### Guide to Infection Prevention for Outpatient Podiatry Settings









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#### **ABBREVIATIONS**

AAMI	Association for the Advancement of Medical Instrumentation	HICPAC	Healthcare Infection Control Practices Advisory Committee
ABHR	Alcohol-based hand rub	HIV	Human immunodeficiency virus
ANSI	American National Standards	HLD	High-level disinfection
	Institute	IPC	Infection prevention and control
ВІ	Biological indicator	MDV	Multi-dose vial
CDC	Centers for Disease Control and Prevention	OSHA	Occupational Safety and Health Administration
EPA	Environmental Protection Agency	PPE	Personal protective equipment
ES	Environmental services	SDV	Single-dose vial
FDA	Food and Drug Administration	SUD	Single-use device
HAI	Healthcare-associated infection	ТВ	Tuberculosis
HBV	Hepatitis B virus	USP	United States Pharmacopeia
HCP	Healthcare personnel	WHO	World Health Organization
HCV	Hepatitis C virus		world Tearth Organization

#### **DEFINITIONS**

**Audit:** Direct observation or monitoring of healthcare personnel's (HCP's) adherence to job-specific infection prevention measures.

**Cleaning:** 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.

**Competency assessment:** The verification of infection prevention competency through the use of knowledge-based testing and direct observation. If direct observation is not included as part of a competency assessment, an alternative method to ensure that HCP possess essential knowledge, skills, and abilities should be used.

**Disinfection:** A process of microbial inactivation (compared to sterilization) that eliminates many or all pathogenic microorganisms except bacterial spores on inanimate objects.

**Feedback:** A summary of audit findings that is used to target performance improvement.

**Healthcare personnel:** All paid and unpaid persons working in healthcare settings. HCP might include (but are not limited to) podiatrists, physicians, nurses, nursing assistants, therapists, technicians, emergency

medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the healthcare facility, and persons (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients.

**Healthcare Personnel Infection Prevention Competency-Based Training:** The provision of job-specific education, training, and assessment to ensure that HCP possess infection prevention competency.

**Healthcare Personnel Infection Prevention Competency:** The proven ability of HCP to apply essential knowledge, skills, and abilities to prevent the transmission of pathogens during the provision of care.

**Off-site podiatric care:** Podiatric care and services provided outside the office setting, such as a nursing home, assisted living facility, or community health center.

**Sterilization:** A process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods. Steam under pressure, dry heat, ethylene oxide (EtO) gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in healthcare facilities.

#### I. INTRODUCTION

This guide was developed as a model for a basic infection prevention and control (IPC) plan for providers in outpatient podiatry offices or those who travel to provide podiatry services at other locations (such as nursing homes, assisted living facilities, and home care). It contains information to help facilities:

- Develop policies and procedures tailored to these settings
- Meet minimal expectations of patient safety
  described in the Centers for Disease Control and
  Prevention (CDC) Guide to Infection Prevention
  for Outpatient Settings: Minimum Expectations for
  Safe Care (available at: https://www.cdc.gov/HAI/
  settings/outpatient/outpatient-care-guidelines.html)

# A. Fundamental Principles of Infection Prevention: Standard and Transmission-Based Precautions

Standard Precautions represent the minimum infection prevention measures that apply to all patient care, regardless of suspected or confirmed infection status of the patient, in any setting where healthcare is delivered.1 These evidence-based practices are designed to both protect healthcare personnel (HCP) and prevent the spread of infections among patients. Standard Precautions replace earlier guidance relating to Universal Precautions and Body Substance Isolation. Standard Precautions include: (1) hand hygiene, (2) use of personal protective equipment (PPE) (e.g., gloves, gowns, face masks), depending on the anticipated exposure, (3) respiratory hygiene and cough etiquette, (4) safe injection practices, and (5) safe handling of potentially contaminated equipment or surfaces in the patient environment.

Transmission-Based Precautions are intended to supplement Standard Precautions in patients with known or suspected colonization or infection of highly transmissible or epidemiologically important pathogens. These additional precautions are used when the route of transmission is not completely interrupted using Standard Precautions. The three categories of Transmission-Based Precautions include: (1) Contact Precautions, (2) Droplet Precautions, and (3) Airborne Precautions. For diseases that have multiple routes of transmission, a combination of Transmission-Based Precautions may be used. Whether used singly or in combination, they are always used in addition to Standard Precautions.

The risk of infection transmission and the ability to implement elements of Transmission-Based Precautions may differ between outpatient and inpatient settings (e.g., because of varying facility design characteristics). However, because patients with infections are routinely encountered in outpatient settings, ambulatory care facilities need to develop specific strategies to control the spread of transmissible diseases pertinent to their setting. This includes developing and implementing systems for early detection and management of potentially infectious patients at initial points of entry to the facility. For detailed information on Standard and Transmission-Based Precautions and summary guidance for outpatient settings, refer to the following documents: CDC Guide to Infection Prevention in Outpatient Settings (available at: http://www.cdc.gov/ HAI/settings/outpatient/outpatient-care-guidelines.html) and CDC 2007 Guideline for Isolation Precautions (available at: http://www.cdc.gov/hicpac/pdf/isolation/ Isolation2007.pdf).

#### **B.** Objectives and Scope

By highlighting existing CDC and Healthcare Infection Control Practices Advisory Committee (HICPAC) recommendations, this summary guide addresses the following objectives: (1) to reaffirm Standard Precautions as the foundation for preventing transmission of infectious agents in all healthcare settings during patient care; (2) to provide basic IPC recommendations for outpatient podiatry settings and off-site podiatry care locations; and (3) to provide links to full guidelines and source documents, which can be referenced for more detailed background and recommendations.

The guide's elements are based primarily on existing CDC evidence-based guidelines and other evidence-based guidance. This guide provides information on the fundamental components of Standard Precautions, practices to be taken with all patients in podiatry settings to prevent the transmission of infectious agents. Specific topic areas include:

- Education and training
- Hand hygiene practices
- PPE use
- Safe injection and medication management
- Environmental cleaning and disinfection
- Cleaning, disinfecting, and sterilizing reusable medical devices

Also included are checklists and observation tools, which can be used to ensure the facility has the appropriate infection prevention supplies, policies, and procedures in place to allow HCP to provide safe care and to systematically assess personnel adherence to correct infection prevention practices.

It should be noted that this document does not replace existing, more detailed information and recommendations found in CDC guidelines. Full CDC guidelines, as cited throughout this guide, should be consulted for additional background, rationale, and scientific evidence behind the recommendations

presented herein (e.g., hand hygiene, sterilization and disinfection, environmental infection control).

Though much of the content is applicable to other settings, this guide was primarily designed to address the needs of freestanding podiatry offices and off-site podiatry settings, such as nursing homes, assisted living facilities, and community health centers, rather than ambulatory surgery centers or hospital-based settings. This guide can be used to aid facilities in developing a podiatry IPC plan, based on the types of services provided, which can be updated and supplemented as needed. Facilities that have a plan should ensure that their current IPC policies and procedures include the elements covered in this document.

This guide was created to address podiatry's use of unique procedures, equipment, and instruments, and to focus attention on IPC issues. It was developed to provide guidance for the development and implementation of IPC plans and activities tailored to outpatient podiatry settings and off-site podiatry services. Adherence to appropriate IPC practices may be challenging, but the same standards must be adhered to when acting as an off-site provider as when delivering care in the usual office setting. Examples of off-site challenges include not having access to a dedicated treatment space when providing care at a long term care facility or being asked to work in treatment areas with a layout that is poorly suited to the provision of podiatric medical services.<sup>2</sup>

All aspects of the services provided by the off-site podiatrist should be clearly outlined in the contract between the facility and the podiatrist, since maintaining IPC in all aspects of care is a shared responsibility between the podiatrist and the facility. For example, podiatrists should work closely with facility managers and other relevant staff to create or identify treatment areas that have the necessary attributes to facilitate safe provision of podiatric

medical care, such as adequate counter space, sinks/ hand hygiene facilities, medical waste disposal bins and sharps containers, and areas clearly demarked for clean versus contaminated equipment and supplies.<sup>2</sup>

Every podiatric facility is unique based on the type of patients seen and the procedures performed. Additionally, there is variation in the level of resources available within each facility. Therefore, this guide serves as a resource to help facilities prioritize their goals as they develop or enhance their IPC program. Also, all medical settings are encouraged to comply with state and federal requirements that apply to their facility and personnel. For example, OSHA has requirements relative to the Bloodborne Pathogens Standard that all healthcare facilities are required to follow.

#### C. Background

Instances of failure in basic infection prevention linked with outbreaks in nonhospital settings have been reported with increased frequency in the last 15 years, a concerning trend indicating that the challenge of providing consistently safe care is not always met.<sup>2</sup> Public health investigations have identified instances

of unsafe practices that have put podiatric patients at risk for bacterial, viral, and fungal infections.<sup>2, 3</sup> Examples of outbreaks related to lapses in infection prevention include:

- Proteus mirabilis wound infections related to contaminated bone drills used during outpatient podiatric surgery
- Methicillin-resistant Staphylococcus aureus softtissue infections after injections at a podiatric medical clinic
- Mycobacterium chelonae subspecies abscessus
   (now referred to as Mycobacterium abscessus)
   soft-tissue infections related to a jet injector used to administer lidocaine at a podiatric medical clinic
- Hepatitis B virus infections at a long term care facility caused by failure to maintain separation of clean and contaminated podiatry equipment<sup>3</sup>

These past investigations highlight lapses in disinfection and sterilization of patient-care instruments, environmental IPC, safe injection practices in podiatric settings, and the importance of infection prevention in avoiding disease transmission.

## II. INFECTION PREVENTION AND CONTROL PROGRAM AND INFRASTRUCTURE

## A. Designate Resources to Infection Prevention (Administrative Resources)

Infection prevention must be a priority in any outpatient podiatry setting or off-site podiatric care location.

### Oversight Responsibility for the IPC Program

Those with primary administrative oversight of the facility must ensure that sufficient human and fiscal resources are available to develop and maintain infection prevention and occupational health programs. This includes the availability of appropriate and sufficient equipment and supplies necessary for consistent adherence to Standard Precautions, including safer devices to reduce percutaneous injuries, hand hygiene products, and PPE (e.g., gloves, gowns, face and eye protection). To be successful, infection prevention programs require visible and tangible support from all levels of the podiatric facility's leadership. Leadership is accountable for ensuring that staffing and resource limitations do not prevent podiatric HCP from consistently adhering to IPC activities.<sup>1, 4</sup> Appendix D provides an example list of IPC roles and responsibilities.

### Importance of Trained Infection Preventionist Involvement

IPC programs must extend beyond Occupational Safety and Health Administration (OSHA) bloodborne pathogens training. At least one individual with training in IPC should be employed by the podiatry facility, or should be regularly available (e.g., by contract), to manage the facility's IPC program. Podiatric healthcare facilities should ensure that this

"It is vital to patient safety that HCP have the knowledge, skills, behaviors, and ability to perform aseptic technique and follow safe injection, infusion, and medication vial practices. To ensure effective engineering of and adherence to safe practices in everyday patient care in all healthcare settings, responsibility for the oversight and monitoring for absolute adherence to these practices should be assigned to appropriate supervisors."

Dolan SA, et al. APIC position paper: Safe injection, infusion, and medication vial practices in health care. Am J Infect Control. 2016 Jul 1;44(7):750-57. Epub 2016 May 13.

individual is involved in the development of written IPC policies and has regular communication with podiatric HCP to address specific issues or concerns related to IPC. This individual's authority should be empowered and supported to ensure the effectiveness of the IPC program.<sup>1</sup>

#### **IPC Policies and Procedures**

The first step in developing policies and procedures is to identify the services provided by the facility and the patient population served. Written policies and procedures should be tailored to the facility and clearly reflect the safeguards needed to prevent disease transmission when performing services and procedures. The development and ongoing refinement of policies

"As health-care delivery has transitioned to ambulatory and long-term care settings, the need for infection control guidance and oversight in these settings has been increasingly recognized."

Wise ME, et al. Infection prevention and control in the podiatric medical setting. Challenges to providing consistently safe care. *J Am Podiatr Med Assoc.* 2015 May;105(3):264-72.

and procedures should be based on evidence-based guidelines, regulations, or standards. Policies and procedures should be reassessed at least annually.

#### **B.** Facility Risk Assessment

#### Purpose of the Facility Risk Assessment

An IPC program plays a key role in the maintenance of a safe work environment for patients, podiatric HCP, and visitors. Identifying and addressing risks is central to an effective infection control program. A risk assessment is a systematic means of identifying risks in the podiatric setting and should be conducted at least annually and whenever new procedures or risks are identified.<sup>5</sup> Regular facility risk assessments help determine the goals and objectives of the podiatry IPC program. The risk assessment should inform the development of the IPC program specific to the practice and of the action plan outlining the steps needed to accomplish each identified objective in the program.<sup>6,7</sup>

### Key Recommendations for Infection Prevention and Control Program and Infrastructure

Leadership is accountable for the success of infection prevention activities and the availability of sufficient human and material resources for infection prevention to ensure consistent and prompt action to remove or mitigate infection risks and stop transmission of infections.

Leadership should:

- Ensure 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.
- Ensure availability of sufficient and appropriate supplies necessary for adherence to Standard Precautions (e.g., hand hygiene products, PPE, and injection equipment, including devices to reduce percutaneous injuries).

- Develop written infection prevention policies and procedures appropriate for the services provided by the facility and based upon evidence-based guidelines, regulations, or standards.
- Ensure the same standard of care is provided by podiatrists in the off-site care setting as it is in the office setting.
- Reassess policies and procedures at least annually.
- Develop a system for early detection and management of potentially infectious persons at initial points of patient encounter.

#### **Inventory of Services and Procedures**

The first step in the facility risk assessment is to complete an inventory or list of the services, procedures, and practices done in the office setting. It can help you identify, for example, which types of invasive and other procedures and tests are performed that use scalpels, nippers, forceps, splitters, or curettes.

The next step is to assess your facility's program and practices. A helpful tool in assessing your organization's practices is the Infection Prevention Checklist for Outpatient Podiatry Settings (Appendix A), which accompanies this guide. Podiatric policies and procedures should be tailored to the facility, based on the facility's risk assessment, and reassessed on a regular basis, taking into consideration the types of services provided by the facility and the patient population served. This process will allow facilities to better prioritize their resources and focus extra attention on those areas determined to pose greater risk to their patient population. For example, a podiatry healthcare setting that performs on-site sterilization of reusable surgical devices would be expected to have more detailed policies regarding device reprocessing than a setting that sends out reusable instruments for off-site sterilization. Both types of facilities, however, should have policies and procedures addressing the handling of reusable medical devices.

### C. Infection Surveillance, Reporting, and Record-Keeping

#### **Process and Outcome Measures**

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., healthcare-associated infections [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

### **Key Recommendations for Facility Risk Assessments**

- Perform a facility risk assessment at least annually to help prioritize resources and focus extra attention on those areas that pose greater risk to the patients.
- 2. Inventory or list facility services and procedures.
- Use the Infection Prevention Checklist for Outpatient Podiatry Settings (Appendix A) to assess practices in the facility.

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 podiatric healthcare facility, patients should be educated in recognizing signs and symptoms of infection and instructed to notify the facility if such signs or symptoms occur. The podiatric facility should ensure there is a written protocol for surveillance practices.

#### **Disease Reporting**

At a minimum, podiatric healthcare facilities need to adhere to local, state, and federal requirements for reportable disease and outbreak reporting. Facilities should check the requirements for their state/region to ensure they are compliant with all regulations and should have contact information for their local and/or state health department available so required reporting is done in a timely manner. The facility should have a written protocol for reporting communicable diseases and maintaining records of reporting activities. (A list of state reportable diseases from the Council of State and Territorial Epidemiologists website is available at: http://www.cste2.org/izenda/entrypage.aspx.

See Appendix B for a place to list your state's reportable diseases and conditions.)

#### **Ongoing Practice Monitoring**

Regular focused practice surveys or audits using a standardized tool (e.g., of infection prevention practices including hand hygiene, medication handling, reprocessing of reusable devices) offer a means to ensure ongoing adherence of podiatric HCP to recommended practices. One such tool is the Infection Prevention Checklist for Outpatient Podiatry Settings (Appendix A). Facilities are encouraged to periodically use the checklist to assess their IPC program and ensure they are meeting the minimum expectations for safe care. Facilities may identify lapses in IPC in the course of this assessment.

### Approaches to Evaluating and Managing Infection Breaches

If IPC lapses are identified, efforts should be made to correct the practices, determine why the correct practices were not being performed, and appropriately educate or reeducate podiatric HCP (as applicable). The risk posed to patients by deficient practices should be considered. Certain lapses (e.g., reuse of syringes on more than one patient, accessing a medication vial with a used needle or syringe, reuse of lancets) have resulted in the transmission of bloodborne pathogens 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 the 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 an Infection Control Breach (available at: https://www.cdc.gov/hai/outbreaks/steps\_for\_eval\_ic\_ breach.html). Additionally, CDC has developed a Patient Notification Toolkit (available at: https://www. cdc.gov/injectionsafety/pntoolkit/) for circumstances

warranting patient notification to assist healthcare facilities in conducting such a patient notification.

#### Audit and Feedback

Surveillance reports should be prepared and distributed periodically to appropriate podiatry staff for any necessary follow-up actions. For example, a high incidence of certain infections or practices may prompt auditing of specific procedures or a thorough infection control assessment.

#### **Record-Keeping**

Another aspect of providing care both within and outside of the podiatric office setting is keeping records of the care delivered. The "who, what, when, and where" of the patient visits should be completely and accurately recorded. This information should also be maintained by the off-site care facility (as indicated) to ensure continuity of care among subsequent caregivers who are caring for the patient. This also promotes and demonstrates adherence to IPC protocols for safe podiatric care:

- Who was seen, and by whom—name of patient and of those who provided the care (podiatrist and any assistants)
- What was done—procedure(s) performed, medications used or prescribed, and any instructions for continuing care
- When was the patient seen—date(s)
- Where was the patient seen—name/location of the site visited and where at the site care was provided (e.g., treatment room, empty office space set up to provide care)

#### **D. Education and Training**

### Competency-Based Training and Education

Education on the basic principles and practices for preventing the spread of infections should be provided to all podiatric HCP, whether employed by the facility or by outside agencies, available by contract, or on a voluntary basis. Competency-based training should

### Key Recommendations for Surveillance, Reporting, and Record-keeping in Podiatric Settings

- Educate patients who have undergone procedures at the podiatric healthcare facility in recognizing 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.
- Adhere to local, state, and federal requirements regarding HAI surveillance, reportable diseases, and outbreak reporting.
- Ensure the podiatric facility has a written protocol for reporting communicable diseases to the public health authority and that it includes an updated list of reportable diseases.
- 4. Perform regular audits of HCP adherence to infection prevention practices.
- 5. If certain lapses are found (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), they should be halted immediately and warrant immediate consultation with state or local health department and appropriate notification and testing of potentially affected patients.

- If lapses are identified, efforts should be made to correct the practices, determine why the correct practice(s) were not being performed, and appropriately educate or reeducate podiatric HCP.
- 7. The risk posed to patients by the deficient practice(s) should be considered.
- Each podiatry facility should routinely audit (monitor and document) adherence to proper practices and provide feedback to staff regarding their performance.
- Each podiatric practice should maintain accurate and timely records of care provided to its patients, whether the care takes place in the office or in an off-site setting.
- Additional resources are available at CDC
   (Steps for Evaluating an Infection Control
   Breach (available at: https://www.cdc.gov/
   hai/outbreaks/steps\_for\_eval\_ic\_breach.
   html) and Patient Notification Toolkit
   (available at: https://www.cdc.gov/
   injectionsafety/pntoolkit/).

include both podiatric HCP safety (e.g., OSHA bloodborne pathogens training) and patient safety, emphasizing job- or task-specific needs. Training should be provided:

- Upon orientation to the facility including any new employees, contract staff, or outside consultants
- When new tasks, procedures, equipment, or supplies are introduced
- Annually, and any time policies or procedures are updated or revised

 In response to recognized lapses in adherence and to address newly recognized infection transmission threats

The competency assessment, through knowledge-based testing or direct observation, should be documented following each training, and records should be maintained according to state and federal requirements.

Training should be adapted to reflect the diversity of the workforce and the patients served and tailored to

### **Key Recommendations for Education** and Training of Podiatric HCP

- 1. 1Job- or task-specific infection prevention education and training should be provided to all podiatric HCP staff. This includes those employed by outside agencies and those available to the facility by contract or on a volunteer basis.
- Training should focus on principles of both HCP safety (e.g., OSHA Bloodborne Pathogens) and patient safety (e.g., Standard Precautions).
- Training should be provided upon hire and repeated annually and when policies or procedures are updated/revised.
- Competencies and adherence to jobspecific infection prevention policies and procedures should be documented both upon hire and through annual evaluations/ assessments.
- 5. Records should be maintained according to state and federal requirements.
- The facility should provide feedback from audits to HCP regarding their performance.

meet the needs of each category of podiatric HCP being trained. Feedback from audits regarding their performance should be provided to HCP.

This guide can be useful as a training tool and to help develop training modules.

While a comprehensive description of strategies for quality improvement is beyond the scope of this guide, examples of evidence-based strategies for improving practices in office settings are readily available. One example is the Agency for Healthcare Research and Quality (AHRQ) TeamSTEPPS® for Office-Based Care,

which is an evidence-based teamwork system to improve communication and teamwork skills among HCP (available at: https://www.ahrq.gov/teamstepps/officebasedcare/index.html). Another tool is the AHRQ Medical Office Survey on Patient Safety Culture, which asks medical office providers and staff for their opinions about the culture of patient safety and healthcare quality in their medical office (available at: https://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/medical-office/index.html). Additional resources can be found at: https://www.ahrq.gov/sites/default/files/wysiwyg/sops/quality-patient-safety/patientsafetyculture/medofficeresourcelist-020118.pdf.

### E. Healthcare Personnel (HCP) Safety

#### **Occupational Health Policies**

Facility administrators should ensure that facility policies and procedures address occupational health needs including vaccination of podiatric HCP. The CDC Advisory Committee on Immunization Practices (ACIP) recommendations on HCP immunizations are available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm.

Facility administrators should also ensure that facility policies and procedures address management of exposures or infections in personnel requiring postexposure prophylaxis and/or work restrictions, and compliance with the OSHA Bloodborne Pathogens Standard (including a facility-specific exposure control plan). It should be noted that HCP health records cannot be combined with personnel records.<sup>8</sup>

A process should be in place and known to all podiatric HCP staff regarding the notification of public health authorities when the illness has public health implications or is required to be reported (e.g., measles, *Mycobacterium tuberculosis* [TB]). The facility should train upon hire and at least annually all podiatric HCP for whom contact with blood or other potentially infectious material is

anticipated. The facility should also track podiatric HCP exposure events and evaluate event data and should develop and implement corrective action plans to reduce the incidence of such events. All podiatric HCP should receive baseline TB screening prior to placement, with repeat testing if appropriate (based on the facility-level risk assessment). Refer to a CDC model TB risk assessment worksheet available at: <a href="https://www.cdc.gov/tb/publications/guidelines/">https://www.cdc.gov/tb/publications/guidelines/</a> AppendixB\_092706.pdf. Referral arrangements for podiatric HCP can be made with qualified HCP in an occupational health program of a hospital, with educational institutions, or with healthcare facilities that offer personnel health services.

If respirators are used, the podiatry facility should have 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 at least annually, as appropriate.<sup>9</sup>

Additionally, the facility should maintain well-defined policies concerning contact of HCP with patients when HCP have potentially transmissible conditions. Policies should include:

- Work-exclusion clauses that encourage reporting of illnesses and do not penalize with loss of wages, benefits, or job status
- Education of HCP on prompt reporting of illness to their supervisor

#### **Key Recommendations for Podiatric HCP Safety**

- The facility should have a written policy regarding immunizing podiatric HCP, including a list of all required and recommended immunizations for podiatric HCP.
- All podiatric HCP for whom contact with blood or other potentially infectious materials is anticipated should be trained on the OSHA bloodborne pathogens standard upon hire and at least annually.
- Following an exposure event, postexposure evaluation and follow-up, including prophylaxis as appropriate, should be available at no cost to employees and should be supervised by a licensed HCP.
- The facility should track HCP exposure events, evaluate event data, and develop/ implement corrective action plans to reduce incidence of such events.

- All podiatric HCP should be screened for TB upon hire regardless of the risk classification of the healthcare setting. The three TB screening risk classifications are low risk, medium risk, and potential ongoing transmission.
- Podiatric HCP should receive repeat TB testing, if appropriate, based on the facilitylevel risk assessment.
- 7. If respirators are used, the facility should have 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.
- The facility should have well-defined policies concerning contact of personnel with patients when personnel have potentially transmissible conditions.

#### III. 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.

Standard Precautions are based on the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain transmissible infectious agents. These practices are designed to both protect podiatric HCP and prevent podiatric HCP from spreading infections among patients.<sup>1</sup>

Standard Precautions include: (1) hand hygiene; (2) use of PPE (e.g., gloves, gown, face masks), depending on the anticipated exposure; (3) respiratory hygiene and cough etiquette; (4) safe injection, medication storage and handling practices; and (5) safe handling of potentially contaminated equipment or surfaces in the patient environment.

Use of PPE during patient care is determined by the extent of anticipated blood, body fluid, or pathogen exposure and the nature of the healthcare worker—patient interaction. For some patient interactions, only gloves may be needed (e.g., performing a dressing change); for other interactions, use of gloves, gown, and a face shield or mask and goggles is necessary.

It is essential that staff be educated and trained on the principles and rationale for the application of Standard Precautions, since an understanding of the principles facilitates appropriate decision-making when staff are faced with new circumstances. Each of these elements of Standard Precautions is 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. Furthermore, at the podiatric facility level, an understanding of the specific procedures performed and typical patient interactions, as part of policy and procedure development as described above, will ensure that necessary equipment and supplies are available.

The application of Standard Precautions, guidance on appropriate selection of PPE, and an example of donning and doffing of PPE is described in detail in the CDC's 2007 Guideline for Isolation Precautions, available at: http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.

#### A. Hand Hygiene

### Rationale for Practicing Appropriate Hand Hygiene

Good hand hygiene, including use of alcohol-based hand rubs (ABHR) or handwashing with soap and water, is critical to reduce the risk of spreading infections in outpatient settings, including those caused by antibiotic-resistant organisms. 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 adherence with recommended hand hygiene practices by requiring less time, irritating hands less, and facilitating hand hygiene at the point of care. 10, 11

hand hygiene in most clinical situations. Soap and water should be used when hands are visibly soiled (e.g., with blood or body fluids) and is also preferred after caring for a patient with known or suspected *Clostridium difficile* or norovirus during an outbreak.<sup>1</sup>

Supplies necessary for adherence to hand hygiene should be readily accessible in all areas where patient care is being delivered, including podiatric office settings and off-site podiatric care locations.

#### **Education and Training**

All podiatric HCP should be educated regarding appropriate indications for hand hygiene upon hire and annually thereafter. They should also be required to demonstrate competency with hand hygiene following each training. Each podiatric facility should routinely audit (monitor and document) adherence to proper hand hygiene practices and provide feedback to staff regarding their hand hygiene performance.

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 Healthcare Settings (available at: https://www.cdc.gov/handhygiene/providers/guideline.html).

### Sample Procedures for Performing Hand Hygiene

### Using Alcohol-Based Hand Rub (follow manufacturer's directions):

- Dispense the recommended volume of product.
- Apply product to the palm of one hand.
- Rub hands together, covering all surfaces of hands and fingers until they are dry (no rinsing is required).

#### Handwashing with Soap and Water:

- Wet hands first with water (avoid using hot water).
- Apply soap to hands.
- Rub hands vigorously for at least 15–20 seconds, covering all surfaces of hands and fingers.

- Rinse hands with water and dry thoroughly with paper towel.
- Use paper towel to turn off faucet.

#### **Surgical Hand Antisepsis**

 Follow the Guideline for Hand Hygiene in Healthcare Settings, available at: https://www.cdc.gov/ handhygiene/providers/guideline.html.

The indications for hand hygiene can be found in the Key Recommendations for Hand Hygiene in Podiatric Settings text box.

### B. Personal Protective Equipment (PPE)

#### Rationale for Appropriate PPE Use

PPE refers to wearable equipment intended to protect podiatric HCP from exposure to or contact with infectious agents. Examples include gloves, gowns, face masks or shields, respirators, and goggles. The selection of PPE is based on the nature of the patient interaction and potential for exposure to blood, body fluids, or infectious agents. Facilities should provide appropriate PPE supplies, including a variety of sizes, throughout the facility. Visiting or off-site podiatry providers should ensure that PPE is available at the care site.

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. 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. Only CDC NIOSH-certified respirators should be used.

#### Key Recommendations for Hand Hygiene in Podiatric Settings

- 1. Key situations where hand hygiene should be performed include:
  - a. Immediately before contact with the patient
  - Before performing an aseptic task (e.g., preparing an injection) or handling invasive medical devices
  - 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. Before moving from a contaminated body site to a clean body site on the same patient
  - f. Immediately after removal of PPE
- Soap and water should be used when hands are visibly soiled (e.g., blood, body fluids), or after caring for a patient with known or suspected Clostridium difficile or norovirus during an outbreak.
   Otherwise, the preferred method of hand hygiene in clinical situations is with an ABHR.
- Supplies necessary for adherence to hand hygiene should be readily accessible in all areas where patient care is being delivered.
- The podiatric facility should periodically monitor and record adherence to hand hygiene and provide feedback to personnel regarding their performance.

Potential inhalation of nail dust is an aspect of respiratory protection specific to podiatric care, particularly from drilling that is done as part of the treatment of onychogryphotic nails. Various studies have reported eye, nose, and throat irritation and chest tightness among podiatrists performing this procedure. While there is insufficient evidence to estimate the risk from inhalational nail dust exposure on which to base a formal recommendation, respirator use may be considered when drilling nails.<sup>12,13</sup>

Hand hygiene should always be performed after removing and disposing of PPE.

#### **Education and Training**

All HCP sho uld be educated regarding the proper selection and use of PPE. Resources to help promote patient safety and increase the safety of the healthcare work environment through improved use of PPE by HCP, including examples of donning and doffing sequences, are available at: https://www.cdc.gov/HAI/prevent/ppe.html.

The type of PPE used will vary based on the level of precaution required. The procedure for donning and doffing PPE should be tailored to the specific type of PPE.

#### General Recommendations for Donning PPE

- Always perform hand hygiene before donning PPE.
- If wearing a gown, don the gown and fasten in back accordingly.
- If wearing a face mask or respirator:
  - Secure ties or elastic band at the back of the head and/or neck.
  - Fit flexible band to nose bridge.
  - Fit snug to face and below chin.
- If wearing goggles or face shield, put on face and adjust to fit.
- If wearing gloves in combination with other PPE, don gloves last. If wearing a gown, extend gloves to cover wrist of gown.

#### General Recommendations for Doffing PPE

- Remove PPE before leaving the exam room or patient environment (except respirators, which should be removed after exiting an airborneisolation room).
- Removal of gloves:
  - Grasp outside of glove with opposite gloved hand; peel off.
  - Hold removed glove in glove hand.
  - Slide ungloved fingers under the remaining glove at the wrist; peel off and discard both gloves.

- Removal of goggles or face shield:
  - Avoid touching the front of the goggles or face shield.
  - Remove by handling the headband or ear pieces and discard.
- Removal of gowns:
  - Remove in such a way as to prevent contamination of clothing or skin.
  - Turn contaminated outside surface to the inside.
  - Roll or fold into a bundle and discard.

#### **Key Recommendations for Use of PPE in Podiatry Settings**

- The podiatric healthcare facility should ensure that sufficient and appropriate PPE is available and readily accessible to podiatric HCP.
- The podiatric facility should educate all podiatric HCP on proper selection and use of PPE.
- The podiatric facility should ensure staff are able to select, put on, remove, and dispose of PPE in a manner that protects themselves, the patient, and others.
- 4. 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.
- Hand hygiene should be performed immediately after removal of PPE.
- Gloves should be worn 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.
- A gown should be worn 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.
  - Remove gown and perform hand hygiene before leaving the patient's environment (e.g., exam room).
- Mouth, nose, and eye protection should be worn during procedures that are likely to generate splashes or sprays of blood or other body fluids.
- The podiatric facility should periodically monitor and record adherence to PPE use and provide feedback to personnel regarding their performance.

- Removal of face mask or respirator:
  - Avoid touching the front of the mask or respirator.
  - Grasp the bottom and the ties/elastic to remove and discard.
- Always perform hand hygiene immediately after removing PPE.

Each podiatric healthcare facility should evaluate the services it provides to determine specific needs and to ensure that sufficient and appropriate PPE is available for adherence to Standard Precautions. All podiatric HCP at the facility should be educated regarding proper selection and use of PPE. The podiatric facility should periodically monitor and record adherence to PPE use and provide feedback to personnel regarding their performance.

#### C. Respiratory Hygiene/Cough Etiquette

#### Rationale for Respiratory Hygiene/ Cough Etiquette

Respiratory hygiene and cough etiquette is an element of Standard Precautions that highlights the need for prompt implementation of infection prevention measures at the first point of a patient's encounter with the facility (e.g., reception and triage areas) and continuing throughout the duration of the visit. This strategy primarily targets patients and accompanying family members or friends with undiagnosed transmissible respiratory infections and applies to any person entering the facility with signs of illness, including cough, congestion, rhinorrhea, or increased production of respiratory secretions. Refer to the CDC 2007 Guideline for Isolation Precautions (available at: https://www.cdc.gov/infectioncontrol/pdf/guidelines/ isolation-guidelines.pdf) or Appendix C, Additional Information About Respiratory Hygiene/Cough Etiquette, for more information about respiratory hygiene and cough etiquette.

#### **Scenario**

A busy podiatrist prefills syringes with an injectable corticosteroid each morning. When seeing a new patient for heel pain, where a corticosteroid injection is sometimes a first-line treatment modality, the podiatrist anticipates needing such an injection to treat the patient. The physician takes a prefilled syringe into the room in anticipation of giving an injection. However, upon review, the patient's symptoms do not warrant an injection and the syringe is placed in an instrument tray that also contains a used and contaminated scalpel and set of nail clippers. At the conclusion of the visit, the physician takes the unused syringe and returns it to the tray of prefilled syringes.

#### **Process Errors**

- Prefilling syringes for later use
- Placing the unused syringe in the tray with used instruments, then returning it for later use to tray of unused syringes

#### **Process Recommendations**

- Prepare injections as close as possible to the time of administration.
- Prefilling and storing batch-prepared syringes must be avoided except in accordance with pharmacy standards.
- Whenever possible, use commercially manufactured or pharmacy-prepared prefilled syringes. Although these can be costly, the cost of an outbreak is greater.<sup>14</sup>
- Clean or sterile patient-care items that come into contact with contaminated items are considered contaminated and must be reprocessed per the manufacturer's recommendations or discarded at the conclusion of the visit.

### Key Recommendations for Respiratory Hygiene/Cough Etiquette in Podiatry Settings

- 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 duration of the visit.
  - a. Post visual alerts (e.g., signs, posters) at entrances to outpatient facilities with instructions to patients with symptoms of respiratory infection to:
    - Inform podiatric HCP of symptoms of a respiratory infection when they first register for care.
    - ii. Cover their mouths/noses when coughing or sneezing.
    - Use and appropriately dispose of tissues.
    - iv. Perform hand hygiene after hands have been in contact with respiratory secretions.
  - Provide tissues and no-touch receptacles for disposal of tissues.

- Provide resources for performing hand hygiene in or near waiting areas (e.g., handwashing facilities, ABHR).
- d. Offer masks to coughing patients and other symptomatic persons upon their 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
  waiting area.
- Educate podiatric HCP on the importance of infection prevention measures for containing respiratory secretions to prevent the spread of respiratory pathogens.
- Ensure that podiatric HCP observe Droplet
  Precautions, in addition to Standard
  Precautions, when examining and caring for
  patients with signs and symptoms of a
  respiratory infection.

#### D. Safe Injection, Medication Storage and Handling Practices

### Rationale for Safe Injection, Medication Storage and Handling

Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, or between a patient and HCP during preparation and administration of parenteral medications. It refers to the proper use and handling of supplies for administering injections and infusions

(e.g., syringes, needles, medication vials, parenteral solutions). Medications should be drawn up in a designated clean medication area that is not adjacent to potential sources of contamination (e.g., contaminated equipment, sinks).

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 and off-site podiatry care settings. For example, efforts to increase uptake of hepatitis B vaccination among HCP and implementation of safety devices that are designed to decrease risks of sharps injury are needed.

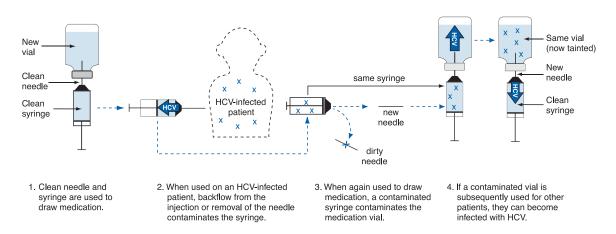
A basic assumption underlying injection safety is that all equipment that has penetrated the skin or that has been attached to equipment that has penetrated the skin must be considered potentially contaminated, including syringes, needles, intravenous tubing, and medication vials.<sup>2</sup> It is a common misperception that contamination is limited to the needle component when a syringe and needle are used together. Since 1946, numerous experimental studies have demonstrated that contamination extends from the needle into the syringe after injections are administered to patients by intradermal, intramuscular, intravenous, and other routes.<sup>2</sup> Figure 1 illustrates how unsafe injection practices can lead to disease transmission.

#### **Medication Storage and Handling**

Parenteral medication storage, handling, and administration should adhere to injection safety measures. Recommendations for safe injection practices are a component of Standard Precautions and should be explicit in all podiatry settings. Medication preparation should take place in a designated space. That space should not be adjacent to areas where potentially contaminated items are placed. In general, any item that could have come in contact with blood or body fluids should not be in the medication preparation area. Examples of contaminated items that should not be placed in or near the medication preparation area include: used equipment such as syringes, needles, IV tubing, blood collection tubes, needle holders (e.g., Vacutainer® holder), or other soiled equipment or materials that have been used in a procedure. All staff personnel who use or handle parenteral medications and related supplies should be aware of labeling and storage requirements.

#### FIGURE 1: Unsafe Injection Practices and Disease Transmission

Reuse of syringes can transmit infectious diseases such as Hepatitis C virus (HCV). The syringe does not have to be used on multiple patients for this to occur.



Source: Centers for Disease Control and Prevention (CDC). *Injection Safety: What Every Healthcare Provider Needs to Know.* Accessed Jan 3, 2018. https://www.cdc.gov/injectionsafety/PDF/SIPC\_ProviderBrochure.pdf

### Unsafe Practices That Can Lead to Patient Harm

Further attention to patient protection is also needed, as evidenced by continued outbreaks in outpatient settings resulting from unsafe injection practices. More than 50 reported outbreaks of viral and bacterial infections have stemmed from unsafe injection practices since 2001. Unsafe practices that have led to patient harm include:

- Use of a single syringe, with or without the same needle, to administer medication to multiple patients, even if the needle was changed or the injection was administered through an intervening length of intravenous (IV) tubing
- 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. Failure to use aseptic technique when preparing and administering injections
- Preparation of medications in an undesignated or unclean area such as on contaminated countertops adjacent to sinks

Guidance on safe injection practices can be found in the CDC's 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/). See the Key Recommendations for Safe Injection, Medication Storage and Handling Practices in Podiatry Settings text box.

The practice of combining two or more medications into a single syringe is considered compounding by the FDA. Compounding of sterile medications must be performed according to standards from the USP (United States Pharmacopeia) General Chapter (797) Pharmaceutical Compounding—Sterile Preparations. Among other requirements, these standards require proper training of personnel who prepare compounded sterile preparations, environmental monitoring of the compounding area, use of primary engineering controls (e.g., ISO Class 5 hood), and other measures.

Note that it is not acceptable to visually inspect syringes to determine whether they are contaminated or can be used again. However, if there are visible signs of contamination (e.g., cloudy liquid), the medication should be discarded. Pathogens, including hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), can be present in sufficient quantities to produce infection in the absence of visible blood. Similarly, bacteria and other microbes can be present without clouding or other visible evidence of contamination. Just because blood or other contaminating material is not visible in a used syringe or IV tubing does not mean the item is free from potentially infectious agents. Used injection supplies and materials are potentially contaminated and should be discarded.18

Podiatric HCP should maintain accurate and timely records of all aspects of medication storage and handling (e.g., refrigerator temperature log, inventory monitoring for expiration dates), whether the care takes place in the office or an off-site setting.

#### **Education and Monitoring of HCP**

To ensure safe injection practices in all healthcare settings, a multifaceted approach that focuses on surveillance, oversight, enforcement, personnel competency, continuing education, and accountability is needed.<sup>19</sup>

#### Safe Use of Injectable Medications

Parenteral medications include single-dose vials (SDV) and multi-dose vials (MDV), ampoules, and bags or bottles of intravenous fluids. Podiatrists and staff should check medication vial label instructions to determine whether the vial is MDV or SDV. SDVs are preferred; however, if MDVs are used they should be dedicated to a single patient when possible. MDVs used for more than one patient should not enter the immediate treatment area.

• Single-dose (or single-use) vials (SDVs) are intended for use in a single patient for a single case/procedure/ injection. SDVs are labeled as such by the manufacturer and typically lack an antimicrobial preservative. For vials that have been opened or accessed (e.g., needle-puncture), the vial should be discarded according to the time the manufacturer specifies for the opened vial or at the end of the procedure for which it is being used, whichever comes first. It should not be stored for future use.

### **Key Recommendations for Safe Injection, Medication Storage and Handling Practices in Podiatry Settings**

- Use aseptic technique when preparing and administering medications.
- Cleanse the access diaphragms of medication vials with 70% alcohol and allow to dry before inserting a device into the vial.
- 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.
- Avoid prefilling and storing batch-prepared syringes except in accordance with pharmacy standards; medications should be prepared as close as possible to the time of administration.
- Whenever possible, use commercially manufactured or pharmacy-prepared prefilled syringes (e.g., heparin, saline).
- 6. Do not reuse a syringe to enter a medication vial or container.

- Do not administer medications from SDVs, ampoules, or bags or bottles of intravenous solution to more than one patient (e.g., do not use one bag of saline as a common source supply for multiple patients).
- Do not use fluid infusion or administration sets (e.g., intravenous tubing) for more than one patient.
- Dedicate MDVs to a single patient whenever possible. If MDVs 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., patient exam room/cubicle).
- 10. Maintain accurate and timely records of all aspects of medication storage and handling (e.g., refrigerator temperature log, inventory monitoring for expiration dates) whether the care takes place in the office or an off-site setting.
- Dispose of used sharps at the point of use in a sharps container that is closable, puncture resistant, and leakproof.

- Multi-dose vials (MDVs) contain more than one dose of medication. They are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. However, these preservatives generally do not have an effect on viruses and do not fully protect against contamination when safe injection practices are not followed. MDVs should be stored in the medication room and not in the immediate patient treatment area. If an MDV enters the immediate patient-care area (e.g., exam room, treatment area), it should be dedicated to that patient and discarded after use. If an MDV has been opened or accessed (e.g., needlepunctured), the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. If an MDV has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.18
- Bags or bottles of intravenous solution (e.g., bag of saline) should not be used for more than one patient.

#### **Topical Medications**

Care should be taken when using creams, ointments, wound dressings, and solutions to avoid contamination during patient procedures. Single-use products are recommended whenever possible, and should only be used on a single patient. However, use of multi-dose tubes, containers, or jars of products is sometimes unavoidable. If multi-dose medications are used on more than one patient, care should be taken to handle, dispense, and store medication only after performing hand hygiene and on a clean surface that is physically separated from patients or potentially contaminated objects or surfaces.

As with any medications, topical products intended for single use and/or labeled as single-use by the manufacturer must be disposed of after use. Likewise, products should be monitored for expiration dates and discarded when the beyond-use date has been met.<sup>13</sup>

The key recommendations for safe injection, medication storage and handling practices are listed in the following text boxes: Key Recommendations for Safe Injection, Medication Storage and Handling Practices in Podiatry Settings and Key Recommendations for Cleaning and Disinfection of Environmental Surfaces in Podiatry Settings.

#### E. Environmental Cleaning

#### **Rationale for Environmental Cleaning**

Podiatric settings should establish policies and procedures for routine cleaning and disinfection of environmental surfaces as part of their infection prevention program. 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., exam tables) and frequently touched surfaces in the patient-care environment (e.g., doorknobs, cabinet doors and drawers). Podiatric healthcare facility policies and procedures should also address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious materials.

#### **Cleaning Practices and Products**

Cleaning procedures should be periodically monitored or assessed to ensure that they are consistently and correctly performed, and staff should receive feedback on their adherence to cleaning and disinfecting procedures. The Environmental Protection Agency (EPA)-registered disinfectants or detergents/ disinfectants with label claims for use in healthcare should be selected. Disinfectant products should not be used as cleaners unless the label indicates the product is suitable for such use (e.g., detergent disinfectants). Podiatric HCP should follow manufacturer's recommendations for use of products selected for cleaning and disinfection (e.g., amount, dilution, contact time, safe use, disposal).

Products and supplies used in the facility should be reviewed periodically (e.g., annually), due to product developments and improvements and to ensure that the materials used are consistent with existing guidelines and meet the needs of the staff.

#### **Education and Training**

Responsibility for routine cleaning and disinfection of environmental surfaces should be assigned to the appropriately trained podiatric HCP. Personnel who clean and disinfect patient-care areas (e.g., environmental service personnel, technicians, nurses) should receive training on cleaning procedures:

- Upon hire, prior to being allowed to perform environmental cleaning
- 2. Annually
- 3. When new equipment or protocols are introduced

If environmental cleaning is performed by contract personnel, then the facility should verify that this training is provided by the contracting company. All contract personnel should be oriented to facility policies and procedures.

Personnel engaged in environmental cleaning should wear appropriate PPE (e.g., gloves, gowns, masks, eye protection) to prevent exposure to infectious agents or chemicals, depending on the infectious or chemical agent and anticipated type of exposure.

Complete guidance for the cleaning and disinfection of environmental surfaces, including cleaning blood or body substance spills, is available in the Guidelines for Environmental Infection Control in Healthcare Facilities (available at: https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html) and the Guideline for Disinfection and Sterilization in Healthcare Facilities (available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html).

#### Frequency of Cleaning and Disinfection

Patient-care areas, medication preparation areas, and bathrooms are cleaned at least daily, with the following exceptions:

- Promptly clean and decontaminate any location with spills of blood and other potentially infectious materials (refer to the Cleaning Spills of Blood and Body Substances section).
- Clean medication preparation areas at least daily and when visibly soiled; if medication preparation takes place in the patient treatment area (outside a designated medication room), clean this area after each patient encounter.
  - a. Ensure the medication preparation area is free of any items contaminated with blood or body fluids (e.g., used equipment such as syringes, needles, IV tubing, blood collection tubes, and needle holders).
  - b. Clean refrigerators for storing medications at defined intervals and, when soiled, in accordance with manufacturer's instructions.
- 3. Clean and disinfect bathrooms after use by a patient with known or suspected infectious diarrhea and before use by another person (refer to "Bathrooms" under the Cleaning and Disinfection Measures for Specific Patient-Care Areas section, below).
- Clean and disinfect environmental surfaces and noncritical patient-care devices when visibly soiled.
- 5. Clean and disinfect high-touch surfaces in rooms where surgical or other invasive procedures are performed, after each procedure.
- 6. Clean and disinfect environmental surfaces and noncritical patient-care devices in between patients if:
  - a. There was direct contact with non-intact skin or mucous membrane or potential contamination with body fluids (e.g., blood, secretions).
  - The patient-care device involves a blood glucose meter or other point-of-care testing device (e.g., prothrombin time [PT]/international normalized ratio [INR] readers) that utilizes

blood samples. To prevent bloodborne pathogen transmission, these devices must be cleaned and disinfected after each use in accordance with manufacturer's instructions.

#### General Cleaning and Disinfection Measures That Apply to Any Patient-Care Area

- 1. Wear appropriate PPE.
- 2. In general, perform cleaning before disinfection, unless a one-step detergent disinfectant is used.
- Use additional surface barriers as indicated by the procedure to minimize environmental contamination (e.g., disposable absorbent pads).
- 4. Wet-dust horizontal surfaces by moistening a cloth with a small amount of an EPA-registered disinfectant.
- 5. Avoid dusting methods that disperse dust (e.g., feather-dusting, sweeping); use damp mops instead.
- 6. Concentrate on cleaning high-touch surfaces (areas frequently touched by patients and facility staff) and those in close proximity to the patient, as outlined below for specific rooms/areas.
- Follow manufacturer's instructions for cleaning and maintaining noncritical medical device/ equipment, including blood pressure cuffs.
- 8. Clean walls and window blinds and curtains when they are visibly dusty or soiled.
- 9. Avoid contamination of cleaning carts and other supplies.
- 10. When cleaning and disinfecting rooms, adhere to the principle of clean to dirty.
- 11. Develop and use checklists to improve consistency.

#### Cleaning Spills of Blood and Body Substances

- Wear protective gloves and use appropriate PPE (e.g., use forceps to pick up any sharps and discard in sharps container).
- Small spills (e.g., a tube of blood) may only require wearing gloves; larger spills require additional PPE, such as gowns, gloves, and face protection, to protect from inadvertent splash.

#### **Scenario**

A podiatrist performs a routine, ingrown nail procedure in her office. Halfway through the procedure, due to unexpected bleeding, the doctor reaches into the supply bin and grabs some gauze, not thinking about her gloves being contaminated with the patient's blood. The doctor realizes that there is blood on a couple of the gauze pads, removes them, and throws them out. She does not throw out the entire stack of gauze as the rest of the gauze looks clean. All other surfaces or items that she touched with her gloves (e.g., table top, alcohol bottle, forceps, etc.) are cleaned with disinfectant wipes. Once the area is cleaned, the podiatrist removes her contaminated gloves and leaves them on top of the counter.

#### **Process Errors**

- Once the podiatrist opened the sterile packaging, it was no longer sterile for future use. For that reason, only the quantity or amount of sterile supplies expected to be needed for the procedure should have been opened and added to the sterile field.
- Once opened packages of gauze or other clean or sterile supplies are touched with contaminated gloves, they should be considered contaminated and be disposed of.
- The podiatrist should remove and dispose of the visibly contaminated gloves prior to performing cleaning or other activities that could result in cross-contamination.
   Counter and work surfaces are potential sources for cross-contamination.
- The podiatrist did not perform hand hygiene after glove removal.

#### Process Recommendations

- If additional clean or sterile supplies are needed from a drawer or bin after the procedure has begun, sterile forceps could be used to take the item from the drawer without contaminating it or other supplies with contaminated gloves. An assistant, if present, could retrieve the extra supplies.
- At the conclusion of the procedure, all remaining disposable supplies are considered contaminated and should be placed in the appropriate waste receptacle. Sharps and syringes (used or unused) should always go in a sharps container.
- Regular trash and regulated medical waste (e.g., biohazardous material and chemical hazardous waste) should be disposed of in their designated containers.
- Only an EPA-registered disinfectant or detergent/disinfectant with label claims for use in healthcare to clean surfaces should be used.
- Manufacturer's recommendations for use of cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, disposal) should be followed.
- 3. If the spill contains large amounts of blood or body fluids (e.g., >10 mL), clean the visible matter with disposable absorbent material and discard in appropriate containers for biohazardous waste.
- 4. Avoid spraying or squirting cleaning solutions/ disinfectants, as this will disperse spill contents.
- 5. For larger spills, first remove visible organic matter with absorbent material (e.g., paper towels), then decontaminate the area using an EPA-registered disinfectant with specific label claims for bloodborne pathogens (e.g., HIV, HBV, HCV) or

- a freshly diluted bleach-based product (preferably EPA-registered), in accordance with manufacturer's instructions, and allow the surface to dry.
- It is preferable to use a ready-to-use bleach solution, since staff should not assume responsibility for mixing bleach and water. As with all cleaning and disinfecting products, use according to label instructions.

#### Cleaning and Disinfection Measures for Specific Patient-Care Areas

#### **Exam Rooms**

- 1. Change the paper covering the exam table and pillows between patients; may use absorbable pads to cover work surfaces. If absorbable pads are used, they should be changed after each patient and during the procedure if they become soaked or saturated. Surfaces under these coverings should be cleaned and disinfected immediately if they become contaminated and minimally at the end of the day.
- Place any used linens (e.g., exam gowns, sheets) in a designated container located in each exam room after each patient use; refer to the Handling and Laundering Soiled Linens section for laundering soiled linens.
- Clean any medication preparation area after each patient encounter and ensure contaminated items (as described above) are not placed in or near the area.
- 4. Focus cleaning on high-touch surfaces at least daily (e.g., exam table, blood pressure cuff, stethoscope [per manufacturer's instructions], chair and exam table stool, and doorknobs).
- Decontaminate high-touch surfaces using an EPA-registered disinfectant with specific claim labels for specific infective agents.
  - a. If patient has suspected infectious diarrhea and the infective agent is unknown, clean high-touch surfaces with an EPA-registered product effective against *Clostridium difficile* spores (see EPA's LIST K at: https://www.epa.gov/ sites/production/files/2018-01/documents/ 2018.10.01.listk\_.pdf)

### Triage Stations and/or Locations for Performing Vital Signs (if not done in exam rooms)

 Focus cleaning on high-touch surfaces and objects, such as the patient chair, blood pressure cuff, pulse oximetry sensors (following manufacturer's instructions), and thermometers, at least daily. (If disposable oral temperature probes are used, they should be discarded after each use.)

#### **Bathrooms**

- 1. Wear appropriate PPE.
- 2. Clean the toilet, the area around the toilet, the sink, and faucet handles at least daily, and the walls if visibly soiled.
- 3. If used by a patient with known or suspected infectious diarrhea, clean the bathroom before it is used again, focusing on the toilet and the area around the toilet:
  - Use an EPA-registered disinfectant with specific claim labels for the infective agent.
  - b. If the infective agent is unknown, use an EPA-registered product effective against *Clostridium difficile* spores (see EPA's LIST K at: https://www.epa.gov/sites/production/files/2018-01/documents/2018.10.01.listk\_.pdf).

#### Handling and Laundering Soiled Linens

- 1. Handle all contaminated linens with minimum agitation to avoid contamination of air, surfaces, and persons; hold soiled linens away from the body so as not to contaminate skin or clothing.
- Do not sort or rinse soiled linens in patient-care areas.
- Use leak-resistant containment for linens contaminated with blood or body substances; ensure that there is no leakage during transport.
- 4. In the laundry area, appropriate PPE (e.g., gloves) should be worn by laundry personnel while sorting soiled linen, and hand hygiene supplies should be available for their use.

- If laundry equipment is available on premises, use and maintain the equipment according to manufacturer's instructions.
  - a. In general, if hot water laundry cycles are used, wash with detergent in water ≥160°F (≥71°C) for ≥25 minutes.
  - b. If low-temperature (<160°F [<70°C]) laundry cycles are used, wash with proper concentrations of laundry chemicals that are suitable for low-temperature washing.
- If commercial laundry facilities are used, ensure that their laundering process is in accordance with current recommendations.

Note: More detailed information on the handling of clean and soiled linen is explained in the CDC's Guidelines for Environmental Infection Control in Health-Care Facilities (available at: https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html).

#### **Waste Disposal**

- Handle, transport, and dispose of regulated waste, including hazardous drugs, in accordance with state and local regulations.
- 2. Provide puncture-resistant, leakproof sharps containers in every patient-care area (e.g., exam room, chemotherapy suite, phlebotomy station).
  - For phlebotomy stations, place a sharps container within a short distance of each phlebotomist's work space.
  - b. Dispose of all sharps in the designated sharps container; do not bend, recap, or break used syringe needles before discarding them into the container.
  - c. Dispose of filled sharps containers in accordance with state-regulated medical waste rules.
- 3. Dispose of regular trash and regulated medical waste (e.g., biohazardous material, chemical hazardous waste) in their designated containers.
- 4. All trash and waste containers should be emptied at least daily by designated, trained personnel using appropriate PPE.

### Key Recommendations for Cleaning and Disinfection of Environmental Surfaces in Podiatry Settings

- Establish policies and procedures for routine cleaning and disinfection of environmental surfaces in the facility. Policies and procedures should also address prompt and appropriate cleaning and decontamination of spills of blood or other potentially infectious materials.
- Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare.
- Follow manufacturer's recommendations for use of cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, disposal).
- 4. Personnel who clean and disinfect patientcare areas (e.g., environmental services [ES], technicians, nurses) should receive training on cleaning procedures:
  - Upon hire, prior to being allowed to perform environmental cleaning
  - b. Annually

- c. When new equipment or protocols are introduced
- Personnel should be required to demonstrate competency with environmental cleaning procedures following each training session.
- If ES are only available after hours (e.g., contactors from outside agency), then designated facility staff should be assigned specific responsibilities for cleaning and disinfection during clinic hours.
- Personnel engaged in environmental cleaning should wear appropriate PPE to prevent exposure to infectious agents or chemicals (e.g., gloves, gowns, masks, eye protection), depending on the infectious or chemical agent and anticipated type of exposure.
- Cleaning procedures should be periodically monitored and assessed to ensure that they are consistently and correctly performed.

#### **Construction and Renovation**

One note relative to IPC that bears mentioning is management of the environment during construction, renovation, remodeling, repairs, and building demolition. To minimize the risk of infection to patients in podiatric facilities undergoing such activities, reaching out to infection preventionists for guidance in practices to minimize patient risk can be helpful when planning construction or renovation in podiatric healthcare facilities. While it is beyond the scope of this guide to provide detailed guidance on measures to minimize these risks, the reader is encouraged to identify and adhere to applicable local

and state regulations, seek the advice of an infection preventionist, and refer to the resources at the end of this document.

#### F. Medical Device Reprocessing Overview

### Rationale for Medical Device Reprocessing

To prevent transmission of infectious agents, all reusable medical devices must be cleaned and disinfected or sterilized and maintained according to the manufacturer's instructions. Cleaning to remove organic material must always precede disinfection or sterilization

because residual debris reduces the effectiveness of the disinfection and sterilization processes. Strict adherence to all aspects of proper reprocessing should be the goal of any podiatric practice. 14,20

#### Reusable Versus Single-Use Devices

Medical devices are labeled by the manufacturer as either reusable or single use. Reusable medical devices (e.g., cuticle and nail nippers, forceps) should be accompanied by instructions for cleaning and disinfection or sterilization as appropriate.

Single-use devices (SUDs) are labeled by the manufacturer for single use only and do not have reprocessing instructions. They may not be reprocessed except by entities that comply with FDA regulatory requirements and have received FDA clearance to reprocess specific SUDs as outlined in FDA Guidance

As part of the 2008 investigation of the first hepatitis B outbreak implicating podiatric care in the United States, several potential modes of transmission were identified, including:

"Used podiatry equipment (e.g., clippers used on nails, tissue and cuticles) were visibly contaminated with blood and placed next to clean equipment for subsequent patient use.... Blood glucose monitoring equipment and environmental surfaces contaminated with blood were disinfected improperly.... Glucometers were not cleaned

Wise ME, et al. Outbreak of acute hepatitis B virus infections associated with podiatric care at a psychiatric long-term care facility. *Am J Infect Control*. 2012 Feb 1(40):18.

consistently between residents."

for Industry and FDA staff (available at: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf). Legally marketed SUDs are available from FDA-registered third-party reprocessors.

Most off-site settings do not provide medical devices used for procedures. Both the staff at the off-site setting and the podiatrist are responsible for ensuring the devices are properly reprocessed and packaged accordingly. Podiatrists, when off-site, should have enough equipment on hand to provide safe care for all patients.

#### **Point-of-Care Devices**

Reusable point-of-care devices, such as blood glucose meters and INR meters, must be cleaned and reprocessed appropriately prior to use on another patient. Podiatric staff should consult and adhere to manufacturer's instructions for reprocessing. The instructions for reprocessing reusable medical equipment should be readily available and posted in the area where the equipment is cleaned and reprocessed. The instructions should also be used to establish clear operating procedures and training content for the podiatric facility. If the manufacturer does not provide instructions for cleaning and disinfection, then the testing meter should not be used for more than one patient.

Fingerstick devices, also called lancets, are used to prick the skin and obtain drops of blood for testing. Singleuse, auto-disabling fingerstick devices should be used for all patients who require blood glucose monitoring. The Spaulding Classification is a traditional approach to determining the level of disinfection or sterilization required for reusable medical devices, based on 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, have greatest risk of transmitting infection, and must be sterile prior to use.

- Semicritical items (e.g., cuticle and nail nippers, forceps) 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, oximeter probes, stethoscopes) 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) 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.

Reusable podiatric medical instruments that are heat stable and have the potential to break intact skin during ordinary use (e.g., nippers, forceps, splitters, curettes) should be ideally sterilized using steam rather than chemical disinfectant for the terminal reprocessing step. Instruments should be sterilized using an FDA-cleared sterilizer. While this approach can be more expensive, it ensures the highest level of patient safety, enhances occupational safety for clinical staff, and simplifies the decision-making process.<sup>2</sup>

#### **Reprocessing Policies**

Podiatric healthcare facilities should establish policies and procedures for containing, transporting, and handling devices that may be contaminated with blood or body fluids. Evidence-based guidelines should be used when developing policies and procedures for sterilization and should be followed by all staff who conduct the reprocessing. Periodic audits (monitoring and feedback) of personnel practices should be done. The facility should also establish policies and procedures outlining the proper response in the event of a reprocessing error or failure (e.g., risk assessment and recall of device). Periodically review policies and procedures for reprocessing.

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.

### Education, Training, and Practice Monitoring

Podiatric HCP with responsibility for cleaning and disinfection or sterilization of medical devices should have training in the reprocessing steps and the appropriate use of PPE necessary for handling contaminated devices:

- Upon hire, prior to being allowed to perform point-of-care testing
- 2. Annually
- 3. When new equipment or protocols are introduced

Competencies of podiatric 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. It is also important to routinely audit (monitor and document) HCP adherence to proper reprocessing procedures and provide feedback to staff regarding their level of adherence to those procedures. Additionally, HCP should demonstrate competency with recommended practices for point-of-care testing following each training.

The facility should also routinely conduct audits of staff adherence to recommended practices during point-of-care testing and reprocessing and provide feedback to staff on their adherence to those practices.

#### Reprocessing Area and Resources

Adequate space should be allotted for reprocessing activities. A workflow pattern should be followed such that devices clearly flow from high-contamination areas to clean/sterile areas, so there is clear separation between soiled and clean work spaces.

Adequate time for reprocessing should be allowed to ensure adherence to all steps recommended by the device manufacturer, including proper drying and storage.

Facilities must have an adequate supply of instruments for the volume of procedures performed and should schedule procedures to allow sufficient time for all reprocessing steps. All medical devices should be stored in a manner to protect them from contamination and damage.

### Care and Maintenance of Devices and Equipment

Routine maintenance of reprocessing equipment (e.g., steam autoclave) should be performed by qualified personnel in accordance with manufacturer's instructions, and maintenance records should be maintained at the facility. This requirement applies to both facility- and podiatrist-owned and operated equipment.

Staff should know and follow protocols to ensure that devices have been properly reprocessed and are ready for patient use; this can be done by using a tagging system or storage in a designated area. Sterilization records (mechanical, chemical, and biological) should be retained for a time period in compliance with standards and state and federal regulations.

The individual in charge of infection prevention at the facility should be consulted whenever new devices or products will be purchased or introduced, to ensure implementation of appropriate reprocessing policies and procedures.

### Reprocessing of Medical Devices with Off-Site Podiatry Care

Most off-site settings do not provide medical devices used for procedures. Both the off-site setting and the podiatrist are responsible for ensuring the devices are properly reprocessed and packaged accordingly. The podiatrist should have enough equipment on hand to provide safe care for all patients. An adequate supply

### Consequences of Failed Reprocessing

The consequences of failed reprocessing could result in serious outcomes for podiatry practices, including:

- Placing patients at risk for contamination or infection
- · Potential outbreaks
- · Legal action
- · Facility closures
- Referral of providers to licensing boards for disciplinary action
- Bad publicity, damage to reputation, or loss of business

of clean and disinfected or sterilized patient-care instruments should be brought to (or be available at) the off-site facility so that items do not have to be reprocessed at the off-site location to maintain clinical workflow. Sterilization records (mechanical, chemical, and biological) should be retained for a time period in compliance with standards and state and federal regulations.

It is important to identify where reprocessing will occur for off-site podiatry services. If reprocessing occurs in the podiatrist's office, all dirty or used equipment should be brought back to the podiatrist's office in a dedicated closeable container and kept separate from clean equipment and supplies to prevent cross-contamination. The container should be puncture proof and leakproof and have a biohazard label as appropriate. It is essential to comply with state and local regulations regarding the transporting of biohazardous material. If reprocessing of instruments must occur in an off-site facility, it should be performed in an area designated for this purpose and should never occur in patient-care areas.

#### **Scenario**

A podiatrist is having a busy day at a nursing home where he performs routine foot care for each patient in his or her room. Based on a rationale that he is performing nail care, and it does not involve heavy breakdown or bleeding, he decides to sterilize all the equipment between patients with disposable alcohol wipes. Once wiped down, he puts the instruments back in the container with the other unused, clean, and sterile instruments that he brought with him for the day and moves on to the next patient. He changes his gloves between each patient, but does not perform hand hygiene before donning the next pair of gloves.

#### **Process Errors**

- Alcohol wipes do not sterilize.
- Contaminated and clean or sterile instruments were not kept separate. The podiatrist must have a mechanism for keeping the instruments separated (for example, separate storage containers for clean and contaminated items for transport).
- Hand hygiene was not performed after the used gloves were doffed.

#### **Process Recommendations**

 Podiatrists should work closely with facility managers and other relevant staff to create or identify treatment areas that have the necessary attributes to facilitate safe

- provision of podiatric medical care. Such attributes include adequate counter space, sinks/hand hygiene facilities, medical waste disposal bins and sharps containers, and areas clearly demarcated for clean versus contaminated equipment and supplies.
- The facility policies and procedures for device reprocessing should be reviewed and any gaps should be mitigated. HCP involved in device use and reprocessing should be educated or reeducated in these policies and procedures.
- All used instruments and equipment must be pre-cleaned to remove any organic material (e.g., blood or tissue) prior to disinfection or sterilization. Instrument pre-cleaning should occur as soon as possible after use to prevent drying of organic material and make manual cleaning easier and less time-consuming. Residual organic material reduces the effectiveness of the disinfection and sterilization processes.
- One solution to this scenario is to use singleuse, disposable instruments or items.
   Provisions should be made for proper disposal of such instruments or items.
- Hand hygiene, either with alcohol-based hand rub or soap and running water, should always be performed after removing contaminated gloves and before donning clean or sterile gloves.

#### G. Sterilization of Reusable Devices

Medical devices that have contact with sterile body tissues or fluids are considered critical items. These items should be sterile when used, as any microbial contamination could result in transmission of infection. Such items include surgical instruments, scalpel blade handles, and biopsy forceps. If these items are heat resistant, the recommended sterilization process is steam sterilization, because this method has the largest margin of safety due to its reliability, lethality, and consistency.

Physician-owned devices must be subjected to the same stringent protocols for sterilization as those owned by a separate organization. It should be noted that glass bead sterilizers are not approved by the FDA and are no longer acceptable for instrument sterilization; this equipment should be replaced, preferably with a steam sterilizer. More information about bead sterilizers is available in the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html) and in CDC's Frequently Asked Questions—Bead Sterilizer (available at: https://www.cdc.gov/oralhealth/infectioncontrol/faq/bead.htm).

#### **Elements of Sterilization Practices**

Some important elements of sterilization practices include:

- Prior to transport to a third-party reprocessor, if applicable, the facility should have a process to perform initial cleaning (pre-cleaning) of devices to prevent soiled materials from becoming dried onto devices.
- Medical devices should be thoroughly cleaned according to manufacturer's instructions and visually inspected for residual soil prior to sterilization.
   Cleaning may be manual (i.e., using friction) and/ or mechanical (e.g., with ultrasonic cleaners, washer disinfectors, washer sterilizers). Ensure appropriately sized cleaning brushes are selected for cleaning

- device channels and lumens. Enzymatic cleaner or detergent should be used for cleaning and should be discarded according to the manufacturer's instructions, typically after each use. Cleaning brushes should be disposable or, if reusable, cleaned and high-level disinfected or sterilized after use per the manufacturer's instructions.
- Once items are cleaned, dried, and inspected, those requiring sterilization must be wrapped or placed in rigid containers and should be arranged in instrument trays/baskets according to the guidelines provided by the Association for the Advancement of Medical Instrumentation (AAMI) and other professional organizations. Refer to the AAMI Comprehensive guide to team sterilization and sterility assurance in health care facilities (a preview copy is available at: https://my.aami.org/aamiresources/previewfiles/ST79\_Wa4\_1310\_preview.pdf).
- Reprocessing heat- and moisture-sensitive items requires use of a low-temperature sterilization technology (e.g., ethylene oxide, hydrogen peroxide gas plasma, peracetic acid).
- The machinery used to sterilize equipment, supplies, and devices must function properly to ensure each item is safe to use for patient care. Sterilizer maintenance and testing is essential as part of the IPC program. Proper testing includes several components.
  - A chemical indicator (process indicator) is correctly placed in the instrument packs in each load.
  - A biological indicator (BI), 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.
  - 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.

- 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.
- Sterile instruments and supplies should ideally be stored in covered or closed cabinets, but open shelving may be used. Instruments and supplies should not be stored under sinks or in other places

Monitoring Sterilizer Performance							
Test	Function	Frequency of Use	Indicates Sterility?				
Chemical Indicator	Process indicator, such as the strips placed in the sterilizer container and the tape used on the outside of packs, that uses sensitive chemicals to assess physical conditions such as temperature and pressure and that changes color during the sterilization process. Use each indicator per the manufacturer's instructions.	Every load	No				
Mechanical Indicator	Measures time, temperature, and pressure via gauges or displays on the sterilizer. Correct readings do not ensure that sterilization has occurred, but incorrect readings could be the first indication that a sterilization cycle has encountered a problem.	Every load	No				
Biological Indicator (BI)	Each BI has a standardized population of live bacterial spores that are resistant to the mode of sterilization being monitored. A control BI (not processed through the sterilizer) from the same lot as the test indicator should be incubated with the test BI. The control BI should yield positive results for bacterial growth. An inactivated BI indicator denotes that potential pathogens in the load have been killed. BIs are the most accepted means of monitoring the sterilization process, as they directly determine whether the most resistant organisms have been killed by the sterilization process rather than merely determining whether the chemical and physical conditions necessary for sterilization have been met.	At least weekly, preferably every day the sterilizer is used, and for every load containing an implantable item	Yes				

Adapted from: Centers for Disease Control and Prevention. Guideline for Disinfection and Sterilization in Healthcare Facilities (2008). (Updated: Dec 28, 2016.) Accessed Jul 12, 2017. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

where they might become wet. Wrapped packages of sterilized instruments should be inspected before opening and use to ensure that the packaging has not been compromised (e.g., wet, torn, punctured) during storage.

Refer to the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 for detailed information about sterilization and disinfection (available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html). An additional reference that should be accessible for facilities performing sterilization is the American National Standards Institute (ANSI) and the AAMI's Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2017), published August 1, 2017.

If the mechanical (e.g., time, temperature, pressure) and chemical (internal or external) indicators suggest that the sterilizer is functioning properly, a single positive spore test result probably does not indicate sterilizer malfunction. Items other than implantable items do not necessarily need to be recalled; however, sterilizer operators should repeat the spore test immediately using the same cycle that produced the positive BI. The sterilizer should be removed from service and sterilization operating procedures reviewed to determine whether operator error could be responsible.

If the result of the repeat spore test is negative and operating procedures were correct, the sterilizer can be returned to service. If the repeat spore test result is positive, the sterilizer should not be used until it has been inspected or repaired and rechallenged with BI tests in three consecutive empty-chamber sterilization cycles. When possible, items from suspect loads dating back to the last negative BI should be recalled, rewrapped, and resterilized. The margin of safety in steam sterilization is substantial; however, if any items from suspect loads were used before retrieval, the infection control professional should help assess the risk of infection in collaboration with the processing

staff and podiatrist. This assessment should consider additional information such as chemical indicators, subsequent BI results, any relevant manufacturer's instructions or regulatory requirements, and the types of procedures that were performed.

Common factors that influence the effectiveness of sterilization are noted in the CDC's Frequently Asked Questions—Sterilization: Monitoring (available at https://www.cdc.gov/oralhealth/infectioncontrol/questions/sterilization/monitoring.html). See examples on page 36.

# Aspects of Quality Control Relative to Sterilization

- Include the following in a quality control program
  for sterilized items: a sterilizer maintenance
  contract with records of service, a system of process
  monitoring, air-removal testing for prevacuum
  steam sterilizers, visual inspection of packaging
  materials, and traceability of load contents.
- For each sterilization cycle, record the type of sterilizer and cycle used; the load identification number; the load contents; the exposure parameters (e.g., time and temperature); the operator's name or initials; and the results of mechanical, chemical, and biological monitoring.
- Establish a policy for how deviations from expected results of process and biologic indicators will be reported and handled.
- Retain sterilization records (mechanical, chemical, and biological) for a time period that complies with standards (e.g., 3 years), statutes of limitations, and state and federal regulations.
- Prepare and package items to be sterilized so that sterility can be achieved and maintained to the point of use. Consult the AAMI or the manufacturers of surgical instruments, sterilizers, and container systems for guidelines.
- Immediate-use steam sterilization, if performed, should only be done in circumstances in which routine sterilization procedures cannot be

- performed. Instruments that undergo immediateuse steam sterilization should be used immediately and not stored.
- After sterilization, medical devices should be stored so that sterility is not compromised.
- Sterile packages should be inspected for integrity; compromised packages should be reprocessed prior to use.
- Training and competency testing of all podiatric HCP who reprocess devices or equipment via sterilization should be performed. Evidence-based guidelines should be used when developing policies and procedures for sterilization and should be followed by all staff who conduct the

- reprocessing. Periodic audits (monitoring and feedback) of personnel practices should be done.
- Periodically review policies and procedures for sterilization.
- Perform preventive maintenance on sterilizers by qualified personnel who are guided by the manufacturer's instruction.

Refer to the CDC's Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 for additional information about quality control and sterilization (available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html).

# **Examples of Common Causes and Potential Problems that Influence the Effectiveness of Sterilization**

Causes	Potential Problems
Improper cleaning of instruments	Protein and debris may insulate organisms from direct contact with the sterilizing agent, thereby interfering with the efficacy of the sterilizing agent.
Wrong packaging material for the method of sterilization	Packaging material may melt; prevents penetration of the sterilizing agent.
Excessive packaging material	Retards penetration of the sterilizing agent.
Overloading of the sterilizer	Retards penetration of the sterilizing agent to the center of the sterilizer load and increases heat-up time.
No separation between packages or cassettes, even without overloading	May prevent or retard thorough contact of the sterilizing agent with all items in the chamber.
Incorrect sterilizer operation	Insufficient time at proper temperature to kill organisms.

Adapted from: Instrument processing. In Miller CH: *Infection Control and Management of Hazardous Materials for the Dental Team*, 6th ed. St. Louis: Mosby, 2018, 113–141.

# H. High-Level Disinfection (HLD) of Reusable Devices

#### Rationale for HLD

Semicritical items contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse. Unlike sterilization, which renders devices free of all organisms, the process of HLD renders devices free of all microbial organisms except spores. Instruments that are not heat stable should be either disposed of after use (if they are designated as single use) or cleaned and chemically disinfected according to the manufacturer's instructions. If manufacturer reprocessing instructions do not exist, the instrument should not be reused.

#### Processing of Items Prior to HLD

Devices must be thoroughly cleaned according to manufacturer's instructions and visually inspected for residual soil prior to high-level disinfection. Cleaning may be manual (i.e., using friction) and/or mechanical (e.g., with ultrasonic cleaners, washer-disinfector, washer-sterilizers). Pre-cleaning should be performed as soon as practical after use (e.g., at the point of use) to prevent soiled materials from becoming dried onto instruments. Enzymatic cleaner or detergent should be used and discarded according to manufacturer's instructions (typically after each use).

#### Follow Manufacturer's Instructions

For chemicals used in HLD, manufacturer's instructions should be followed for the product preparation, testing for appropriate concentration, and replacement (i.e., upon expiration or loss of efficacy). Devices should be disinfected as specified by the manufacturer's instructions (1) for the appropriate length of time as specified by manufacturer's instructions, (2) at the appropriate temperature as specified by manufacturer's instructions, and (3) appropriately rinsed after HLD as specified by manufacturer's instructions.

After undergoing chemical disinfection, these instruments should be handled with sterile forceps or gloves, thoroughly rinsed with sterile water (not tap water), and dried with a sterile towel. Processed devices should be stored in a manner to protect them from damage or contamination (e.g., a sealable container or closed drawer that is lined with clean or sterile towels).<sup>2</sup>

Routine maintenance for HLD equipment should be performed according to manufacturer's instructions, and maintenance logs should be maintained. Strict adherence to all aspects of proper reprocessing should be the goal of any podiatric practice.

# **Key Recommendations for Cleaning and Disinfection or Sterilization of Medical Devices in Podiatry Settings**

- Podiatric facilities should ensure that reusable medical devices (e.g., blood glucose meters and other point-of-care devices, surgical instruments) are cleaned and reprocessed appropriately prior to use on another patient.
- Evidence-based guidelines should be used when developing policies and procedures for reprocessing.
- 3. Podiatric HCP with assigned responsibility for cleaning and disinfection or sterilization of medical devices should have training in the reprocessing steps and the appropriate use of PPE necessary for handling contaminated devices. Training should be provided upon hire (prior to HCP being allowed to reprocess devices), annually, and when new devices are introduced or policies/procedures change.
- Podiatric HCP should be required to demonstrate competency with reprocessing procedures (i.e., correct technique is observed by trainer) following each training.
- Podiatric HCP should have access to and wear appropriate PPE when handling and reprocessing contaminated medical devices.
- Copies of the manufacturer's instructions for reprocessing of devices in use at the facility should be maintained; instructions should be posted at locations where reprocessing is performed.
- Pre-cleaning should be performed as soon as practical after use (e.g., at the point of use) to prevent soiled materials from becoming dried onto instruments.

- Reusable medical devices must be cleaned, visually inspected for residual soil prior to reprocessing (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 multipatient use.
- 9. When performing HLD:
  - Enzymatic cleaner or detergent should be used and discarded according to manufacturer's instructions (typically after each use).
  - For chemicals used in HLD, manufacturer's instructions should be followed for the product preparation, testing for appropriate concentration, and replacement (e.g., upon expiration of loss of efficacy).
  - o Devices must be disinfected for the appropriate length of time as specified by manufacturer's instructions, at the appropriate temperature as specified by manufacturer's instructions, and appropriately rinsed after HLD, also as specified by the manufacturer.
- Routinely monitor podiatric HCP adherence to proper reprocessing procedures, and provide feedback to staff regarding their level of adherence to reprocessing procedures.
- Strict adherence to all aspects of proper reprocessing should be a goal of any podiatric practice.<sup>12,14</sup>

## IV. TRANSMISSION-BASED PRECAUTIONS

In addition to consistent use of Standard Precautions, additional precautions may be warranted in certain situations. Podiatrists along with all other HCP should observe instructions for Transmission-Based Precautions as posted on door signs, in the patient's medical record, or as otherwise directed when entering isolation rooms to provide care. Commonly encountered examples could be contact precautions for drug-resistant bacteria and *Clostridium difficile* infection in acute and long term care settings.

Most outpatient settings are not designed to implement all of the isolation practices and other Transmission-Based Precautions that are recommended for hospital settings (e.g., Airborne Precautions for patients with suspected TB, measles, or chicken pox). Also see the Appendix C: Additional Information About Respiratory Hygiene/Cough Etiquette section of this guide for additional information. Nonetheless, specific syndromes involving diagnostic uncertainty (e.g., diarrhea, febrile respiratory illness, febrile rash, draining wounds) are routinely encountered in outpatient settings and deserve appropriate triage. Therefore, podiatry facility staff should remain alert for any patient arriving with symptoms of an active infection. One way to identify patients with active infections is to have them complete a brief "systems overview" on arrival to the office, in which patients can check off symptoms they might be experiencing (e.g., diarrhea, productive cough, fever). Any symptoms that are concerning could then be brought to the attention of the nurse, who could evaluate the need for any special measures (e.g., evaluate patient further, move patient to a single room, reschedule patient's appointment).

The categories of Transmission-Based Precautions include Contact Precautions, Droplet Precautions, and Airborne Precautions.

# **Key Recommendations for Transmission-Based Precautions**

- Podiatric facilities should develop and implement systems to permit the early detection of potentially infectious patients (e.g., patients with rashes, diarrhea) at the initial points of entry to the facility.
- To the extent possible, appropriate action should include prompt placement of such patients in a single room.
- Contact, Droplet, or Airborne Precautions, in addition to Standard Precautions, should be implemented depending on the known or suspected pathogen and the mode of transmission.
- Precautions should be adjusted or discontinued when more clinical information becomes available (e.g., confirmatory laboratory results).
- If patients require transfer to another facility, accepting facilities and the transporting agency should be notified about suspected infections and the need for Transmission-Based Precautions.
- Podiatrists and podiatric HCP should learn, be trained in, and adhere to Transmission-Based Precautions as directed when providing podiatric care in other facility types, such as long term care.

CDC guidelines for isolation precautions are available at: https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines.pdf.

### V. CONCLUSION

#### Conclusion

Infection prevention is an ongoing process relevant to patients, visitors, and HCP. Podiatric facilities are encouraged to use this document as a model to develop, improve, and implement their IPC plan. Podiatry facilities are also encouraged to use the Infection Prevention Checklist for Outpatient Podiatry Settings (Appendix A) to periodically assess their practices to ensure they are meeting the minimum expectations for safe care. When lapses are identified, efforts should be made to correct the practices, determine why the correct practice was not being performed, and appropriately educate podiatric HCP.

The recommendations described in this guide represent the minimum infection prevention expectations for safe care in podiatric outpatient (ambulatory care) settings. This guide is not all encompassing. Podiatric facilities should refer to the original source documents, which provide more detailed guidance and references for the information included in this guide.

Through effective implementation and monitoring for adherence to recommended IPC practices, podiatric facilities can reduce the risk of transmitting infections, thereby improving patient safety and protecting their healthcare workers.

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### **APPENDIX A**

# Centers for Disease Control and Prevention (CDC) Infection Prevention Checklist for Outpatient Podiatry Settings

#### Minimum Expectations for Safe Care

The following checklist is a companion to the *Guide to Infection Prevention for Outpatient Podiatry Settings*. The checklist is divided into four sections: the first three sections (Sections A, B, and C) can be used to assess the infection control program and infrastructure; the fourth section (Section D) can be used to conduct observations of facility practices. As such, the checklist should be used:

- To ensure that the podiatric 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 (Assessment of adherence should be conducted by direct observation of HCP during the performance of their duties. See observation tools in the back of this guide.)

Podiatric 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 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., reuse of syringes on more than one patient or to access a medication container that is used for subsequent patients; reuse 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.

#### **Infection Control Domains within Checklist**

#### Section A: Fundamental Elements

- Resources Needed for Infection Prevention (Administrative Resources)
- Facility Risk Assessment
- · Infection Surveillance, Reporting, and Record-Keeping
- Education, Training, and Competency
- Healthcare Personnel (HCP) Safety

#### Section B: Adherence to Standard Precautions

- Hand Hygiene
- Personal Protective Equipment (PPE)
- Respiratory Hygiene/Cough Etiquette
- Safe Injection, Medication Storage and Handling Practices
- Point-of-Care Testing
- · Environmental Cleaning
- Reprocessing of Reusable Medical Devices
- Sterilization of Reusable Instruments and Devices
- High-Level Disinfection of Reusable Instruments and Devices

#### Section C: Transmission-Based Precautions

#### Section D: Personnel and Patient-Care Observations

- Hand Hygiene Observations
- Personal Protective Equipment (PPE) Correct Use Observations
- Respiratory Hygiene/Cough Etiquette Observations
- Safe Injection Use Observations
- Environmental Cleaning Observations
- Reprocessing of Reusable Instruments and Devices Observations
- Point-of-Care Testing Observations
- Sterilization of Reusable Instruments and Devices Observations
- High-Level Disinfection of Reusable Instruments and Devices Observations

### **Section A: Fundamental Elements**

Resources Needed for Infection Prevention (Administrative Resources)			
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement	
A. Written infection prevention policies and procedures are available, current, and derived from evidence-based guidelines (e.g., CDC 's Healthcare Infection Control Practices Advisory Committee [HICPAC]), regulations, or standards.	Yes No		
Note: Policies and procedures should be appropriate for services provided by the podiatric facility and should extend beyond Occupational Safety and Health Administration (OSHA) bloodborne pathogen training.			
B. Infection prevention policies and procedures are reassessed 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 (e.g., by contract) to the facility to manage the facility's infection prevention program.	Yes No		
D. Supplies necessary and sufficient for adherence to Standard Precautions are readily available.  Note: This includes hand hygiene products, personal protective equipment (PPE), and injection equipment including devices to reduce percutaneous injuries.	Yes No		
E. A system or process is in place 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 implementing elements described under respiratory hygiene/cough etiquette (in Section B).	Yes No		

F. If the podiatrist(s) provides care outside the office setting, an arrangement and system or process is in place to assure the same high level of infection prevention and control (IPC) is maintained, including:	Yes	No	
1. An appropriate area to deliver care	Yes	No	
<ol><li>Supplies/equipment the podiatrist will bring to the off-site location and supplies/equipment the off-site location is willing to provide</li></ol>	Yes	No	
<ol><li>A process to bring in clean, disinfected, or sterile supplies/equipment to the facility and to remove them after care is provided</li></ol>	Yes	No	
<ol> <li>A process for separating clean and dirty supplies/ equipment</li> </ol>	Yes	No	
5. A provision for discarding sharps	Yes	No	

Facility Risk Assessment			
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement	
A. An annual risk assessment is performed to help prioritize resources and focus extra attention on those areas that pose greater risk to the patients, visitors, and staff.	Yes No		
B. As part of the risk assessment, an inventory of the facility's services and procedures is conducted.	Yes No		
C. As part of the risk assessment, this checklist (Appendix A) is used to assess the practices in the facility.	Yes No		

Infection Surveillance, Reporting, and Record-Keeping			
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement	
A. Patients who undergo procedures at the podiatric healthcare facility are educated regarding signs and symptoms of infection that may be associated with the procedure and are instructed to notify the facility if such signs and symptoms occur.	Yes No		
B. The podiatric facility can demonstrate compliance with local, state, and federal mandatory reporting requirements for reportable diseases, healthcareassociated infections (HAIs), and potential outbreaks.	Yes No		

C. A written protocol for reporting communicable diseases to the public health authority is in place.	Yes No
D. An updated list of diseases reportable to the public health authority is readily available to all podiatric HCP.	Yes No
E. Regular audits of podiatric HCP are performed to assess adherence to infection prevention practices, and feedback is provided to staff regarding their performance.	Yes No
F. Efforts are made to correct lapses in practice identified by the risk assessment and to determine why the correct practice was not being performed.	Yes No
G. If a serious lapse in practice is identified (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) the practice is halted immediately, and immediate consultation with state or local health department and appropriate notification and testing of potentially affected patients occurs.	Yes No
H. Podiatric HCP are educated on correct practice when lapses in practice are identified.	Yes No
The podiatric facility maintains accurate and timely records for care provided to its patients, whether their care takes place in the office or at an off-site setting.	Yes No

Education, Training, and Competency			
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement	
A. Podiatric HCP receive job- or task-specific education and training on infection prevention policies and procedures:	Yes No		
<ol> <li>Upon hire, prior to provision of care</li> <li>Annually</li> <li>When policies or procedures are updated/revised, or according to state or federal requirements</li> </ol>			
Note: This applies also to those employed by outside agencies and those available by contract or on a volunteer basis to the facility. See sections below for more specific assessment of training related to hand hygiene, PPE, injection safety, environmental cleaning, point-of-care testing, and device reprocessing.			

B. Training includes principles of both HCP safety and patient safety.	Yes No	
C. Competency with job- or task-specific infection prevention policies and procedures (i.e., correct technique is observed by trainer) are documented both upon hire and through annual evaluations/ assessments.	Yes No	
D. The facility provides feedback to HCP regarding their performance.	Yes No	
E. Education and training records are maintained according to state and federal requirements.	Yes No	

Healthcare Personnel (HCP) Safety			
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement	
A. The podiatric 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).	Yes No		
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			
B. All podiatric HCP for whom contact with blood or other potentially infectious materials is anticipated are trained on the OSHA Bloodborne Pathogens Standard upon hire and at least annually.	Yes No		
C. Following an exposure event, postexposure evaluation and follow-up, including prophylaxis as appropriate, are available at no cost to employees and are supervised by a licensed healthcare professional.	Yes No		
D. The podiatric facility tracks HCP exposure events, evaluates event data, and develops/implements corrective action plans to reduce incidence of such events.	Yes No		

E. The podiatric facility follows recommendations of the Advisory Committee on Immunization Practices (ACIP) for immunization of HCP, including offering hepatitis B and influenza vaccinations.  Note: Immunization of Health-Care Personnel: Recommendations of the ACIP is available at: http://	Yes	No	
www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm			
F. All podiatric HCP receive baseline tuberculosis (TB) screening prior to placement; HCP receive repeat testing, if appropriate, based on the facility-level risk assessment.	Yes	No	
Note: For more information, facilities should refer to the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005 available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm			
G. If respirators are used, the podiatric 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	
H. The podiatric facility has well-defined policies concerning contact of HCP with patients when personnel have potentially transmissible conditions. These policies include:	Yes	No	
<ol> <li>Work-exclusion clauses that encourage reporting of illnesses and do not penalize with loss of wages, benefits, or job status</li> <li>Education of personnel on prompt reporting of illness to supervisor</li> </ol>			

### **Section B: Adherence to Standard Precautions**

Hand Hygiene		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. The podiatric 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 podiatric HCP in patient-care areas.	Yes No	
B. Podiatric HCP are educated regarding appropriate indications for handwashing with soap and water versus hand rubbing with alcohol-based hand rub.	Yes No	
Note: Soap and water should be used when hands are visibly soiled (e.g., blood, body fluids) and is also preferred after caring for a patient with known or suspected C. difficile or norovirus during an outbreak.		
C. The podiatric facility periodically monitors and records adherence to hand hygiene and provides feedback to personnel regarding their performance.	Yes No	

Personal Protective Equipment		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. Podiatric HCP receive training on proper selection and use of PPE:	Yes No	
<ol> <li>Upon hire, prior to provision of care</li> <li>Annually</li> <li>When new equipment or protocols are introduced</li> </ol>		
B. Podiatric HCP are required to demonstrate competency with selection and use of PPE following each training.	Yes No	
C. The podiatric facility routinely audits (monitors and documents) adherence to proper PPE selection and use.	Yes No	
D. The podiatric facility provides feedback from audits to personnel regarding their performance with selection and use of PPE.	Yes No	
E. The podiatric facility has sufficient and appropriate PPE available and readily accessible to podiatric HCP.	Yes No	

Respiratory Hygiene/Cough Etiquette		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. The podiatric facility has written policies and procedures regarding the containment of respiratory secretions in persons and accompanying individuals 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:	Yes No	
1. Posting visual alerts at entrances to facility (with instructions to patients with symptoms of respiratory infection to inform podiatric HCP of symptoms of a respiratory infection when they first register for care, cover their mouths/noses when coughing or sneezing, use and properly dispose of tissues, and perform hand hygiene after hands have been in contact with respiratory secretions).	Yes No	
<ol><li>Providing tissues and no-touch receptacles for disposal of tissues.</li></ol>	Yes No	
<ol><li>Providing resources for performing hand hygiene in or near waiting areas (e.g., handwashing facilities, alcohol-based hand rub).</li></ol>	Yes No	
<ol> <li>Offering face masks to coughing patients and other symptomatic persons upon entry to the facility, and during periods of increased respiratory infection activity in the community.</li> </ol>	Yes No	
<ol><li>Providing space and encouraging persons with symptoms of respiratory infections to sit as far away from others as possible.</li></ol>	Yes No	
Note: If a separate area is available, facilities may wish to place these patients there while they wait for care.		
B. To prevent the spread of respiratory pathogens, the podiatric facility educates podiatric HCP on the importance of infection prevention measures for containing respiratory secretions.	Yes No	

Safe Injection, Safe Medication Storage and Handling Practices			
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement	
A. The podiatric facility has policies and procedures regarding the tracking of podiatric HCP's access to controlled substances to prevent narcotics theft/diversion.	Yes No		
B. Medication purchasing decisions at the podiatric facility reflect selection of vial sizes that most appropriately fit the procedure needs of the podiatric facility and limit need for sharing of multiple-dose vials (MDV).	Yes No		
C. Medications are prepared in a designated clean medication area that is not adjacent to potential sources of contamination (e.g., contaminated equipment, sinks).	Yes No		
D. Single-dose vials (SDV) are discarded according to the time the manufacturer specifies for the opened vial or at the end of the procedure for which it is being used, whichever comes first.	Yes No		
Note: SDVs should not be stored for future use.			
E. MDVs to be used for more than one patient are stored in the medication room and do not enter the immediate patient treatment area.	Yes No		
Note: If an MDV enters the immediate patient-care area (e.g., exam room or treatment area), it should be dedicated to that patient and discarded after use.			
F. MDVs are dated when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.	Yes No		
G. The podiatric facility has a policy and procedure for topical medication storage that includes:	Yes No		
<ol> <li>Monitoring for expiration dates</li> <li>Disposing of single-use medications after use</li> </ol>			
H. Podiatric HCP maintain accurate and timely records of all aspects of medication storage and handling (e.g., refrigerator temperature log, inventory monitoring for expiration dates) whether the care takes place in the office or at an off-site setting.	Yes No		

### **Point-of-Care Testing**

If point-of-care testing is never performed at the facility, skip to Environmental Cleaning

Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. The podiatric facility has a policy and procedure regarding the appropriate cleaning and reprocessing of reusable point-of-care devices, such as blood glucose meters and international normalized ratio (INR) meters, prior to use on another patient.	Yes No	
B. Instructions for reprocessing reusable medical equipment are readily available and posted in the area where the equipment is cleaned and reprocessed.	Yes No	
C. Podiatric HCP who perform point-of-care testing receive training on recommended practices:  1. Upon hire, prior to being allowed to perform point-of-care testing  2. Annually  3. When new equipment or protocols are introduced	Yes No	
D. Podiatric HCP are required to demonstrate competency with recommended practices for point-of-care testing following each training.	Yes No	
E. The podiatric facility routinely audits (monitors and documents) adherence to recommended practices during point-of-care testing.	Yes No	
F. The podiatric facility provides feedback from audits to personnel regarding their adherence to recommended practices.	Yes No	

Environmental Cleaning		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. The podiatric facility has policies and procedures regarding routine cleaning and disinfection of environmental surfaces in the facility, including identification of responsible personnel.	Yes No	
B. The podiatric facility has a policy and procedure regarding cleaning and decontamination of spills of blood or other potentially infectious materials.	Yes No	

C. The podiatric facility uses Environmental Protection Agency (EPA)-registered disinfectants or detergents/ disinfectants with label claims for use in healthcare when cleaning environmental surfaces in the facility.	Yes No
D. Podiatric HCP follow manufacturer's recommendations when using cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, disposal.)	Yes No
Podiatric HCP who clean and disinfect patient-care areas (e.g., environmental services [ES], technicians, nurses) receive training on cleaning procedures:	Yes No
<ol> <li>Upon hire, prior to being allowed to perform environmental cleaning</li> <li>Annually</li> <li>When new equipment or protocols are introduced</li> </ol>	
F. If ES are only available after-hours (e.g., contactors from outside agency), then designated facility staff are assigned specific responsibilities for cleaning and disinfection during clinic hours.	Yes No
G. Podiatric HCP are periodically monitored and assessed to ensure that they are consistently and correctly performing cleaning procedures and receive feedback regarding their performance.	Yes No
H. Podiatric HCP are required to demonstrate competency with environmental procedures (i.e., correct technique is observed by trainer) at hire and through annual evaluations/assessments.	Yes No

Reprocessing of Reusable Medical Devices			
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement	
A. The podiatric facility has policies and procedures regarding the appropriate cleaning and reprocessing of reusable medical devices prior to use on another patient.	Yes No		
Note: This includes clear delineation of responsibility among podiatric HCP for cleaning and disinfection of equipment, including noncritical equipment, mobile devices, and other electronics (e.g., point-of-care devices) that might not be reprocessed in a centralized reprocessing area.			

B. Policies, procedures, and manufacturer's reprocessing instructions for reusable medical devices used in the podiatric facility are available in the reprocessing area(s).	Yes No
C. The podiatric facility has a written policy and procedure regarding the discarding of single-use devices (SUDs) after use.	Yes No
D. If the podiatric facility reprocesses SUDs, reprocessing is done only by entities that have complied with U.S. Food and Drug Administration (FDA) regulatory requirements and have received FDA clearance as a third-party reprocessor to reprocess specific SUDs, as outlined in FDA Guidance for Industry and FDA Staff.	Yes No
Note: For more information, refer to "Reprocessing of Reusable Medical Devices" available at: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf	
E. If the podiatric facility uses a third-party reprocessor for SUDs, documentation from the third-party reprocessor confirming this is the case is on file.	Yes No
F. 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
G. Podiatric HCP appropriately clean and reprocess reusable medical devices (e.g., blood glucose meters and other point-of-care devices, surgical instruments) prior to use on another patient.	Yes No
H. Responsibility for reprocessing of medical devices is assigned to podiatric HCP with appropriate training.	Yes No
Podiatric 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:	Yes No
<ol> <li>Upon hire, prior to being allowed to reprocess devices</li> <li>Annually</li> <li>When new devices are introduced or policies/ procedures change</li> </ol>	
Note: If device reprocessing is performed by contract personnel, facility should verify this is correctly provided by contracting company.	

J. The podiatric facility cleans and reprocesses (by disinfection or sterilization) reusable equipment according to manufacturer's instructions.  Note: If the manufacturer does not provide such instructions, the device may not be suitable for multipatient use.	Yes No
K. Podiatric HCP have access to and wear appropriate PPE when handling and reprocessing contaminated medical devices.	Yes No
L. Adequate space is allotted for reprocessing activities.	Yes No
<ol> <li>A workflow pattern for device reprocessing clearly flows from high contamination areas to clean/sterile areas, with clear separation between soiled and clean workspaces.</li> </ol>	Yes No
2. Adequate time for reprocessing is allowed to ensure adherence to all steps recommended by the device's manufacturer, including proper drying and storage.	Yes No
<ol> <li>An adequate supply of instruments for the volume of procedures performed is available, and procedures should be scheduled to allow sufficient time for all reprocessing steps.</li> </ol>	Yes No
M. All medical devices are stored in a manner to protect them from contamination and damage.	Yes No
N. The podiatric facility has protocols to ensure that podiatric 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
O. The podiatric facility has policies and procedures outlining facility response (e.g., risk assessment and recall of device) in the event of a reprocessing error or failure.	Yes No
P. Routine maintenance for reprocessing equipment (e.g., steam autoclave) is performed by qualified personnel in accordance with manufacturer's instructions.	Yes No
Q. The podiatric facility routinely audits (monitors and documents) HCP adherence to reprocessing procedures.	Yes No
R. The podiatric facility provides feedback from audits to HCP regarding their adherence to reprocessing procedures.	Yes No

Sterilization of Reusable Instruments and Devices		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. The podiatric facility uses evidence-based guidelines on sterilization of reusable instruments and devices when developing its policies and procedures.	Yes No	
B. Podiatric HCP who reprocess devices or equipment receive training on sterilization procedures.	Yes No	
Podiatric HCP who reprocess devices or equipment demonstrate competency with sterilization procedures (i.e., correct technique is observed by trainer):		
<ol> <li>Upon hire, prior to being allowed to sterilize devices</li> <li>Annually</li> <li>When new equipment or protocols are introduced</li> </ol>		
C. If sterilization occurs at another facility, such as a third-party reprocessing company, a process is in place to perform initial cleaning of devices prior to transport to that reprocessing facility.	Yes No	
D. All reusable critical instruments and devices are sterilized prior to use.	Yes No	
Machinery used to sterilize equipment, supplies, and devices functions properly.	Yes No	
F. Routine maintenance for sterilization equipment is performed according to manufacturer's instructions (confirm maintenance records are available).	Yes No	
G. Sterilization records are retained for a time period that complies with standards, statutes of limitations, and state and federal regulations.	Yes No	

High-Level Disinfection of Reusable Instruments and Devices			
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement	
A. The podiatric facility uses evidence-based guidelines when developing policies and procedures for high-level disinfection.	Yes No		
B. Podiatric HCP who reprocess devices or equipment receive training on high-level disinfection procedures.	Yes No		

C. Podiatric HCP who reprocess devices or equipment are required to demonstrate competency with high-level disinfection procedures (i.e., correct technique is observed by trainer):	Yes	No	
<ol> <li>Upon hire, prior to being allowed to perform HLD</li> <li>Annually</li> <li>When new equipment or protocols are introduced</li> </ol>			
D. All reusable semicritical items receive at least high- level disinfection prior to reuse.	Yes	No	
E. Devices are thoroughly cleaned according to manufacturer's instructions and visually inspected for residual soil prior to high-level disinfection.	Yes	No	
F. Pre-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	
G. Enzymatic cleaner or detergent is used and discarded according to manufacturer's instructions (typically after each use).	Yes	No	
<ol> <li>For chemicals used in high-level disinfection, manufacturer's instructions are followed for:         <ul> <li>The product preparation</li> <li>Testing for appropriate concentration</li> <li>Replacement (e.g., upon expiration or loss of efficacy)</li> </ul> </li> </ol>	Yes	No	
<ul> <li>2. Devices must be disinfected:</li> <li>a. For the appropriate length of time as specified by manufacturer's instructions</li> <li>b. At the appropriate temperature as specified by manufacturer's instructions</li> <li>c. Appropriately rinsed after high-level disinfection, also as specified by the manufacturer</li> </ul>	Yes	No	
H. Routine maintenance for high-level disinfection equipment is performed according to manufacturer's instructions (confirm maintenance records are available).	Yes	No	

### **Section C: Transmission-Based Precautions**

Transmission-Based Precautions		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
<ul> <li>A. The podiatric facility has policies and procedures that address when to supplement Standard Precautions with Transmission-Based Precautions to control the spread of transmissible diseases and conditions:</li> <li>1. Contact Precautions</li> <li>2. Droplet Precautions</li> <li>3. Airborne Precautions</li> </ul>	Yes No	
B. The podiatric facility has a system or process that addresses:		
<ol> <li>Early detection of potentially infectious patients (e.g., patients with rashes, diarrhea) at the initial point of entry to the facility</li> </ol>	Yes No	
Prompt placement of potentially infectious patients in a single room	Yes No	
3. If such patients need transfer to another facility from the podiatric facility, notification of both the transferring agency and the accepting facility of the type of infection that is suspected	Yes No	
C. Podiatric HCP receive education and training on Transmission-Based Precautions including:	Yes No	
<ol> <li>Contact Precautions</li> <li>Droplet Precautions</li> <li>Airborne Precautions</li> </ol>		
D. Podiatric HCP are required to demonstrate competency with Transmission-Based Precautions (i.e., correct technique is observed by trainer):	Yes No	
<ol> <li>Upon hire</li> <li>Annually</li> <li>When new equipment or protocols are introduced</li> </ol>		

#### Section D: Personnel and Patient-Care Observations

Observation tools can be used to assist podiatric facilities in assessing HCP's infection prevention practices. These tools can also be used to conduct quality improvement audits and guide quality improvement activities by addressing deficient practices or identified gaps. The following observation tools allow for multiple observations of HCP.

#### Instructions for Use

The observer notes if the HCP has correctly performed the practice. YES means that the correct practice was performed; NO indicates that the correct practice was not performed. A plan for improvement should be developed when deficient practices or gaps are identified.

Hand Hygiene Observa	ations										
Practice	Practice Observe	- 1	Practic Observ	_	Practic Observ		Practic Observ		Practic Observ		Plan for Improvement
A. Immediately before contact with the patient	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
B. Before performing an aseptic task (e.g., providing injection, wound dressing change) or handling invasive medical device (even if gloves are worn)	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
C. After contact with the patient or objects in the immediate vicinity of patient	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
D. After contact with blood, body fluids, or contaminated surfaces (even if gloves are worn)	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
E. Before moving hands from a contaminated body site to a clean body site on same patient (even if gloves are worn)	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
F. Before exiting the patient's care area after touching the patient or the patient's immediate environment (even if gloves are worn)	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	

Personal Protective Eq	uipment	t (PP	E) Corr	ect L	Jse Obs	serva	tions				
Practice	Practic Observ	-	Practice Observed		Practice Observed		Practice Observed		Practice Observed		Plan for Improvement
A. Hand hygiene is performed before donning PPE.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
B. PPE, other than respirators, is removed and discarded prior to leaving the patient's room or care area.  Note: If 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.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
C. Hand hygiene is performed immediately after removal of PPE.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
D. Gloves:  1. Podiatric HCP wear gloves for potential contact with blood, body fluids, mucous membranes, non-intact skin, or contaminated equipment.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
<ol> <li>Podiatric HCP do not wear the same pair of gloves for the care of more than one patient.</li> </ol>	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
<ol> <li>Podiatric HCP do not wash gloves for the purpose of reuse.</li> </ol>	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	

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E. Gowns:											
1. Podiatric HCP wear gowns to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated.	Yes	No									
Podiatric HCP do not wear the same gown for the care of more than one patient.	Yes	No									
F. Facial protection:											
1. Podiatric 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									

Respiratory Hygiene/Cough Etiquette Observations												
Practice	Practic Observ	~	Practic Obser	~	Practic Observ	~	Practic Observ	~	Practic Observ	~	Plan for Improvement	
A. Offer face masks to coughing patients and other symptomatic persons upon entry to the facility.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No		
B. Coughing patients are placed in an exam room with a closed door as soon as possible. If an exam room is not available, the patient is asked to sit as far from other patients as possible in the waiting area.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No		

C. Podiatric HCP observe Droplet Precautions, in addition to Standard Precautions, when examining and caring for patients with signs and symptoms of a respiratory infection.	Yes	No										
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Safe Injection Use Obs	ervatior	าร									
Practice	Practic Observ	-	Practic Observ		Practice Observed		Practice Observed		Practice Observed		Plan for Improvement
A. Aseptic technique is used when preparing and administering medications.	Yes	No	Yes	No	Yes	No	Yes	No	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	Yes	No	Yes	No	Yes	No	Yes	No	
C. The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
D. Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
E. SDVs, ampules, and bags or bottles of intravenous solution are used for only one patient.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
F. Injections are prepared as close as possible to administration.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
G. Syringes are not batch prepared.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	

H. Medication administration tubing and connectors are used for only one patient.	Yes	No									
I. MDVs are dated by podiatric 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.	Yes	No									
Note: This is different from the expiration date printed on the vial.											
<ul> <li>J. MDVs are dedicated to individual patients whenever possible.</li> </ul>	Yes	No									
K. MDVs 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).	Yes	No									
Note: If MDVs enter the immediate patient treatment area they should be dedicated for single-patient use and discarded immediately after use.											
L. All sharps are disposed of in a puncture-resistant sharps container.	Yes	No									
M. Filled sharps containers are disposed of in accordance with state-regulated medical waste rules.	Yes	No									

N. All controlled substances (e.g., Schedule II, III, IV, and V drugs) are kept locked within a secure area.	Yes	No										
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Environmental Cleanin	g Observ	/atic	ons								
Practice	Practice Observe		Practice Observed		Practice Observed		Practice Observed		Practice Observed		Plan for Improvement
A. Podiatric HCP engaged in environmental cleaning wear appropriate PPE (e.g., gloves, gowns, masks, eye protection) to prevent exposure to infectious agents or chemicals, depending on the infectious or chemical agent and anticipated type of exposure.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
B. 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	Yes	No	Yes	No	Yes	No	Yes	No	
C. Cleaners and disinfectants are used in accordance with manufacturer's instructions (e.g., dilution, storage, shelf life, contact time).	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	

Reprocessing of Reusa	ble Instrum	ents and De	vices Obser	vations		
Practice	Practice Observed	Practice Observed	Practice Observed	Practice Observed	Practice Observed	Plan for Improvement
A. Reusable medical devices are cleaned, reprocessed (disinfection or sterilization), and maintained according to the manufacturer's instructions.  Note: If the manufacturer does not provide such instructions, the device may not be suitable for multipatient use.	Yes No					
B. SUDs are discarded after use and not used for more than one patient.  Note: If the podiatric facility elects to reuse SUDs, these devices must be reprocessed prior to reuse by a third-party reprocessor that is registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question. The podiatric facility should have documentation from the third-party reprocessor confirming its FDA status.	Yes No					

| C. Podiatric HCP follow the established reprocessing area 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 work spaces). | Yes | No |  |
|--|-----|----|-----|----|-----|----|-----|----|-----|----|--|
| D. Podiatric HCP store medical devices in a manner to protect them from damage and contamination.  | Yes | No |  |

Point-of-Care Testing C	bservat	ions									
Practice		Practice Observed		Practice Observed		Practice Observed		Practice Observed		e ved	Plan for Improvement
A. New single-use, auto-disabling lancing device is used for each patient.  Note: Lancet holder devices are not suitable for multipatient use.	Yes	No	Yes	No	Yes	No	Yes	No	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's instructions.	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	
Note: If the manufacturer does not provide instructions for cleaning and disinfection, then the testing meter should not be used for more than one patient.											

Sterilization of Reusable Instruments and Devices Observations											
Practice	Practice Observed		Plan for Improvement								
A. Items are thoroughly pre-cleaned according to manufacturer's instructions and visually inspected for residual soil prior to sterilization.  Note: For lumened instruments, device channels and lumens must be cleaned using	Yes	No									
appropriately sized cleaning brushes.											
B. Enzymatic cleaner or detergent is used for pre-cleaning and discarded according to manufacturer's instructions (typically after each use).	Yes	No									
C. Cleaning brushes either are disposable or are cleaned and high-level disinfected or sterilized (per manufacturer's 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 |  |
| Logs for each sterilizer     cycle are current and     include results from     each load.   | Yes | No |  |
| J. After sterilization,<br>medical devices and<br>instruments are stored<br>so that sterility is not<br>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, if performed, is only done in circumstances in which routine sterilization procedures cannot be performed. | Yes | No |  |

M. Instruments that are sterilized by immediate-use steam sterilization are used immediately and not stored.	Yes	No										
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High-Level Disinfection of Reusable Instruments and Devices Observations											
Practice	Practice Observed		Plan for Improvement								
A. Items are thoroughly pre-cleaned according to manufacturer's instructions and visually inspected for residual soil prior to high-level disinfection.	Yes	No									
B. Enzymatic cleaner or detergent is used and discarded according to manufacturer's instructions (typically after each use).	Yes	No									
C. Cleaning brushes either are disposable or are cleaned and high-level disinfected or sterilized per manufacturer's instructions after each use.	Yes	No									
D. For chemicals used in high-level disinfection, manufacturer's instructions are followed for:											
1. Preparation	Yes	No									
Testing for appropriate concentration	Yes	No									
Replacement (e.g., prior to expiration or loss of efficacy)	Yes	No									

		1		-						-	
E. If automated reprocessing equipment is used, proper connectors are used to assure that channels and lumens are appropriately disinfected.	Yes	No									
F. Devices are disinfected for the appropriate length of time as specified by manufacturer's instructions.	Yes	No									
G. Devices are disinfected at the appropriate temperature as specified by manufacturer's instructions.	Yes	No									
H. After high-level disinfection, devices are appropriately rinsed as specified by the manufacturer.	Yes	No									
I. Devices are dried thoroughly prior to reuse.	Yes	No									
J. After high-level disinfection, devices are stored in a manner to protect them from damage or contamination.	Yes	No									

## **APPENDIX B**

## **Reportable Diseases/Conditions**

[Insert a list of reportable diseases/conditions specific to your state and the appropriate contact information for your local and state health authorities. This information may be found at your state department of health website and/or at the following weblink: http://www.cste2.org/izenda/entrypage.aspx.]

## **APPENDIX C**

### **Additional Information About Respiratory Hygiene/Cough Etiquette**

To prevent the transmission of all respiratory infections in healthcare settings, including influenza, the following infection control measures should be implemented at the first point of contact with a potentially infected person. They should be incorporated into infection control practices as one component of Standard Precautions (see https://www.cdc.gov/flu/professionals/ infectioncontrol/resphygiene.htm). The transmission of SARS coronavirus in emergency departments by patients and their family members during the widespread SARS outbreaks in 2003 highlights the need for vigilance and prompt implementation of infection control measures at the first point of encounter. These practices have a strong evidence base (CDC 2007 Guideline for Isolation Precautions, available at http://www.cdc.gov/hicpac/pdf/isolation/ Isolation2007.pdf).

# Identifying People with Potential Respiratory Infection

If transmission in office-based settings is to be prevented, screening for potentially infectious symptomatic and asymptomatic individuals, especially those who may be at risk for transmitting airborne infectious agents (e.g., influenza, *Mycobacterium tuberculosis*, varicellazoster virus, rubeola [measles]), is necessary at the start of the initial patient encounter. Upon identifying a potentially infectious patient, prevention measures, including prompt separation of the potentially infectious patient, should be implemented and appropriate control measures put in place (2007 isolation guideline). Basic elements of identifying people with potential respiratory infections include:

- Facility staff should remain alert for anyone arriving with symptoms of a respiratory infection.
- Signs should be posted at the reception area instructing patients and accompanying persons to:
  - Self-report symptoms of a respiratory infection during registration.
  - Practice respiratory hygiene/cough etiquette (technique described below), and wear a face mask as needed.

#### **Availability of Supplies**

The following supplies are provided in the reception area and other common waiting areas:

- Face masks, tissues, and no-touch waste receptacles for disposing of used tissues
- Alcohol-based hand rub (ABHR) dispensers

#### Respiratory Hygiene/Cough Etiquette

People with signs and symptoms of a respiratory infection (including facility staff) are instructed to:

- Cover the mouth and nose with a tissue when coughing or sneezing.
- Dispose of the used tissue in the nearest waste receptacle.
- Perform hand hygiene after contact with respiratory secretions and contaminated objects/materials.

# Masking and Separation of People with Respiratory Symptoms

Upon entry to the facility, coughing patients should be instructed to don a face mask (e.g., a procedure or surgical mask). When space permits, separate patients with respiratory symptoms from others as soon as

possible (e.g., during triage or upon entry into the facility). If possible, place patients requiring Droplet Precautions in an exam room or cubicle as soon as possible and instruct them on respiratory hygiene/cough etiquette.

#### Healthcare Personnel (HCP) Responsibilities

- HCP should observe Droplet Precautions in addition to Standard Precautions when examining and caring for patients with signs and symptoms of a respiratory infection (if suspicious for an infectious agent spread by airborne route).
- These precautions should be maintained until it is determined that the cause of the symptoms is not an infectious agent that requires Droplet or Airborne Precautions.
- All HCP, including staff who are not directly employed by the facility but provide essential daily services, should be aware of facility sick leave policies.
- HCP with a respiratory infection should avoid direct patient contact; if this is not possible, then a face mask should be worn while providing patient care and frequent hand hygiene should be reinforced.
- HCP should not work when ill, also known as presenteeism, as this puts others at risk of becoming ill.
- HCP should be up-to-date with all recommended vaccinations, including annual influenza vaccine.

# Enhanced Screening During Periods of Increased Community Respiratory Virus Activity (e.g., Influenza Season)

Designated personnel should regularly review information on local respiratory virus activity provided by the local health department and the Centers for Disease Control and Prevention (CDC) to determine if the facility will need to implement enhanced screening for respiratory symptoms.

In addition to the aforementioned infection prevention measures, the following enhanced screening measures should be implemented:

- When scheduling and/or confirming appointments:
  - Prescreen all patients and schedule those with respiratory symptoms to come when the facility might be less crowded, if possible.
  - Instruct patients with respiratory symptoms to don a face mask upon entry to the facility.
- Upon entry to the facility and during the visit:
  - Patients identified with respiratory symptoms should be placed in a private exam room as soon as possible; if an exam room is not available, patients should be provided a face mask and placed in a separate area as far as possible from other patients while awaiting care.
  - If possible, family members, caregivers, and visitors with symptoms of respiratory infection should be encouraged not to enter the facility.

Additional information related to respiratory hygiene/ cough etiquette can be found in the resources section.

# **APPENDIX D**

## **Example List of Contact Persons and Roles/Responsibilities**

Contact Person(s) <sup>a</sup> Name/Title	Contact Information	Roles/Responsibilities			
	Phone: Pager: Email:	<ul> <li>Infection prevention personnel/consultant:</li> <li>Assist with infection control plan development, update/revision, and implementation; include a protocol for transferring patients who require Airborne Precautions (if applicable).</li> </ul>			
	Phone: Pager: Email:	<ul> <li>Educate and train facility staff (including environmental services [ES]/housekeeping).</li> <li>Assess for competency of jobs/tasks:         <ul> <li>Hand hygiene performance/compliance</li> <li>Proper use of personal protective equipment (PPE)</li> <li>Environmental cleaning/disinfection</li> <li>Triage/screening, taking vital signs</li> <li>Phlebotomy service</li> </ul> </li> <li>Determine when to implement enhanced respiratory screening measures.</li> <li>Ensure facility sick leave policies are in place and followed.</li> </ul>			
	Phone: Pager: Email:	<ul> <li>Collect, manage, and analyze healthcare-associated infections (HAI) data for surveillance purposes.</li> <li>Prepare and distribute surveillance reports.</li> <li>Notify state and local health departments of reportable diseases/conditions and outbreaks.</li> </ul>			
	Phone: Pager: Email:	<ul> <li>Provide fit-testing for N95 respirators (if used in facility) and appropriate respiratory protection training to facility staff.</li> </ul>			
	Phone: Pager: Email:	<ul> <li>Assess patients presenting with symptoms of active infection (may be notified by registration staff upon patient arrival).</li> <li>Determine patient placement as needed.</li> </ul>			

Phone: Pager: Email:	<ul> <li>ES/housekeeping staff:</li> <li>Ensure supplies are restocked.</li> <li>Clean patient-care areas daily.</li> <li>Disinfect bathrooms as needed.</li> <li>Clean large spills of blood or other potentially infectious materials.<sup>b</sup></li> <li>Empty regular trash and dispose of regulated waste accordingly.</li> </ul>			
Phone: Pager: Email:	<ul> <li>Clean/disinfect areas and/or surfaces that require more frequent cleaning or are not routinely cleaned by ES/housekeeping staff:</li> <li>Medication preparation area after each patient encounter</li> <li>Patient-care devices after each use</li> <li>Exam rooms and/or chemotherapy suite after each patient encounter (e.g., change paper covering on exam table)</li> <li>Patient-care areas after contamination with body fluids<sup>c</sup></li> </ul>			
Phone: Pager: Email:	<ul> <li>Monitor medication/vaccine refrigerator temperature log.</li> <li>Ensure alternative storage method is in place in the event of power failure; specify method.</li> </ul>			

<sup>&</sup>lt;sup>a</sup> Several roles/tasks may be performed by the same person, e.g., infection prevention personnel, or a single task may be performed by more than one person.

<sup>&</sup>lt;sup>b</sup> Cleaning/disinfection of spills of blood or other potentially infectious materials should be assigned to personnel trained to handle such situations; this may include facility staff other than ES/housekeeping staff.

<sup>&</sup>lt;sup>c</sup> Ensure this task is assigned to personnel who are available to respond in a timely manner; in some facilities, ES/housekeeping staff may be better equipped to handle this type of cleaning/disinfection.

## **APPENDIX E**

#### Infection Control Guidelines and Other Resources

#### **General Infection Prevention**

- Association for Professionals in Infection Control and Epidemiology, APIC Text of Infection Control & Epidemiology, 4th ed. Arlington, VA: Association for Professionals in Infection Control and Epidemiology, 2014. Accessed Jul 12, 2017. https://apic.org/APICStore/Products/Product?id=SLSTXT14
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Leadership Support), available at: https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- Facility Guidelines Institute. Guidelines for Design and Construction of Hospitals and Outpatient Facilities.
   Chicago: American Society for Healthcare Engineering, 2018, available at: https://www.fgiguidelines.org/guidelines/2018-fgi-guidelines/
- Tinley PD, Eddy K, Collier P. Contaminants in human nail dust: An occupational hazard in podiatry? *J Foot Ankle Res.* 2014 Feb 20;7(1):15.
- US Pharmacopeial Convention, Inc. General Chapter <797>: Pharmaceutical Compounding Sterile Preparations.
   *United States Pharmacopeia 38 National Formulary 33*. Rockville, MD: United States Pharmacopeial Convention,
   Inc., 2017:39-82.
- WHO Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility Level, available at: http://who.int/infection-prevention/publications/ipc-components-guidelines/en/
- Wise ME, et al. Infection prevention and control in the podiatric medical setting. Challenges to providing consistently safe care. J Am Podiatr Med Assoc. 2015 May;105(3):264-72. Review.

#### **Facility Risk Assessment**

- Australasian Podiatry Council. Section 4: Quality and risk management. Infection Prevention and Control Guidelines for Podiatrists 2012. Brunswick East, Victoria: Australasian Podiatry Council, 2012. Accessed Jul 18, 2017. https://www.cpd.apodc.com.au/activityitem/download/5911/3648
- · CDC Patient Notification Toolkit, available at: https://www.cdc.gov/injectionsafety/pntoolkit/
- CDC Steps for Evaluating an Infection Control Breach, available at: https://www.cdc.gov/hai/outbreaks/steps\_for\_eval\_ic\_breach.html
- The APIC/JCR Infection Prevention and Control Workbook, 3rd ed., available at: http://www.jcrinc.com/the-apic/ jcr-infection-prevention-and-control-workbook-third-edition/
- WHO Guidelines on Core Components of Infection Prevention and Control Programmes at the National and Acute Health Care Facility Level, available at: http://www.who.int/gpsc/core-components.pdf

#### Resources to Assist with Evaluation and Response to Breaches in Infection Control

- CDC Patient Notification Toolkit, available at: http://www.cdc.gov/injectionsafety/pntoolkit/index.html
- CDC Steps for Evaluating an Infection Control Breach, available at: http://www.cdc.gov/hai/outbreaks/steps\_for\_eval\_IC\_breach.html
- 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.

#### Healthcare Personnel (HCP) Safety

- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Occupational Health), available at: https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC Guideline for Infection Control in Healthcare Personnel, available at: https://www.cdc.gov/hicpac/pdf/infectcontrol98.pdf
- CDC Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005, available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm
- CDC Immunization of Health-Care Personnel: Recommendations of the ACIP, available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm
- CDC Promote Influenza (Flu) Vaccination, available at: https://www.cdc.gov/flu/resource-center/partners/ promote-vaccination.htm
- CDC Recommended Vaccines for Healthcare Workers, available at: https://www.cdc.gov/vaccines/adults/rec-vac/ hcw.html
- CDC Weekly U.S. Influenza Surveillance Report, available at: https://www.cdc.gov/flu/weekly/index.htm#ILIMap; and http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s\_cid=rr5417a1\_eOSHA
- OSHA Bloodborne Pathogens and Needlestick Prevention, available at: https://www.osha.gov/SLTC/bloodbornepathogens/index.html
- OSHA model exposure control plan (meets the requirements of the OSHA Bloodborne Pathogens Standard), available at: https://www.osha.gov/Publications/osha3186.pdf
- OSHA Respirator Fit Testing, available at: https://www.osha.gov/video/respiratory\_protection/fittesting\_transcript.html
- OSHA Respiratory Protection Standard, available at: https://www.osha.gov/pls/oshaweb/owadisp.show\_document?p\_table=standards&p\_id=12716

#### Infection Surveillance and Reporting Healthcare-associated Infections

- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Performance Monitoring and Feedback), available at: https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CMS Outpatient Audit Tool, available at: http://www.cms.gov/manuals/downloads/som107\_exhibit\_351.pdf
- State Reportable Diseases and Conditions, available at: http://www.cste2.org/izenda/entrypage.aspx

#### Hand Hygiene

- CDC Clean Hands Count infographic, available at: https://www.cdc.gov/handhygiene/campaign/promotional.html
- CDC Fight Antibiotic Resistance It's in Your Hands infographic, available at: https://www.cdc.gov/handhygiene/index.html
- CDC Hand Hygiene in Healthcare Settings, available at: http://www.cdc.gov/handhygiene/
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Hand Hygiene), available at: https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC Guideline for Hand Hygiene in Healthcare Settings, available at: https://www.cdc.gov/handhygiene/providers/guideline.html
- CDC offers two education courses for healthcare providers on hand hygiene, available at: https://www.cdc.gov/handhygiene/providers/training/index.html
  - Hand Hygiene, Glove Use, and Preventing Transmission of C. difficile (2017), available at: http://aaohn.org/blog/cdc-new-course-hand-hygiene,-glove-use,-and-preventing-transmission-of-c.-difficile
  - Hand Hygiene & Other Standard Precautions to Prevent Healthcare-Associated Infections (2005), available at: https://www.cdc.gov/handhygiene/training/interactiveEducation/
- CDC MMWR Weekly Report 51 (RR-16): Guideline for Hand Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. Oct 15, 2002. Accessed Jul 12, 2017, available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/ rr5116a1.htm
- Examples of tools that can be used to conduct a formal audit of hand hygiene practices, available at: http://www.jointcommission.org/assets/1/18/hh\_monograph.pdf; and https://vinci.cs.uiowa.edu/scrubwatch/iscrub.php
- WHO Guidelines on Hand Hygiene in Health Care, available at: http://www.who.int/gpsc/5may/tools/9789241597906/en/

#### **Personal Protective Equipment**

- CDC 2007 Guideline for Isolation Precautions, available at: http://www.cdc.gov/hicpac/pdf/isolation/ Isolation2007.pdf
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to PPE), available at: https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC resources on use of PPE by health care personnel, available at: https://www.cdc.gov/HAl/prevent/ppe.html

#### Respiratory Hygiene/Cough Etiquette

- CDC 2007 Guideline for Isolation Precautions, available at: https://www.cdc.gov/hicpac/pdf/isolation/ Isolation2007.pdf
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Minimizing Potential Exposures), available at: https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC Cover Your Cough infographic, available at: https://www.cdc.gov/flu/pdf/protect/cdc\_cough.pdf
- CDC Flu Activity & Surveillance, available at: https://www.cdc.gov/flu/weekly/fluactivitysurv.htm
- CDC recommendations for preventing the spread of influenza are available at: https://www.cdc.gov/flu/ professionals/infectioncontrol/
- Minnesota Department of Health. Cover Your Cough Poster for Health Care. Nov 7, 2016. Accessed Jul 12, 2017. http://www.health.state.mn.us/divs/idepc/dtopics/infectioncontrol/cover/hcp/hcpposter.html

#### **Injection Safety**

- Anderson L, et al. Challenges to safe injection practices in ambulatory care. Infect Control Hosp Epidemiol. 2017 May;38(5):614-616. Epub 2017 Feb 27.
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Injection and Medication Safety), available at: http://cdc.gov/hicpac/pdf/core-practices.pdf
- CDC Frequently Asked Questions (FAQs) Regarding Safe Practices for Medical Injections, available at: https://www.cdc.gov/injectionsafety/providers/provider\_faqs.html
- CDC Injection Safety Web Materials available at: http://www.cdc.gov/injectionsafety/
- One Needle, One Syringe, Only One Time infographic, available at: https://www.cdc.gov/injectionsafety/PDF/ InjectionSafety-Infographic-508.pdf
- Safety Steps: Follow These Injection Safety Steps for Success! available at: http://www.oneandonlycampaign.org/sites/default/files/upload/image/CDC\_0%260\_Single-dose%20and%20Multi-dose%20vial%20infographic.pdf
- Single-dose or multi-dose? infographic available at: http://www.cdc.gov/injectionsafety/PDF/SDVMDV\_ infographic.pdf
- Steps Every Healthcare Provider Should Take infographic, available at: https://www.cdc.gov/injectionsafety/PDF/ InjectionSafety-Infographic-508.pdf
- CDC training video and related Safe Injection Practices Campaign materials, available at: http://www.oneandonlycampaign.org/ http://www.cdc.gov/injectionsafety/providers/provider\_faqs.html https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC Protect Patients Against Preventable Harm from Improper Use of Single-Dose/Single-Use Vials.
   Misperceptions vs. Facts. (Updated: Aug 30, 2016.) Accessed Jul 12, 2017. Available at: https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html
- Perz JF, et al. US outbreak investigations highlight the need for safe injection practices and basic infection control. Clin Liver Dis. 2010 Feb;14(1):137-51. Review.
- Pugliese G, et al. Injection practices among clinicians in United States health care settings. *Am J Infect Control*. 2010 Dec;38(10):789-98.
- World Health Organization. Injection Safety. Accessed Jul 12, 2017. Available at: http://www.who.int/infection-prevention/tools/injections/en/

#### **Point-of-Care Testing**

- CDC 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
- CDC Infection Prevention during Blood Glucose Monitoring and Insulin Administration, available at: http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html

#### **Environmental Cleaning**

- Association for Healthcare Environment (AHE). Practice Guidance for Healthcare Environmental Cleaning (2nd ed.)
   Available at: http://www.ahe.org/Education/publications\_home.shtml
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Environmental Cleaning and Disinfection), available at: http://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html
- CDC Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings, available at: http://www.cdc.gov/hicpac/pdf/norovirus/Norovirus-Guideline-2011.pdf
- CDC Guidelines for Environmental Infection Control in Health-Care Facilities, available at: http://www.cdc.gov/hicpac/pdf/guidelines/eic\_in\_HCF\_03.pdf

#### **Reprocessing of Reusable Medical Devices**

- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Reprocessing of Reusable Medical Equipment), available at: https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC 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
- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html
- CDC Materials specific for the handling of blood glucose monitoring devices are available at: https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html
- FDA regulations on reprocessing of single-use devices are available at: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf

#### Sterilization of Reusable Instruments and Devices

- American National Standards Institute and the Association for the Advancement of Medical Instrumentation
  Comprehensive guide to steam sterilization and sterility assurance in health care facilities (ANSI/AAMI ST79:2017),
  published August 1, 2017. A preview copy is available at: https://my.aami.org/aamiresources/previewfiles/ST79\_
  Wa4\_1310\_preview.pdf
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Reprocessing of Reusable Medical Equipment), available at: https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html
- CDC Frequently Asked Questions: Bead Sterilizer: Are bead sterilizers an effective means of sterilization?
   Available at: https://www.cdc.gov/oralhealth/infectioncontrol/fag/bead.htm
- · The Joint Commission. Improperly sterilized or HLD equipment—a growing problem. Quick Safety. 2017 May;33.

#### **High-Level Disinfection of Reusable Instruments and Devices**

- American National Standards Institute and the Association for the Advancement of Medical Instrumentation
   Chemical sterilization and high-level disinfection in health care facilities (ANSI/AAMI ST58:2013), published August
   21, 2013. A preview copy is available at: my.aami.org/aamiresources/previewfiles/ST58\_1308\_preview.pdf
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Reprocessing of Reusable Medical Equipment), available at: http://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, available at: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html; and https://www.cdc.gov/hicpac/pdf/core-practices.pdf

#### **Transmission-Based Precautions**

- CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Against in Healthcare Settings, available at: https://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, available at: https://www.cdc.gov/hicpac/pdf/core-practices.pdf
- CDC Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care, available at: https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html
- CDC Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005, available at: http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf
- Francis J. Curry National Tuberculosis Center, FAQ: How long does it take to clear the air in an isolation or high-risk procedure room? Available at: http://www.flpic.com/TB\_air\_exchange.pdf

#### **Quality Improvement-Related Resources**

- Agency for Healthcare Research and Quality (AHRQ) TeamSTEPPS for Office-Based Care, 2017, available at: https://www.ahrq.gov/teamstepps/officebasedcare/index.html
- AHRQ Medical Office Survey on Patient Safety Culture, available at: https://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/medical-office/index.html
- AHRQ Safety Program for Ambulatory Surgery: Everyone in Ambulatory Surgery Centers (ASCs) Plays a Role in Preventing Surgical Site and Other Harmful Infections, available at: https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/hais/tools/ambulatory-surgery/sections/implementation/implementation-guide/appendix-l.pdf
- Additional resources on improving patient safety in medical offices can be found at: https://www.ahrq.gov/sites/ default/files/wysiwyg/sops/quality-patient-safety/patientsafetyculture/medofficeresourcelist-020118.pdf

#### Additional Resources and Evidence-based Guidelines available at:

https://www.cdc.gov/infectioncontrol/guidelines/index.html

For more information please contact Centers for Disease Control and Prevention

Telephone: 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348

Email: www.cdc.gov/info

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# NOTES

## **NOTES**