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

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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 outpatient 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

INTRODUCTION

The transition of healthcare delivery from acute care hospitals to outpatient (ambulatory care) settings, along with ongoing outbreaks and patient notification events (http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html), have demonstrated the need for greater understanding and implementation of basic infection prevention guidance. This *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 outpatient and community-based settings. Outpatient 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 outpatient settings. For example, more than three-quarters of all operations in the United States are performed in settings outside the hospital.[1] In addition, between 1995 and 2007, the average person made three visits each year to physician offices.[2] By 2007, the total number of physician offices visits approached one billion.[3] Vulnerable patient populations rely on frequent and intensive use of outpatient care to maintain or improve their health. For example, each year more than one million cancer patients receive outpatient chemotherapy, radiation therapy, or both[4]. 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, outpatient 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 outpatient 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 outpatient settings. It is intended for use by anyone needing information about general infection prevention measures in outpatient 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, outpatient 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, behavioral health clinics and physical therapy and rehabilitation centers). Healthcare personnel (HCP) are defined as all persons, paid and unpaid, working in outpatient settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and devices, 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 (available at: http://www.cdc.gov/dialysis/ and http://www.cdc.gov/oralhealth/infectioncontrol/index.htm, respectively). 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 resusable devices, 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 OUTPATIENT 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 outpatient facility 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 (e.g., by contract) to manage the facility's infection prevention program. 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 reusable surgical devices, would be expected to have more detailed policies regarding device reprocessing than a primary care office, where on-site sterilization is less likely to be performed. However, both facilities should have policies and procedures addressing handling of reusable medical devices. 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 resources: Guideline for infection control in healthcare personnel (available at: http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf), Recommended Vaccines for Healthcare Workers (available at: http://www.cdc.gov/vaccines/adults/rec-vac/hcw.html), and OSHA Bloodborne Pathogens and Needlestick Prevention (available at: http://www.osha.gov/SLTC/bloodbornepathogens/index.html).

Key administrative recommendations for outpatient settings:

1. Develop and maintain infection prevention and occupational health programs.
2. Assure availability of 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 (e.g., by contract) to manage the facility's infection prevention program.
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.

Educate and Train Healthcare Personnel

Ongoing education and competency-based 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. Training should be provided upon orientation to the facility and, to maintain competency, should be repeated annually and anytime policies or procedures are updated/revised. Competencies should be documented following each training. Refer to the *Infection Prevention Checklist for Outpatient Settings* (Appendix A) for an example checklist.

Key recommendations for education and training of healthcare personnel in outpatient 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 hire and repeated annually and when policies or procedures are updated/revised.
4. Competencies should be documented following each training.

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 outpatient 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). To assist with identification of infections that may be related to care provided by the facility, patients should be educated regarding signs and symptoms of infection and instructed to notify the facility if such signs or symptoms occur.

At a minimum, outpatient 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, reprocessing of reusable devices) offer a means to ensure ongoing compliance of HCP with recommended practices. One example of an audit tool being used by federal surveyors to assess infection control in ambulatory surgical centers is available at: http://www.cms.gov/manuals/downloads/som107_exhibit_351.pdf. Another tool is the *Infection Prevention Checklist for Outpatient Settings* (Appendix A), a companion to this guide.

Key recommendations for HAI surveillance and reporting in outpatient settings:

1. Educate patients who have undergone procedures at the facility regarding signs and symptoms of infection that may be associated with the procedure and instruct them to notify the facility if such signs and symptoms occur.
2. Adhere to local, state and federal requirements regarding HAI surveillance, reportable diseases, and outbreak reporting.
3. Perform regular audits 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 (ABHR) and handwashing with soap and water, is critical to reduce the risk of spreading infections in outpatient settings. Use of ABHR 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, ABHR is the preferred method for hand hygiene in all clinical situations except when hands are visibly soiled (e.g., blood, body fluids), or after caring for patients with known or suspected *Clostridium difficile* or 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).

Key recommendations for hand hygiene in outpatient settings:

1. Key situations where hand hygiene should be performed include:
   - **a.** Before contact with a patient.
   - **b.** Before performing an aseptic task (e.g., insertion of IV, preparing an injection).
   - **c.** After contact with the patient or objects in the immediate vicinity of the patient.
   - **d.** After contact with blood, body fluids or contaminated surfaces.
   - **e.** If hands will be moving from a contaminated-body site to a clean-body site during patient care.
   - **f.** After removal of personal protective equipment (PPE).
2. Use soap and water when hands are visibly soiled (e.g., blood, body fluids), or after caring for patients with known or suspected *Clostridium difficile* or norovirus. Otherwise, the preferred method of hand hygiene in clinical situations is with an alcohol-based hand rub.

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.

Each outpatient facility 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).

Key recommendations for use of PPE in outpatient 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.
   a. PPE, other than respirators, should be removed and discarded prior to leaving the patient's room or care area. If a respirator is used, it should be removed and discarded (or reprocessed if reusable) after leaving the patient room or care area and closing the door.
   b. Hand hygiene should be performed immediately after removal of PPE.
3. 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.
4. 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.
5. Wear mouth, nose and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids.

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 outpatient 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 outpatient 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 and, 4) failure to 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).

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 other educational resources, please visit OneandOnlyCampaign.org

Key recommendations for safe injection practices in outpatient settings:

1. Use aseptic technique when preparing and administering medications.
2. Cleanse the access diaphragms of medication vials with 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 sharps at the point of use in a sharps container that is closable, puncture-resistant, and leak-proof.
9. 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).

Environmental Cleaning

Outpatient 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 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 should 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 outpatient settings:

1. Establish policies and procedures for routine cleaning and disinfection of environmental surfaces in the facility.
   a. Policies and procedures should also address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious materials.
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 Devices

Medical devices are labeled by the manufacturer as either reusable or single-use. Reusable medical devices (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 devices 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 devices that may be contaminated with blood or body fluids. Manufacturer's instructions for reprocessing any reusable medical device 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 device reprocessing is performed. Responsibility for cleaning and disinfection or sterilization of medical devices should be assigned to HCP with training in the required reprocessing steps and in the appropriate use of PPE necessary for handling of contaminated devices. Competencies of HCP responsible for reprocessing of devices should be documented initially upon assignment of those duties, annually, and whenever new devices are introduced or policies/procedures change.

Recommendations for the cleaning, disinfection, and sterilization of medical devices, 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 devices 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 and disinfection or sterilization of medical devices in outpatient settings:

1. Facilities should ensure that reusable medical devices (e.g., blood glucose meters and other point-of-care devices, surgical instruments, endoscopes) are cleaned and reprocessed appropriately prior to use on another patient.
2. Reusable medical devices 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 devices to HCP with appropriate training.
   a. Maintain copies of the manufacturer's instructions for reprocessing of devices in use at the facility; post instructions at locations where reprocessing is performed.
   b. Hands-on training on proper selection and use of PPE and recommended steps for reprocessing assigned devices should be provided upon hire (prior to being allowed to reprocess devices), annually, and when new devices are introduced or policies/procedures change.
      i. HCP should be required to demonstrate competency with reprocessing procedures (i.e., correct technique is observed by trainer) following each training.
4. Assure HCP have access to and wear appropriate PPE when handling and reprocessing contaminated medical devices.

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 (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/.

Key recommendations for Respiratory Hygiene/Cough Etiquette in outpatient 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.** Inform HCP of symptoms of a respiratory infection when they first register for care,
     - **ii.** Cover their mouths/noses when coughing or sneezing,
     - **iii.** Use and dispose of tissues,
     - **iv.** 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, at a minimum, during periods of increased respiratory infection activity in the community.
   - **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.

Considerations Related to Transmission-based Precautions

The majority of outpatient 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 outpatient 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 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)

Risk Assessment

Facilities are encouraged to use the *Infection Prevention Checklist for Outpatient Settings* (Appendix A), a companion to the summary guide, to periodically assess practices in their facility and ensure they are meeting the minimum expectations for safe care. In the course of auditing practices, facilities may identify lapses in infection control. If such lapses are identified, efforts should be made to correct the practices, appropriately educate HCP (if applicable), and determine why the correct practice was not being performed. In addition, consideration should also be made for determining the risk posed to patients by the deficient practices. Certain infection control lapses (e.g., reuse of syringes on more than one patient or to access a medication container that is used for subsequent patients; reuse of lancets) have resulted 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. Additional resources describing approaches to evaluation and management of infection control breaches identified in healthcare settings, including those involving lapses related to reprocessing of medical devices, can be found in CDC's Steps for Evaluating and Infection Control Breach (available at: http://www.cdc.gov/hai/outbreaks/steps_for_eval_IC_breach.html). In addition, for circumstances warranting patient notification, CDC has developed a Patient Notification Toolkit (available at: http://www.cdc.gov/injectionsafety/pntoolkit/index.html) to assist healthcare facilities with conducting a patient notification.

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 preventing the spread of influenza in health care facilities:
http://www.cdc.gov/flu/professionals/infectioncontrol/

CDC Website on Recommended Vaccines for Healthcare Workers:
http://www.cdc.gov/vaccines/adults/rec-vac/hcw.html

CDC Website on Guidance for the Selection and Use of Personal Protective Equipment in Healthcare Settings:
http://www.cdc.gov/HAI/prevent/ppe.html

CDC Website on Steps for Evaluating an Infection Control Breach:
http://www.cdc.gov/hai/outbreaks/steps_for_eval_IC_breach.html

CDC Healthcare-Associated Infection Outbreak Investigation Toolkit:
http://www.cdc.gov/hai/outbreaks/outbreaktoolkit.html

CDC Patient Notification Toolkit:
http://www.cdc.gov/injectionsafety/pntoolkit/index.html

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APPENDIX A: INFECTION PREVENTION CHECKLIST FOR OUTPATIENT SETTINGS

This checklist is a companion to the *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care* and is intended to assist in the assessment of infection control programs and practices in outpatient settings. 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 (HCP) to provide safe care.
2. To systematically assess personnel adherence to correct infection prevention practices. In order to complete the assessment, direct observation of infection control practices will be necessary.

Providers using this checklist should identify all procedures performed in their facility 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 HCP (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) have resulted 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.

Overview

Section 1: Facility Demographics

Section 2: Infection Control Program and Infrastructure

Section 3: Direct Observation of Facility Practices

Section 4: Infection Control Guidelines and Other Resources

Infection Control Domains for Gap Assessment

I.	Infection Control Program and Infrastructure
II.	Infection Control Training and Competency
III.	Healthcare Personnel Safety
IV.	Surveillance and Disease Reporting
V.a/b.	Hand Hygiene
VI.a/b.	Personal Protective Equipment (PPE)
VII.a/b.	Injection Safety
VIII.a/b.	Respiratory Hygiene/Cough Etiquette
IX.a/b.	Point-of-Care Testing (if applicable)
X.a/b.	Environmental Cleaning
XI.a/b.	Device Reprocessing (if applicable)
XII.	Sterilization of Reusable Devices (if applicable)
XIII.	High-level Disinfection of Reusable Devices (if applicable)

Section 1: Facility Demographics

Questions	Details
Is the facility licensed by the state?	○ Yes ○ No If yes, Date of last inspection: _____ Were any infection control deficiencies identified during last inspection? ○ Yes ○ No If Yes, ensure those elements are evaluated during the assessment.
Is the facility certified by the Centers for Medicare & Medicaid Services (CMS)?	○ Yes ○ No If yes, Date of last inspection: _____ Were any infection control deficiencies identified during last inspection? ○ Yes ○ No If Yes, ensure those elements are evaluated during the assessment.
Is the facility accredited?	○ Yes ○ No If yes, List the accreditation organization: ☐ Accreditation Association for Ambulatory Health Care (AAAHC) ☐ American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF) ☐ American Osteopathic Association (AOA) ☐ The Joint Commission (TJC) ☐ Other (specify): _____ Date of last inspection: _____ Were any infection control deficiencies identified during last inspection? ○ Yes ○ No If Yes, ensure those elements are evaluated during the assessment.
Is the facility affiliated with a hospital?	○ Yes ○ No If yes, consider engaging with the hospital infection prevention program for assistance in remediation of any identified lapses.
Which procedures are performed by the facility? Select all that apply.	☐ Chemotherapy ☐ Endoscopy ☐ Ear/Nose/Throat ☐ Imaging (MRI/CT) ☐ Immunizations ☐ OB/Gyn ☐ Ophthalmologic ☐ Orthopedic ☐ Pain remediation ☐ Plastic/reconstructive ☐ Podiatry ☐ Other (specify) _____

Section 2: Infection Control Program and Infrastructure

I. Infection Control Program and Infrastructure

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Written infection prevention policies and procedures are available, current, and based on evidence-based guidelines (e.g., CDC/HICPAC), regulations, or standards. *Note: Policies and procedures should be appropriate for the services provided by the facility and should extend beyond OSHA bloodborne pathogen training*	○ Yes ○ No	
B. Infection prevention policies and procedures are re-assessed at least annually or according to state or federal requirements, and updated if appropriate.	○ Yes ○ No	
C. At least one individual trained in infection prevention is employed by or regularly available (e.g., by contract) to manage the facility's infection control program. *Note: Examples of training may include: Successful completion of initial and/or recertification exams developed by the Certification Board for Infection Control & Epidemiology; participation in infection control courses organized by the state or recognized professional societies (e.g., APIC, SHEA).*	○ Yes ○ No	
D. Facility has system for early detection and management of potentially infectious persons at initial points of patient encounter. *Note: System may include taking a travel and occupational history, as appropriate, and elements described under respiratory hygiene/cough etiquette.*	○ Yes ○ No	

II. Infection Control Training and Competency

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has a competency-based training program that provides job-specific training on infection prevention policies and procedures to healthcare personnel. *Note: This includes those employed by outside agencies and available by contract or on a volunteer basis to the facility.* *See sections below for more specific assessment of training related to: hand hygiene, personal protective equipment (PPE), injection safety, environmental cleaning, point-of-care testing, and device reprocessing.*	○ Yes ○ No	

III. Healthcare Personnel Safety

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has an exposure control plan that is tailored to the specific requirements of the facility (e.g., addresses potential hazards posed by specific services provided by the facility). *Note: A model template, which includes a guide for creating an exposure control plan that meets the requirements of the OSHA Bloodborne Pathogens Standard is available at: https://www.osha.gov/Publications/osha3186.pdf*	○ Yes ○ No	
B. HCP for whom contact with blood or other potentially infectious material is anticipated are trained on the OSHA bloodborne pathogen standard upon hire and at least annually.	○ 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. *Note: An exposure incident refers to a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an individual's duties.*	○ Yes ○ No	
D. Facility tracks HCP exposure events and evaluates event data and develops/implements corrective action plans to reduce incidence of such events.	○ Yes ○ No	
E. Facility follows recommendations of the Advisory Committee on Immunization Practices (ACIP) for immunization of HCP, including offering Hepatitis B and influenza vaccination. *Note: Immunization of Health-Care Personnel: Recommendations of the ACIP available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm*	○ Yes ○ No	
F. All HCP receive baseline tuberculosis (TB) screening prior to placement, and those with potential for ongoing exposure to TB receive periodic screening (if negative) at least annually.	○ Yes ○ No	
G. If respirators are used, the facility has a respiratory protection program that details required worksite-specific procedures and elements for required respirator use, including provision of medical clearance, training, and fit testing as appropriate.	○ Yes ○ No ○ Not Applicable	

III. Healthcare Personnel Safety *(continued)*

Elements to be assessed	Assessment	Notes/Areas for Improvement
H. Facility has well-defined policies concerning contact of personnel with patients when personnel have potentially transmissible conditions. These policies include:	○ Yes ○ No	
i. Work-exclusion policies that encourage reporting of illnesses and do not penalize with loss of wages, benefits, or job status.	○ Yes ○ No	
ii. Education of personnel on prompt reporting of illness to supervisor.	○ Yes ○ No	

IV. Surveillance and Disease Reporting

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. An updated list of diseases reportable to the public health authority is readily available to all personnel.	○ Yes ○ No	
B. Facility can demonstrate knowledge of and compliance with mandatory reporting requirements for notifiable diseases, healthcare associated infections (as appropriate), and for potential outbreaks.	○ Yes ○ No	
C. Patients who have undergone procedures at the facility are educated regarding signs and symptoms of infection that may be associated with the procedure and instructed to notify the facility if such signs or symptoms occur.	○ Yes ○ No	

V.a. Hand Hygiene

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. All HCP are educated regarding appropriate indications for hand hygiene: i. Upon hire, prior to provision of care ii. Annually	 O Yes O No O Yes O No	
B. HCP are required to demonstrate competency with hand hygiene following each training.	O Yes O No	
C. Facility regularly audits (monitors and documents) adherence to hand hygiene.	O Yes O No	
D. Facility provides feedback from audits to personnel regarding their hand hygiene performance.	O Yes O No	
E. Hand hygiene policies promote preferential use of alcohol-based hand rub over soap and water in all clinical situations except when hands are visibly soiled (e.g., blood, body fluids) or after caring for a patient with known or suspected *C. difficile* or norovirus.	O Yes O No	

VIa. Personal Protective Equipment (PPE)

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. HCP who use PPE receive training on proper selection and use of PPE: i. Upon hire, prior to provision of care ii. Annually iii. When new equipment or protocols are introduced	 O Yes O No O Yes O No O Yes O No	
B. HCP are required to demonstrate competency with selection and use of PPE following each training.	O Yes O No	
C. Facility regularly audits (monitors and documents) adherence to proper PPE selection and use.	O Yes O No	
D. Facility provides feedback from audits to personnel regarding their performance with selection and use of PPE.	O Yes O No	

VII.a. Injection Safety (This element does not include assessment of pharmacy/ compounding practices)

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. HCP who prepare and/or administer parenteral medications receive training on safe injection practices: i. Upon hire, prior to being allowed to prepare and/or administer parenteral medications ii. Annually iii. When new equipment or protocols are introduced	 ○ Yes ○ No ○ Yes ○ No ○ Yes ○ No	
B. HCP are required to demonstrate competency with safe injection practices following each training.	○ Yes ○ No	
C. Facility regularly audits (monitors and documents) adherence to safe injection practices.	○ Yes ○ No	
D. Facility provides feedback from audits to personnel regarding their adherence to safe injection practices.	○ Yes ○ No	
E. Facility has policies and procedures to track HCP access to controlled substances to prevent narcotics theft/diversion. *Note: Policies and procedures should address: how data are reviewed, how facility would respond to unusual access patterns, how facility would assess risk to patients if tampering (alteration or substitution) is suspected or identified, and who the facility would contact if diversion is suspected or identified.*	○ Yes ○ No	

VIII.a. Respiratory Hygiene/Cough Etiquette

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. 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. Policies include:	○ Yes ○ No	
i. Offering facemasks to coughing patients and other symptomatic persons upon entry to the facility, at a minimum, during periods of increased respiratory infection activity in the community.	○ Yes ○ No	
ii. Providing space in waiting rooms and encouraging persons with symptoms of respiratory infections to sit as far away from others as possible. *Note: If available, facilities may wish to place patients with symptoms of a respiratory infection in a separate area while waiting for care.*	○ Yes ○ No	
B. Facility educates HCP on the importance of infection prevention measures to contain respiratory secretions to prevent the spread of respiratory pathogens.	○ Yes ○ No	

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

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. HCP who perform point-of-care testing receive training on recommended practices:		
i. Upon hire, prior to being allowed to perform point-of-care testing	○ Yes ○ No	
ii. Annually	○ Yes ○ No	
iii. When new equipment or protocols are introduced	○ Yes ○ No ○ Not applicable	
B. HCP are required to demonstrate competency with recommended practices for point-of-care testing following each training.	○ Yes ○ No ○ Not applicable	
C. Facility regularly audits (monitors and documents) adherence to recommended practices during point-of-care testing.	○ Yes ○ No ○ Not applicable	
D. Facility provides feedback from audits to personnel regarding their adherence to recommended practices.	○ Yes ○ No ○ Not applicable	

X.a. Environmental Cleaning

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has written policies and procedures for routine cleaning and disinfection of environmental surfaces, including identification of responsible personnel.	○ Yes ○ No	
B. Personnel who clean and disinfect patient care areas (e.g., environmental services, technicians, nurses) receive training on cleaning procedures:		
i. Upon hire, prior to being allowed to perform environmental cleaning	○ Yes ○ No	
ii. Annually	○ Yes ○ No	
iii. When new equipment or protocols are introduced	○ Yes ○ No	
Note: If environmental cleaning is performed by contract personnel, facility should verify this is provided by contracting company.		
C. HCP are required to demonstrate competency with environmental cleaning procedures following each training.	○ Yes ○ No	
D. Facility regularly audits (monitors and documents) adherence to cleaning and disinfection procedures, including using products in accordance with manufacturer's instructions (e.g., dilution, storage, shelf-life, contact time).	○ Yes ○ No	
E. Facility provides feedback from audits to personnel regarding their adherence to cleaning and disinfection procedures.	○ Yes ○ No	
F. Facility has a policy/procedure for decontamination of spills of blood or other body fluids.	○ Yes ○ No	

X.a. Environmental Cleaning *(continued)* – Operating room

Elements to be assessed	Assessment	Notes/Areas for Improvement
G. Operating rooms are terminally cleaned after last procedure of the day.	○ Yes ○ No ○ Not applicable	
H. Facility regularly audits (monitors and documents) adherence to recommended infection control practices for surgical infection prevention including:		
i. Adherence to preoperative surgical scrub and hand hygiene	○ Yes ○ No	
ii. Appropriate use of surgical attire and drapes	○ Yes ○ No	
iii. Adherence to aseptic technique and sterile field	○ Yes ○ No	
iv. Proper ventilation requirements in surgical suites	○ Yes ○ No	
v. Minimization of traffic in the operating room	○ Yes ○ No	
vi. Adherence to cleaning and disinfection of environmental surfaces	○ Yes ○ No ○ Not applicable	
I. Facility provides feedback from audits to personnel regarding their adherence to surgical infection prevention practices.	○ Yes ○ No ○ Not applicable	

XI.a. Device Reprocessing

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

Categories of Medical Devices:

- **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 item**s (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: Cleaning must always be performed prior to sterilization and disinfection

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility has policies and procedures to ensure that reusable medical devices are cleaned and reprocessed appropriately prior to use on another patient. *Note: This includes clear delineation of responsibility among HCP for cleaning and disinfection of equipment including, non-critical equipment, mobile devices, and other electronics (e.g., point-of-care devices) that might not be reprocessed in a centralized reprocessing area.*	○ Yes ○ No	
B. The individual(s) in charge of infection prevention at the facility is consulted whenever new devices or products will be purchased or introduced to ensure implementation of appropriate reprocessing policies and procedures.	○ Yes ○ No	
C. HCP responsible for reprocessing reusable medical devices receive hands-on training on proper selection and use of PPE and recommended steps for reprocessing assigned devices: i. Upon hire, prior to being allowed to reprocess devices ii. Annually iii. When new devices are introduced or policies/procedures change. *Note: If device reprocessing is performed by contract personnel, facility should verify this is provided by contracting company.*	 ○ Yes ○ No ○ Yes ○ No ○ Yes ○ No	
D. HCP are required to demonstrate competency with reprocessing procedures (i.e., correct technique is observed by trainer) following each training.	○ Yes ○ No	
E. Facility regularly audits (monitors and documents) adherence to reprocessing procedures.	○ Yes ○ No	
F. Facility provides feedback from audits to personnel regarding their adherence to reprocessing procedures.	○ Yes ○ No	
G. Facility has protocols to ensure that HCP can readily identify devices that have been properly reprocessed and are ready for patient use (e.g., tagging system, storage in designated area).	○ Yes ○ No	
H. Facility has policies and procedures outlining facility response (i.e., risk assessment and recall of device) in the event of a reprocessing error or failure.	○ Yes ○ No	
I. Routine maintenance for reprocessing equipment (e.g., automated endoscope reprocessors, steam autoclave) is performed by qualified personnel in accordance with manufacturer instructions; confirm maintenance records are available.	○ Yes ○ No ○ Not applicable	

Section 3: Direct Observation of Facility Practices

V.b. Hand hygiene

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Supplies necessary for adherence to hand hygiene (e.g., soap, water, paper towels, alcohol-based hand rub) are readily accessible to HCP in patient care areas.	○ Yes ○ No	
Hand hygiene is performed correctly:		
B. Before contact with the patient	○ Yes ○ No	
C. Before performing an aseptic task (e.g., insertion of IV or preparing an injection)	○ Yes ○ No	
D. After contact with the patient	○ Yes ○ No	
E. After contact with objects in the immediate vicinity of the patient	○ Yes ○ No	
F. After contact with blood, body fluids or contaminated surfaces	○ Yes ○ No	
G. After removing gloves	○ Yes ○ No	
H. When moving from a contaminated-body site to a clean-body site during patient care	○ Yes ○ No	

VI.b. Personal Protective Equipment (PPE)

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Sufficient and appropriate PPE is available and readily accessible to HCP.	○ Yes ○ No	
PPE is used correctly:		
B. PPE, other than respirator, is removed and discarded prior to leaving the patient's room or care area. If a respirator is used, it is removed and discarded (or reprocessed if reusable) after leaving the patient room or care area and closing the door.	○ Yes ○ No	
C. Hand hygiene is performed immediately after removal of PPE.	○ Yes ○ No	
D. Gloves i. HCP wear gloves for potential contact with blood, body fluids, mucous membranes, non-intact skin, or contaminated equipment. ii. HCP do not wear the same pair of gloves for the care of more than one patient. iii. HCP do not wash gloves for the purpose of reuse.	 ○ Yes ○ No ○ Yes ○ No ○ Yes ○ No	
E. 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 do not wear the same gown for the care of more than one patient.	 ○ Yes ○ No ○ Not applicable ○ Yes ○ No ○ Not applicable	
F. 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.	 ○ Yes ○ No ○ Not applicable	

VII.b. Injection safety (This element does not include assessment of pharmacy/ compounding practices)

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment.	○ Yes ○ No	
B. Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).	○ Yes ○ No	
C. The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	○ Yes ○ No	
D. Medication containers are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	○ Yes ○ No	
E. Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient.	○ Yes ○ No	
F. Medication administration tubing and connectors are used for only one patient.	○ Yes ○ No	
G. 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. *Note: This is different from the expiration date printed on the vial.*	○ Yes ○ No ○ Not applicable (Facility does not use multi-dose vials or discards them after single patient use)	
H. Multi-dose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area (e.g,. operating room, patient room/cubicle). *Note: If multi-dose vials enter the immediate patient treatment area they should be dedicated for single-patient use and discarded immediately after use.*	○ Yes ○ No ○ Not applicable (Facility does not use multi-dose vials or discards them after single patient use)	
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	

VII.b. Injection safety (This element does not include assessment of pharmacy/ compounding practices) *(continued)*

Elements to be assessed	Assessment	Notes/Areas for Improvement
K. All controlled substances (e.g., Schedule II, III, IV, V drugs) are kept locked within a secure area.	○ Yes ○ No	
L. 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 ○ Not applicable (Facility does not perform spinal injection procedures)	

VIII.b. Respiratory Hygiene/Cough Etiquette

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Facility:		
i. Posts signs at entrances with instructions to patients with symptoms of respiratory infection to: a. Inform HCP of symptoms of a respiratory infection when they first register for care, and b. Practice Respiratory Hygiene/Cough Etiquette (cover their mouths/noses when coughing or sneezing, use and dispose of tissues, and perform hand hygiene after hands have been covered with respiratory secretions).	○ Yes ○ No	
ii. Provides tissues and no-touch receptacles for disposal of tissues.	○ Yes ○ No	
iii. Provides resources for performing hand hygiene in or near waiting areas.	○ Yes ○ No	

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

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. New single-use, auto-disabling lancing device is used for each patient. *Note: Lancet holder devices are not suitable for multi-patient use.*	○ Yes ○ No ○ Not applicable	
B. If used for more than one patient, the point-of-care testing meter is cleaned and disinfected after every use according to manufacturer's instructions. *Note: If the manufacturer does not provide instructions for cleaning and disinfection, then the testing meter should not be used for >1 patient.*	○ Yes ○ No ○ Not applicable	

X.b. Environmental Cleaning

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Supplies necessary for appropriate cleaning and disinfection procedures (e.g., EPA-registered disinfectants) are available. *Note: If environmental services are performed by contract personnel, facility should verify that appropriate EPA-registered products are provided by contracting company*	○ Yes ○ No	
B. High-touch surfaces in rooms where surgical or other invasive procedures (e.g., endoscopy, spinal injections) are performed are cleaned and then disinfected with an EPA-registered disinfectant after each procedure.	○ Yes ○ No ○ Not applicable	
C. Cleaners and disinfectants are used in accordance with manufacturer's instructions (e.g., dilution, storage, shelf-life, contact time).	○ Yes ○ No	
D. HCP engaged in environmental cleaning wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection). *Note: The exact type of correct PPE depends on infectious or chemical agent and anticipated type of exposure.*	○ Yes ○ No	

XI.b. Device Reprocessing

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Policies, procedures, and manufacturer reprocessing instructions for reusable medical devices used in the facility are available in the reprocessing area(s).	○ Yes ○ No	
B. Reusable medical devices are cleaned, reprocessed (disinfection or sterilization) and maintained according to the manufacturer instructions. *Note: If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use.*	○ Yes ○ No	
C. Single-use devices are discarded after use and not used for more than one patient. *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.*	○ Yes ○ No	
D. Reprocessing area: i. Adequate space is allotted for reprocessing activities. ii. A workflow pattern is followed 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 ○ Yes ○ No	
E Adequate time for reprocessing is allowed to ensure adherence to all steps recommended by the device manufacturer, including drying and proper storage. *Note: Facilities should have an adequate supply of instruments for the volume of procedures performed and should schedule procedures to allow sufficient time for all reprocessing steps.*	○ Yes ○ No	
F. HCP engaged in device reprocessing wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection). *Note: The exact type of correct PPE depends on infectious or chemical agent and anticipated type of exposure.*	○ Yes ○ No	
G. Medical devices are stored in a manner to protect from damage and contamination.	○ Yes ○ No	

XII. Sterilization of Reusable Devices

(Note: If all device sterilization is performed off-site, skip to items M-O below.)

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Devices are thoroughly cleaned according to manufacturer instructions and visually inspected for residual soil prior to sterilization. *Note: Cleaning may be manual (i.e., using friction) and/or mechanical (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers).* *Ensure appropriately sized cleaning brushes are selected for cleaning device channels and lumens.*	○ Yes ○ No ○ Not applicable	
B. Cleaning is performed as soon as practical after use (e.g., at the point of use) to prevent soiled materials from becoming dried onto devices.	○ Yes ○ No ○ Not applicable	
C. Enzymatic cleaner or detergent is used for cleaning and discarded according to manufacturer's instructions (typically after each use).	○ Yes ○ No ○ Not applicable	
D. Cleaning brushes are disposable or, if reusable, cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after use.	○ Yes ○ No ○ Not applicable	
E. After cleaning, instruments are appropriately wrapped/packaged for sterilization (e.g., package system selected is compatible with the sterilization process being performed, items are placed correctly into the basket, shelf or cart of the sterilizer so as not to impede the penetration of the sterilant, hinged instruments are open, instruments are disassembled if indicated by the manufacturer).	○ Yes ○ No ○ Not applicable	
F. A chemical indicator (process indicator) is placed correctly in the instrument packs in every load.	○ Yes ○ No ○ Not applicable	
G. A biological indicator, intended specifically for the type and cycle parameters of the sterilizer, is used at least weekly for each sterilizer and with every load containing implantable items.	○ Yes ○ No ○ Not applicable	
H. For dynamic air removal-type sterilizers (e.g., prevacuum steam sterilizer), an air removal test (Bowie-Dick test) is performed in an empty dynamic-air removal sterilizer each day the sterilizer is used to verify efficacy of air removal.	○ Yes ○ No ○ Not applicable	
I. Sterile packs are labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and, if applicable, the expiration date.	○ Yes ○ No ○ Not applicable	

XII. Sterilization of Reusable Devices *(continued)*

Elements to be assessed	Assessment	Notes/Areas for Improvement
J. Sterilization logs are current and include results from each load.	○ Yes ○ No ○ Not applicable	
K. Immediate-use steam sterilization, if performed, is only done in circumstances in which routine sterilization procedures cannot be performed.	○ Yes ○ No ○ Not applicable	
L. Instruments that undergo immediate-use steam sterilization are used immediately and not stored.	○ Yes ○ No ○ Not applicable	
M. After sterilization, medical devices are stored so that sterility is not compromised.	○ Yes ○ No ○ Not applicable	
N. Sterile packages are inspected for integrity and compromised packages are reprocessed prior to use.	○ Yes ○ No ○ Not applicable	
O. The facility has a process to perform initial cleaning of devices (to prevent soiled materials from becoming dried onto devices) prior to transport to the off-site reprocessing facility.	○ Yes ○ No ○ Not applicable	

XIII. High-Level Disinfection of Reusable Devices

(Note: If all high-level disinfection is performed off-site, skip to items L-N below.)

Elements to be assessed	Assessment	Notes/Areas for Improvement
A. Flexible endoscopes are inspected for damage and leak tested as part of each reprocessing cycle. Any device that fails the leak test is removed from clinical use and repaired.	○ Yes ○ No ○ Not applicable	
B. Devices are thoroughly cleaned according to manufacturer instructions and visually inspected for residual soil prior to high-level disinfection. *Note: Cleaning may be manual (i.e., using friction) and/or mechanical (e.g,. with ultrasonic cleaners, washer-disinfector, washer-sterilizers).* *Ensure appropriately sized cleaning brushes are selected for cleaning device channels and lumens.*	○ Yes ○ No ○ Not applicable	
C. Cleaning is performed as soon as practical after use (e.g., at the point of use) to prevent soiled materials from becoming dried onto instruments.	○ Yes ○ No ○ Not applicable	
D. Enzymatic cleaner or detergent is used and discarded according to manufacturer instructions (typically after each use).	○ Yes ○ No ○ Not applicable	

Elements to be assessed	Assessment	Notes/Areas for Improvement
E. Cleaning brushes are disposable or, if reusable, cleaned and high-level disinfected or sterilized (per manufacturer instructions) after use.	○ Yes ○ No ○ Not applicable	
F. For chemicals used in high-level disinfection, manufacturer instructions are followed for: i. Preparation ii. Testing for appropriate concentration, and iii. Replacement (i.e., upon expiration or loss of efficacy)	○ Yes ○ No ○ Yes ○ No ○ Yes ○ No ○ Not applicable	
G. If automated reprocessing equipment is used, proper connectors are used to assure that channels and lumens are appropriately disinfected.	○ Yes ○ No ○ Not applicable	
H. Devices are disinfected for the appropriate length of time as specified by manufacturer instructions.	○ Yes ○ No ○ Not applicable	
I. Devices are disinfected at the appropriate temperature as specified by manufacturer instructions.	○ Yes ○ No ○ Not applicable	
J. 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. *Note: There is no recommendation to use sterile or filtered water rather than tap water for rinsing semi-critical equipment that contact the mucous membranes of the rectum or vagina*	○ Yes ○ No ○ Not applicable	
K. Devices are dried thoroughly prior to reuse. *Note: For lumened instruments (e.g., endoscopes) this includes flushing all channels with alcohol and forcing air through channels.*	○ Yes ○ No ○ Not applicable	
L. After high-level disinfection, devices are stored in a manner to protect from damage or contamination. *Note: Endoscopes should be hung in a vertical position.*	○ Yes ○ No ○ Not applicable	
M. Facility maintains a log for each endoscopy procedure which includes: patient's name and medical record number (if available), procedure, date, endoscopist, system used to reprocess the endoscope (if more than one system could be used in the reprocessing area), and serial number or other identifier of the endoscope used.	○ Yes ○ No ○ Not applicable	
N. The facility has a process to perform initial cleaning of devices (to prevent soiled materials from becoming dried onto devices) prior to transport to the off-site reprocessing facility.	○ Yes ○ No ○ Not applicable	

Section 4: Infection Control Guidelines and Other Resources

- General Infection Prevention
  - ❑ CDC/HICPAC Guidelines and recommendations: http://www.cdc.gov/HAI/prevent/prevent_pubs.html
- Healthcare Personnel Safety
  - ❑ Guideline for Infection Control in Healthcare Personnel: http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf
  - ❑ Immunization of HealthCare Personnel: http://www.cdc.gov/vaccines/spec-grps/hcw.htm
  - ❑ Occupational Safety & Health Administration (OSHA) Bloodborne Pathogens and Needlestick Prevention Standard: http://www.osha.gov/SLTC/bloodbornepathogens/index.html
  - ❑ OSHA Respiratory Protection Standard: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=STANDARDS
  - ❑ OSHA Respirator Fit Testing: https://www.osha.gov/video/respiratory_protection/fittesting_transcript.html
- Hand Hygiene
  - ❑ Guideline for Hand Hygiene in Healthcare Settings: http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf
  - ❑ Hand Hygiene in Healthcare Settings: http://www.cdc.gov/handhygiene/
  - ❑ Examples of tools that can be used to conduct a formal audit of hand hygiene practices:
    - – http://www.jointcommission.org/assets/1/18/hh_monograph.pdf
    - – http://compepi.cs.uiowa.edu/index.php/Research/IScrub
- Personal Protective Equipment
  - ❑ 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf
  - ❑ Guidance for the Selection and Use of Personal Protective Equipment in Healthcare Settings: http://www.cdc.gov/HAI/prevent/ppe.html
- Injection Safety
  - ❑ 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf
  - ❑ CDC Injection Safety Web Materials: http://www.cdc.gov/injectionsafety/
  - ❑ CDC training video and related Safe Injection Practices Campaign materials: http://www.oneandonlycampaign.org/

- Respiratory Hygiene/Cough Etiquette
  - ❑ 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf
  - ❑ Recommendations for preventing the spread of influenza: http://www.cdc.gov/flu/professionals/infectioncontrol/
- Environmental Cleaning
  - ❑ Guidelines for Environmental Infection Control in Healthcare Facilities: http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf
  - ❑ Options for Evaluating Environmental Infection Control: http://www.cdc.gov/HAI/toolkits/Evaluating-Environmental-Cleaning.html
- Equipment Reprocessing
  - ❑ Guideline for Disinfection and Sterilization in Healthcare Facilities: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
  - ❑ FDA regulations on reprocessing of single-use devices: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434
- Point-of-Care Testing
  - ❑ Infection Prevention during Blood Glucose Monitoring and Insulin Administration: http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
  - ❑ Frequently Asked Questions (FAQs) regarding Assisted Blood Glucose Monitoring and Insulin Administration: http://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html
- Resources to assist with evaluation and response to breaches in infection control
  - ❑ Patel PR, Srinivasan A, Perz JF. Developing a broader approach to management of infection control breaches in health care settings. Am J Infect Control. 2008 Dec;36(10);685-90
  - ❑ Steps for Evaluating an Infection Control Breach: http://www.cdc.gov/hai/outbreaks/steps_for_eval_IC_breach.html
  - ❑ Patient Notification Toolkit: http://www.cdc.gov/injectionsafety/pntoolkit/index.html

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