SPECIAL COMMUNICATION

Infection Prevention and Control in the Podiatric Medical Setting

Challenges to Providing Consistently Safe Care

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Unsafe practices are an underestimated contributor to the disease burden of bloodborne viruses. Outbreaks associated with failures in basic infection prevention have been identified in nonhospital settings with increased frequency in the United States during the past 15 years, representing an alarming trend and indicating that the challenge of providing consistently safe care is not always met. As has been the case with most medical specialties, public health investigations by state and local health departments, and the Centers for Disease Control and Prevention, have identified some instances of unsafe practices that have placed podiatric medical patients at risk for viral, bacterial, and fungal infections. All health-care providers, including podiatric physicians, must make infection prevention a priority in any setting in which care is delivered. (J Am Podiatr Med Assoc 105(3): 264-272, 2015)

Unsafe practices are an underestimated contributor to the disease burden of bloodborne viruses.[1-4] Outbreaks associated with failures in basic infection prevention, such as unsafe injection practices, have been identified with increased frequency in the United States during the past 15 years.[1] This represents an alarming trend and indicates that the challenge of providing consistently safe care is not always met. Public health investigations by state and local health departments and the Centers for Disease Control and Prevention (CDC) have identified some instances of unsafe practices that have placed podiatric medical patients at risk for viral, bacterial, and fungal infections. All health-care providers, including podiatric physicians, must make infection prevention a priority in any setting in which care is delivered. This article summarizes observations from recent investigations and reviews infection prevention and injection safety standards that should be adhered to by all health-care providers, including podiatric physicians and other

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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health professionals involved in the delivery of podiatric medical care.

Public Health Investigations Involving Podiatric Medical Care

Los Angeles County, California: Skilled Nursing Facility

In 2008, the Los Angeles County Department of Public Health and the CDC conducted a joint investigation of a hepatitis B outbreak in residents of a skilled nursing facility.[5] Nine acute hepatitis B virus (HBV) infections were identified, of which five received care from a visiting podiatric physician at the facility on a single date. Further investigation uncovered that the first resident seen by the podiatric physician on that date was infected with HBV at the time. Observation of the visiting podiatrist's practices revealed that instruments (eg, nail, cuticle, and tissue nippers) became visibly contaminated with blood after use, such as nail clipping and debridement of wounds. There was no separation of clean and dirty counter space, and these contaminated instruments were placed on the same surfaces as sterile instruments in close proximity to one another, likely leading to cross-contamination of the sterile instruments with blood. Three residents who underwent podiatric medical procedures on that date had viral specimens available for characterization by the CDC Hepatitis Reference Laboratory: the infected resident who had been seen first that day and two of the acutely infected residents. These three viral specimens had the same genotype and highly related genetic sequences. The other four acutely infected residents who did not undergo podiatric medical procedures on that date had other risk factors for infection, but they all had podiatric medical procedures during the period they likely became infected. Although this outbreak identified multiple potential modes of transmission, epidemiologic and molecular evidence pointed to breakdowns in basic infection prevention and control procedures by the visiting podiatric physician as the primary mode of transmission.

Los Angeles County, California: Assisted Living Facility

In 2011, the Los Angeles County Department of Public Health conducted an investigation of two new HBV infections in residents of a single assisted living facility, which included a review of visiting podiatric medical services provided at the facility. Several infection control breaches related to podiatric medical practices at the facility were observed. These breaches included no separation of clean and dirty counter space (eg, clean gloves, unopened scalpel blades, and hand sanitizer were all placed next to dirty scalpel handles and a disinfection tray containing used nail nippers); lack of environmental cleaning and disinfection between patients (eg, callus shavings and nail/skin debris were left on the floor and on the patient's chair without cleaning or disinfection between patients); failure to appropriately clean podiatric medical equipment before disinfection or sterilization; and failure to rinse and dry equipment after disinfection according to the manufacturer's recommendations. Although the exact source of the HBV infections could not be directly linked to the breaches by the podiatrists, these breaches posed a risk to patient safety and could have led to the transmission of HBV or other pathogens in this facility.

Ocean County, New Jersey: Skilled Nursing Facility

In June 2012, the Ocean County Health Department in collaboration with the New Jersey Department of Health conducted an investigation of a new HBV infection in a resident of a skilled nursing facility. The investigation team reviewed medical records, interviewed the resident, and performed on-site inspections of facilities where the resident underwent invasive procedures. The team visited the facility and identified breaches related to assisted monitoring of blood glucose levels and injection safety. The team also visited a private podiatric medical office where the resident underwent toenail avulsion during the period the resident likely became infected. Numerous lapses in infection prevention practices were noted at the podiatric physician's office, including reuse of single-use blades for multiple patients, failure to appropriately clean podiatric medical equipment before disinfection and sterilization, failure to appropriately monitor disinfection and sterilization processes with biological and chemical indicators, failure to ensure the recommended soaking time for chemical disinfection, and failure to store and prepare medication from multidose vials in a dedicated clean area. The podiatric physician also provided care to patients at two other residential care facilities in New Jersey. At these facilities, podiatric medical equipment was not appropriately cleaned and disinfected or sterilized before being used on

other patients. Letters notifying patients of potential exposure to HBV, hepatitis C virus, and human immunodeficiency virus were sent to 182 residents of the skilled nursing facility where the infected resident lived and to all 1,115 patients who received care from the podiatric physician in any setting.

Multiple Counties, Virginia: Assisted Living Facilities

Between 2009 and 2012, the Virginia Department of Health conducted hepatitis B outbreak investigations in four separate assisted living facilities.[6] Although the causes of these outbreaks were ultimately attributed to infection control lapses during assisted monitoring of blood glucose levels, the initial investigation involved assessing other possible routes for HBV transmission, including through podiatric treatment. As an example, during a 2009 investigation, public health staff interviewed a podiatric physician and observed infection control practices because several patients with acute HBV infection had had podiatric medical procedures before becoming infected. Through these observations, multiple opportunities for pathogen transmission were identified. The podiatrist did not routinely change gloves between patients (gloves were changed only if blood was visible or if a patient had poor foot hygiene), there was a lack of environmental cleaning and disinfection between patients (the surface on which patients' feet were examined was covered with an absorbent pad that was not changed between patients), podiatric medical equipment was not appropriately cleaned before disinfection, and public health staff did not observe proper procedures for sharps disposal. Lastly, the podiatric physician had not been vaccinated against HBV despite having occupational exposure to blood and other body fluids.

Past Outbreaks Associated with Podiatric Medical Care

Before the investigations described previously herein, the CDC and state and local health departments investigated several outbreaks of bacterial infections related to lapses in infection prevention in the podiatric medical setting, including an outbreak of six *Proteus mirabilis* wound infections related to contaminated bone drills used during outpatient podiatric surgery,[7] an outbreak of 13 methicillin-resistant *Staphylococcus aureus* soft-tissue infections after injections at a podiatric medical clinic,[8] and ten *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.[9] These past investigations highlighted similar issues regarding lapses in disinfection and sterilization of patient-care instruments, environmental infection prevention and control, and safe injection practices and also showed that pathogen transmission in the podiatric medical setting is not limited to viral hepatitis.

Infection Prevention Recommendations

The observations above are anecdotal and do not represent a systematic assessment of infection prevention practices among podiatric physicians. In most instances, transmission of pathogens to patients could not be directly linked to infection prevention breakdowns in the podiatric medical setting. Nevertheless, a high proportion of assessments of podiatric medical settings performed by CDC and state and local health officials have identified concerning practices that could place patients at risk for infection. Below is a summary of infection prevention and injection safety standards that should be adhered to by health-care providers in all settings.

Cleaning, Disinfection, and Sterilization of Podiatric Medical Instruments

Given the challenges with cleaning, disinfection, and sterilization of podiatric medical instruments seen in these outbreaks, disposable, single-use instruments and devices should be used whenever possible and disposed of immediately after use in accordance with state and local medical waste regulations. All reusable patient-care instruments and devices used must be first cleaned and then disinfected or, preferably, sterilized before use to prevent patient-to-patient transmission of infectious agents (Table 1). Cleaning before disinfection and sterilization procedures is critical to ensure that residual organic and inorganic debris does not reduce the effectiveness of the disinfection and sterilization processes[10] and is normally accomplished in clinical settings by mechanically scrubbing instruments with water and detergents or with enzymatic products, followed by rinsing and drying. Cleaning, disinfection, and sterilization should be performed in dedicated non–patient-care areas with staff wearing appropriate personal protective equipment (PPE). All environmental surfaces used for cleaning, disinfection, and sterilization should also

Table 1. Best Practices and Rationales Regarding Infection Prevention in the Podiatric Medical Setting

Best Practice	Rationale for Practice
Manually cleaning instruments such as nail nippers and burrs is necessary before disinfecting or sterilizing them.	Organic material, such as dirt or skin, can block the action of disinfection or sterilization. Therefore, all patient-care items must be appropriately and effectively cleaned before either disinfection or sterilization to remove organic and inorganic material that can reduce the effectiveness of these processes.
Any instrument that has been used on a patient is considered contaminated and must be properly cleaned and disinfected before being used on subsequent patients.	Pathogens can remain viable on instruments even when not visibly contaminated (eg, hepatitis B virus can remain viable on surfaces for a week or more). Therefore, patient-care instruments should always be cleaned and either disinfected or sterilized between patients or disposed of after use.
Reading the instructions for chemical disinfectants is important.	Although many disinfectant solutions require at least 10–20 min of contact time, chemicals vary by manufacturer. When using chemical disinfectants for instruments and environmental surfaces, always follow the manufacturer's instructions.
Syringes always are used on only one patient.	Experimental studies have demonstrated that syringes become contaminated after use, even if the needle is changed. Each injection given to a patient should be drawn and administered using a new sterile needle and a new sterile syringe.
Single-dose vials are used for only one patient.	Single-dose vials are considered contaminated after the first time they are used. Medications from single-dose vials should not be used on multiple patients because they do not contain the same preservatives as multidose vials.
Dedicate multidose vials to single patients whenever possible. If the multidose vial must be used for >1 patient, it should be kept and accessed in a dedicated clean room, regardless of setting.	If multidose vials must be used for >1 patient, they should not be kept or accessed in the immediate patient treatment area. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients.
Gloves are necessary when performing routine procedures.	Gloves should be worn during any procedure that involves potential contact with blood and other body fluids, including routine procedures, such as clipping nails and debriding calluses.
Changing gloves is necessary between each patient even if they do not become visibly contaminated.	Pathogens can adhere to gloves even in the absence of visible contamination. Furthermore, disposable gloves are not impermeable and can contain microscopic holes or tears. Therefore, gloves should be changed and hand hygiene performed between each patient.
Instruments should be reprocessed in the same manner whether they are used in the usual office setting or at an outside facility, such as an assisted living facility or a nursing home.	The same infection prevention standards apply wherever health care is delivered. Podiatric physicians should ensure that adequate supplies are brought when visiting health-care facilities and that adequate treatment space exists to ensure safe care.

be appropriately cleaned and disinfected before reprocessing instruments. In 2010, APMA updated their *Disinfection and Sterilization Guideline Recommendations for Podiatric Physicians* to further harmonize this document with CDC infection prevention recommendations. This guideline is available to all APMA members at www.apma.org.

Spaulding Classification of Patient-Care Instruments and Devices. Reusable medical instruments can be categorized based on the degree of risk of transmitting infections.[11] The Spaulding classification divides patient-care instruments and devices into three categories: critical, semicritical, and noncritical. Critical instruments (eg, scalpels, bone files, retractors, and surgical burrs) penetrate soft tissue, bone, or the bloodstream (ie, normally sterile body sites) and confer a high risk of infection if they are contaminated with any microorganism at the time of use. Consequently, items in this category must be cleaned and sterilized between uses. Semicritical instruments (eg, cuticle and nail nippers, forceps, and elevators) contact mucous membranes or nonintact skin, such as open wounds. These items require, at a minimum, cleaning followed by high-level disinfection with a Food and Drug Administration–cleared chemical disinfectant[12] according to the instrument reprocessing instructions and the disinfectant label instructions.

Noncritical instruments (eg, blood pressure cuffs and blade handles) contact only fully intact skin. Items in this category should minimally undergo cleaning followed by low- or intermediate-level disinfection after use with an Environmental Protection Agency–registered disinfectant according to the instrument and disinfectant manufacturer's instructions.

Considerations for Disinfection and Sterilization in Podiatric Medicine. After cleaning, the instrument is subjected to terminal reprocessing (ie, disinfection or sterilization) that is meant to either eliminate or drastically reduce the number of viable organisms on a piece of equipment. In addition to the Spaulding classification, the compatibility of instrument materials with disinfection or sterilization processes is an important factor in selection of the most appropriate method of terminal reprocessing.[13,14] Any reusable podiatric medical instruments that are heat stable and have the potential to break intact skin during ordinary use (eg, nippers, forceps, splitters, and curettes) should ideally be sterilized using steam rather than using chemical disinfectants for the terminal reprocessing step. Instruments should be sterilized using a Food and Drug Administration–cleared sterilizer. Although this approach can be more expensive, a similar strategy was adopted in the CDC *Guidelines for Infection Control in Dental Health-Care Settings* and greatly simplifies decision making regarding reusable instrument reprocessing, ensures the highest level of patient safety, and enhances occupational safety for clinic staff.[10,15] Sterilization of all podiatric medical instruments has been adopted as the standard of care in other countries.[16,17] The steam sterilization process entails several steps after cleaning, including placing cleaned and dried instruments in wrappers (or other appropriate containment) and monitoring the sterilization process with the use of chemical and biological indicators in accordance with current guidelines and standards.[10,18] Note that bead sterilizers are no longer acceptable for sterilization of instruments. This equipment should be phased out immediately and replaced preferably with a steam sterilizer.[10]

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. Cleaned, reusable, non–heat-stable instruments should remain immersed in a disinfectant for the manufacturer-recommended contact time and temperature (Table 1). After undergoing chemical disinfection, these instruments should be handled with sterile gloves or forceps and should be thoroughly rinsed with sterile water (not tap water), dried with a sterile towel, and placed inside a closed drawer or sealable container lined with clean or sterile towels. The high-level disinfectant must be monitored using chemical potency indicators as recommended by the manufacturer and replaced with fresh disinfectant as indicated by the manufacturer. Comprehensive guidance on disinfection and sterilization has been published by the federal Healthcare Infection Control Practices Advisory Committee (HICPAC).[10]

Injection Safety

The risks associated with improperly handled injectable medications are often underestimated.[2,19,20] Injection safety, or safe injection practices, is a set of measures taken to perform injections in an optimally safe manner for patients and health-care personnel.[19] A safe injection does not harm the patient, does not expose the provider to avoidable risks, and does not result in waste that is dangerous for the community.[21] Safe injection practices are intended to prevent transmission of infectious diseases from patient to patient or between patients and health-care providers, including by preventing needlestick injuries. 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 needles, syringes, intravenous tubing, and medication vials. The American Podiatric Medical Association has recently joined the One and Only Campaign, an initiative led by the CDC and the Safe Injection Practices Coalition that aims to eliminate all outbreaks associated with unsafe injection practices.[22] The CDC has made comprehensive information on injection safety available online.[23]

Syringes and Needles. There is a common misperception that contamination is limited to the needle component when a syringe and needle are used together (Table 1). Since 1946, numerous experimental studies have demonstrated that contamination extends from the needle into the syringe after injections are administered to patients by the intramuscular, intradermal, intravenous, and other routes.[24-32] Additional potential for syringe contamination results from the negative pressure that occurs when a contaminated needle is removed from the syringe. Used needles or syringes not only pose a risk when directly used on another patient

but also when used to withdraw medication from a vial, which can result in transfer of pathogens to the vial (Fig. 1).[23] Therefore, syringes that have been attached to needles that have been used on any patient, regardless of infection status, must never be reused for patient care or to withdraw medication from a vial.[33] Finally, needles and syringes should be removed from the sterile wrapper at the time of use; storing unwrapped needles and syringes is not appropriate because their sterility cannot be guaranteed.

Medication Vials. All medication vials must be stored in accordance with the manufacturer's recommendations at the appropriate temperature, used in a clean room or other clean area dedicated to medication preparation, and discarded whenever sterility has been compromised or is in doubt.[19,34] The rubber septum of all medication vials should always be rubbed with an appropriate disinfectant, as specified by the vial manufacturer, and allowed to dry before entry with a sterile needle and syringe. Syringes should be filled with medication as close to the time of use as possible.

Podiatric physicians are advised to check medication vial label instructions to determine whether the vial is single dose or multidose. Medication packaged as a single-dose vial should never be used for more than one patient because single-dose vials do not have bacteriostatic agents and must be considered contaminated after the first use (Table 1). Any medication packaged as multidose should be assigned to a single patient whenever possible.[35] Once used or opened, multidose vials need to be dated and discarded no longer than 28 days after first use unless the manufacturer specifies a different interval or disposal date for the vial.[36] Of note, the bacteriostatic agents in multidose vials do not inactivate viruses such as hepatitis C virus and HBV.[19]

Other Aspects of Standard Precautions

In addition to injection safety and reprocessing of patient-care instruments and devices, standard precautions also include hand hygiene, use of PPE, and safe handling of potentially contaminated surfaces in the patient environment. 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 health care is delivered.[34,35] These practices are designed to protect health-care providers and to prevent health-care providers from spreading infections to patients. Comprehensive guidance on standard precautions has been drafted by the HICPAC,[34] and guidance on standard precautions in outpatient

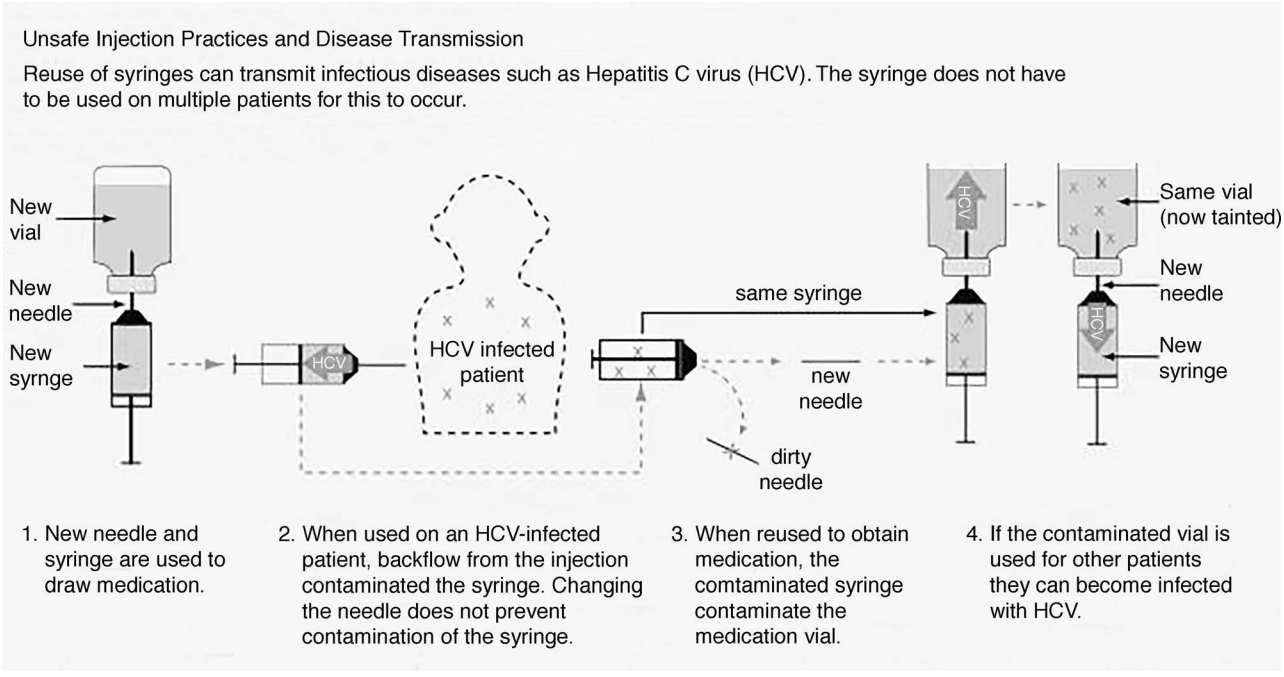


Figure 1. Unsafe injection practices and disease transmission. HCV, hepatitis C virus. (Adapted from Centers for Disease Control and Prevention.[33])

settings, such as podiatric medical offices, has been drafted by the CDC.[35]

Hand Washing and Alcohol-Based Hand Sanitizer. Hand washing with soap and water or hand sanitizing with alcohol-based hand rub is critical to reduce the risk of spreading infections in all settings where health care is delivered. Use of alcohol-based hand rub is recommended by the CDC as the primary mode of hand hygiene in health-care settings because of its activity against a broad spectrum of pathogens and because (compared with soap and water) the use of alcohol-based hand rub requires less time, irritates hands less, and facilitates hand hygiene at the point of care.[35,37] When hands are visibly soiled (eg, with dirt or blood) or after caring for patients with known or suspected infectious diarrhea, hand washing with soap and water should be used instead of alcohol-based hand rub. Key situations where hand hygiene should be performed include before touching a patient; before exiting the patient-care area (after touching the patient or the patient's immediate environment); before performing an aseptic task (eg, preparing an injection); before hands move from a contaminated body site to a clean body site; after contact with blood, body fluids, excretions, or wound dressings; and after glove removal.[35] Comprehensive information on hand hygiene is available on the CDC Hand Hygiene in Healthcare Settings website.[38]

Personal Protective Equipment. Personal protective equipment is intended to protect health-care providers and patients from exposure to infectious agents. Selection of appropriate PPE is based on the anticipated nature of the patient interaction. Examples of appropriate PPE use include using gloves in situations involving potential contact with blood, body fluids, mucous membranes, nonintact skin, or potentially infectious material (eg, when debriding a wound or cutting an ingrown toenail) and using a gown to protect skin and clothing during procedures where contact with blood or body fluids is anticipated.[35] To prevent the spread of pathogens, always change PPE, including gloves (and gowns when worn), between patients (Table 1). Gloves should be removed whenever leaving the treatment area. Hand hygiene is always the final step after removing and disposing of PPE. Comprehensive information on PPE can be found on the CDC Tools for Protecting Healthcare Personnel website.[39]

Cleaning and Disinfection of Environmental Surfaces. All health-care providers, including podiatric physicians, should have an infection prevention plan with established policies and procedures for cleaning and disinfection of environmental surfaces and other equipment (eg, drill handles used in burring procedures) between patients. Cleaning and disinfection should be concentrated on surfaces that are most likely to become contaminated, such as seats, foot stools, other surfaces on which procedures are performed, and tabletops in patient rooms. Cleaning and disinfection are also required in areas where patient medications are prepared or instrument disinfection or sterilization takes place. Environmental Protection Agency–registered disinfectants that have been specifically designated for use in health care (as indicated on the label) should be selected for disinfection. Before using a disinfectant, surfaces should be cleaned to remove any organic or inorganic material that could reduce the effectiveness of disinfectants. Providers should follow the manufacturer's recommendations for the use of products selected for cleaning and disinfection with respect to dilution, contact time, safe use, and disposal. Spraying disinfectant onto a surface and immediately wiping it off is not sufficient to disinfect environmental surfaces; adequate contact time is necessary. Comprehensive guidance on environmental infection control has been published by the HICPAC and is available online.[40]

Infection Control for Visiting Health-Care Providers

Although podiatric medical care frequently occurs in offices and other outpatient settings, podiatric physicians may also provide care outside their usual office setting as consulting health-care providers in facilities such as hospitals, nursing homes, patient residences, and assisted living facilities. This may make adherence to appropriate infection prevention and control practices challenging. Nevertheless, the same infection prevention standards must be adhered to when acting as a visiting provider as when delivering care in the usual office setting (Table 1). For example, providers may not have access to a dedicated treatment space when visiting long-term care facilities or may be asked to work in treatment areas with a layout that is poorly suited to the provision of podiatric medical services. Podiatric physicians should work with facility managers and other relevant staff to identify or create treatment areas with the necessary attributes that facilitate the safe provision of podiatric medical care (eg, sinks, adequate counter space, medical waste disposal bins, sharps containers, and an ability to demark clean and dirty counter space). In addition, an adequate supply of clean and

disinfected or sterilized patient-care instruments should be brought to (or be available at) the facility so that items do not have to be reprocessed on-site to maintain clinical workflow. If reprocessing occurs in the podiatric physician's office, all dirty or used equipment should be brought back to the podiatric physician's office in a dedicated container that is separate from clean equipment and supplies to prevent cross-contamination. If reprocessing of instruments must occur in the facility, it should be performed in an area designated for this purpose and should never occur in patient-care or resident living areas.

Summary

Podiatric physicians provide important services to patients every day in the United States. However, recent public health investigations have identified inappropriate infection prevention and control practices in some podiatric medical care settings. The CDC, the HICPAC, and APMA have published guidelines that address standard precautions,[34,35] including disinfection and sterilization of reusable patient-care instruments,[10] safe injection practices,[23] hand hygiene,[37] use of PPE, and environmental infection control.[40] Failure to follow these basic standards poses a risk to patients and is a practice liability when outbreaks do occur. We recommend that the American Podiatric Medical Association consider expanding its current disinfection and sterilization guidance to incorporate all aspects of standard precautions. This would facilitate a standardized approach to infection prevention across the profession while further supporting the efforts of podiatric physicians to meet the challenge of providing consistently safe care to their patients.

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