in infection prevention is employed by or regularly available to the facility. This individual should be involved in the development of written infection prevention policies and have regular communication with HCP to address specific issues or concerns related to infection prevention. The development and ongoing refinement of infection prevention policies and procedures should be based on evidence-based guidelines, regulations, or standards. These policies and procedures should be tailored to the facility and re-assessed on a regular basis (e.g., annually), taking into consideration the types of services provided by the facility and the patient population that is served. This process (referred to as risk assessment by the Infection Prevention profession) will allow facilities to better prioritize

resources and focus extra attention on those areas that are determined to pose greater risk to their patients. For example, an ambulatory surgical center, which performs on-site sterilization of surgical equipment, would be expected to have more detailed policies regarding equipment reprocessing than a substance abuse clinic, where on-site sterilization is unlikely to be performed. However, both facilities should have policies and procedures addressing handling of reusable medical equipment. Similarly, a clinic primarily serving patients infected with tuberculosis will have infection prevention needs beyond those of a general pediatric office.

Facility administrators should also assure that facility policies and procedures address occupational health needs including vaccination of HCP, management of exposures or infections in personnel requiring post-exposure prophylaxis and/or work restrictions, and compliance with OSHA bloodborne pathogen standards. Recommendations for prevention of infections in HCP can be found in the following documents: Guideline for infection control in healthcare personnel (available at: <http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf>), Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization (available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00050577.htm>), and OSHA Bloodborne Pathogens and Needlestick Prevention (available at: <http://www.osha.gov/SLTC/bloodbornepathogens/index.html>).

Key administrative recommendations for ambulatory care settings:

1. Develop and maintain infection prevention and occupational health programs
2. Assure sufficient and appropriate supplies necessary for adherence to Standard Precautions (e.g., hand hygiene products, personal protective equipment, injection equipment)
3. Assure at least one individual with training in infection prevention is employed by or regularly available to the facility
4. Develop written infection prevention policies and procedures appropriate for the services provided by the facility and based upon evidence-based guidelines, regulations, or standards

Key recommendations for education and training of healthcare personnel in ambulatory care settings:

1. Provide job- or task-specific infection prevention education and training to all HCP
 - a. This includes those employed by outside agencies and available by contract or on a volunteer basis to the facility
2. Training should focus on principles of both HCP safety and patient safety
3. Training should be provided upon orientation and repeated regularly (e.g., annually)
4. Competencies should be documented initially and repeatedly, as appropriate for the specific HCP positions

Educate and Train Healthcare Personnel

Ongoing education and training of HCP are critical for ensuring that infection prevention policies and procedures are understood and followed. Education on the basic principles and practices for preventing the spread of infections should be provided to all HCP. Training should include both HCP safety (e.g., OSHA bloodborne pathogen training) and patient safety, emphasizing job- or task-specific needs. Education and training should be provided upon orientation to the facility and should be repeated regularly (e.g., annually) to maintain competency, including anytime policies or procedures are updated/revised. Competencies should be documented initially and as appropriate for the specific HCP positions. Refer to the *Infection Prevention Checklist for Outpatient Settings* (Appendix A) for an example checklist.

Monitor and Report Healthcare-associated Infections

Surveillance is defined as the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health. Surveillance typically refers to tracking of outcome measures (e.g., HAIs) but can also refer to tracking of adherence to specific process measures (e.g., hand hygiene, environmental cleaning) as a means to reduce infection transmission. Surveillance for outcome measures in ambulatory care settings is challenging because patient encounters may be brief or sporadic and evaluation and treatment of consequent infections may involve different healthcare settings (e.g., hospitals).

At a minimum, ambulatory care facilities need to adhere to local, state, and federal requirements regarding reportable disease and outbreak reporting. Certain types of facilities (e.g.,

ambulatory surgical centers) may also be subject to additional HAI surveillance or process measure reporting requirements, for example as part of accreditation, Medicare certification, or state/local statutes. Facilities should check the requirements for their state/region to assure that they are compliant with all regulations and should have contact information for their local and/or state health department available to ensure required reporting is done in a timely manner. (A list of state reportable disease websites is available at: <http://www.cste.org/?StateReportable>)

Regular focused practice surveys or audits (e.g., audits of infection prevention practices including hand hygiene, medication handling and preparation, reprocessing of patient equipment, environmental cleaning) offer a means to assess competencies of HCP as recommended under Education and Training. One example of an audit tool being used by federal surveyors to assess adherence to elements of Standard Precautions in ambulatory surgical centers is available at: http://www.cms.gov/manuals/downloads/som107_exhibit_351.pdf. Another example of a tool is the *Infection Prevention Checklist for Outpatient Settings* (Appendix A), which is a companion to this summary guide.

Key recommendations for HAI surveillance and reporting in ambulatory care settings:

1. Adhere to local, state, and federal requirements regarding HAI surveillance, reportable diseases, and outbreak reporting
2. Perform regular audits and competency evaluations of HCP adherence to infection prevention practices

Adhere to Standard Precautions

Standard Precautions are the minimum infection prevention practices that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is delivered. These practices are designed to both protect HCP and prevent HCP from spreading infections among patients. Standard Precautions include: 1) hand hygiene, 2) use of personal protective equipment (e.g., gloves, gowns, masks), 3) safe injection practices, 4) safe handling of potentially contaminated equipment or surfaces in the patient environment, and 5) respiratory hygiene/cough etiquette. Each of these elements of Standard Precautions are described in the sections that follow.

Education and training on the principles and rationale for recommended practices are critical elements of Standard Precautions because they facilitate appropriate decision-making and promote adherence. Further, at the facility level, an understanding of the specific procedures performed and typical patient interactions, as described above in Administrative Measures as part of policy and procedure development, will assure that necessary equipment is available.

The application of Standard Precautions and guidance on appropriate selection and an example of donning and removal of personal protective equipment is described in detail in the 2007 Guideline for Isolation Precautions (available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>).

Hand Hygiene

Good hand hygiene, including use of alcohol-based hand rubs and handwashing with soap and water, is critical to reduce the risk of spreading infections in ambulatory care settings. Use of alcohol-based hand rub as the primary mode of hand hygiene in healthcare settings is

recommended by the CDC and the World Health Organization (WHO) because of its activity against a broad spectrum of epidemiologically important pathogens, and because compared with soap and water, use of ABHR in healthcare settings can increase compliance with recommended hand hygiene practices by requiring less time, irritating hands less, and facilitating hand hygiene at the patient bedside. For these reasons, alcohol-based hand rub is the preferred method for hand hygiene except when hands are visibly soiled (e.g., dirt, blood, body fluids), or after caring for patients with known or suspected infectious diarrhea (e.g., *Clostridium difficile*, norovirus), in which case soap and water should be used.

Complete guidance on how and when hand hygiene should be performed, including recommendations regarding surgical hand antisepsis and artificial nails can be found in the Guideline for Hand Hygiene in Health-Care Settings (available at: <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>).

Personal Protective Equipment

Personal Protective Equipment (PPE) refers to wearable equipment that is intended to protect

HCP from exposure to or contact with infectious agents. Examples include gloves, gowns, face masks, respirators, goggles and face shields. The selection of PPE is based on the nature of the patient interaction and potential for exposure to blood, body fluids or infectious agents. Examples of appropriate use of PPE for adherence to Standard Precautions include: use of gloves in situations involving possible contact with blood or body fluids, mucous membranes, non-intact skin or potentially infectious material; use of a gown to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated; use of mouth, nose and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids. Hand hygiene is always the final step after removing and disposing of PPE.

In addition to protection of HCP, face masks are also effective in limiting the dispersal of oropharyngeal droplets and are recommended when placing a catheter or injecting materials into epidural or subdural spaces, as during myelography or spinal or epidural anesthesia. Failure to wear face masks during these procedures has resulted in development of

Key recommendations for hand hygiene in ambulatory care settings:

1. Key situations where hand hygiene should be performed include:
 - a. Before touching a patient, even if gloves will be worn
 - b. Before exiting the patient's care area after touching the patient or the patient's immediate environment
 - c. After contact with blood, body fluids or excretions, or wound dressings
 - d. Prior to performing an aseptic task (e.g., placing an IV, preparing an injection)
 - e. If hands will be moving from a contaminated-body site to a clean-body site during patient care
 - f. After glove removal
2. Use soap and water when hands are visibly soiled (e.g., blood, body fluids), or after caring for patients with known or suspected infectious diarrhea (e.g., *Clostridium difficile*, norovirus). Otherwise, the preferred method of hand decontamination is with an alcohol-based hand rub.

bacterial meningitis in patients undergoing these procedures¹⁰. Each ambulatory care facility/setting should evaluate the services they provide to determine specific needs and to assure that sufficient and appropriate PPE is available for adherence to Standard Precautions. All HCP at the facility should be educated regarding proper selection and use of PPE.

Complete guidance on the appropriate selection of PPE, including one approach for donning and removing PPE is provided in the 2007 Guideline for Isolation Precautions (available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>).

Injection Safety

Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, or between a patient and healthcare provider during preparation and administration of parenteral medications.

Implementation of the OSHA Bloodborne Pathogens Standard has helped increase the protection of HCP from blood exposure and sharps injuries, but there is room for improvement in ambulatory care settings. For example, efforts to increase uptake of hepatitis B vaccination and implementation of safety devices that are designed to decrease risks of sharps injury are needed.

Further attention to patient protection is also needed as evidenced by continued outbreaks in ambulatory settings resulting from unsafe injection practices. Unsafe practices that have led to patient harm include 1) use of a single syringe, with or without the same needle, to administer medication to multiple patients, 2) reinsertion of a used syringe, with or without the same needle, into a medication vial or solution container (e.g., saline bag) to obtain additional medication for a single patient and then using that vial or solution container for subsequent patients, 3) preparation of medications in close proximity to contaminated supplies or equipment.

Key recommendations for use of PPE in ambulatory care settings:

1. Facilities should assure that sufficient and appropriate PPE is available and readily accessible to HCP
2. Educate all HCP on proper selection and use of PPE
3. Remove and discard PPE before leaving the patient's room or area
4. Wear gloves for potential contact with blood, body fluids, mucous membranes, non-intact skin or contaminated equipment
 - a. Do not wear the same pair of gloves for the care of more than one patient
 - b. Do not wash gloves for the purpose of reuse
 - c. Perform hand hygiene immediately after removing gloves
5. Wear a gown to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated
 - a. Do not wear the same gown for the care of more than one patient
6. Wear mouth, nose and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids
7. Wear a surgical mask when placing a catheter or injecting material into epidural or subdural space

Complete guidance on safe injection practices can be found in the 2007 Guideline for Isolation Precautions (available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>). Additional materials, including a list of frequently asked questions from providers and a patient notification toolkit, are also available (<http://www.cdc.gov/injectionsafety/>). The *One & Only Campaign* is a public health effort to eliminate unsafe medical injections. The Campaign is led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC). To learn more about safe injection practices, and access training videos and resources, please visit OneandOnlyCampaign.org

Environmental Cleaning

Ambulatory care facilities should establish policies and procedures for routine cleaning and disinfection of environmental surfaces as part of

their infection prevention plan. Cleaning refers to the removal of visible soil and organic contamination from a device or environmental surface using the physical action of scrubbing with a surfactant or detergent and water, or an energy-based process (e.g., ultrasonic cleaners) with appropriate chemical agents. This process removes large numbers of microorganisms from surfaces and must always precede disinfection. Disinfection is generally a less lethal process of microbial inactivation (compared to sterilization) that eliminates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

Emphasis for cleaning and disinfection should be placed on surfaces that are most

Key recommendations for safe injection practices in ambulatory care settings:

1. Use aseptic technique when preparing and administering medications
2. Cleanse the access diaphragms of medication vials with 70% alcohol before inserting a device into the vial
3. Never administer medications from the same syringe to multiple patients, even if the needle is changed or the injection is administered through an intervening length of intravenous tubing
4. Do not reuse a syringe to enter a medication vial or solution
5. Do not administer medications from single-dose or single-use vials, ampoules, or bags or bottles of intravenous solution to more than one patient
6. Do not use fluid infusion or administration sets (e.g., intravenous tubing) for more than one patient
7. Dedicate multidose vials to a single patient whenever possible. If multidose vials will be used for more than one patient, they should be restricted to a centralized medication area and should not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle)
8. Dispose of used syringes and needles at the point of use in a sharps container that is closable, puncture-resistant, and leak-proof.
9. Adhere to federal and state requirements for protection of HCP from exposure to bloodborne pathogens.

likely to become contaminated with pathogens, including those in close proximity to the patient (e.g., bedrails) and frequently-touched surfaces in the patient-care environment (e.g., doorknobs). Facility policies and procedures should also address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious materials.

Responsibility for routine cleaning and disinfection of environmental surfaces should be assigned to appropriately trained HCP. Cleaning procedures can be periodically monitored or assessed to ensure that they are consistently and correctly performed. EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare should be selected for disinfection. Disinfectant products should not be used as cleaners unless the label indicates the product is suitable for such use. Healthcare professionals should follow manufacturer's recommendations for use of products selected for cleaning and disinfection (e.g., amount, dilution, contact time, safe use, and disposal).

Complete guidance for the cleaning and disinfection of environmental surfaces, including for cleaning blood or body substance spills, is available in the Guidelines for Environmental Infection Control in Health-Care Facilities (available at: http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf) and the Guideline for Disinfection and Sterilization in Healthcare Facilities (available at: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf).

Key recommendations for cleaning and disinfection of environmental surfaces in ambulatory care settings:

1. Establish policies and procedures for routine cleaning and disinfection of environmental surfaces in ambulatory care settings
 - a. Focus on those surfaces in proximity to the patient and those that are frequently touched
2. Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare
3. Follow manufacturer's recommendations for use of cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, and disposal)

Medical Equipment

Medical equipment is labeled by the manufacturer as either reusable or single-use. Reusable medical equipment (e.g., endoscopes) should be accompanied by instructions for cleaning and disinfection or sterilization as appropriate. Single-use devices (SUDs) are labeled by the manufacturer for only a single use and do not have reprocessing instructions. They may not be reprocessed except by entities which have complied with FDA regulatory requirements and have received FDA clearance to reprocess specific SUDs as outlined in FDA Guidance for Industry and FDA Staff (available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434>). Legally marketed SUDs are available from FDA-registered Third Party Reprocessors.

All reusable medical equipment must be cleaned and maintained according to the manufacturer's instructions to prevent patient-to-patient transmission of infectious agents. The Spaulding Classification is a traditional approach that has been used to determine the level of disinfection or sterilization required for reusable medical devices, based upon the degree of risk for transmitting infections if the device is contaminated at the time of use.

- ❑ Critical items (e.g., surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use.
- ❑ Semi-critical items (e.g., endoscopes used for upper endoscopy and colonoscopy) contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse.
- ❑ Noncritical items (e.g., blood pressure cuffs) are those that may come in contact with intact skin but not mucous membranes and should undergo low- or intermediate-level disinfection depending on the nature and degree of contamination.
- ❑ Environmental surfaces (e.g., floors, walls) are those that generally do not contact the patient during delivery of care. Cleaning may be all that is needed for the management of these surfaces but if disinfection is indicated, low-level disinfection is appropriate.

Cleaning to remove organic material must always precede disinfection or sterilization because residual debris reduces the effectiveness of the disinfection and sterilization processes.

Facilities should establish policies and procedures for containing, transporting, and handling equipment that may be contaminated with blood or body fluids. Manufacturer's instructions for reprocessing any reusable medical equipment in the facility (including point-of-care devices such as blood glucose meters) should be readily available and used to establish clear and appropriate policies and procedures. Instructions should be posted at the site where equipment reprocessing is performed. Responsibility for cleaning, disinfection and/or sterilization of medical equipment should be assigned to HCP with training in the required reprocessing steps and in the appropriate use of PPE necessary for handling of contaminated equipment. Competencies of HCP responsible for reprocessing of equipment should be documented initially upon assignment of those duties, whenever new equipment is introduced, and periodically (e.g., semi-annually).

Recommendations for the cleaning, disinfection, and sterilization of medical equipment, including general guidance on endoscope reprocessing are available in the Guideline for Disinfection and Sterilization in Healthcare Facilities (available at: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf). Materials specific for the handling of blood glucose monitoring equipment are also available. (<http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>)

FDA regulations on reprocessing of single-use devices are available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434> and <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/default.htm>.

Key recommendations for cleaning, disinfection, and/or sterilization of medical equipment in ambulatory care settings:

1. Facilities should ensure that reusable medical equipment (e.g., blood glucose meters and other point-of-care devices, surgical instruments, endoscopes) is cleaned and reprocessed appropriately prior to use on another patient
2. Reusable medical equipment must be cleaned and reprocessed (disinfection or sterilization) and maintained according to the manufacturer's instructions. If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use
3. Assign responsibilities for reprocessing of medical equipment to HCP with appropriate training
 - a. Maintain copies of the manufacturer's instructions for reprocessing of equipment in use at the facility; post instructions at locations where reprocessing is performed
 - b. Observe procedures to document competencies of HCP responsible for equipment reprocessing upon assignment of those duties, whenever new equipment is introduced, and on an ongoing periodic basis (e.g., quarterly)
4. Assure HCP have access to and wear appropriate PPE when handling and reprocessing contaminated patient equipment

Respiratory Hygiene/Cough Etiquette

Respiratory Hygiene/Cough Etiquette is an element of Standard Precautions that highlights the need for prompt implementation of infection prevention measures at the first point of encounter with the facility/ambulatory settings (e.g., reception and triage areas). This strategy is targeted primarily at patients and accompanying family members or friends with undiagnosed transmissible respiratory infections, and applies to any person with signs of illness including cough, congestion, rhinorrhea, or increased production of respiratory secretions when entering the facility.

Additional information related to respiratory hygiene/cough etiquette can be found in the 2007 Guideline for Isolation Precautions (available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>). Recommendations for preventing the spread of influenza are available at: <http://www.cdc.gov/flu/professionals/infectioncontrol/>.

Additional Considerations

The majority of ambulatory care settings are not designed to implement all of the isolation practices and other Transmission-Based Precautions (e.g., Airborne Precautions for patients with suspected tuberculosis, measles or chicken pox) that are recommended for hospital settings. Nonetheless, specific syndromes involving diagnostic uncertainty (e.g., diarrhea, febrile respiratory illness, febrile rash) are routinely encountered in ambulatory settings and deserve appropriate triage. Facilities should develop and implement systems for early detection and management of potentially infectious patients at initial points of entry to the facility. To the extent possible, this includes prompt placement

Key recommendations for Respiratory Hygiene/Cough Etiquette in ambulatory care settings:

- 1.** Implement measures to contain respiratory secretions in patients and accompanying individuals who have signs and symptoms of a respiratory infection, beginning at point of entry to the facility and continuing throughout the duration of the visit.
 - a.** Post signs at entrances with instructions to patients with symptoms of respiratory infection to:
 - i.** Cover their mouths/noses when coughing or sneezing
 - ii.** Use and dispose of tissues
 - iii.** Perform hand hygiene after hands have been in contact with respiratory secretions
 - b.** Provide tissues and no-touch receptacles for disposal of tissues
 - c.** Provide resources for performing hand hygiene in or near waiting areas
 - d.** Offer masks to coughing patients and other symptomatic persons upon entry to the facility
 - e.** Provide space and encourage persons with symptoms of respiratory infections to sit as far away from others as possible. If available, facilities may wish to place these patients in a separate area while waiting for care
- 2.** Educate HCP on the importance of infection prevention measures to contain respiratory secretions to prevent the spread of respiratory pathogens when examining and caring for patients with signs and symptoms of a respiratory infection.

of such patients into a single-patient room and a systematic approach to transfer when appropriate. When arranging for patient transfer, facilities should inform the transporting agency and the accepting facility of the suspected infection type.

Additional information related to Transmission-Based Precautions (contact precautions, droplet precautions and airborne precautions) can be found in the 2007 Guideline for Isolation Precautions (available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>). Recommendations regarding management of multidrug-resistant organisms can be found in the Guideline for the Management of Multidrug-Resistant Organisms in Healthcare Settings, 2006 available at: <http://www.cdc.gov/hicpac/pdf/guidelines/MDROGuideline2006.pdf>

Conclusions

The recommendations described in the preceding document represent the absolute minimum infection prevention expectations for safe care in outpatient (ambulatory care) settings. This guidance is not all-encompassing. Facilities and HCP are encouraged to refer to the original source documents, which provide more detailed guidance and references for the information included in this document.

SOURCE DOCUMENTS

Source Documents

All evidence-based recommendations for prevention of healthcare-associated infections from CDC/HICPAC can be found at the following site:
<http://www.cdc.gov/hicpac/pubs.html>

Guidelines available at this webpage include:

General

2008 Guideline for Disinfection, and Sterilization in Healthcare Facilities
http://www.cdc.gov/hicpac/Disinfection_Sterilization/1_sumIntroMethTerms.html

Guidelines for Environmental Infection Control in Healthcare Facilities
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm>

Guideline for Hand Hygiene in Healthcare Settings
<http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>

2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
http://www.cdc.gov/hicpac/2007IP/2007ip_ExecSummary.html

Guideline for the Prevention of Surgical Site Infection, 1999
<http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/SSI.pdf>

Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011
<http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf>

Drug-resistant Organisms

Management of Multi-drug Resistant Organisms in Healthcare Settings, 2006
http://www.cdc.gov/hicpac/mdro/mdro_toc.html

Healthcare Personnel

Influenza Vaccination of Health-Care Personnel, 2006
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm>

Guideline for Infection Control in Healthcare Personnel 1998
<http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf>

Specialized Settings

Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm>

Guidelines for Infection Control in Dental Health-Care Settings – 2003 available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5217a1.htm>

Key Links for Additional Information

CDC Website on Healthcare-associated infections:
www.cdc.gov/hai

CDC Website on Hand Hygiene in Healthcare facilities: www.cdc.gov/handhygiene

CDC Website on Injection Safety:
www.cdc.gov/injectionsafety

CDC's *One & Only Campaign*:
www.oneandonlycampaign.org

CDC Website on Influenza: www.cdc.gov/flu

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APPENDIX A: INFECTION PREVENTION CHECKLIST FOR OUTPATIENT SETTINGS:

Minimum Expectations for Safe Care

The following checklist is a companion to the *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*. The checklist should be used:

1. To ensure that the facility has appropriate infection prevention policies and procedures in place and supplies to allow healthcare personnel to provide safe care.
2. To systematically assess personnel adherence to correct infection prevention practices. (Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.)

Facilities using this checklist should identify all procedures performed in their ambulatory setting and refer to appropriate sections to conduct their evaluation. Certain sections may not apply (e.g., some settings may not perform sterilization or high-level disinfection). If the answer to any of the listed questions is No, efforts should be made to correct the practice, appropriately educate healthcare personnel (if applicable), and determine why the correct practice was not being performed. Consideration should also be made for determining the risk posed to patients by the deficient practice. Certain infection control lapses (e.g., re-use of syringes on more than one patient or to access a medication container that is used for subsequent patients; re-use of lancets) can result in bloodborne pathogen transmission and should be halted immediately. Identification of such lapses warrants immediate consultation with the state or local health department and appropriate notification and testing of potentially affected patients.

Section I: Administrative Policies and Facility Practices

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. Written infection prevention policies and procedures are available, current, and based on evidence-based guidelines (e.g., CDC/ HICPAC), regulations, or standards <i>Note: Policies and procedures should be appropriate for the services provided by the facility and should extend beyond OSHA bloodborne pathogen training</i>	Yes No	
B. Infection prevention policies and procedures are re-assessed at least annually or according to state or federal requirements	Yes No	
C. At least one individual trained in infection prevention is employed by or regularly available to the facility	Yes No	
D. Supplies necessary for adherence to Standard Precautions are readily available <i>Note: This includes hand hygiene products, personal protective equipment, and injection equipment.</i>	Yes No	

General Infection Prevention Education and Training

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. Healthcare Personnel (HCP) receive job-specific training on infection prevention policies and procedures upon hire and at least annually or according to state or federal requirements <i>Note: This includes those employed by outside agencies and available by contract or on a volunteer basis to the facility.</i>	Yes No	
B. Competency and compliance with job-specific infection prevention policies and procedures are documented both upon hire and through annual evaluations/assessments	Yes No	

Occupational Health

For additional guidance on occupational health recommendations consult the following resource(s):

Guideline for Infection Control in Healthcare Personnel available at:

<http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf>

Immunization of HealthCare Personnel, guidance available at:

<http://www.cdc.gov/vaccines/spec-grps/hcw.htm>

Occupational Safety & Health Administration (OSHA) Bloodborne Pathogens and Needlestick Prevention Standards available at:

<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. HCP are trained on the OSHA bloodborne pathogen standard upon hire and at least annually	Yes No	
B. The facility maintains a log of needlesticks, sharps injuries, and other employee exposure events	Yes No	
C. Following an exposure event, post-exposure evaluation and follow-up, including prophylaxis as appropriate, are available at no cost to employee and are supervised by a licensed healthcare professional	Yes No	
D. Hepatitis B vaccination is available at no cost to all employees who are at risk of occupational exposure	Yes No	
E. Post-vaccination screening for protective levels of hepatitis B surface antibody is conducted after third vaccine dose is administered	Yes No	

Facility Policies	Practice Performed	If answer is No, document plan for remediation
F. All HCP are offered annual influenza vaccination at no cost	Yes No	
G. All HCP who have potential for exposure to tuberculosis (TB) are screened for TB upon hire and annually (if negative)	Yes No	
H. The facility has a respiratory protection program that details required worksite-specific procedures and elements for required respirator use	Yes No	
I. Respiratory fit testing is provided at least annually to appropriate HCP	Yes No	
J. Facility has written protocols for managing/preventing job-related and community-acquired infections or important exposures in HCP, including notification of appropriate Infection Prevention and Occupational Health personnel when applicable	Yes No	

Surveillance and Disease Reporting

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. An updated list of diseases reportable to the public health authority is readily available to all personnel	Yes No	
B. The facility can demonstrate compliance with mandatory reporting requirements for notifiable diseases, healthcare associated infections, and for potential outbreaks.	Yes No	

Hand Hygiene

For additional guidance on hand hygiene and resources for training and measurement of adherence, consult the following resource(s).

Guideline for Hand Hygiene in Healthcare Settings available at:

<http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>

Hand Hygiene in Healthcare Settings available at: <http://www.cdc.gov/handhygiene/>

List of tools that can be used to measure adherence to hand hygiene available at:

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

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. The facility provides supplies necessary for adherence to hand hygiene (e.g., soap, water, paper towels, alcohol-based hand rub) and ensures they are readily accessible to HCP in patient care areas	Yes No	
B. HCP are educated regarding appropriate indications for hand washing with soap and water versus hand rubbing with alcohol-based hand rub <i>Note: Soap and water should be used when bare hands are visibly soiled (e.g., blood, body fluids) or after caring for a patient with known or suspected infectious diarrhea (e.g., Clostridium difficile or norovirus). In all other situations, alcohol-based hand rub may be used.</i>	Yes No	
C. The facility periodically monitors and records adherence to hand hygiene and provides feedback to personnel regarding their performance Examples of tools used to record adherence to hand hygiene: http://www.jointcommission.org/assets/1/18/hh_monograph.pdf	Yes No	

Personal Protective Equipment (PPE)

For additional guidance on personal protective equipment consult the following resource(s):

2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. The facility has sufficient and appropriate PPE available and readily accessible to HCP	Yes No	
B. HCP receive training on proper selection and use of PPE	Yes No	

Injection Safety

For additional guidance on injection safety consult the following resource(s): **2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings** available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

CDC Injection Safety Web Materials available at: <http://www.cdc.gov/injectionsafety/>

Frequently Asked Questions (FAQs) regarding Safe Practices for Medical Injections available at: http://www.cdc.gov/injectionsafety/providers/provider_faqs.html

CDC's One & Only Campaign training videos and materials available at: <http://www.oneandonlycampaign.org>

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. Medication purchasing decisions at the facility reflect selection of vial sizes that most appropriately fit the procedure needs of the facility and limit need for sharing of multi-dose vials	Yes No	
B. Injections are required to be prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment	Yes No	
C. Facility has policies and procedures to track HCP access to controlled substances to prevent narcotics theft/diversion	Yes No	

Respiratory Hygiene/Cough Etiquette

For additional guidance on respiratory hygiene/cough etiquette consult the following resource(s):

2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>

Recommendations for preventing the spread of influenza available at: <http://www.cdc.gov/flu/professionals/infectioncontrol/>

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. The facility has policies and procedures to contain respiratory secretions in persons who have signs and symptoms of a respiratory infection, beginning at point of entry to the facility and continuing through the duration of the visit. Measures include: i. Posting signs at entrances (with instructions to patients with symptoms of respiratory infection to cover their mouths/noses when coughing or sneezing, use and dispose of tissues, and perform hand hygiene after hands have been in contact with respiratory secretions.) ii. Providing tissues and no-touch receptacles for disposal of tissues iii. Providing resources for performing hand hygiene in or near waiting areas iv. Offering facemasks to coughing patients and other symptomatic persons upon entry to the facility v. Providing space and encouraging persons with symptoms of respiratory infections to sit as far away from others as possible. If available, facilities may wish to place these patients in a separate area while waiting for care	Yes No Yes No Yes No Yes No Yes No	
B. The facility educates HCP on the importance of infection prevention measures to contain respiratory secretions to prevent the spread of respiratory pathogens when examining and caring for patients with signs and symptoms of a respiratory infection.	Yes No	

Environmental Cleaning

For additional guidance on environmental cleaning consult the following resource(s):

Guidelines for Environmental Infection Control in Healthcare Facilities available at:

http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. Facility has written policies and procedures for routine cleaning and disinfection of environmental services, including identification of responsible personnel	Yes No	
B. Environmental services staff receive job-specific training and competency validation at hire and when procedures/policies change	Yes No	
C. Training and equipment are available to ensure that HCP wear appropriate PPE to preclude exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection)	Yes No	
D. Cleaning procedures are periodically monitored and assessed to ensure that they are consistently and correctly performed	Yes No	
E. The facility has a policy/procedure for decontamination of spills of blood or other body fluids	Yes No	

Reprocessing of Reusable Medical Devices

The following basic information allows for a general assessment of policies and procedures related to reprocessing of reusable medical devices. Ambulatory facilities that are providing on-site sterilization or high-level disinfection of reusable medical equipment should refer to the more detailed checklists related to sterilization and high-level disinfection in separate sections of this document devoted to those issues.

Critical items (e.g., surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use (see Sterilization Section).

Semi-critical items (e.g., endoscopes for upper endoscopy and colonoscopy, vaginal probes) are objects that contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse (see High-level Disinfection Section).

Non-critical items (e.g., blood pressure cuffs) are objects that may come in contact with intact skin but not mucous membranes and should undergo cleaning and low- or intermediate-level disinfection depending on the nature and degree of contamination.

Single-use devices (SUDs) are labeled by the manufacturer for a single use and do not have reprocessing instructions. They may not be reprocessed for reuse except by entities which have complied with FDA regulatory requirements and have received FDA clearance to reprocess specific SUDs.

Note: Pre-cleaning must always be performed prior to sterilization and/or disinfection

For additional guidance on reprocessing of medical devices consult the manufacturer instructions for the device and the following resource(s):

Guideline for Disinfection and Sterilization in Healthcare Facilities available at:

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

FDA regulations on reprocessing of single-use medical devices available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434>

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. Facility has policies and procedures to ensure that reusable medical devices are cleaned and reprocessed appropriately prior to use on another patient <i>Note: This includes clear delineation of responsibility among HCP.</i>	Yes No	
B. Policies, procedures, and manufacturer reprocessing instructions for reusable medical devices used in the facility are available in the reprocessing area(s)	Yes No	
C. HCP responsible for reprocessing reusable medical devices are appropriately trained and competencies are regularly documented (at least annually and when new equipment is introduced)	Yes No	
D. Training and equipment are available to ensure that HCP wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection). <i>Note: The exact type of PPE depends on infectious or chemical agent and anticipated type of exposure.</i>	Yes No	

Sterilization of Reusable Instruments and Devices

For additional guidance on sterilization of medical devices consult the manufacturer instructions for the device and the following resource(s):

Guideline for Disinfection and Sterilization in Healthcare Facilities available at:

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

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. All reusable critical instruments and devices are sterilized prior to reuse	Yes No	
B. Routine maintenance for sterilization equipment is performed according to manufacturer instructions (confirm maintenance records are available)	Yes No	
C. Policies and procedures are in place outlining facility response (i.e., recall of device and risk assessment) in the event of a reprocessing error/failure.	Yes No	

High-Level Disinfection of Reusable Instruments and Devices

For additional guidance on reprocessing of high-level disinfection devices consult the manufacturer instructions for the device and the following resource(s):

Guideline for Disinfection and Sterilization in Healthcare Facilities available at:

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

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. All reusable semi-critical items receive at least high-level disinfection prior to reuse	Yes No	
B. The facility has a system in place to identify which instrument (e.g., endoscope) was used on a patient via a log for each procedure	Yes No	
C. Routine maintenance for high-level disinfection equipment is performed according to manufacturer instructions; confirm maintenance records are available	Yes No	

Additional Resources and Evidence-based Guidelines available at:

http://www.cdc.gov/HAI/prevent/prevent_pubs.html

Section II: Personnel and Patient-care Observations

Hand hygiene performed correctly	Practice Performed	If answer is No, document plan for remediation
A. Before contact with the patient or their immediate care environment (even if gloves are worn)	Yes No	
B. Before exiting the patient's care area after touching the patient or the patient's immediate environment (even if gloves are worn)	Yes No	
C. Before performing an aseptic task (e.g., insertion of IV or preparing an injection) (even if gloves are worn)	Yes No	
D. After contact with blood, body fluids or contaminated surfaces (even if gloves are worn)	Yes No	
E. When hands move from a contaminated-body site to a clean-body site during patient care (even if gloves are worn)	Yes No	

Person Protective Equipment (PPE) is correctly used	Practice Performed	If answer is No, document plan for remediation
A. PPE is removed and discarded prior to leaving the patient's room or care area	Yes No	
B. Hand hygiene is performed immediately after removal of PPE	Yes No	
C. Gloves i. HCP wear gloves for potential contact with blood, body fluids, mucous membranes, non-intact skin, or contaminated equipment ii. HCP <u>do not</u> wear the same pair of gloves for the care of more than one patient iii. HCP <u>do not</u> wash gloves for the purpose of reuse	Yes No Yes No Yes No	
D. Gowns: i. HCP wear gowns to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated ii. HCP <u>do not</u> wear the same gown for the care of more than one patient	Yes No Yes No	
E. Facial protection: i. HCP wear mouth, nose, and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids ii. HCP wear a facemask (e.g., surgical mask) when placing a catheter or injecting material into the epidural or subdural space (e.g., during myelogram, epidural or spinal anesthesia)	Yes No Yes No	

Injection Safety	Practice Performed	If answer is No, document plan for remediation
A. Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)	Yes No	
B. The rubber septum on a medication vial is disinfected with alcohol prior to piercing	Yes No	
C. Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient	Yes No	
D. Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient	Yes No	
E. Medication administration tubing and connectors are used for only one patient	Yes No	
F. Multi-dose vials are dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial <i>Note: This is different from the expiration date printed on the vial.</i>	Yes No	
G. Multi-dose vials are dedicated to individual patients whenever possible.	Yes No	
H. Multi-dose vials to be used for more than one patient are kept in a centralized medication area and <u>do not</u> enter the immediate patient treatment area (e.g., operating room, patient room/cubicle) <i>Note: If multi-dose vials enter the immediate patient treatment area they should be dedicated for single-patient use and discarded immediately after use.</i>	Yes No	
I. All sharps are disposed of in a puncture-resistant sharps container	Yes No	
J. Filled sharps containers are disposed of in accordance with state regulated medical waste rules	Yes No	
K. All controlled substances (e.g., Schedule II, III, IV, V drugs) are kept locked within a secure area	Yes No	

Point-of-Care Testing (e.g., blood glucose meters, INR monitor)

For additional guidance on infection prevention during point-of-care testing consult the following resource(s):

Infection Prevention during Blood Glucose Monitoring and Insulin Administration available at:

<http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>

Frequently Asked Questions (FAQs) regarding Assisted Blood Glucose Monitoring and Insulin Administration available at:

http://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html

Point-of-Care Testing	Practice Performed	If answer is No, document plan for remediation
A. New single-use, auto-disabling lancing device is used for each patient <i>Note: Lancet holder devices are not suitable for multi-patient use.</i>	Yes No	
B. If used for more than one patient, the point-of-care testing meter is cleaned and disinfected after every use according to manufacturer instructions <i>Note: If the manufacturer does not provide instructions for cleaning and disinfection, then the testing meter should not be used for >1 patient.</i>	Yes No	

Environmental Cleaning	Practice Performed	If answer is No, document plan for remediation
A. Environmental surfaces, with an emphasis on surfaces in proximity to the patient and those that are frequently touched, are cleaned and then disinfected with an EPA-registered disinfectant	Yes No	
B. Cleaners and disinfectants are used in accordance with manufacturer instructions (e.g., dilution, storage, shelf-life, contact time)	Yes No	

Reprocessing of Reusable Instruments and Devices	Practice Performed	If answer is No, document plan for remediation
A. Reusable medical devices are cleaned, reprocessed (disinfection or sterilization) and maintained according to the manufacturer instructions. <i>Note: If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use.</i>	Yes No	
B. Single-use devices are discarded after use and not used for more than one patient. <i>Note: If the facility elects to reuse single-use devices, these devices must be reprocessed prior to reuse by a third-party reprocessor that it is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. The facility should have documentation from the third party reprocessor confirming this is the case.</i>	Yes No	
C. Reprocessing area has a workflow pattern such that devices clearly flow from high contamination areas to clean/sterile areas (i.e., there is clear separation between soiled and clean workspaces)	Yes No	
D. Medical devices are stored in a manner to protect from damage and contamination	Yes No	

Sterilization of Reusable Instruments and Devices	Practice Performed	If answer is No, document plan for remediation
A. Items are thoroughly pre-cleaned according to manufacturer instructions and visually inspected for residual soil prior to sterilization <i>Note: For lumened instruments, device channels and lumens must be cleaned using appropriately sized cleaning brushes.</i>	Yes No	
B. Enzymatic cleaner or detergent is used for pre-cleaning and discarded according to manufacturer instructions (typically after each use)	Yes No	
C. Cleaning brushes are disposable or cleaned and high-level disinfected or sterilized (per manufacturer instructions) after each use	Yes No	
D. After pre-cleaning, instruments are appropriately wrapped/packaged for sterilization (e.g., package system selected is compatible with the sterilization process being performed, hinged instruments are open, instruments are disassembled if indicated by the manufacturer)	Yes No	
E. A chemical indicator (process indicator) is placed correctly in the instrument packs in every load	Yes No	
F. A biological indicator is used at least weekly for each sterilizer and with every load containing implantable items	Yes No	
G. For dynamic air removal-type sterilizers, a Bowie-Dick test is performed each day the sterilizer is used to verify efficacy of air removal	Yes No	
H. Sterile packs are labeled with the sterilizer used, the cycle or load number, and the date of sterilization	Yes No	
I. Logs for each sterilizer cycle are current and include results from each load	Yes No	
J. After sterilization, medical devices and instruments are stored so that sterility is not compromised	Yes No	
K. Sterile packages are inspected for integrity and compromised packages are reprocessed prior to use	Yes No	
L. Immediate-use steam sterilization (flash sterilization), if performed, is only done in circumstances in which routine sterilization procedures cannot be performed	Yes No	
M. Instruments that are flash-sterilized are used immediately and not stored	Yes No	

High-Level Disinfection of Resuable Instruments and Devices	Practice Performed	If answer is No, document plan for remediation
A. Flexible endoscopes are inspected for damage and leak tested as part of each reprocessing cycle	Yes No	
B. Items are thoroughly pre-cleaned according to manufacturer instructions and visually inspected for residual soil prior to high-level disinfection <i>Note: For lumened instruments, device channels and lumens must be cleaned using appropriately sized cleaning brushes.</i>	Yes No	
C. Enzymatic cleaner or detergent is used and discarded according to manufacturer instructions (typically after each use)	Yes No	
D. Cleaning brushes are disposable or cleaned and high-level disinfected or sterilized (per manufacturer instructions) after each use.	Yes No	
E. For chemicals used in high-level disinfection, manufacturer instructions are followed for: i. preparation ii. testing for appropriate concentration iii. replacement (i.e., prior to expiration or loss of efficacy)	Yes No Yes No Yes No	
F. If automated reprocessing equipment is used, proper connectors are used to assure that channels and lumens are appropriately disinfected	Yes No	
G. Devices are disinfected for the appropriate length of time as specified by manufacturer instructions	Yes No	
H. Devices are disinfected at the appropriate temperature as specified by manufacturer instructions	Yes No	
I. After high-level disinfection, devices are rinsed with sterile water, filtered water, or tap water followed by a rinse with 70% - 90% ethyl or isopropyl alcohol	Yes No	
J. Devices are dried thoroughly prior to reuse <i>Note: Lumened instruments (e.g., endoscopes) require flushing channels with alcohol and forcing air through channels.</i>	Yes No	
K. After high-level disinfection, devices are stored in a manner to protect from damage or contamination <i>Note: Endoscopes should be hung in a vertical position</i>	Yes No	

Additional Resources and Evidence-based Guidelines available at:

http://www.cdc.gov/HAI/prevent/prevent_pubs.html

