

# Guide to Infection Prevention in Orthopedic and Pain Management Office Settings



**Centers for Disease  
Control and Prevention**  
National Center for Emerging and  
Zoonotic Infectious Diseases

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## ABBREVIATIONS

<b>AAMI</b>	Association for the Advancement of Medical Instrumentation	<b>HLD</b>	High-level disinfection
<b>AAOS</b>	American Academy of Orthopaedic Surgeons	<b>INR</b>	International normalized ratio
<b>ABHR</b>	Alcohol-based hand rub	<b>IPC</b>	Infection prevention and control
<b>ACIP</b>	Advisory Committee on Immunization Practices	<b>IV</b>	Intravenous
<b>ANSI</b>	American National Standards Institute	<b>MRSA</b>	Methicillin-resistant <i>Staphylococcus aureus</i>
<b>BI</b>	Biological indicator	<b>MSSA</b>	Methicillin-susceptible <i>Staphylococcus aureus</i>
<b>CDC</b>	Centers for Disease Control and Prevention	<b>MDV</b>	Multi-dose vial
<b>EPA</b>	Environmental Protection Agency	<b>OSHA</b>	Occupational Safety and Health Administration
<b>ES</b>	Environmental services	<b>PBP</b>	Pharmacy bulk product
<b>FDA</b>	Food and Drug Administration	<b>PPE</b>	Personal protective equipment
<b>HAI</b>	Healthcare-associated infection	<b>SDV</b>	Single-dose vial
<b>HCP</b>	Healthcare personnel	<b>SSI</b>	Surgical site infection
<b>HBV</b>	Hepatitis B virus	<b>SUD</b>	Single-use device
<b>HCV</b>	Hepatitis C virus	<b>TB</b>	Tuberculosis
<b>HIV</b>	Human immunodeficiency virus	<b>USP</b>	United States Pharmacopeia
<b>HICPAC</b>	Healthcare Infection Control Practices Advisory Committee	<b>WHO</b>	World Health 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 cleaner) 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 Infection Prevention**

**Competency:** The proven ability of HCP to apply essential knowledge, skills, and capabilities to prevent the transmission of pathogens during the provision of care.

### **Healthcare Personnel Infection Prevention**

**Competency-Based Training:** The provision of job-specific education, training, and assessment to ensure that HCP possess IP competency.

**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

## I. Introduction

This guide was developed as a model for a basic infection prevention and control (IPC) plan for orthopedic and pain management outpatient settings. It contains information that can help facilities:

- Identify gaps in staff knowledge and current practice
- Develop policies and procedures tailored to these settings
- Meet minimum expectations of patient safety as 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.<sup>1</sup> 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/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 document: 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 orthopedic and pain management settings; 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, HICPAC guidelines, and other evidence-based guidance. This guide provides information on the fundamental components of Standard Precautions and practices to be taken with all patients in orthopedic and pain management 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.

This document does not replace existing CDC guidelines,<sup>2</sup> which as noted 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).

This guide was primarily designed to address the needs of orthopedic and pain management office-based settings. In addition to the office setting, this guide applies to mobile, remote, and temporary medical clinics. While much of the content in this guide is applicable to settings in which ambulatory surgery and other invasive procedures take place, the guide was not designed for surgical settings, nor does it include the expansive body of literature related to preventing surgical site infections (SSIs). Neither does it address topics related to pre-, intra-, or postoperative recommendations for the prevention of SSIs (including ambulatory joint replacement surgery), such as antimicrobial prophylaxis, surgical attire, or surgical technique. Several other detailed resources provide such guidance.<sup>3-6</sup>

Intended users of this document include frontline clinicians and practitioners, patient care technicians and medical assistants, infection control personnel, quality and safety personnel, staff educators, environmental services, practice administrators and leadership, and others who have oversight and/or day-to-day responsibility for preventing infections. The document should be used as a starting point for facilities that do not have an existing plan, to aid in developing a facility-specific plan that can be updated and supplemented as needed, based on the types of services provided. Facilities that have a plan should ensure that their current IPC policies and procedures include the elements covered in this document.

Every orthopedic and pain management facility is unique based on the type of patients seen and the procedures most often performed. Additionally, the level of resources available to providers may vary. Therefore, this guide serves as a resource to help facilities prioritize their goals as they develop or

enhance their IPC program. All medical settings are encouraged to comply with state and federal requirements that apply to their facility and personnel. For example, the Occupational Safety and Health Administration (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, including orthopedic and pain management clinics, have been reported with increased frequency in the last several years.<sup>7,8</sup> These outbreaks have resulted in hospitalizations for patients and have negatively

impacted public trust because providers failed to follow the most basic IPC concepts.<sup>7</sup> Examples of outbreaks are listed in the Infection Surveillance, Reporting, and Record-Keeping section of this guide.

Reports describe the transmission of Gram-negative and Gram-positive bacteria, mycobacteria, viruses, parasites, and outbreaks and other adverse events resulting from breaches in basic IPC practices (e.g., reuse of syringes resulting in the transmission of bloodborne pathogens, reuse of single-dose medication vials).<sup>9,10</sup> The challenge of consistently providing safe care is not always met, as evidenced by increasing reports of outbreaks associated with unsafe injection practices and related breaches in basic IPC practices.<sup>7</sup>

## 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 setting.

#### 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 IPC 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 facility's leadership. Leadership is accountable for ensuring that staffing and resources do not prevent HCP from consistently adhering to IPC activities.<sup>1</sup>

#### Importance of Trained Infection Preventionist Involvement

IPC programs must extend beyond OSHA bloodborne pathogens training. At least one individual with training in IPC should be employed by the facility, or should be regularly available (e.g., by contract), to advise on the facility's IPC program. Healthcare facilities should ensure that this individual is involved in developing written IPC policies and has regular communication with HCP to address specific issues or concerns related to IPC, including plans for

*“Approaches to providing the necessary oversight in all ambulatory settings need to be identified and implemented. These include not only having an appointed representative who is responsible for ensuring that the facility or practice is in compliance with all legal and infection-control accreditation standards and other current guidelines and infection-control recommendations, but also that the means by which staff are supervised and the procedures by which potential problems or errors are reported are explicit and clear.”*

Williams IT, Perz JF, Bell BP. Viral hepatitis transmission in ambulatory health care settings. *Clin Infect Dis*. 2004 Jun 1;38(11):1592–1598.

equipment purchases and engineering and maintenance issues for the environment of care. This individual should be empowered and supported to ensure the effectiveness of the IPC program.<sup>1</sup>

To assist in organizing and ensuring accountability within your IPC program, please see Appendix D for an example list of IPC roles and responsibilities.

#### IPC Policies and Procedures

The first step in developing policies and procedures is to identify the services provided by the facility and to

identify the patient population served. The development and ongoing refinement of policies and procedures should be based on evidence-based guidelines, regulations, and/or standards. Written policies and procedures should be tailored to the facility and should clearly reflect the safeguards needed to prevent disease transmission when performing services and procedures. Additionally, all facilities should have policies and protocols for the early detection and management of potentially infectious persons at initial points of patient encounter. Note that IPC-related policies and procedures should be applied to both staff and contracted personnel. 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 maintaining a safe work environment for patients, 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 health care setting and should be conducted at least annually and whenever new procedures or risks are identified.<sup>11,12</sup>

Facility 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 resources and focus extra attention on areas determined to pose greater risk to the patient population. For example, a healthcare setting that performs on-site sterilization of reusable surgical devices would be expected to have more detailed policies regarding device reprocessing than a primary care clinic, where on-site sterilization is less

### Key Recommendations for IPC Program and Infrastructure

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

Leadership should:

1. 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.
2. Develop written infection prevention policies and procedures appropriate for the

services provided by the facility and based on evidence-based guidelines, regulations, or standards.

3. Ensure availability of sufficient and appropriate supplies necessary for adherence to Standard Precautions (e.g., hand hygiene products; PPE; injection equipment, including devices to reduce percutaneous injuries).
4. Develop a system for early detection and management of potentially infectious persons at initial points of patient encounter.
5. Reassess policies and procedures at least annually.

likely to be performed. Both types of facilities, however, should have policies and procedures addressing handling of reusable medical devices.

### 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 performed in the outpatient setting. The next step is to assess the facility's program and practices. A helpful tool in assessing the organization's practices is the Infection Prevention Checklist for Outpatient Orthopedic and Pain Management Settings (Appendix A), which accompanies this guide. Determine which procedures and tests are done most frequently and which ones are most invasive.

## 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.<sup>13</sup>

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 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 HAIs, patients should be educated in recognizing signs and symptoms of infection and instructed to notify the facility if such signs or symptoms occur. Clinicians should consider

### Key Recommendations for Conducting Facility Risk Assessments

1. Inventory or list facility services and procedures.
2. Perform a facility risk assessment at least annually to help prioritize resources and to focus extra attention on areas that pose greater risk to patients.
3. Tailor policies and procedures to the facility, based on the facility's risk assessment, and reassess on a regular basis.

developing a protocol for early identification of infection in patients who have undergone procedures, possibly by scheduling routine follow-up phone calls or visits for all postprocedure patients.<sup>14</sup> Many education tools for this purpose are available for download.<sup>15-19</sup>

### Disease Reporting

At a minimum, outpatient settings must adhere to local, state, and federal requirements for reportable disease and outbreak reporting. Outpatient settings should check the requirements for their state or region to ensure that 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. A list of state reportable diseases and conditions from the Council of State and Territorial Epidemiologists website is available at: <http://www.cste.org/?page=StateReportable>. Use Appendix D as a place to insert your state information and local contacts.

*“In this [outbreak] investigation, clinic staff were unaware of state reporting requirements that all outbreaks should be immediately reported to the local health department. This outbreak likely would have gone unidentified except for the hospital-based providers and infection preventionists who recognized three hospitalized patients experiencing similar infections after injections at the same pain clinic and reported this to the local health department.”*

Radcliffe R, et al. Severe methicillin-susceptible *Staphylococcus aureus* infections associated with epidural injections at an outpatient pain clinic. *Am J Infect Control*. 2012 Mar;40(2):144–149.

Staff should be alert to possible indications of clusters or outbreaks of infection that may be associated with patient care and report these concerns to local health authorities. Prompt identification and reporting of such concerns contribute to the ability of public health staff and other stakeholders to quickly identify sources of infection and appropriately intervene to prevent additional infections from occurring. For example:

- An astute clinician notified the Tennessee Department of Health of a patient diagnosed with *Aspergillus fumigatus* meningitis following an epidural steroid injection. This report helped uncover a 2012 multistate outbreak of fungal meningitis and other infections that occurred among hundreds of patients who received contaminated steroid injection medications manufactured at a New England compounding center.<sup>20</sup>
- An alert staff member at a county public health department in New York noticed that two patients who had been newly diagnosed with hepatitis C virus (HCV) had recently received epidural injections from the same pain management clinic. This realization sparked a visit by state public health officials to the clinic. During the visit, they observed the physician who treated both patients withdrawing medication from a multi-dose vial (MDV) with a previously used syringe topped with a new needle, a serious breach of safe injection practices that may have contaminated the vial and exposed subsequent patients to potential bloodborne infections. The physician was not aware of the risk posed by this practice.<sup>21</sup>
- The New York City Department of Health and Mental Hygiene (DOHMH) was notified by a hospital infection preventionist that four patients were recently admitted for surgical debridement of laboratory-confirmed methicillin-susceptible *Staphylococcus aureus* (MSSA) skin and soft tissue infections after receiving outpatient steroid injections in December 2011. DOHMH initiated an investigation to determine whether the illnesses were related to common exposures, identify the source of the outbreak, and recommend IPC improvements to prevent future outbreaks. The investigation revealed a pervasive lack of aseptic technique that led to multiple opportunities for medication contamination.<sup>22</sup>
- The Oklahoma State Department of Health and the CDC investigated the occurrence of unexplained HCV infections in six patients who were treated at the same pain remediation clinic in 2002. Further testing of patients at the clinic identified a total of 102 out of 795 patients to have HCV or hepatitis B virus (HBV) infection during the study period. Review of staff practices identified a nurse anesthetist who used the same syringe needle to sequentially administer sedation medications to every treated patient each clinic day.<sup>23</sup>
- The Kentucky Department of Public Health was notified of an epidemiologically linked cluster of methicillin-resistant *Staphylococcus aureus* (MRSA) infections in patients who had received joint

injections at an orthopedic clinic. Five patients were hospitalized with complaints of increased pain in a knee joint after receiving a joint injection at the clinic. All had received an injection of bupivacaine, lidocaine, and methylprednisolone acetate on the same day.<sup>24</sup>

- The Pennsylvania Department of Health investigated an outbreak of invasive MRSA at an outpatient pain clinic. Infections suffered by eight patients involved in the outbreak included bacteremia, epidural abscess, osteomyelitis, and retroperitoneal abscess. All received injections containing iohexol radiographic contrast dye, lidocaine, triamcinolone, 0.9% sodium chloride, and bupivacaine. The investigation revealed that the outbreak likely occurred due to contamination of single-dose vials of contrast dye that were inappropriately used for multiple patients across multiple days, exacerbated by poor hand hygiene.<sup>25</sup>

### Ongoing Practice Monitoring

Regular, focused practice surveys or audits (e.g., audits of IPC practices including hand hygiene, medication handling, reprocessing of reusable devices) offer a means to ensure ongoing adherence of HCP to recommended practices. One such tool is the Infection Prevention Checklist for Outpatient Orthopedic and Pain Management 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. Outpatient settings 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 practice was not being performed, and appropriately educate or re-educate HCP (as applicable). The risk posed to patients by the deficient practice(s) should be evaluated. Certain lapses (e.g., reuse of a syringe on more than one patient; reuse of a syringe to withdraw

medication from an MDV and then using that medication for another patient; 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 the CDC's *Steps for Evaluating an Infection Control Breach* (available at: [https://www.cdc.gov/hai/outbreaks/steps\\_for\\_eval\\_ic\\_breach.html](https://www.cdc.gov/hai/outbreaks/steps_for_eval_ic_breach.html)). Additionally, the CDC has developed a *Patient Notification Toolkit* (available at: <https://www.cdc.gov/injectionsafety/pntoolkit/>) to help healthcare facilities conduct such notifications.

### Audit and Feedback

Internal surveillance reports should be prepared and distributed periodically to appropriate HCP 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 is keeping records of the care delivered. The “who, what, when, and where” of patient visits should be completely and accurately recorded, as would be done to provide documentation of the care delivered to any third-party payers. This also promotes and demonstrates adherence to IPC protocols for safe care:

- *Who* was seen, and by whom — names of patient and of those who provided the care (physician and any assistants)
- *What* was done — procedure(s) performed, medications used or prescribed, and any instructions for continuing care

## Key Recommendations for Surveillance, Reporting, and Record-Keeping in Orthopedic and Pain Management Settings

1. Maintain accurate and timely records of care provided to patients, whether the care takes place in the office or in an off-site setting, such as a mobile clinic.
2. Educate patients who have undergone procedures at the 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.
3. Adhere to local, state, and federal requirements regarding HAI surveillance, reportable diseases, and outbreak reporting; most states require reporting of unusual occurrences of infections and possible (not just confirmed) outbreaks.
4. Ensure the facility has an updated list of diseases reportable to the public health authority and makes it readily available to all personnel.
5. Routinely audit (monitor and document) adherence to proper practices and provide feedback to staff regarding performance as part of internal surveillance.
6. Use the Infection Prevention Checklist for Outpatient Orthopedic and Pain Management Settings (Appendix A) to assess facility practices.
7. Evaluate the risk posed to patients by the deficient practice(s).
8. Lapses with a previously documented risk of transmission or a high likelihood of blood exposure as a result of the breach (e.g., reuse of syringes on more than one patient or to access a medication container used for subsequent patients; reuse of lancets) should be halted immediately and warrant immediate consultation with state or local health departments and appropriate notification and testing of potentially affected patients.
9. If lapses in correct practice are identified, determine why the correct practice was not performed and appropriately educate or re-educate HCP.
10. Additional resources are available from the CDC (Steps for Evaluating an Infection Control Breach, available at: [https://www.cdc.gov/hai/outbreaks/steps\\_for\\_eval\\_ic\\_breach.html](https://www.cdc.gov/hai/outbreaks/steps_for_eval_ic_breach.html)) and the Patient Notification Toolkit (available at: <https://www.cdc.gov/injectionsafety/pntoolkit/>).

- *When* was the patient seen — date(s)
- *Where* was the patient seen — document the 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

Ongoing education and competency-based training of all HCP is critical for ensuring that IPC policies and procedures are understood and followed. Lack of sufficient healthcare knowledge and skills can directly affect patient safety and quality of care, which can lead

to increased patient morbidity and mortality. Education on the basic principles and practices for preventing the spread of infections should be provided to all HCP, whether employed by the facility or by outside agencies, available by contract, or on a volunteer basis. Training should include both HCP safety (e.g., OSHA bloodborne pathogens training) and patient safety, emphasizing job- or task-specific needs. Training should be provided at these times:

- Upon orientation to the facility, to include any new employees, contract staff, or outside consultants
- When new tasks, procedures, equipment, or supplies are introduced
- Annually and anytime 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 after 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 meet the needs of each category of HCP being trained.

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/teamsteps/officebasedcare/index.html>). Another tool is the AHRQ's Medical Office Survey on Patient Safety

## Key Recommendations for Education and Training of HCP

1. Job- or task-specific infection prevention education and training should be provided to all HCP staff. This includes those employed by outside agencies and those available to the facility by contract or on a volunteer basis.
2. Training should focus on principles of both HCP safety (e.g., OSHA Blood-Borne Pathogens Standard) and patient safety (e.g., Standard Precautions).
3. Training should be provided upon hire and repeated annually and when policies or procedures are updated/revised, and when new tasks, procedures, equipment, or supplies are introduced.
4. Competencies and adherence to job-specific 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.
6. Facility should provide feedback from audits to HCP regarding their performance.

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/medofficersourcelist-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 HCP. The CDC's 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 (including postexposure follow-up and evaluation and prophylaxis as appropriate, at no cost to the employee and supervised by licensed HCP), 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>26</sup>

The American Academy of Orthopaedic Surgeons (AAOS) notes that every medical office and facility should have an occupational health plan for the prevention and treatment of exposures to bloodborne pathogens, including orthopedic settings where surgeons and staff perform procedures that can put them at risk for contact with a patient's blood or other potentially infected body fluids. The AAOS further notes that all HCP who may be exposed to blood or other body fluids should receive the hepatitis B vaccination series.<sup>27</sup>

A process should be in place and known to all HCP regarding the notification of public health authorities when an HCP illness has public health implications or when an illness is required to be reported (e.g., measles, *Mycobacterium tuberculosis* [TB]). The facility should train upon hire and at least annually all HCP

*“Because there is currently no vaccine or post-exposure prophylaxis available to protect HCWs [HCP] against HCV infection, prevention efforts will continue to rely on strict adherence to Standard Precautions, appropriate work techniques, and use of safety devices.”*

Williams IT, Perz JF, Bell BP. Viral hepatitis transmission in ambulatory health care settings. *Clin Infect Dis*. 2004 Jun 1;38(11):1592–1598.

for whom contact with blood or other potentially infectious material is anticipated. The facility should also track HCP exposure events and evaluate event data, and should develop and implement corrective action plans to reduce the incidence of such events. All HCP should receive baseline TB screening prior to placement, with repeat testing if appropriate (based on the facility-level risk assessment). The CDC's *TB Risk Assessment Worksheet* is a tool to guide a healthcare facility through conducting the annual risk assessment (available at: [https://www.cdc.gov/tb/publications/guidelines/AppendixB\\_092706.pdf](https://www.cdc.gov/tb/publications/guidelines/AppendixB_092706.pdf)). Healthcare facilities can work with their state or local health department TB programs for assistance in performing the risk assessment. Referral arrangements for medical services 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 HCP are likely to be exposed to airborne hazards, the facility should have a respiratory protection program that details required worksite-specific procedures and elements for respirator use, including provision of medical clearance, training, and fit-testing at least annually, as appropriate.<sup>28</sup>

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

- Work-exclusion policies 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

Finally, remember that many activities associated with IPC can be considered part of an ongoing process that involves development, measurement, evaluation, and improvement. Additional information and resources are provided in Appendix E.

### Key Recommendations for Orthopedic and Pain Management HCP Safety

1. Facility should have a written policy regarding immunizing HCP, including a list of all required and recommended immunizations for HCP.
2. All 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.
3. 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.
4. Facility should track HCP exposure events and evaluate event data to develop and implement corrective action plans to reduce incidence of such events.
5. All HCP should be screened for TB infection 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).<sup>29</sup>
6. HCP should receive repeat TB testing, if appropriate, based on the facility-level risk assessment, or after exposure to M. tuberculosis.
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.
8. 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. They 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 both to protect HCP and to prevent HCP from spreading infections among patients.<sup>1,27</sup>

The elements of Standard Precautions, described in the sections that follow, include: (1) hand hygiene; (2) use of PPE (e.g., gloves, gown, face masks), depending on the anticipated exposure; (3) respiratory hygiene/cough etiquette; (4) safe injection and 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., for changing a dressing); for other interactions, use of gloves, gown, and a face shield or mask and goggles is necessary.

Education and training on the principles and rationale for recommended practices are a critical part of Standard Precautions because they facilitate appropriate decision making and promote adherence. Further, at the facility level, an understanding of the specific procedures performed and typical patient interactions, as described above as part of policy and procedure development, 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) and handwashing with soap and water, is critical to reducing 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 the ABHR’s activity against a broad spectrum of epidemiologically important pathogens. 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.<sup>30,31</sup> For these reasons, ABHR is the preferred method for 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 *Clostridioides difficile* (also known as *Clostridium difficile*) or norovirus during an outbreak.<sup>1,27,32</sup> Supplies necessary for adherence to hand hygiene should be readily accessible in all areas where patient care is delivered.

## Education and Training

All HCP should be educated regarding appropriate indications for hand hygiene upon hire, prior to provision of care, and annually thereafter. They should understand the importance of working from clean to dirty tasks when working sequentially and should be required to demonstrate competency with hand hygiene after each training. Each facility should routinely audit (monitor and document) adherence to proper hand hygiene practices and provide feedback to staff regarding their 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 CDC's *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 (ABHR) (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.

The indications for hand hygiene can be found in the Key Recommendations for Hand Hygiene in Orthopedic and Pain Management Outpatient Settings text box.

## Key Recommendations for Hand Hygiene in Orthopedic and Pain Management Settings

1. Perform hand hygiene in the following situations:
  - a. Immediately before contact with the patient
  - b. Before performing an aseptic task (e.g., preparing an injection) or handling invasive medical devices
  - c. After contact with the patient or objects in the immediate vicinity of the patient
  - d. After contact with blood, body fluids, or contaminated surfaces
  - e. Before moving from a contaminated body site to a clean body site on the same patient
  - f. Immediately after removal of PPE
2. 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 *C. difficile* or norovirus during an outbreak. Otherwise, the preferred method of hand hygiene in clinical situations is with an ABHR.
3. Supplies necessary for adherence to hand hygiene should be readily accessible in all areas where patient care is being delivered.
4. All HCP should be periodically monitored for adherence to hand hygiene.
5. Facility should maintain records of hand hygiene adherence and provide feedback to staff regarding their adherence.

## B. Personal Protective Equipment (PPE)

### Rationale for Appropriate PPE Use

PPE refers to wearable equipment intended to protect 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. 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 likely to generate splashes or sprays of blood or other body fluids. PPE, other than respirators, should be removed and discarded prior to the HCP's leaving the patient's room or care area. If a respirator is used, it should be removed and discarded (or reprocessed if reusable) after the HCP leaves the patient room or care area and closes the door. Only CDC NIOSH-certified respirators should be used.

An important aspect of selecting PPE is anticipating the nature of the contact with the patient and the anticipated exposure to blood, body fluid, or infectious agents; for example, staff about to perform an incision and drainage need to wear gowns, gloves, and possibly facial protection to protect themselves and to help contain any infectious material.

At the end of a procedure, the provider should use care not to contaminate areas outside of the surgical field with blood. The outer layer of gloves should be changed and the dressing applied while this pair of gloves is clean. Next, the contaminated drapes should be removed and discarded into a designated biohazard container. The provider should then remove the

surgical gown and gloves. Clean, nonsterile gloves should be used to handle any equipment that is not grossly contaminated. These gloves should then be removed, and the provider should wash hands. All contaminated clothing should be removed in a manner that avoids contact with blood. Care must be taken to avoid contamination of other areas with bloody shoe covers, gloves, or scrub attire.<sup>27,32</sup>

Hand hygiene is always the final step after glove removal and when removing and disposing of other PPE.

### Education and Training

All HCP should be educated regarding the proper selection and use of PPE. One approach to and sequence of donning and doffing PPE is described below. Resources to help promote patient safety and increase the safety of the healthcare work environment through improved use of PPE by HCP, including a poster illustrating 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 precautions 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 first 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 mask or respirator 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 the room).
- Removal of gloves:
  - Grasp outside of glove with opposite gloved hand; peel off.
  - Hold removed glove in gloved 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 earpieces and discard.
- Removal of gowns:
  - Remove in such a way as to prevent contamination of clothing or skin.
  - Turn contaminated outside surface toward the inside.
  - Roll or fold into a bundle and discard.
- 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.
- Perform hand hygiene immediately after removing PPE.

## Key Recommendations for Use of PPE in Orthopedic and Pain Management Outpatient Settings

1. Facility should ensure that sufficient and appropriate PPE is available and readily accessible to HCP.
2. Facility should educate all HCP on proper selection and use of PPE.
3. 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 the HCP leaves the patient room or care area and closes the door.
5. Hand hygiene should be performed immediately after removal of PPE.
6. 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.
7. 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.
  - b. Remove gown and perform hand hygiene before leaving the patient's environment (e.g., exam room).
8. Mouth, nose, and eye protection should be worn during procedures likely to generate splashes or sprays of blood, or other body fluids.
9. A face mask (e.g., surgical mask) should be worn when placing a catheter or injecting material into the epidural or subdural space, such as during a myelogram or when administering epidural anesthesia (as discussed on page 22).

Each 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 HCP at the facility should be educated regarding proper selection and use of PPE.

## C. Respiratory Hygiene/Cough Etiquette

### Rationale for Respiratory Hygiene/Cough Etiquette

Respiratory hygiene/cough etiquette is an element of Standard Precautions that highlights the need for prompt implementation of infection prevention

measures at the first point of 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 when entering the facility. Refer to the CDC's *2007 Guideline for Isolation Precautions* (available at: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines.pdf>) or Appendix C for more information about respiratory hygiene/cough etiquette.

### Key Recommendations for Respiratory Hygiene/Cough Etiquette in Orthopedic and Pain Management Settings

1. Implement measures to contain respiratory secretions in patients and accompanying individuals who have signs and symptoms of a respiratory infection, beginning at point of entry to the facility and continuing throughout duration of the visit.
  - a. Post visual alerts (e.g., signs, posters) at facility entrances with instructions to patients with symptoms of respiratory infection to do the following:
    - o Inform HCP of symptoms of a respiratory infection when they first register for care.
    - o Cover their mouths/noses when coughing or sneezing.
    - o Use and appropriately dispose of tissues.
    - o Perform hand hygiene after hands have been in contact with respiratory secretions.
  - b. Provide tissues and no-touch receptacles for their disposal.
  - c. 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 people upon their entry to the facility, at a minimum, during periods of increased respiratory infection activity in the community.
  - e. Provide space and encourage people 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.
2. Educate HCP on the importance of infection prevention measures for containing respiratory secretions to prevent the spread of respiratory pathogens.
3. Educate HCP to 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 and Medication Storage and Handling Practices

### Injection Safety

Injected medicines are commonly used in outpatient orthopedic and pain management settings for the prevention, diagnosis, and treatment of various illnesses and injuries (e.g., ultrasound guided injections, viscosupplementation [i.e., injection of lubricating fluid into a joint], trigger point injections, refilling of intrathecal pain pumps, trial spinal cord stimulation). Unsafe injection practices put patients and HCP at risk of infectious and noninfectious adverse events. Serious outbreaks have been associated with a variety of outpatient orthopedic and pain management procedures and settings. This harm is preventable. Safe injection practices are part of Standard Precautions and are aimed at maintaining basic levels of patient safety and provider protections.<sup>33</sup>

Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, or between a patient and a healthcare provider 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).

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, and intravenous (IV) tubing. It remains a common misperception, however, that contamination is limited to the needle device when a syringe and needle are used as a unit. This mistaken belief may underlie some risky behaviors. As decades of experimental studies have demonstrated, contamination does extend to the syringe when injections are administered by the intramuscular, intradermal, IV, or other routes.<sup>7</sup>

*“Failures to adhere to basic principles of aseptic technique for the preparation and administration of parenteral medications have resulted in outbreaks in ambulatory care settings. These outbreaks have raised concerns that some health care workers . . . do not consistently adhere to fundamental infection control principles, aseptic techniques, and safe injection practices.”*

Williams IT, Perz JF, Bell BP. Viral hepatitis transmission in ambulatory health care settings. *Clin Infect Dis*. 2004 Jun 1;38(11):1592–1598.

While intradiscal injection therapy for the treatment of pain carries a small risk of both superficial and deep infections, the introduction of a needle or other treatment device into the intervertebral disc does carry the risk of introducing microorganisms. This underscores the importance of following evidence-based practices, including aseptic technique and safe injection practices, in the management of patients receiving such therapies.<sup>34</sup>

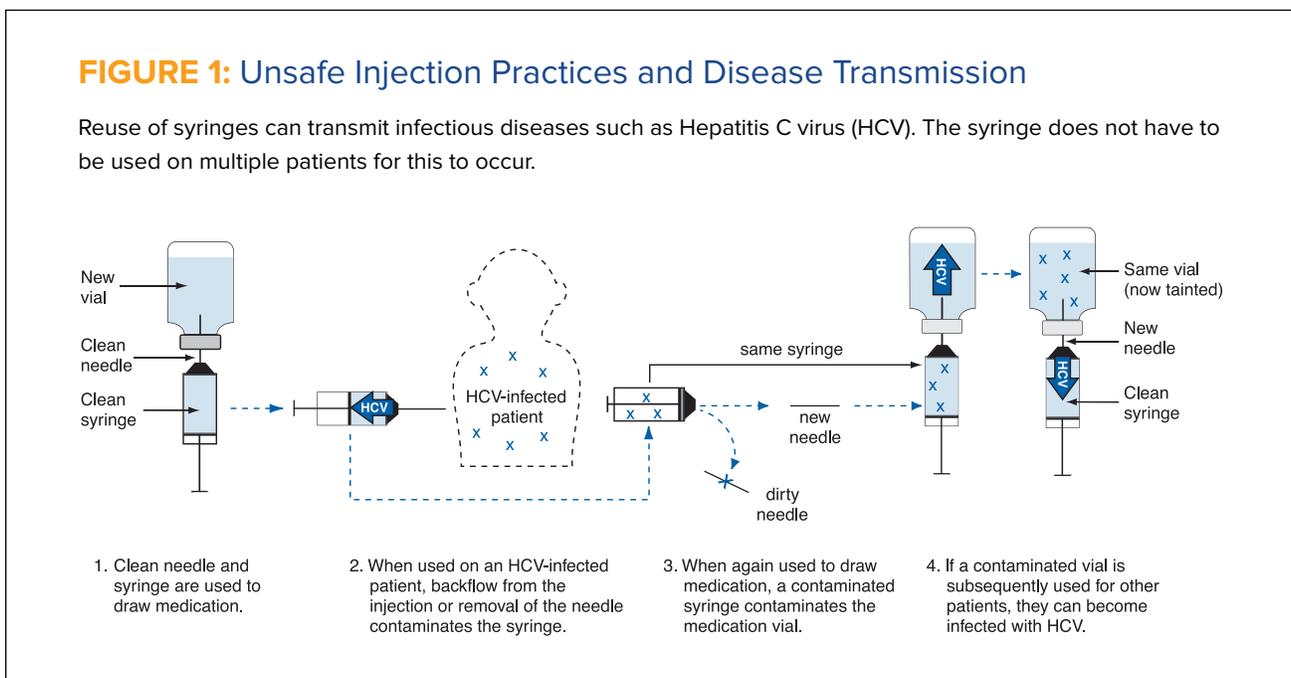
Regional anesthesia carries with it the risk of infectious complications, and with some procedures (e.g., neuraxial anesthesia and analgesia), these complications can be especially concerning, potentially resulting in meningitis, paralysis, or even death.<sup>6</sup> While the relationship between contamination, colonization, and clinical infection may not always be clear, most experts recommend that exhaustive efforts be directed at minimizing both intrinsic and extrinsic sources of infection whenever performing a regional anesthetic technique.<sup>5</sup> Removing jewelry before hand hygiene, hand hygiene before gloving, and use of sterile gloves are all prudent IPC practices.<sup>6</sup>

The patient's skin is a major source of pathogens for a surgical site infection, which elevates the importance of using an appropriate skin antiseptic agent when performing a neuromodulation procedure such as spinal cord stimulation. Ideally, antiseptic agents should have the following characteristics: 1) broad-spectrum antimicrobial activity, 2) rapid bactericidal activity, 3) prolonged efficacy following application, 4) maintenance of bactericidal and bacteriostatic effects in the presence of organic matter, 5) limited systemic exposure, and 6) lack of skin irritant properties. Chlorhexidine-based products for skin preparation, allowing for adequate drying time, appear to be the antiseptic agents of choice for neuromodulation procedures.<sup>35-37</sup>

The success of Standard Precautions, first recommended in the CDC's *1996 Guideline for Isolation Precautions in Hospitals*,<sup>38</sup> has led to a reaffirmation of this approach as the foundation for preventing transmission of infectious agents in all healthcare settings. Updates and additions to Standard Precautions, and safe injection

practices in particular, include the use of a mask when performing certain high-risk, prolonged procedures involving spinal canal punctures. This recommendation grew from evidence of an associated risk for developing meningitis caused by respiratory flora. Wearing a face mask shields against droplet spread of oral flora during spinal procedures. In October 2005, HICPAC reviewed the evidence and concluded that the additional protection of a face mask for the individual placing a catheter or injecting material into the spinal or epidural space is warranted.<sup>39,40</sup>

For other spinal procedures (e.g., diagnostic and therapeutic lumbar punctures) or handling of devices to access cerebrospinal fluid (e.g., Ommaya reservoir), there is limited evidence of a similar risk. At a minimum, HCP should use aseptic technique and follow safe injection practices, such as dedicating single-dose vials (SDVs) to single-patient use for these procedures; a face mask can be considered an additional precaution.<sup>40</sup> Figure 1 illustrates how unsafe injection practices can lead to disease transmission.



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](https://www.cdc.gov/injectionsafety/PDF/SIPC_ProviderBrochure.pdf)

## Scenario

A medical assistant prepares for a busy day of trigger point injections in an outpatient pain management office. He looks for available space on a cluttered counter in a patient exam room to draw up several syringes of cortisone. He moves used patient care items to the side and lays out a paper towel on the counter on which he puts his supplies. He attaches the needle to the first syringe. He preps the septum of the MDV by wiping it with the alcohol wipe and then inserts the needle. He notices that the vial does not have an expiration date, but he proceeds to draw up the first syringe. He leaves the needle inserted in the vial septum, separates the needle hub from the syringe, attaches the second syringe, and then proceeds to draw up the medication. He repeats the process until all syringes are filled. He leaves the unlabeled syringes in a bin in the patient exam room cabinet.

## Process Errors

- The MDV was brought from the centralized medication area to the patient room.
- The MDV was not marked with an expiration date.
- The patient exam room was not properly cleaned after patient use. The countertop had used patient care items that had not been removed, and there was no indication from the scenario that the countertop had been cleaned.
- Hand hygiene was not performed prior to medication preparation.
- The syringes were not marked with the name and dose/concentration of the medication or the date and time of preparation.

## Process Recommendations

- Limit the use of MDV whenever possible. If MDVs are used for more than one patient, they should not be brought outside the central medication area to patient rooms or other treatment areas.
- Hand hygiene, either with ABHR or soap and running water, should always be performed before handling medications.
- A needle should never be left inserted into a medication vial septum for multiple uses. This provides a direct route for microorganisms to enter the vial and contaminate the fluid.
- Medications should be drawn up in a designated clean medication area that is not adjacent to areas where potentially contaminated items are placed. If medication preparation takes place in the patient treatment area (outside a designated medication room), the area should be cleaned after each patient encounter.
- MDVs should always be dated upon opening with the beyond-use date. MDVs are only good for 28 days from the date of opening unless the manufacturer stipulates another beyond-use date.
- Prefilling and storing batch-prepared syringes should be avoided except in accordance with pharmacy standards.<sup>41</sup>
- Prefilled syringes should always be dated with the medication type, dose/concentration, and the date and time of being prepared.
- Whenever possible, use commercially manufactured or pharmacy-prepared prefilled syringes.

## Unsafe Practices That Can Lead to Patient Harm

Further attention to patient protection is 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.<sup>42</sup> Unsafe practices that have led to patient harm include:

1. Use of a single syringe, with or without the same needle, to administer medication to multiple patients, even if the needle was changed or the injection was administered through an intervening length of IV tubing.
2. Reinsertion of a used syringe, with or without the same needle, into a medication vial or solution container (e.g., saline bag) to obtain additional medication for a single patient and then using that vial or solution container for subsequent patients.
3. Failure to use aseptic technique when preparing and administering injections.
4. Preparation of medications in an undesignated or unclean area such as on a contaminated countertop adjacent to sinks.

It should further be noted that HCP who divert injectable medications such as opioids may also serve as sources of provider-to-patient transmission of infections. Policies and procedures should be in place to track HCP access to controlled substances. If controlled substances are administered by the clinic, they should ensure there are policies and procedures in place to prevent, detect, and respond to drug diversion. See <https://www.cdc.gov/injectionsafety/drugdiversion/index.html> for additional information about drug diversions.

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

## Outbreak Summary

**An outbreak of forty-one septic arthritis cases associated with intra-articular injections administered in an outpatient practice was identified in New Jersey in March 2017. Multiple breaches of recommended IPC practices were identified in the course of a public health investigation, including the preparation and administration of pharmacy bulk products (PBPs), which are intended for single-use as outlined by United States Pharmacopeia (USP) standards. Breaches included the mistaken belief by staff members that PBP contrast material could be used as a multi-dose container outside of pharmacy conditions (e.g., use of a laminar flow hood, in accordance with sterile compounding standards). These breaches resulted in contamination of the product and served as a source of pathogens for multiple patients.<sup>43</sup>**

patient notification toolkit, are also available at: <http://www.cdc.gov/injectionsafety/>. See the Key Recommendations for Safe Injection and Medication Storage and Handling Practices text box.

## Fluoroscopy-guided Injections

For injections that require the aid of fluoroscopic guidance, it is important to remember that the fluoroscopy machine may become a source of contamination particularly with maneuvering of the C-arm. To protect the integrity of the sterile field with open, invasive procedures, the C-arm must be appropriately covered or draped. While it may not be necessary to cover or drape the fluoroscope C-arm in the outpatient setting where minimally invasive procedures are performed, care should be taken to avoid making contact with the C-arm to minimize contamination of the sterile field.<sup>44</sup>

## Medication Storage and Handling

In general, 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 outpatient settings. Medication preparation should take place in a designated clean medication area that is not adjacent to potential sources of contamination (e.g., sinks, areas where contaminated items are placed). Any item that could have come in contact with blood or body fluids should not be in the medication preparation area. To the extent possible, medication preparation should occur in dedicated medication rooms. All personnel who use or handle parenteral medications and related supplies should be aware of labeling and storage requirements. For example, one outbreak was associated with inappropriate refrigeration.<sup>45</sup>

Manufacturer's recommendations for safe storage of medications may vary, even within a class of drugs, so HCP should carefully follow manufacturer's instructions. As described in the example below and the scenario presented later in this guide, sometimes lidocaine needs to be refrigerated and sometimes it does not. Medications that require refrigeration should be stored in a dedicated, labeled refrigerator that meets requirements for such storage (e.g., thermostat control). In the event of a power outage for a day or more, any medication that requires refrigeration should be thrown away, unless the medication label says otherwise.<sup>46</sup>

The practice of combining two or more medications into a single syringe is considered compounding by the Food and Drug Administration (FDA). Compounding of sterile medications should be performed according to standards from the USP 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 controls.<sup>47</sup> It should be noted that this outpatient guide is not intended to describe the standards and recommended practices for sterile compounding. If compounding, as defined by the FDA,<sup>48</sup> is performed in your facility, refer to other guidelines/standards, including USP 797.<sup>47</sup>

The CDC notes that it is not possible to visually inspect vials or syringes to determine whether they are free from contamination. However, if there are visible signs of contamination (e.g., cloudy liquid or particulate matter), the medication should be discarded. Pathogens, including HBV, 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

*“A multiple-dose vial (MDV) of lidocaine was likely contaminated with S. aureus and the source of an outbreak. A possible contributing factor was refrigeration after the use of MDVs of lidocaine; the manufacturer had recommended storage at room temperature. Refrigeration allowed the prolonged survival of microorganisms in the extrinsically contaminated medications. The Centers for Disease Control and Prevention has recommended, therefore, that the manufacturer’s instructions be consulted to determine the proper storage temperatures of MDVs, which are product specific.”*

Kirschke DL, et al. Outbreak of joint and soft-tissue infections associated with injections from a multiple-dose medication vial. *Clin Infect Dis*. 2003 Jun 1; 36(11):1369–1373.

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.

All HCP should maintain accurate and timely records of all aspects of medication storage and handling (for example, refrigerator temperature log, inventory monitoring for expiration dates).

### Education and Monitoring of HCP

To ensure safe injection practices in all healthcare settings, a multifaceted approach that focuses on surveillance, oversight, enforcement, and personnel competency, continuing education and accountability is needed.<sup>49</sup>

### Safe Use of Injectable Medications

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

- Single-dose (or single-use) vials 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 SDVs that have been opened or accessed (e.g., needle-punctured), 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.
- Multi-dose vials 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, this preservative generally has no effect on viruses and does 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 or treatment area), it should be dedicated to that patient and discarded after use. Although MDVs can be used for more than one patient when aseptic technique is followed, ideally MDVs are used for only one patient (see the CDC's One & Only Campaign, at: <http://www.oneandonlycampaign.org/>). If an MDV has been opened or accessed (e.g., needle-punctured) 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.<sup>50</sup>

- Bags or bottles of IV solution (e.g., saline) should not be used for more than one patient.

### Contrast Media

Contrast media used in imaging studies can also become contaminated and serve as a source of infection if not handled safely. Outbreaks of infection in outpatient orthopedic and pain management practices have repeatedly been associated with inappropriate use of SDVs or pharmacy bulk packaged contrast media for more than one patient.<sup>43,51-53</sup>

Facilities should follow the labeling on the contrast media packaging. Unless a container is specifically labeled as "multi-dose" it should not be used for more than one patient, even if it contains more medication than needed for a single patient. SDVs should be dedicated for a single patient as part of a single procedure. Any contrast medium remaining at the end of the procedure should be discarded. Products labeled as "pharmacy bulk package" or "PBP" are intended only for use in a pharmacy setting using standards outlined by USP.

## Scenario

A physician at a pain management clinic typically performs multiple lumbar epidural steroid injections daily. The physician draws up the contrast agent from SDVs that contain more agent than is required for a single patient, so leftover contents are combined for use with other patients throughout the day. Anticipating a busy day, he proceeds to draw up multiple syringes on the procedure room counter and places them in a bin in the procedure room cabinet. The physician dons gloves and, under the guidance of a mobile C-arm fluoroscope, administers each lumbar epidural steroid injection using aseptic technique, although he doesn't wear a face mask. He removes his gloves after the procedure but doesn't wash his hands before seeing the next patient.

### Process Errors

- An SDV of contrast solution was used for more than one patient.
- Syringes were prefilled and saved for administration later in the day.
- An alcohol pad was not used to swab the medication vial stopper prior to drawing up the contrast agent.
- Syringes were not marked with the name and dose/concentration of the medication or the date and time of preparation.
- A face mask was not worn during the spinal injection procedure.
- Hand hygiene was not performed both before donning gloves and after glove removal.
- The counter was not cleaned after drawing up medications.

### Process Recommendations

- Adherence to safe injection practices is crucial, including the use of aseptic technique and using an SDV of medication or contrast solution for only one patient.
- A face mask should always be worn when injecting material or inserting a catheter into the epidural or subdural space. Face masks are effective in limiting the dispersal of airborne droplets.<sup>41</sup>
- It is important to maintain meticulous precautions to keep the field sterile and avoid contamination from the C-arm.<sup>44</sup>
- Hand hygiene, either with ABHR or soap and running water, should always be performed before donning gloves and after glove removal. Wearing gloves is not a substitute for hand hygiene.
- Prefilling and storing batch-prepared syringes should be avoided except in accordance with pharmacy standards.<sup>41</sup>
- Prefilled syringes should always be dated with the medication type, dose/concentration, and the date and time of being prepared.
- Medications should be prepared as close as possible to the time of administration.
- A separate alcohol pad should be used to swab medication vial stoppers prior to piercing.
- 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).

## 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 might be unavoidable in some situations. 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 from potentially contaminated objects or surfaces.

The product label and packaging should be read thoroughly. As with any other medication, topical products intended for single use and/or labeled as single use by the manufacturer must be disposed of after use on one patient. Likewise, products should be monitored for expiration dates and discarded when the beyond-use date has been met.<sup>42</sup>

### Key Recommendations for Safe Injection and Medication Storage and Handling Practices

1. Use aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment when preparing and administering medications.
2. Cleanse the access diaphragms of medication vials with 70% alcohol and allow to dry before inserting a device into the vial.
3. Never administer medications from the same syringe to multiple patients, even if the needle is changed or the injection is administered through an intervening length of IV tubing.
4. Avoid prefilling and storing batch-prepared syringes except in accordance with pharmacy standards.
5. Use commercially manufactured or approved pharmacy-prepared prefilled syringes (for example, heparin, saline) whenever possible.
6. Select vial sizes that most appropriately fit the procedure needs of the facility and limit the need for sharing of MDVs when making a purchasing decision.
7. Never reuse a syringe to enter a medication vial or container.
8. Never administer medications from SDVs, ampoules, or bags or bottles of IV solution to more than one patient (e.g., do not use one bag of saline as a common source supply for multiple patients).
9. Never use fluid infusion or administration sets (for example, IV tubing) for more than one patient.
10. 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).
11. Dispose of used sharps at the point of use in a sharps container that is closable, puncture-resistant, and leakproof.
12. Ensure policies and procedures are in place regarding the tracking of HCP access to controlled substances to prevent narcotics theft/diversion.
13. Ensure the facility has policy and procedure for topical medication storage that includes:
  - Monitoring for expiration dates
  - Disposing of single-use topical medications after use

### Scenario

When preparing to give an intra-articular injection to a patient with knee pain, a physician assistant in an orthopedic outpatient office retrieves an MDV of lidocaine from the refrigerator. After drawing up the medication, she puts the vial back in the refrigerator, thinking this method of storage provides the best IPC practice. Using a separate syringe, the physician assistant proceeds to draw up the contrast agent using a previously opened vial, not realizing it was intended to be an SDV.

### Process Errors

- The solution was automatically refrigerated without regard to manufacturer's recommendation. Although counterintuitive, refrigeration of open MDV medications after use is not always recommended; checking the labeling may reveal that refrigeration can prolong the persistence of microorganisms and has been cited as a potentiating factor in previous outbreaks.<sup>45</sup>

- An SDV was used for more than a single patient and for more than a single case/procedure/injection.

### Process Recommendations

- The manufacturer's storage requirements should be carefully read. Some manufacturers recommend storage of lidocaine at room temperature. Adherence to manufacturer's instructions for safe storage of MDVs is critical.
- Even if an SDV appears to contain more medication than is needed for a single patient it should not be used for more than one patient.
- Once an SDV has been opened or accessed (e.g., needle-punctured) the vial should be discarded according to the time the manufacturer specifies for the opened vial or at the end of the case/procedure for which it is being used, whichever comes first. It should not be stored for future use.<sup>54</sup>

## General Safe Injection and Medication Storage and Handling Practices

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

## E. Environmental Cleaning

### Rationale for Environmental Cleaning

Outpatient facilities should establish policies and procedures for routine cleaning and disinfection of environmental surfaces as part of their infection prevention program. Cleaning refers to the removal of

visible soil and organic contamination from a device or from an 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. The cleaning process removes large numbers of microorganisms from surfaces and must always precede disinfection. Disinfection is generally a less lethal process of microbial inactivation (compared with sterilization) that eliminates virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

Emphasis for cleaning and disinfection should be placed on surfaces most likely to become contaminated

with pathogens, including surfaces in close proximity to the patient (e.g., exam tables) and frequently touched surfaces in the patient care environment (e.g., doorknobs, cabinet doors, drawers). Outpatient 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). HCP should follow manufacturers' 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) because of product developments and improvements and to ensure that the materials used are consistent with existing guidelines and meet HCP cleaning and disinfection needs.

### Education and Training

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

1. 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 appropriate 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), depending on the infectious or chemical agent and anticipated type of clinical situation, to prevent exposure.

Complete guidance for the cleaning and disinfection of environmental surfaces, including cleaning blood or body substance spills, is available in the CDC's *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 (outside pharmacy/compounding areas), and bathrooms are cleaned at least daily, with the following exceptions:

1. Promptly clean and decontaminate any location having spills of blood and other potentially infectious materials (refer to the Cleaning Spills of Blood and Body Substances section).
2. 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, 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” next page).
4. 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).
  - b. 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 uses blood samples. To prevent blood-borne pathogen transmission, these devices must be cleaned and disinfected after each use in accordance with manufacturer’s instructions.
6. Concentrate on cleaning high-touch surfaces (areas frequently touched by patients and staff) and surfaces in close proximity to the patient, as outlined below for specific rooms/areas.
7. Follow manufacturer’s instructions for cleaning and maintaining noncritical medical devices/ equipment, including blood pressure cuffs. (See Spaulding Classification on page 35)
8. Clean walls, window blinds, and window 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.

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

1. Wear appropriate PPE.
2. In general, cleaning should be performed before disinfection unless a one-step detergent/ disinfectant is used.
3. 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).
6. 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 Spills of Blood and Body Substances

1. Wear protective gloves and use appropriate PPE (e.g., use forceps to pick up any sharps and discard in sharps container).
2. 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.
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. Place paper towels over spill area, 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.

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

### Exam Rooms

1. Change the paper covering the exam table and the pillows between patients; may use absorbent pads to cover work surfaces. If absorbent 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.
2. 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 below for laundering soiled linens.
3. 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 (e.g., exam table, blood pressure cuff, stethoscope, chair and exam table stool, doorknobs) at least daily. Follow manufacturer's instructions for cleaning all equipment and devices.
5. 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 *C. difficile* spores (List K, available at: <https://www.epa.gov/pesticide-registration/list-k-epas-registered-antimicrobial-products-effective-against-clostridium>).

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

1. Focus cleaning on high-touch surfaces and objects, such as patient chairs, blood pressure cuffs, pulse oximetry sensors (following manufacturer's

instructions), and thermometers, at least daily. (If disposable oral temperature probes are used, discard 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 clean the walls if visibly soiled.
3. If the bathroom is used by a patient with known or suspected infectious diarrhea, clean it before it is used again, focusing on the toilet and the area around the toilet:
  - a. 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 *C. difficile* spores (List K; at: <https://www.epa.gov/pesticide-registration/list-k-epas-registered-antimicrobial-products-effective-against-clostridium>).

### Handling and Laundering Soiled Linens

1. Handle all contaminated linens with minimum agitation to avoid contamination of air, surfaces, and people; hold soiled linens away from the body so as not to contaminate skin or clothing.
2. Do not sort or rinse soiled linens in patient-care areas.
3. Use leak-resistant containment for linens contaminated with blood or body substances; ensure 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 use.
5. 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  $\geq 160^{\circ}\text{F}$  ( $\geq 71^{\circ}\text{C}$ ) for  $\geq 25$  minutes.

- b. If low temperature (<160°F [ $<71^{\circ}\text{C}$ ]) laundry cycles are used, wash with proper concentrations of laundry chemicals suitable for low-temperature washing.
6. 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 available from the CDC in Guidelines for Environmental Infection Control in Health-Care Facilities (2003) (available at: <https://www.cdc.gov/infectioncontrol/guidelines/environmental/index.html>).

### Waste Disposal

1. Puncture-resistant, leakproof sharps containers should be located in every patient-care area (e.g., exam room, chemotherapy suite, phlebotomy station).
  - a. Specifically for phlebotomy stations, a sharps container should be located within a short distance of each phlebotomist's work space.
  - b. All sharps should be disposed of in the designated sharps container; do not bend, recap, or break used syringe needles before discarding them into the container.
  - c. Filled sharps containers should be disposed of in accordance with state-regulated medical waste rules.
2. Regular trash and regulated medical waste (e.g., biohazardous material and chemical hazardous waste) should be disposed of in designated containers following local and state regulations.
3. All trash and waste containers should be emptied at least daily by designated personnel.
  - a. Personnel should wear appropriate PPE.
  - b. The handling, transporting, and disposing of regulated waste, including hazardous drugs, should be done in accordance with state and local regulations.

### Construction and Renovation

IPC management of the environment is required during construction, renovation, remodeling, repairs, and building demolition. To minimize the risk of infection to patients in 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 healthcare facilities. While it is beyond the scope of this guide to provide detailed guidance on measures to minimize the risks associated with these activities, 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 in Appendix E.

## F. Medical Devices and Reprocessing

### 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 a goal of any outpatient practice.<sup>7,55</sup>

### Types of Medical Devices

#### Reusable Versus Single-Use Devices (SUDs)

Medical devices are labeled by the manufacturer as either reusable or single-use devices (SUDs). Reusable medical devices (e.g., surgical instruments, ultrasound probes) should be accompanied by instructions for cleaning and disinfection or sterilization as appropriate.

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

## Key Recommendations for Cleaning and Disinfection of Environmental Surfaces

1. 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.
2. Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare.
3. Follow manufacturer's recommendations for use of cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, disposal).
4. Personnel who clean and disinfect patient-care areas (e.g., environmental services [ES] workers, technicians, nurses) should receive training on cleaning procedures:
  - a. Upon hire, prior to being allowed to perform environmental cleaning
  - b. Annually
  - c. When new equipment or protocols are introduced
5. Personnel should be required to demonstrate competency with environmental cleaning procedures following each training.
6. If ES are only available after hours (e.g., contractors from outside agency), then designated facility staff should be assigned specific responsibilities for cleaning and disinfection during clinic hours.
7. 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 clinical situation to prevent exposure.
8. Cleaning procedures should be periodically monitored and assessed to ensure that they are consistently and correctly performed. Periodic feedback should be provided to HCP who perform cleaning procedures.

with the FDA regulatory requirements and have received FDA clearance to reprocess specific SUDs as outlined in the *FDA's Guidance for Industry and FDA Staff* (available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm>). Legally marketed SUDs are available from FDA-registered third-party reproducers.

### 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. 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 facility.<sup>11</sup> If the manufacturer does not provide instructions for cleaning and disinfection, then point-of-care devices should not be used for more than one patient.

## Spaulding Classification for Determining Levels of Disinfection or Sterilization

All reusable medical devices must be cleaned and maintained according to manufacturer's instructions to prevent patient-to-patient transmission of infectious agents. 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. It categorizes these levels as follows:

- Critical items (e.g., surgical instruments, implants, scalpels, burrs) 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., ultrasound equipment touching a wound) contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection (HLD) 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.

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

## Reprocessing Policies

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 HLD and should be followed by all staff who conduct the reprocessing. The facility should also establish policies and procedures outlining the proper response (e.g., risk assessment and recall of device) in the event of a reprocessing error or failure. 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

HCP with responsibility for cleaning and disinfection or sterilization of medical devices should have training in the reprocessing steps and the correct choice of PPE for handling contaminated devices. Additionally, HCP who perform point-of-care testing should 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

Competencies of HCP responsible for reprocessing 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 monitor HCP adherence to proper reprocessing procedures and provide feedback to staff regarding their level of adherence to these procedures.

The facility should also routinely audit (monitor and document) staff members' adherence to recommended practices during point-of-care testing and provide feedback on these practices.

## Space and Resources for Reprocessing

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 clear separation exists 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 that protects them from contamination or damage.

## Care and Maintenance of Devices and Equipment

Qualified personnel should perform routine maintenance of reprocessing equipment (e.g., steam autoclave) in accordance with manufacturer's instructions, and maintenance records should be maintained onsite.

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 by 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 IPC 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.

## Medical Ultrasound

Medical ultrasound is an imaging modality that involves contact between an ultrasound transducer and a patient's skin, mucous membranes, or sterile tissues.

## Consequences of Failed Reprocessing

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

1. Patients at risk for contamination or infection
2. Potential outbreaks
3. Legal action
4. Facility closures
5. Referral of providers to licensing boards for disciplinary action
6. Bad publicity, damage to reputation, or loss of business

*“Multiple published case reports have identified ultrasound gel as the source of health care-associated infections, including those where ultrasound procedures were performed on intact skin. Staff may assume that if the procedure is performed on intact skin, the gel is a noncritical item, but serious Staphylococcus aureus infections have occurred in neonates undergoing noninvasive hip ultrasound procedures.”*

Provenzano DA, et al. Investigation of current infection-control practices for ultrasound coupling gel: A survey, microbiological analysis, and examination of practice patterns. *Reg Anesth Pain Med.* 2013 Sep-Oct;38(5): 415–424.

Risks associated with the transmission of infection can be minimized by following proper use, cleaning, and reprocessing of the equipment.<sup>56</sup> This text will cover three key areas associated with the use of transducers: use of transducer covers, ultrasound gel use, and cleaning/HLD of the probes.

Use of transducer covers reduces the risk of contamination, but these covers frequently contain small, unrecognized perforations even before they are used, and the covers can become further compromised during use.<sup>56</sup> Condoms have been found to be superior to commercially available probe covers for covering the ultrasound probe (1.7% leakage for condoms versus 8.3% leakage for commercial probe covers); studies underscore the need for routine probe disinfection between examinations.<sup>56</sup>

Ultrasound probes used during surgical procedures also may contact sterile body sites, placing them in the category of critical devices requiring sterilization. These probes can be covered with a sterile sheath to reduce the level of contamination on the probe and reduce the risk for infection. Since the sheath does not completely protect the probe, the probes should be sterilized between each patient use as with other critical items. If sterilization is not possible, at a minimum the probe should undergo HLD and be covered with a sterile probe cover.<sup>56</sup> Manufacturer's instructions for probe covers, sterilization, or HLD must be followed.

Because ultrasound transducers are heat sensitive, they need to be sterilized or disinfected with low-temperature chemical/disinfecting agents or by using approved automated systems. Any product used in reprocessing transducers must be compatible with the equipment, as determined by the manufacturer.

The following is a summary of key aspects of the cleaning and disinfecting processes for ultrasound transducers:<sup>56</sup>

- Manually remove all ultrasound gel prior to cleaning.
- Thoroughly clean all surfaces of the medical device, as organic residue may interfere with the contact of the disinfectant with all contaminated surfaces. Follow manufacturer's instructions for cleaning.
- Use an approved sterilant or HLD, as recommended by the manufacturer.
- Thoroughly rinse the transducer with clean water after HLD and dry before use.

Ultrasound gels may be sterile or nonsterile and have been identified as the source of several past infection outbreaks.<sup>57-61</sup> Although these gels contain methyl benzoate or parabens, which are commonly thought to render them bacteriostatic, some Gram-negative bacteria can degrade these components.<sup>58</sup> A CDC report<sup>57</sup> notes that no national guidelines exist in the United States to recommend specific types of gel for specific procedures. In addition, the CDC report further supports a recommendation for the use of only sterile gels for invasive procedures and procedures involving contact with non-intact skin or mucous membranes.<sup>57</sup>

## **G. Sterilization of Reusable Devices**

### **Rationale for 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.

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 the 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 processor, 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 (e.g., 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. Cleaning should be done as soon as practical after use, preferably at the point of use, to prevent soiled materials from drying on the devices. Enzymatic cleaner or detergent should be used for cleaning and should be discarded according to 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 manufacturer's instructions after use.
- 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's *Comprehensive Guide to Steam 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](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 [EtO] gas, 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 a facility's IPC program. Proper testing (see the Monitoring Sterilizer Performance text box) includes:
  - 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 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>).

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.

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 according to 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 indicator 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 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>.

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.

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/faqs/index.html>), and in the textbox titled Key

Recommendations for Cleaning and Disinfection or Sterilization of Medical Devices.

### Aspects of Quality Control Relative to Sterilization

The following should be included 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 should be implemented.
- For each sterilization cycle, a record should be made of the type of sterilizer and cycle used; the load identification number; the load contents; the

#### Scenario

A nurse in an outpatient clinic is preparing instruments for sterilization. She is in a hurry and does not run the cycle with the proper controls for the instruments. When the cycle is done, the nurse sees a very small tear in one of the peel packs and notices that the peel packs are damp, so she sets them out on the counter to dry.

#### Process Errors

- The sterilization process did not include proper control monitoring.
- Placing the damp packs on the counter to dry does not address either the now-compromised state of the packs nor the reason(s) the packs were wet, which signals a potential equipment or human process error.

#### Process Recommendations

- The sterilizer manufacturer's instructions for use must be followed. This includes instructions for the care and maintenance of the sterilizer.

- Mechanical and chemical monitoring should be done for every sterilizer load to help detect process errors and equipment malfunctions. BI testing should be done at least weekly, preferably daily, and in every load containing implants.
- There should be sufficient space between packs as they are loaded to permit air removal and steam penetration. Proper spacing enhances drying.
- A wet load signals a potential equipment malfunction or process error, such as overloading the sterilizer or packaging the instruments incorrectly; a full investigation should take place to identify the cause and correct the problem.
- If the integrity of the packaging is compromised, such as if it is wet or torn, then the item should be considered contaminated and must be repackaged and reprocessed before use.
- Sufficient time should be allowed for reprocessing to ensure adherence to all steps recommended by the device manufacturer.<sup>56</sup>

exposure parameters (e.g., time and temperature); the operator's name or initials; and the results of mechanical, chemical, and biological monitoring.

- Sterilization records (mechanical, chemical, and biological) should be retained for a time period that complies with standards (e.g., three years), statutes of limitations, and state and federal regulations.
- Items to be sterilized should be prepared and packaged so that sterility can be achieved and maintained to the point of use. AAMI or the manufacturers of surgical instruments, sterilizers, and container systems should be consulted 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 immediate-use steam sterilization should be used immediately and should not be 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.
- Preventive maintenance should be performed on sterilizers by qualified personnel who are guided by the manufacturer's instructions.

### 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 agent.
Wrong packaging material for the method of sterilization	Packaging material may melt, and it may prevent 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, edition: *Infection Control and Management of Hazardous Materials for the Dental Team*, 6th ed. St. Louis: Mosby, 2018,113–141.

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>).

## 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, HLD prior to reuse. Unlike sterilization, which renders devices free of all organisms, 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 manufacturer's instructions. If manufacturer's 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 HLD. Cleaning may be manual (i.e., using friction) and/or mechanical (e.g., with ultrasonic cleaners, washer-disinfectors, washer-sterilizers). Precleaning should be performed as soon as

practical after use (e.g., at 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).

### Following Manufacturer's Instructions

For chemicals used in HLD, manufacturer's instructions must be followed for the product preparation, testing for appropriate concentration, and replacement (upon expiration or loss of efficacy). Devices should be disinfected 1) for the appropriate length of time as specified by manufacturer's instructions and 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, 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 that protects them from damage or contamination (e.g., a sealable container or closed drawer that is lined with clean or sterile towels).<sup>56</sup>

Routine maintenance for HLD equipment should be performed according to manufacturer's instructions, and maintenance logs should be maintained.

## Key Recommendations for Cleaning and Disinfection or Sterilization of Medical Devices

1. 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.
2. Evidence-based guidelines should be used when developing policies and procedures for reprocessing.
3. HCP with assigned responsibility for cleaning and disinfection or sterilization of medical devices should have training in the reprocessing steps and the appropriate choice of PPE for handling contaminated devices. Training should be provided upon hire (prior to HCPs being allowed to reprocess devices), annually, and when new devices are introduced or policies/procedures change.
4. HCP should be required to demonstrate competency with reprocessing procedures (i.e., correct technique is observed by trainer) after each training.
5. HCP should have access to and wear appropriate PPE when handling and reprocessing contaminated medical devices.
6. 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.
7. 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.
8. Reusable medical devices should 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:
  - o Enzymatic cleaner or detergent should be used and discarded according to manufacturer's instructions (typically after each use).
  - o For chemicals used in HLD, manufacturer's instructions should be followed for product preparation, testing for appropriate concentration, and replacement (upon expiration of loss of efficacy).
  - o Devices should be disinfected for the appropriate length of time and at the appropriate temperature as specified by manufacturer's instructions, and appropriately rinsed after HLD, also as specified by the manufacturer.
10. HCP adherence to proper reprocessing procedures should be routinely monitored and feedback provided to staff regarding their level of adherence to reprocessing procedures.

## IV. TRANSMISSION-BASED PRECAUTIONS

In addition to consistent use of Standard Precautions, additional precautions may be warranted in certain situations. 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). 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, facility staff should remain alert for any patient arriving with symptoms of an active infection. Patients suspected of having an illness that places others at risk should be separated in another area for further evaluation, or their appointment should be rescheduled.

One way to approach these situations is to have patients, upon arrival to the facility, complete a brief

### Use of Principles of Transmission-Based Precautions for Known or Uncertain Diagnoses

1. Systems should be developed and implemented to permit the early detection of potentially infectious patients (e.g., patients with rashes, diarrhea) at the initial points of entry to the facility.
2. To the extent possible, appropriate action should include prompt placement of such patients in a single room.
3. 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.
4. Precautions should be adjusted or discontinued when more clinical information becomes available (e.g., confirmatory laboratory results).
5. HCP should receive education and training on Transmission-Based Precautions, including Contact Precautions, Droplet Precautions, and Airborne Precautions.
6. HCP should be required to demonstrate competency on Transmission-Based Precautions.
7. 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.
8. Consult the CDC Isolation Guideline for the type and duration of precautions for selected infections and conditions (also available at: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines.pdf>)

symptoms overview, on which they can check off symptoms they might be experiencing (e.g., diarrhea, productive cough, fever). Any concerning symptoms could then be brought to the attention of the nurse, who could further evaluate the need for any special measures (e.g., evaluate patient further, move patient to a single room, or reschedule patient's appointment).

The categories of Transmission-Based Precautions include Contact Precautions, Droplet Precautions and Airborne Precautions. For more information see the CDC 2007 Guideline for Isolation Precautions, available at: <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>).

## V. CONCLUSION

### Conclusion

Infection prevention is an ongoing process important to patients, visitors, and HCP. Outpatient orthopedic and pain management settings are encouraged to use this document as a model to develop, improve, and implement their IPC plans. Facilities are also encouraged to use the Infection Prevention and Control Checklist for Outpatient Orthopedic and Pain Management Settings (Appendix A) to periodically assess their practices to ensure they meet 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 HCP.

The recommendations described in this guide represent the minimum infection prevention expectations for safe care in outpatient settings. This guide is not all-encompassing. 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, outpatient orthopedic and pain management settings can reduce the risk of developing and transmitting infections, thereby improving patient safety and protecting their health care workers.

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## Centers for Disease Control and Prevention (CDC) Infection Prevention and Control Checklist for Outpatient Orthopedic and Pain Management Settings

### Minimum Expectations for Safe Care

The following checklist is a companion to the CDC's Guide to Infection Prevention in Outpatient Orthopedic and Pain Management Settings. This checklist is divided into four sections: The first three sections (Sections A, B, and C) can be used to assess the infection prevention and control (IPC) program and infrastructure; the fourth section (Section D) can be used to conduct observations of facility practices. As such, the checklist should be used:

1. To ensure that the facility has appropriate IPC policies and procedures in place and supplies to allow healthcare personnel (HCP) to provide safe care.
2. To systematically assess personnel adherence to correct IPC 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.)

Orthopedic and pain management settings 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 [HLD]). 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; use of single-dose medication vials for more than one patient; 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
<p>A. Written IPC policies and procedures are available, current, and derived from evidence-based guidelines (e.g., CDC/ Healthcare Infection Control Practices Advisory Committee [HICPAC]), regulations, or standards.</p> <p><i>Note: Policies and procedures should be appropriate for services provided by the facility and should extend beyond Occupational Safety and Health Administration (OSHA) bloodborne pathogen training.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>B. IPC policies and procedures are reassessed at least annually or according to state or federal requirements.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>C. At least one individual trained in IPC is employed by or regularly available (e.g., by contract) to the facility to manage the facility's IPC program.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>D. Supplies necessary and sufficient for adherence to Standard Precautions are readily available.</p> <p><i>Note: This includes hand hygiene products, personal protective equipment (PPE), and injection equipment, including devices to reduce percutaneous injuries.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>E. A system or process is in place for early detection and management of potentially infectious persons at initial points of patient encounter.</p> <p><i>Note: System may include taking a travel and occupational history, as appropriate, and implementing elements described under respiratory hygiene/cough etiquette (in section B)</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> 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 areas that pose greater risk to the patients, visitors, and staff.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. As part of the risk assessment, an inventory of the facility's services and procedures is conducted; particular attention should be paid to various forms of care involving injections, as well as other invasive procedures.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. As part of the risk assessment, this checklist (Appendix A) is used to assess the practices in the facility.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## Infection Surveillance, Reporting, and Record-Keeping

Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. Patients who undergo procedures at the 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. The facility can demonstrate compliance with local, state, and federal mandatory reporting requirements for reportable diseases, healthcare-associated infections (HAIs), and potential outbreaks.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. A written protocol for reporting communicable diseases to the public health authority is in place.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
D. An updated list of diseases reportable to the public health authority is readily available to all HCP.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
E. HCP are oriented and trained to report concerns of possible indications of clusters or outbreaks of infection that may be associated with patient care to their local health authority.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
F. Regular audits of HCP are performed to assess adherence to IPC practices, and feedback is provided to staff regarding their performance.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

G. Efforts are made to correct lapses in practice identified by the risk assessment and to determine why the correct practice was not being performed.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
H. If a 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I HCP are educated on correct practice when lapses in practice are identified.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

<b>Education and Training</b>		
<b>Elements to Be Assessed</b>	<b>Practice Performed</b>	<b>Notes/Areas for Improvement</b>
A. HCP receive job- or task-specific education and training on IPC policies and procedures upon hire, and this is repeated annually when policies or procedures are updated/revised; or when new tasks, procedures, equipment, or supplies are introduced; or according to state or federal requirements.  <i>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.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. Training includes principles of both HCP safety and patient safety.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. Competency with job- or task-specific IPC policies and procedures (i.e., correct technique is observed by trainer) are documented both upon hire and through annual evaluations/assessments.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
D. The facility provides feedback to HCP regarding their performance.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
E. Records are maintained according to state and federal requirements.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## Healthcare Personnel (HCP) Safety

Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
<p>A. The facility has an exposure control plan that is tailored to the specific requirements of the facility (i.e., addresses potential hazards posed by specific services provided by the facility).</p> <p><i>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: <a href="https://www.osha.gov/Publications/osh3186.pdf">https://www.osha.gov/Publications/osh3186.pdf</a></i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>B. All 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.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>C. Following an exposure event, postexposure evaluation and follow-up, including prophylaxis as appropriate, are available at no cost to employee and are supervised by a licensed healthcare professional.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>D. The facility tracks HCP exposure events, evaluates event data, and develops/implements corrective action plans to reduce incidence of such events.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>E. The facility follows recommendations of the Advisory Committee on Immunization Practices (ACIP) for immunization of HCP, including offering hepatitis B and influenza vaccinations.</p> <p><i>Note: Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP) is available at: <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6007a1.htm</a></i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>F. All HCP receive baseline tuberculosis (TB) screening prior to placement; HCP receive repeat testing, if appropriate, based on the facility-level risk assessment or after exposure to TB.</p> <p><i>Note: For more information, facilities should refer to the Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005 available at: <a href="https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm">https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm</a></i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>G. If respirators are used, the facility has a respiratory protection program that details required worksite-specific procedures and elements for required respirator use, including provision of medical clearance, training, and fit-testing, as appropriate.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

<p>H. The facility has well-defined policies concerning contact of HCP with patients when HCP have potentially transmissible conditions. These policies include:</p> <ol style="list-style-type: none"><li>1. Work-exclusion clauses that encourage reporting of illnesses and do not penalize with loss of wages, benefits, or job status</li><li>2. Education of personnel on prompt reporting of illness to supervisor</li></ol>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
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## Section B: Adherence to Standard Precautions

Hand Hygiene		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. The facility provides supplies necessary for adherence to hand hygiene (e.g., soap, water, paper towels, alcohol-based hand rub [ABHR]) and ensures they are readily accessible to HCP in patient-care areas.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. HCP are educated regarding appropriate indications for handwashing with soap and water versus hand rubbing with ABHR.  <i>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 Clostridioides difficile or norovirus during an outbreak.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. The facility periodically monitors and records adherence to hand hygiene and provides feedback to personnel regarding their performance.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Personal Protective Equipment (PPE)		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. HCP receive training on proper selection and use of PPE: 1. Upon hire, prior to provision of care 2. Annually 3. When new equipment or protocols are introduced	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. HCP are required to demonstrate competency with selection and use of PPE after each training.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. The facility routinely audits (monitors and documents) adherence to proper PPE selection and use.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
D. The facility provides feedback from audits to personnel regarding their performance with selection and use of PPE.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
E. The facility has sufficient and appropriate PPE available and readily accessible to HCP.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## Respiratory Hygiene/Cough Etiquette

Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
<p>A. The facility has written policies and procedures regarding the containment of 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 through the duration of the visit. Measures include:</p> <ol style="list-style-type: none"> <li>1. Posting visual alerts at entrances to facility (with instructions to patients with symptoms of respiratory infection to inform HCP of symptoms when they first register for care, to 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).</li> <li>2. Providing tissues and no-touch receptacles for disposal of tissues.</li> <li>3. Providing resources for performing hand hygiene in or near waiting areas (e.g., handwashing facilities, ABHR).</li> <li>4. Offering face masks to coughing patients and other symptomatic persons upon entry to the facility, at a minimum, during periods of increased respiratory infection activity in the community.</li> <li>5. Providing space and encouraging patients with symptoms of respiratory infections to sit as far away from others as possible.</li> </ol> <p><i>Note: If a separate area is available, facilities may wish to place these patients there while they wait for care.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>B. To prevent the spread of pathogens, the facility educates HCP on the importance of IPC measures for containing respiratory secretions.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## Safe Injection, Medication Storage and Handling Practices

Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
<p>A. The facility has policies and procedures regarding the tracking of HCP access to controlled substances to prevent narcotics theft/diversion.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

<p>B. Medication purchasing decisions at the facility reflect selection of vial sizes that most appropriately fit the procedure needs of the facility and limit need for sharing of multi-dose vials (MDVs).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>C. Injections are required to be prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids, or contaminated equipment.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>D. Single-dose vials (SDVs) are discarded according to the time the manufacturer specifies for the opened vial or at the end of the procedure for which the vial is being used, whichever comes first.</p> <p><i>Note: SDVs should not be stored for future use.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>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.</p> <p><i>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.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>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.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>G. The facility has a policy and procedure for topical medication storage that includes:</p> <ol style="list-style-type: none"> <li>1. Monitoring for expiration dates</li> <li>2. Disposing of single-use topical medications after use</li> </ol>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>H. Masks are used when placing a catheter or injecting material into the spinal canal or subdural space (e.g., myelograms, lumbar puncture, spinal or epidural anesthesia).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>I. Any medication remaining in SDVs or prefilled single-use syringes is discarded immediately.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> 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 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. The instructions for reprocessing reusable medical equipment are readily available and posted in the area where the equipment is cleaned and reprocessed.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. 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	<input type="checkbox"/> Yes <input type="checkbox"/> No	
D. HCP are required to demonstrate competency with recommended practices for point-of-care testing after each training.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
E. The facility routinely audits (monitors and documents) adherence to recommended practices during point-of-care testing.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
F. The facility provides feedback from audits to personnel regarding their adherence to recommended practices.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## Environmental Cleaning

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

C. The facility uses EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare when cleaning environmental surfaces in the facility.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
D. HCP follow manufacturer's recommendations when using cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, disposal).	<input type="checkbox"/> Yes <input type="checkbox"/> No	
E. HCP who clean and disinfect patient-care areas (e.g., environmental services [ES], technicians, nurses) receive training on cleaning procedures: 1. Upon hire, prior to being allowed to perform environmental cleaning 2. Annually 3. When new equipment or protocols are introduced	<input type="checkbox"/> Yes <input type="checkbox"/> No	
F. If ES are only available after-hours (e.g., contractors from outside agency), then designated facility staff are assigned specific responsibilities for cleaning and disinfection during clinic hours.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
G. HCP are periodically monitored and assessed to ensure that they are consistently and correctly performing cleaning procedures and receive feedback regarding their performance.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
H. HCP are required to demonstrate competency with environmental cleaning procedures (i.e., correct technique is observed by trainer) at hire and through annual evaluations/assessments, and feedback is given regarding performance.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## Reprocessing of Reusable Medical Devices

Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. The facility has policies and procedures regarding the appropriate cleaning and reprocessing of reusable medical devices prior to use on another patient.  <i>Note: This includes clear delineation of responsibility among 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.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

<p>B. Policies, procedures, and manufacturer’s reprocessing instructions for reusable medical devices used in the facility are available in the reprocessing area(s).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>C. The facility has a written policy and procedure regarding the discarding of single-use devices (SUDs) after use.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>D. If the 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.</p> <p><i>Note: For more information, refer to “Reprocessing of Reusable Medical Devices” available at: <a href="https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf">https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf</a></i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>E. If the facility uses a third-party reprocessor for SUDs, documentation from that reprocessor confirming this is the case is on file.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>F. The individual(s) in charge of IPC at the facility is consulted whenever new devices or products will be purchased or introduced to ensure appropriate reprocessing policies and procedures are implemented.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>G. 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.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>H. Responsibility for reprocessing of medical devices is assigned to HCP with appropriate training.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>I. 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:</p> <ol style="list-style-type: none"> <li>1. Upon hire, prior to being allowed to reprocess devices</li> <li>2. Annually</li> <li>3. When new devices are introduced or policies/ procedures change</li> </ol> <p><i>Note: If device reprocessing is performed by contract personnel, facility should verify that the reprocessing is correctly performed by contracting company.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

J. The facility maintains copies of the manufacturer's instructions for reprocessing of devices in use at the facility, and posts instructions in locations where reprocessing is performed.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
K. HCP are required to demonstrate competency with reprocessing procedures (i.e., correct technique is observed by trainer) at hire and through annual evaluations/assessments. Feedback is given to HCP regarding their performance.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
L. HCP clean and reprocess (by disinfection or sterilization) reusable equipment according to manufacturer's instructions.  <i>Note: If the manufacturer does not provide such instructions, the device may not be suitable for multipatient use.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
M. HCP have access to and wear appropriate PPE when handling and reprocessing contaminated medical devices.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
N. Adequate space is allotted for reprocessing activities.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
O. A workflow pattern for device reprocessing clearly flows from high-contamination areas to clean/sterile areas, with clear separation between soiled and clean work spaces.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
P. Adequate time for reprocessing is allowed to ensure adherence to all steps recommended by the device's manufacturer, including proper drying and storage.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Q. 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
R. All medical devices are stored in a manner that protects them from contamination and damage.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
S. The facility has protocols to ensure that HCP can readily identify devices that have been properly reprocessed and are ready for patient use (e.g., tagging system, storage in designated area).	<input type="checkbox"/> Yes <input type="checkbox"/> No	
T. The facility has policies and procedures outlining facility response (i.e., risk assessment and device recall) in the event of a reprocessing error or failure.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

U. Routine maintenance for reprocessing equipment (e.g., steam autoclave) is performed by qualified personnel in accordance with manufacturer's instructions.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
V. The facility routinely audits (monitors and documents) adherence to reprocessing procedures.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
W. The facility provides feedback from audits to personnel regarding their adherence to reprocessing procedures.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
X. If ultrasound probes used during surgical procedures cannot be sterilized, HCP assure at a minimum that the probes are high-level disinfected and covered with a sterile condom or probe cover.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Y. HCP use single-use sterile gels for invasive procedures that pass through tissue, procedures involving sterile equipment or nonintact skin, and procedures that contact mucous membranes.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Z. HCP assure ultrasound transducers are high-level disinfected according to manufacturer's instructions.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Sterilization of Reusable Instruments and Devices		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
A. The facility uses evidence-based guidelines on sterilization of reusable instruments and devices when developing its policies and procedures.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. HCP who reprocess devices or equipment receive training on sterilization procedures.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. HCP who reprocess devices or equipment demonstrate competency with sterilization procedures (i.e., correct technique is observed by trainer):  1. Upon hire, prior to being allowed to sterilize devices 2. Annually 3. When new equipment or protocol are introduced	<input type="checkbox"/> Yes <input type="checkbox"/> No	
D. If sterilization occurs off-site, such as at a third-party reprocessing company, a process is in place to perform initial cleaning of devices prior to transport to that reprocessing facility.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

E. All reusable critical instruments and devices are sterilized prior to use.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
F. Machinery used to sterilize equipment, supplies, and devices functions properly.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
G. Routine maintenance for sterilization equipment is performed according to manufacturer's instructions.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
H. Sterilization records are retained for a period that complies with standards, statutes of limitations, and state and federal regulations.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

<b>High-Level Disinfection (HLD) of Reusable Instruments and Devices</b>		
<b>Elements to Be Assessed</b>	<b>Practice Performed</b>	<b>Notes/Areas for Improvement</b>
A. The facility uses evidence-based guidelines when developing policies and procedures for HLD.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. HCP who reprocess devices or equipment receive training on HLD procedures.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
C. HCP who reprocess devices or equipment are required to demonstrate competency with HLD procedures (i.e., correct technique is observed by trainer):  1. Upon hire 2. Annually 3. When new equipment or protocols are introduced	<input type="checkbox"/> Yes <input type="checkbox"/> No	
D. All reusable semicritical items receive at least HLD prior to reuse.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
E. Devices are thoroughly cleaned according to manufacturer's instructions and visually inspected for residual soil prior to HLD.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
F. Cleaning is performed as soon as practical after use (e.g., at point of use) to prevent soiled materials from becoming dried onto instruments.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
G. Enzymatic cleaner or detergent is used and discarded according to manufacturer's instructions (typically after each use).	<input type="checkbox"/> Yes <input type="checkbox"/> No	

<p>H. For chemicals used in HLD, manufacturer's instructions are followed for:</p> <ol style="list-style-type: none"> <li>1. Product preparation</li> <li>2. Testing for appropriate concentration</li> <li>3. Replacement (upon expiration or loss of efficacy)</li> </ol>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>I. Devices must be:</p> <ol style="list-style-type: none"> <li>1. Disinfected for the appropriate length of time as specified by manufacturer's instructions</li> <li>2. Disinfected at the appropriate temperature as specified by manufacturer's instructions</li> </ol>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>J. Appropriately rinsed after HLD, also as specified by the manufacturer</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>K. For chemicals used in HLD, manufacturer's instructions are followed for:</p> <ol style="list-style-type: none"> <li>1. Product preparation</li> <li>2. Testing for appropriate concentration</li> <li>3. Replacement (upon expiration or loss of efficacy)</li> </ol>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>L. Routine maintenance for HLD equipment is performed according to manufacturer's instructions (confirm maintenance records are available).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## Section C: Transmission-Based Precautions

Transmission-Based Precautions		
Elements to Be Assessed	Practice Performed	Notes/Areas for Improvement
<p>A. The 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:</p> <ol style="list-style-type: none"> <li>1. Contact Precautions</li> <li>2. Droplet Precautions</li> <li>3. Airborne Precautions</li> </ol>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>B. The facility has a system or process that addresses:</p> <ol style="list-style-type: none"> <li>1. Early detection of potentially infectious patients (e.g., patients with rashes, diarrhea) at the initial points of entry to the facility</li> <li>2. Prompt placement of potentially infectious patients in a single room.</li> <li>3. If such patients need transfer to another facility, notification of both the transferring agency and the accepting facility of the type of infection suspected</li> </ol>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>C. HCP receive education and training on Transmission-Based Precautions, including:</p> <ol style="list-style-type: none"> <li>1. Contact Precautions</li> <li>2. Droplet Precautions</li> <li>3. Airborne Precautions</li> </ol>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>D. HCP are required to demonstrate competency with Transmission-Based Precautions (i.e., correct technique is observed by trainer):</p> <ol style="list-style-type: none"> <li>1. Upon hire</li> <li>2. Annually</li> <li>3. When new equipment or protocols are introduced</li> </ol>	<input type="checkbox"/> Yes <input type="checkbox"/> No	

## Section D: Personnel and Patient-Care Observations

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

## Personal Protective Equipment (PPE) Correct Use Observations

| Practice  | Practice Observed  | Plan for Improvement |
|---|--|--|--|--|--|----------------------|
| A. Hand hygiene is performed before donning PPE.  | <input type="checkbox"/> Yes <input type="checkbox"/> No |                      |
| B. PPE, other than respirators, is removed and discarded prior to leaving the patient room or care area.<br><br><i>Note: If respirator is used, it should be removed and discarded (or reprocessed if reusable) after HCP leaves the patient room or care area and closes the door.</i>               | <input type="checkbox"/> Yes <input type="checkbox"/> No |                      |
| C. Hand hygiene is performed immediately after removal of PPE.  | <input type="checkbox"/> Yes <input type="checkbox"/> No |                      |
| D. Gloves:<br><br>1. HCP wear gloves for potential contact with blood, body fluids, mucous membranes, non-intact skin, or contaminated equipment.<br><br>2. HCP do not wear the same pair of gloves for the care of more than one patient.<br><br>3. HCP do not wash gloves for the purpose of reuse. | <input type="checkbox"/> Yes <input type="checkbox"/> No |                      |

<p>E. Gowns:</p> <p>1. HCP wear gowns to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated.</p> <p>2. HCP do not wear the same gown for the care of more than one patient.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>F. Facial protection:</p> <p>1. HCP wear mouth, nose, and eye protection during procedures likely to generate splashes or sprays of blood or other body fluids.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					

Respiratory Hygiene/Cough Etiquette Observations						
Practice	Practice Observed	Plan for Improvement				
<p>A. HCP offer face masks to coughing patients and other symptomatic persons upon entry to the facility, at a minimum, during periods of increased respiratory infection activity in the community.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>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.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					

C. HCP observe Droplet Precautions, in addition to Standard Precautions, when examining and caring for patients with signs and symptoms of a respiratory infection.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
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Safe Injection Use Observations						
Practice	Practice Observed	Plan for Improvement				
A. Aseptic technique is used when preparing and administering medications.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
B. Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices, such as insulin pens).	<input type="checkbox"/> Yes <input type="checkbox"/> No					
C. The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
D. Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
E. SDVs, ampoules, and bags or bottles of intravenous (IV) solution are used for only one patient.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
F. Injections are prepared as close as possible to administration.	<input type="checkbox"/> Yes <input type="checkbox"/> No					

G. Syringes are not batch prepared.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
H. Medication administration tubing and connectors are used for only one patient.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
I. MDVs are dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.  <i>Note: This date is different from the expiration date printed on the vial.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
J. MDVs are dedicated to individual patients whenever possible.	<input type="checkbox"/> Yes <input type="checkbox"/> 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).  <i>Note: If MDVs enter the immediate patient treatment area, they should be dedicated for single-patient use and discarded immediately after use.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No					

L. All sharps are disposed of in a puncture-resistant sharps container.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
M. Filled sharps containers are disposed of in accordance with state-regulated medical waste rules.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
N. All controlled substances (e.g., Schedule II, III, IV, and V drugs) are kept locked within a secure area.	<input type="checkbox"/> Yes <input type="checkbox"/> No					

Environmental Cleaning						
Practice	Practice Observed	Plan for Improvement				
A. 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.	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No					

C. Cleaners and disinfectants are used in accordance with manufacturer's instructions (e.g., dilution, storage, shelf life, contact time).	<input type="checkbox"/> Yes <input type="checkbox"/> No					
D. HCP are required to demonstrate competency with environmental procedures (i.e., correct technique is observed by trainer) at hire and through annual evaluations/assessments.	<input type="checkbox"/> Yes <input type="checkbox"/> No					

Reprocessing of Reusable Instruments and Devices						
Practice	Practice Observed	Plan for Improvement				
<p>A. Reusable medical devices are cleaned, reprocessed (disinfection or sterilization), and maintained according to manufacturer's instructions.</p> <p><i>Note: If the manufacturer does not provide such instructions, the device may not be suitable for multipatient use.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					

<p>B. SUDs are discarded after use and not used for more than one patient.</p> <p><i>Note: If the facility elects to reuse SUDs, a third-party reprocessor, registered with the FDA as a third-party reprocessor and cleared by the FDA to reprocess the specific device in question, must reprocess these devices prior to reuse. The facility should have documentation from the third-party reprocessor confirming its FDA status.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>C. 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).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>D. HCP store medical devices in a manner to protect them from damage and contamination.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					

Point-of-Care Testing						
Practice	Practice Observed	Plan for Improvement				
<p>A. New single-use, auto-disabling lancing device is used for each patient.</p> <p><i>Note: Lancet holder devices are not suitable for multipatient use.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					

<p>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.</p> <p><i>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.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
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Sterilization of Reusable Instruments and Devices						
Practice	Practice Observed	Plan for Improvement				
<p>A. Items are thoroughly pre-cleaned according to manufacturer's instructions and visually inspected for residual soil prior to sterilization.</p> <p><i>Note: For lumened instruments, device channels and lumens must be cleaned using appropriately sized cleaning brushes.</i></p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>B. Enzymatic cleaner or detergent is used for pre-cleaning and discarded according to manufacturer's instructions (typically after each use).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>C. Cleaning brushes either are disposable or are cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after each use.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> 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).	<input type="checkbox"/> Yes <input type="checkbox"/> No					
E. A chemical indicator (process indicator) is placed correctly in the instrument packs in every load.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
F. A biological indicator (BI) is used at least weekly for each sterilizer and with every load containing implantable items.	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
H. Sterile packs are labeled with the sterilizer used, the cycle or load number, and the date of sterilization.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
I. Logs for each sterilizer cycle are current and include results from each load.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
J. After sterilization, medical devices and instruments are stored in a manner such that sterility is not compromised.	<input type="checkbox"/> Yes <input type="checkbox"/> No					

K. Sterile packages are inspected for integrity, and compromised packages are reprocessed prior to use.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
L. Immediate-use steam sterilization (flash sterilization), if performed, is only done in circumstances in which routine sterilization procedures cannot be performed.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
M. Instruments that are flash-sterilized are used immediately and not stored.	<input type="checkbox"/> Yes <input type="checkbox"/> No					

High-Level Disinfection (HLD) of Reusable Instruments and Devices						
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 HLD.	<input type="checkbox"/> Yes <input type="checkbox"/> No					
B. Enzymatic cleaner or detergent is used and discarded according to manufacturer's instructions (typically after each use).	<input type="checkbox"/> Yes <input type="checkbox"/> No					
C. Cleaning brushes are either disposable or are cleaned and high-level disinfected or sterilized (per manufacturer's instructions) after each use.	<input type="checkbox"/> Yes <input type="checkbox"/> No					

<p>D. For chemicals used in HLD, manufacturer's instructions are followed for:</p> <p>1. Preparation</p> <p>2. Testing for appropriate concentration</p> <p>3. Replacement (prior to expiration or loss of efficacy)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>E. If automated reprocessing equipment is used, proper connectors are used to assure that channels and lumens are appropriately disinfected.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>F. Devices are disinfected for the appropriate length of time as specified by manufacturer's instructions.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>G. Devices are disinfected at the appropriate temperature as specified by manufacturer instructions.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>H. After HLD, devices are appropriately rinsed as specified by the manufacturer.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>I. Devices are dried thoroughly prior to reuse.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<p>J. After HLD, devices are stored in a manner to protect them from damage or contamination.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> 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 prevention and control (IPC) measures should be implemented at the first point of contact with a potentially infected person. They should be incorporated into IPC 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 IPC measures at the first point of encounter. These practices have a strong evidence base (see the Centers for Disease Control and Prevention's [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 outpatient 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, TB, varicella zoster virus, rubeola [measles]), is necessary at the start of the initial patient encounter. Upon identifying a potentially infectious patient, IPC measures, including prompt separation of the potentially infectious patient, should be implemented and appropriate control measures put in place.<sup>35</sup> 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 should be 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) should be 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 Isolation 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, patients requiring Droplet Precautions should be placed in an exam room or cubicle as soon as possible and instructed on respiratory hygiene/cough etiquette. Patients who question the need for this practice may be referred to a clinician present in the practice.

### Healthcare Personnel (HCP) Responsibilities

- HCP should regularly review information on local respiratory virus activity provided by the local health department and the CDC to determine if the facility will need to implement enhanced screening for respiratory symptoms.
- 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)

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

- When scheduling and/or confirming appointments:
  - Patients should be prescreened and those with respiratory symptoms scheduled 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 with 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(s)/Title(s)	Contact Information	Roles/Responsibilities
	Phone: Pager: Email:	<b>Infection prevention personnel/consultant:</b> <ul style="list-style-type: none"> <li>Assist with IPC plan development, update/revision, and implementation; include a protocol for transferring patients who require Airborne Precautions (if applicable).</li> </ul>
	Phone: Pager: Email:	<ul style="list-style-type: none"> <li>Educate and train facility staff (including environmental services [ES]/housekeeping).</li> <li>Assess for competency of jobs/tasks:               <ul style="list-style-type: none"> <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 style="list-style-type: none"> <li>Collect, manage, and analyze healthcare-associated infection (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 style="list-style-type: none"> <li>Provide fit-testing for N-95 respirators (if used in facility) and appropriate respiratory protection training to facility staff.</li> </ul>
	Phone: Pager: Email:	<ul style="list-style-type: none"> <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:	<p><b>ES/housekeeping staff:</b></p> <ul style="list-style-type: none"> <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 style="list-style-type: none"> <li>• Clean/disinfect areas and/or surfaces that require more frequent cleaning or are not routinely cleaned by ES/housekeeping staff: <ul style="list-style-type: none"> <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 on covering exam table)</li> <li>◦ Patient-care areas after contamination with body fluids<sup>c</sup></li> </ul> </li> </ul>
	Phone: Pager: Email:	<ul style="list-style-type: none"> <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>

Adapted from Centers for Disease Control and Prevention. *Basic Infection Control and Prevention Plan for Outpatient Oncology Settings*. Available at: <https://www.cdc.gov/hai/pdfs/guidelines/basic-infection-control-prevention-plan-2011.pdf>

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

<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>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). *APIC Text of Infection Control & Epidemiology*. 4th ed. Arlington, VA: Association for Professionals in Infection Control and Epidemiology; 2014. Available at: <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>
- CDC Guideline for the Prevention of Surgical Site Infections, 1999, available at: <https://stacks.cdc.gov/view/cdc/7160>
- CDC Guideline for Prevention of Surgical Site Infection, 2017, available at: <http://jamanetwork.com/journals/jamasurgery/fullarticle/2623725>
- Facility Guidelines Institute. *Guidelines for Design and Construction of Hospitals and Outpatient Facilities*. Chicago: American Society for Healthcare Engineering, 2018, available at: <https://www.fgiguide.org/guidelines/2018-fgi-guidelines/>
- US Pharmacopeial Convention, Inc. General Chapter <797>: *Pharmaceutical compounding — sterile preparations*. 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/>

### Facility Risk Assessment

- 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](https://www.cdc.gov/hai/outbreaks/steps_for_eval_ic_breach.html)
- APIC/Joint Commission Resources. *The APIC/JCR Infection Prevention and Control Workbook*, 3rd ed. January 2017. 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>

## Evaluation and Response to Infection Control Breaches

- 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](http://www.cdc.gov/hai/outbreaks/steps_for_eval_IC_breach.html)

## Healthcare Personnel (HCP) Safety

- AAOS. Preventing the transmission of bloodborne pathogens, 2001 (updated June 2012), available at: [https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion\\_Statements/advistmt/1018%20Preventing%20the%20Transmission%20of%20Bloodborne%20Pathogens.pdf](https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1018%20Preventing%20the%20Transmission%20of%20Bloodborne%20Pathogens.pdf)
- 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 Advisory Committee on Immunization Practices (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/> and [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm?s\\_cid=rr5417a1\\_eOSHA](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](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](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=12716)

## Infection Surveillance and Reporting of Healthcare-Associated Infections (HAIs)

- AAOS. OrthoInfo: Infections, available at: <https://orthoinfo.aaos.org/topic.cfm?topic=A00197>
- 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](http://www.cms.gov/manuals/downloads/som107_exhibit_351.pdf)
- Council of State and Territorial Epidemiologists (CSTE). State Reportable Diseases and Conditions, available at: <http://www.cste2.org/izenda/entrypage.aspx>

## Hand Hygiene

- AAOS. Preventing the transmission of bloodborne pathogens, 2001 (updated June 2012), available at: [https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion\\_Statements/advistmt/1018%20Preventing%20the%20Transmission%20of%20Bloodborne%20Pathogens.pdf](https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1018%20Preventing%20the%20Transmission%20of%20Bloodborne%20Pathogens.pdf)
- American Association of Nurse Anesthetists (AANA). *Infection Prevention and Control Guidelines for Anesthesia Care*. 2015;1–35. Available at: [https://www.aana.com/docs/default-source/practice-aana-com-web-documents-\(all\)/infection-prevention-and-control-guidelines-for-anesthesia-care.pdf?sfvrsn=850049b1\\_4](https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/infection-prevention-and-control-guidelines-for-anesthesia-care.pdf?sfvrsn=850049b1_4)
- 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 Guidelines for 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 Health-Care 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/>
- American Association of Occupational Health Nurses (AAOHN). Hand Hygiene, Glove Use, and Preventing Transmission of *C. difficile*, available at: <http://aaohn.org/blog/cdc-new-course-hand-hygiene,-glove-use,-and-preventing-transmission-of-c.-difficile>
- The Joint Commission; University of Iowa. 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](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 (PPE)

- AANA. *Infection Prevention and Control Guidelines for Anesthesia Care*, 2015, available at: [https://www.aana.com/docs/default-source/practice-aana-com-web-documents-\(all\)/infection-prevention-and-control-guidelines-for-anesthesia-care.pdf?sfvrsn=850049b1\\_4](https://www.aana.com/docs/default-source/practice-aana-com-web-documents-(all)/infection-prevention-and-control-guidelines-for-anesthesia-care.pdf?sfvrsn=850049b1_4)
- AAOS. Preventing the transmission of bloodborne pathogens, 2001 (updated June 2012), available at: [https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion\\_Statements/advistmt/1018%20Preventing%20the%20Transmission%20of%20Bloodborne%20Pathogens.pdf](https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1018%20Preventing%20the%20Transmission%20of%20Bloodborne%20Pathogens.pdf)
- CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents 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 (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/HAI/prevent/ppe.html>

## Respiratory Hygiene/Cough Etiquette

- CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents 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 (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](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, available at: <https://www.cdc.gov/flu/professionals/infectioncontrol/>
- Minnesota Department of Health. Cover Your Cough Poster for Health Care. Nov 7, 2016, available at: <http://www.health.state.mn.us/divs/idepc/dtopics/infectioncontrol/cover/hcp/hcposter.html>

## Injection Safety

- CDC Clinical Reminder: Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis, available at: <https://www.cdc.gov/injectionsafety/spinalinjection-meningitis.html>
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings (related to Injection and Medication Safety), available at: <https://www.cdc.gov/hicpac/recommendations/core-practices.html>
- CDC Frequently Asked Questions (FAQs) regarding Safe Practices for Medical Injections, available at: <https://www.cdc.gov/injectionsafety/pdf/faqs-safe-practices-for-medical-injections.pdf>
- CDC Injection Safety Web Materials, available at: <http://www.cdc.gov/injectionsafety/>
- CDC One Needle, One Syringe, Only One Time infographic, available at: <https://www.cdc.gov/injectionsafety/PDF/InjectionSafety-Infographic-508.pdf>
- CDC Safety Steps: Follow These Injection Safety Steps for Success!, available at: [http://www.oneandonlycampaign.org/sites/default/files/upload/image/CDC\\_0%26O\\_Single-dose%20and%20Multi-dose%20vial%20infographic.pdf](http://www.oneandonlycampaign.org/sites/default/files/upload/image/CDC_0%26O_Single-dose%20and%20Multi-dose%20vial%20infographic.pdf)
- CDC Single-Dose or Multi-Dose? infographic, available at: [http://www.cdc.gov/injectionsafety/PDF/SDVMDV\\_infographic.pdf](http://www.cdc.gov/injectionsafety/PDF/SDVMDV_infographic.pdf)
- CDC 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](http://www.cdc.gov/injectionsafety/providers/provider_faqs.html)
- CDC Protect Patients Against Preventable Harm from Improper Use of Single-Dose/Single-Use Vials. Misperceptions vs. Facts (updated Aug 30, 2016), available at: <https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html>
- WHO Injection Safety, available at: <http://www.who.int/infection-prevention/tools/injections/en/>
- CDC. Invasive *Staphylococcus aureus* infections associated with pain injections and reuse of single-dose vials — Arizona and Delaware, 2012. *Morbidity and Mortality Weekly Report*. July 13, 2012. Available at: [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm?s\\_cid=mm6127a1\\_w](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm?s_cid=mm6127a1_w)
- Institute for Safe Medication Practices (ISMP) Inappropriate Use of Pharmacy Bulk Packages of IV Contrast Media Increases Risk of Infections, 2013, available at: <https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=31>

## 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](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 the Healthcare Environment of the American Hospital Association (AHE). *Practice Guidance for Healthcare Environmental Cleaning*, 2nd ed. Chicago: AHE. available at: [http://www.ahe.org/Education/publications\\_home.shtml](http://www.ahe.org/Education/publications_home.shtml)
- CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings — Recommendations of the Healthcare Infections Control Practices Advisory Committee (Category 5b: Environmental Cleaning and Disinfection), 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 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: <https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines.pdf>

## Reprocessing of Reusable Medical Devices

- Australasian Society for Ultrasound in Medicine and the Australasian College for Infection Prevention and Control. Guidelines for reprocessing ultrasound transducers. *Australas J Ultrasound Med*. 2017 Feb 23;20(1):1–11. Available at: <http://onlinelibrary.wiley.com/doi/10.1002/ajum.12042/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 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](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, available at: <https://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>
- Centers for Disease Control and Prevention. *Pseudomonas aeruginosa* respiratory tract infections associated with contaminated ultrasound gel used for transesophageal echocardiography — MI, Dec 2011–Jan 2012. *MMWR Recomm Rep*. 2012 Apr 20; 61(15):262–264. Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6115a3.htm>
- FDA Regulations on Reprocessing of Single-use Devices, available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm>
- Australasian Society for Ultrasound in Medicine and the Australasian College for Infection Prevention and Control. Guidelines for reprocessing ultrasound transducers. *Australas J Ultrasound Med*. 2017 Feb 23;20(1):1–11. Available at: <http://onlinelibrary.wiley.com/doi/10.1002/ajum.12042/pdf>
- Health Canada. Risk of Serious Infection from Ultrasound and Medical Gels—Notice to Hospitals; Oct 20, 2004 (archived). Accessed Mar 10, 2018. Available at: [http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2004/14290a-eng.php?\\_ga=2.178450276.1925571576.1520540677-157664369.1520540677](http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2004/14290a-eng.php?_ga=2.178450276.1925571576.1520540677-157664369.1520540677)

## Sterilization of Reusable Instruments and Devices

- American National Standards Institute and the Association for the Advancement of Medical Instrumentation's *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* (ANSI/AAMI ST79:2017), August 1, 2017. A preview copy is available at: [http://my.aami.org/aamiresources/previewfiles/1709\\_ST79Preview.pdf](http://my.aami.org/aamiresources/previewfiles/1709_ST79Preview.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/faq/bead.htm>
- The Joint Commission. Improperly sterilized or HLD equipment — a growing problem. *Quick Safety*. 2017 May;33. Available at: [https://www.jointcommission.org/assets/1/23/qs\\_33a\\_2017.pdf](https://www.jointcommission.org/assets/1/23/qs_33a_2017.pdf)

## High-Level Disinfection (HLD) of Reusable Instruments and Devices

- American National Standards Institute and the Association for the Advancement of Medical Instrumentation's (AANSI/AAMI) *Chemical Sterilization and High-level Disinfection in Health Care Facilities* (ANSI/AAMI ST58:2013). August 21, 2013. A preview copy is available at: [https://my.aami.org/aamiresources/previewfiles/ST79\\_Wa4\\_1310\\_preview.pdf](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 (2008), available at: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>
- CDC Healthcare Infection Control Practices Advisory Committee (HICPAC). Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings — Recommendations of the Healthcare Infection Control Practices Advisory Committee, available at: <https://www.cdc.gov/hicpac/pdf/core-practices.pdf>

## Transmission-Based Precautions

- CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents 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: [https://www.currytbcenter.ucsf.edu/sites/default/files/ic\\_book\\_2011.pdf](https://www.currytbcenter.ucsf.edu/sites/default/files/ic_book_2011.pdf)
- Curry International Tuberculosis Center. Tuberculosis Infection Control: A Practical Manual for Preventing TB, 2011. Room Clearance Time Calculation Worksheet (Appendix G, p. 150–151). Available at: [https://www.currytbcenter.ucsf.edu/sites/default/files/ic\\_book\\_2011.pdf](https://www.currytbcenter.ucsf.edu/sites/default/files/ic_book_2011.pdf)

## Quality Improvement Related Resources

- Agency for Healthcare Research and Quality (AHRQ) TeamSTEPS for Office-Based Care, 2017, available at: <https://www.ahrq.gov/teamsteps/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 are available at: <https://www.ahrq.gov/sites/default/files/wysiwyg/sops/quality-patient-safety/patientsafetyculture/medofficersourcelist-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

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TTY: 1-888-232-6348

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# NOTES

