An APIC Guide

2010

Guide to the Elimination of Infections in Hemodialysis

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Table of Contents

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Acronyms

AAMI	Association for the Advancement of Medical Instrumentation
APIC	Association for Professionals in Infection Control
AV	arteriovenous
AVF	arteriovenous fistula
AVG	arteriovenous graft
BSI	bloodstream infection
CDC	Centers for Disease Control and Prevention
CFU	colony forming units
CHG	chlorhexidine
CKD	chronic kidney disease
CMS	Centers for Medicare and Medicaid Services
CVC	central venous catheter
EPA	U.S. Environmental Protection Agency
ESRD	end stage renal disease
EU	endotoxin unit
FDA	U.S. Food and Drug Administration
HBV	hepatitis B virus
HCV	hepatitis C virus
HD	hemodialysis
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIV	human immunodeficiency virus
IP	infection preventionist
IV	intravenous
KDOQI	Kidney Disease Outcome Quality Initiative
MDRO	multidrug-resistant organism
mL	milliliter
MMWR	*Morbidity and Mortality Weekly Report*
MRSA	methicillin-resistant *Staphylococcus aureus*
MWCO	molecular weight cut off
NHANES	National Health and Nutrition Examination Survey
PPE	personal protective equipment
ppm	parts per million
QAPI	quality assurance and performance improvement
RO	reverse osmosis

SHEA	Society for Healthcare Epidemiology of America
SPSS	Statistical Program for Social Sciences
USRDS	U.S. Renal Data System
VAD	vascular access device
VRE	vancomycin-resistant *Enterococcus*

Guide Overview

Purpose

The purpose of this document is to provide evidence-based guidance for the prevention of healthcare-associated infections in all hemodialysis settings: acute, chronic, and home. The Guide has been designed for use by those responsible for infection prevention in these settings. In some settings, this may be the infection preventionist (IP), in others it may be the dialysis technician, dialysis nurse, or other.

Introduction

Hemodialysis (HD) patients are uniquely vulnerable to the development of healthcare-associated infections because of multiple factors including exposure to invasive devices, immunosuppression, the lack of physical barriers between patients in the outpatient hemodialysis environment, and frequent contact with healthcare workers during procedures and care. Efforts and actions designed to reduce the risk of infection are recommended for all settings where HD services are provided. The infection prevention measures detailed in this Guide can also be used to reduce infection risk in peritoneal dialysis, but this document will not specifically address peritoneal dialysis.

The recommendations contained in this Guide were developed by reviewing available published literature and consulting with specialists in the field. There are references provided for each section. Some of the published documents that were reviewed to develop this Guide are listed as follows, in the order published:

1. Centers for Disease Control and Prevention (CDC). *Recommendations for Control of Hepatitis B in Dialysis Centers*. Atlanta, GA: Author, 1997.
2. CDC. Recommendations for preventing transmission of infections among chronic hemodialysis patients. *MMWR* 2001;50(RR05):1–43.
3. Centers for Medicare and Medicaid Services (CMS). 2008 Conditions for Coverage

The infection prevention strategies in this Guide include basic measures that have strong evidence and regulatory requirements to support them (Category I level evidence):

Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and a strong theoretical rationale.
Category IC. Required by state or federal regulations, rules, or standards.

In addition, measures or best practices are also included even though evidence may be lacking or less than Category I.

HD Infection Prevention and Control Program

An effective infection prevention and control program for HD units is comprised of multiple interventions which are designed to reduce the risk of infection based on the unique characteristics of the HD patient population and environment.

The role of the IP, or the individual with this accountability if there is no dedicated IP in a hemodialysis unit/facility, includes oversight of infection prevention efforts in addition to development of new and ongoing staff training program, facilitation of performance improvement projects, and periodic surveillance to assess risk and guide these projects. It is important that the IP or individual with this accountability communicates and networks with all members of the HD team including nurses, technicians, physicians, environmental services professionals, and the patient/family. The success of an infection prevention and control program requires that all members of the HD team understand their role. Each team member must be held accountable for compliance with infection prevention, control strategies, and interventions.

Typically, only inpatient or hospital-based dialysis units will have a resident IP. In hospitals where inpatient HD services are provided, patients are cared for by regular nursing staff between dialysis sessions. It is important that these staff nurses receive training regarding their role, scope, and limitations related to HD, as well as who to contact for any dialysis associated issues. Similarly, in outpatient dialysis units and in Home Care services, most often there is not a dedicated IP. In these arenas, someone else should be given this role and accountability. These individuals must also receive comprehensive training. In all medical settings, the medical director is ultimately responsible for ensuring that this role is filled and performed adequately.

Emergency Preparedness

HD facilities should have plans in place addressing how dialysis services will be provided in the event of a disaster/emergency, including hotlines that providers/patients can call for information. The renal community (e.g., Kidney Community Emergency Response Coalition, dialysis provider organizations, and Medicare) should be consulted by HD facilities during the development of emergency/disaster preparedness plans in order to leverage services/materials already developed. See Appendices for a web link for Kidney Community Emergency Response Coalition.

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4. Centers for Medicare & Medicaid Services. *Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule*. Available online at http://www.cms.hhs.gov/cfcsandcops/downloads/esrdfinalrule0415.pdf. Accessed 4/1/2010.

Problem Identification

As of December 31, 2006, there were 327,754 patients on maintenance HD in the United States (U.S.). The vast majority of these were treated in free-standing outpatient facilities, with a decreasing number being treated in hospital-based units.[1] The free-standing nature of the standard dialysis facility means that these centers typically do not have ready access to infection prevention/control professionals, and it is therefore important that the centers designate a staff member who is given responsibility for ensuring performance of effective infection prevention and control practice as well as education of staff and patients. However, it is important to note that an HD staff member given this responsibility would not capable of providing the same level of service as a certified IP.

Infection as a cause of hospitalization for HD patients in the U.S. has increased in recent years. Between 1993 and 2006, hospitalization rates for infection rose 34%, and the rate of hospitalization for vascular access infections in HD patients more than doubled.[1] The admission rate for pneumonia rose 7.3%, for bacteremia/septicemia 31%, and for cellulitis 20.3%. In 2006, there were 103 admissions per 1000 patient years with the diagnosis of bacteremia/septicemia and 129 per 1000 patient years with the diagnosis of vascular access-associated infection.[1] Infection is reported as the second most common cause of death in HD patients (20.2% in 2006), after cardiovascular disease.[1]

Patients on maintenance HD are strikingly vulnerable to infection for many reasons, including the immunodepressed state intrinsic to end stage renal disease (ESRD), the high prevalence of diabetes, exposure to other patients in the HD facility three times per week, frequent hospitalization, and the invasiveness of the HD procedure.

Many of the acute bacterial infections in HD patients are caused by *Staphylococcus aureus*, and are related to temporary central venous catheters (CVCs). These infections can lead to sepsis and result in bacterial seeding/infection of implants such as total hip/knee and cardiac valves. This is a serious complication that can result in significant additional morbidity and may require removal/replacement of implants. Bacterial seeding/infection of compression spine fractures has also been reported resulting in long-term antibiotic therapy.

Other infection-associated risks include pneumococcal pneumonia, which also remains common in the HD population. The associated immunization (Pneumovax) is indicated for HD patients, and is helpful in preventing pneumonia and bloodstream invasion by bacteria. Pneumonia is one of many reasons that antibiotics are prescribed for HD patients which in turn increases the risk of developing colonization or infection with multidrug-resistant organisms (MDROs) such as methicillin-resistant *S. aureus* (MRSA) and the development of *Clostridium difficile*. This is probably also related to the frequent hospitalization, antibiotic administration, and repetitive procedures provided to HD patients. The most effective intervention for reducing the risk of *C. difficile* and antibiotic resistance is formal ongoing monitoring and control of antibiotic use. This may not occur, especially in outpatient dialysis units. Another serious concern for HD patients is seasonal influenza, which can be transmitted by both unvaccinated dialysis staff and patients.

Exposure to bloodborne pathogens, specifically hepatitis B (HBV), hepatitis C (HCV), and human immunodeficiency virus (HIV) is a serious risk for HD patients and employees. There is always the risk of transmission of these pathogens and hence, Standard Precautions (formerly Universal Precautions) need to be rigidly observed in the HD facility. The risk of HBV acquisition in HD facilities remains despite the dramatic fall in HBV carriers because of the widespread use of HBV vaccine, the testing of blood transfusions for hepatitis B surface antigen (HBsAg), and the reduced need for transfusion in the chronic kidney disease (CKD) population because of erythropoietin.[2] Patients with CKD tend to become life-long carriers of HBV if infected, and therefore

special care is taken to prevent spread of infection to other patients and those staff who are susceptible to HBV infection because they either have not been vaccinated or did not respond to HBV vaccine.

HBsAg positive individuals may have a very high load of circulating virus, and the virus can survive on environmental surfaces for greater than 1 week in dried blood.[3] Infectious HBV virions have also been demonstrated on environmental surfaces in the dialysis facility in the absence of visible blood.[4]

Outpatient HD centers have characteristics unique among healthcare facilities. Treatment is generally in the same center for months or years on a repetitive basis, and is not curative but life-sustaining. Patients are treated in three or four shifts per day, so that the staff are subject to periods of intense activity, during which one shift of patients must have their treatment terminated and the next shift have their treatment initiated. Most of the care is provided by certified dialysis technicians under the supervision of dialysis trained registered nurses. A typical staffing ratio is one nurse to every 12 patients on a shift, and one patient care technician for every 4 patients.

Outpatient HD facilities are designed in a number of ways. Some are open plan as this is felt to support ease in visualizing and accessing machine alarms during treatment as well as rapid patient intervention as needed. Other facilities are designed in a manner which separates patients into groups or pods which are separated by half walls. The open plan design provides no physical barriers between patients, while the pod design with half walls can serve as a reminder regarding hand hygiene and personal protective equipment (PPE) removal between patients.

The design of HD facility layouts are driven by the need for proximity of the dialysis machines, the central acid and water supply, the drain used for dialysate, and electrical power outlets. In the HD facilities where the patient treatment stations (dialysis machine and patient chair) are lined up in proximity to each other along the walls, hand-washing sinks are often located at a distance in the center of the facility. However, alcohol hand sanitizer at each patient station can be used to support hand hygiene.

Conclusion

Hemodialysis places patients at high risk for infection because of patient comorbidities and numerous human, environmental, and procedural factors. Establishing an infection prevention and control program which includes a bundle of strategies and interventions that are consistently performed will reduce the infection risk for both employees and patients.

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Infection Prevention and Control in HD

Introduction

This chapter of the Guide will address the key measures designed to reduce the risk of infection in HD patients by preventing the direct or indirect transmission of microorganisms. As with any risk reduction effort, the more reliably and consistently performed, the better the opportunity to improve outcomes.

Included at the end of this Guide is an Appendix with checklists, tools, templates, and reference materials that can be useful for routine assessment of compliance with infection prevention measures in HD settings. These resources also provide an opportunity for employee teaching related to infection prevention and control.

A listing of key infection prevention measures included in this Guide follows (basic versus "plus"). This is not an exhaustive list.

Basic Measures—Category I Level Evidence Supports These Measures	Plus Measures—Level of Evidence Supporting These Measures is Less Than Category I Level
1. Environmental and equipment cleaning/disinfection • Use U.S. Environmental Protection Agency (EPA)-registered hospital disinfectants labeled tuberculocidal or with specific label claims for HIV or HBV in accordance with label instructions to decontaminate spills of blood and other body fluids. • Use standard cleaning and disinfection protocols and EPA-registered hospital disinfectants for confirmed or suspected antibiotic-resistant Gram-positive cocci (e.g., MRSA, vancomycin intermediate–resistant *S. aureus*, or vancomycin-resistant *Enterococcus* [VRE]). • Using friction, clean and disinfect high-touch surfaces in patient-care areas (e.g., HD chairs, HD machines, tables, carts, bedside commodes). • When contact precautions are indicated for patient care, use disposable patient-care items (e.g., blood pressure cuffs) whenever possible to minimize cross-contamination with multiple-resistant microorganisms. • Items taken into a patient station should be disposed of after use, dedicated for use on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. • Nondisposable items that cannot be comprehensively cleaned and disinfected (e.g., adhesive tape, cloth-covered blood pressure cuffs) should be dedicated for use on a single patient.	1. Environmental and equipment cleaning/disinfection • Because no EPA-registered products are specific for inactivating *C. difficil*e spores, use hypochlorite-based products for disinfection of environmental surfaces in those patient-care areas where surveillance and epidemiology indicate ongoing transmission of *C. difficil*e. • Use microfiber cloths and mops if possible (more effective cleaning products than regular cotton cleaning cloths).

Basic Measures—Category I Level Evidence Supports These Measures	Plus Measures—Level of Evidence Supporting These Measures is Less Than Category I Level
• External pressure transducer filters/protectors should be changed after each patient treatment. Items taken into an individual HD patient station should be disposed of after use, dedicated for use on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient. • External venous and arterial pressure transducer filters/protectors should be changed after each patient treatment and should not be reused. Internal transducer filters do not need to be changed routinely between patients. • The internal HD machine dialysate pathway should be subjected to heat disinfection at the end of each treatment day. • In the event of a blood leak, disinfection of the internal HD machine pathway must be performed prior to on a successive patient.	
2. Hand hygiene • To improve hand hygiene adherence among personnel who work in areas in which high workloads and high intensity of patient care are anticipated, make an alcohol-based hand rub available at the entrance to the patient's room or at the bedside, in other convenient locations, and in individual pocket-sized containers to be carried by healthcare workers (HCWs). • Perform hand hygiene before and after contact with patient or patient environment. • Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between uses with different patients. • Perform hand hygiene after glove removal. • If hands are not visibly soiled, use an alcohol-based hand rub for routinely cleaning hands instead of soap and water. • Do not wear artificial fingernails or extenders when having direct contact with patients.	

Basic Measures—Category I Level Evidence Supports These Measures	Plus Measures—Level of Evidence Supporting These Measures is Less Than Category I Level
3. Immunizations and tuberculosis (TB) screening • Vaccine status of all patients should be assessed at the start of dialysis. Eligible HD patients should be immunized against HBV, tetanus, pneumococcal disease, and influenza. • CDC recommends one-time baseline screening of HD patients for TB (plus anytime an exposure is suspected). • Employees in HD settings must receive immunization for measles, mumps, rubella, pertussis, diphtheria, tetanus, MMR (measles, mumps, rubella), be offered HBV and influenza immunization, and be screened for TB per local regulations (usually annual).	
4. Medication/injection safety: • Single-dose vials should be dedicated to one patient only and should not be re-entered. • Parenteral medications should be prepared in a designated clean area away from patient treatment stations. • Do not use medication carts to transport medications to patient stations. • Scrub the hub of intravenous (IV) tubing and medication vials prior to accessing. • Use aseptic technique when preparing/handling parenteral medications/fluid. • Never use infusion supplies such as needles, syringes, flush solutions, administration sets, or IV fluids on more than one patient.	4. Medication/injection safety: • Avoid use of multidose vials
5. Pre- and postsurgical infection prevention • Presurgical hair removal should be performed with clippers instead of a razor.	5. Pre- and postsurgical infection prevention • Antiseptic impregnated postoperative dressings for fistulas/grafts • Active surveillance testing for MRSA and decolonization should be performed as indicated (e.g., preoperatively). • Preoperative antiseptic bathing/showering
6. Standard/transmission based precautions • Respiratory etiquette should be employed routinely. • Standard Precautions should be practiced routinely. • Patient identified with a suspected airborne disease should be masked immediately and geographically separated from other patients, preferably in a single room. • HBV isolation should be employed routinely on all patients known to be HBsAg positive.	6. Standard/transmission based precautions • Contact precautions in HD facilities should be employed in the event of known or suspected MDRO.

Basic Measures—Category I Level Evidence Supports These Measures	Plus Measures—Level of Evidence Supporting These Measures is Less Than Category I Level
7. Vascular Access: • Support transition from temporary (e.g., CVC) to permanent (e.g., arteriovenous fistula [AVF] or graft [AVG]) vascular access whenever possible. • Full barrier precautions and skin antisepsis with chlorhexidine (CHG) alcohol prep prior to insertion of HD CVC.	7. Vascular access • Routine use of CHG impregnated bathing cloths. • Application of CHG impregnated insertion site dressing for HD central catheters. • *Prophylactic* use of antimicrobial catheter locking solution. • Soak the hub of HD catheters in povidone-iodine solution or wrap with gauze saturated with povidone-iodine solution for 5 minutes prior to removing the cap.[1] • Application of povidone-iodine or triple antibiotic ointment for HD catheter exit site dressings after dialysis session.
8. Water treatment • Adhere to current Association for Advancement of Medical Instrumentation (AAMI) standards for quality assurance performance of devices and equipment used to treat, store, and distribute water in HD centers and for the preparation of concentrates and dialysate. • Conduct microbiological testing specific to water in dialysis settings. • Disinfect water distribution systems in dialysis settings on a regular schedule.	8. Water treatment • Ultrapure dialysate

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Environmental Cleaning/Disinfection

Background

The outpatient HD setting presents a unique set of challenges related to environmental cleaning and disinfection because of the spatial cohort of patients and the temporal demands of multiple shifts. This setting is one in which patients are typically not segregated from one another by physical barriers, such as walls or privacy curtains.

Conditions common to HD settings can also interfere with environmental cleaning, such as the typical 1:4 staff-to-patient ratio for dialysis technicians, the fast turn-around between patient treatments, and the procedurally intensive process of the dialysis treatment.

In the outpatient HD setting, each "patient station" contains a dialysis chair, the dialysis machine, and any other ancillary equipment/supplies necessary to provide the treatment. It may also include a bedside television set and phone. The space for each patient dialysis station or seating must be considered as the patient's exclusive treatment area, and sharing of equipment between patients should be avoided. Any equipment or item used for the patient must not be shared from patient to patient without prior cleaning and disinfection.

In a typical hospital setting, environmental cleaning and surface disinfection is performed by trained housekeeping staff dedicated to ensuring that the room is completely cleaned and disinfected between patients. A typical outpatient dialysis unit has no such luxury. The nurse or dialysis technician must perform surface cleaning and disinfection (machine, chair, phone, table, etc.) in the short gap between patient treatments. Sufficient time between the completion of one patient's treatment and postdialysis care and the initiation of the next patient's care is important for permitting reliable and consistent cleaning and disinfection of the patient station.

Cleaning and Disinfection of Environmental Surfaces

The process of physical cleaning of environmental surfaces using detergent (soap), water, and friction is the critical step required prior to surface disinfection. The combination of the cleaning and disinfection processes is designed to remove and kill vegetative microorganisms on surfaces. Disinfection will not be effective in the presence of dirt, blood, or other bioburden. The goal of the cleaning step is to remove bioburden and with it, the majority of pathogens. Disinfection is designed to be a synergistic and somewhat redundant step to ensure comprehensive removal/kill of pathogens on surfaces. The CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*, states that, "noncritical surfaces (e.g., dialysis bed or chair, countertops, external surfaces of dialysis machines) should be disinfected with an EPA-registered disinfectant unless the item is visibly contaminated with blood. In that case, an EPA registered tuberculocidal agent with specific label claims for HBV and HIV should be used."[1] One commonly used disinfectant for blood contaminated environmental surfaces is a 1:100 dilution of bleach (500–600 parts per million [ppm] free chlorine).

The environmental surfaces in HD settings at highest risk of transmitting germs are described using different terms. From the perspective of the patient, the term "patient zone" is used to refer to the surfaces which the patient can touch, or can touch the patient, including the chair, armrests, bedside table top/counter, and drawer/cupboard handles. From the HCW or dialysis staff perspective, the term "high touch surfaces" is used to describe surfaces which are frequently touched by HCWs. These include the same surfaces in the patient zone in addition to others such as the exterior surfaces of the HD machine, computer screens, and keyboards. Cleaning and disinfection of these surfaces (patient zone/high touch surfaces) should be performed between all patient treatments, no matter

what the patient diagnosis is, in order to prevent spread of environmentally transmitted pathogens including MDROs (e.g., MRSA, VRE, *C. difficile*) and bloodborne pathogens (e.g., HBV, HCV). Of note, microorganisms can live for varying periods of time in the environment. MRSA has been documented as viable at 38 weeks on external sterile packaging and VRE at 6 months on a wheelchair. HBV can survive for 7 days in dried blood.

There are certain products and principles which are recommended in order to optimize environmental cleaning in healthcare settings, including HD facilities. These include the following tasks which are typically performed by the dialysis nurse or technician.

- Store cleaner/disinfectant separately from skin antiseptics/patient supplies (separate shelves and below patient supplies to avoid potential contamination).
- Perform hand hygiene before and after cleaning the patient station.
- Don gloves when using cleaner/disinfectants.
- Use one set of cleaning cloths or disposable germicidal wipes for each patient station.
- Use microfiber cloths and mops if possible (more effective cleaning products than regular cotton cleaning cloths).
- Clean all frequently touched or "high touch" surfaces in the "patient zone" between patient treatments (chair, armrests, counters, drawer/cupboard handles, exterior surface of the HD machine)—please note that some of these high touch surfaces may be right outside the patient zone (e.g., computer stations), and must also be cleaned between patient treatments.
- Clean the top of an object first and work down to avoid soiling surfaces just cleaned.
- If using cleaning cloths instead of disposable germicidal wipes:
  - When using a disinfectant cleaner, wet the surface, use friction to clean, and allow to air dry.
  - Fold the cleaning cloth in a series of squares to provide a number of potential cleaning surfaces. A wadded cloth does not clean efficiently.
  - Replace cloth as needed. More than one cloth may be required for a patient station.
  - Never use the same cleaning cloth for more than one patient unit.
  - Never re-dip used cloth into clean disinfectant solution.

Additional cleaning functions, typically performed by housekeeping staff in HD facilities, should include:

- At the end of the day:
  - Wet mop the floor
  - Clean patient/staff bathrooms and restock paper products/hand hygiene supplies
  - Check and refill all hand hygiene product dispensers in nursing stations and at patient stations (soap, paper towels, lotion, alcohol-based hand sanitizer)
- On a routine basis, walls and high dusting should be performed.

MDRO Cleaning and Disinfection

Many HCWs believe the environment of patients with MDROs require special cleaning. HCWs in HD facilities should clean the environment of the MDRO patient as they would for any patient, as many more patients than are known are colonized/infected with an MDRO. Cleaning involves the use of friction on environmental surfaces to physically remove the soil and germs. The wet contact time of the germicide on the surface helps kill or inactivate any remaining microorganisms. The exception is *C. difficile*, which requires removal by friction and is not inactivated by any surface disinfectant except bleach.

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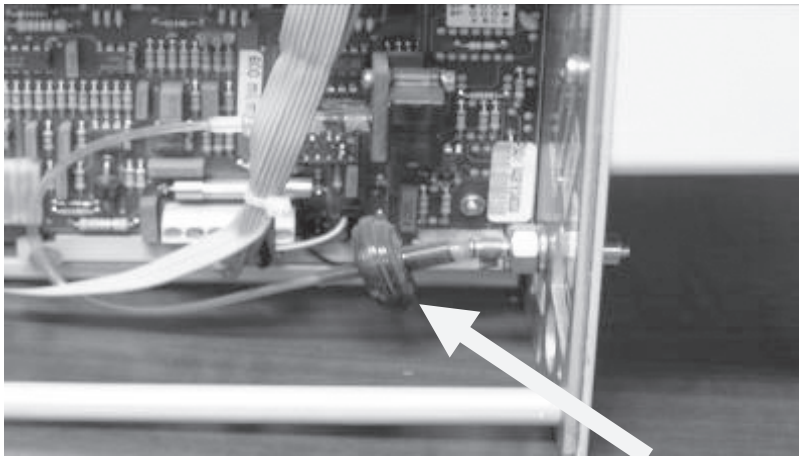
Equipment Cleaning/Disinfection

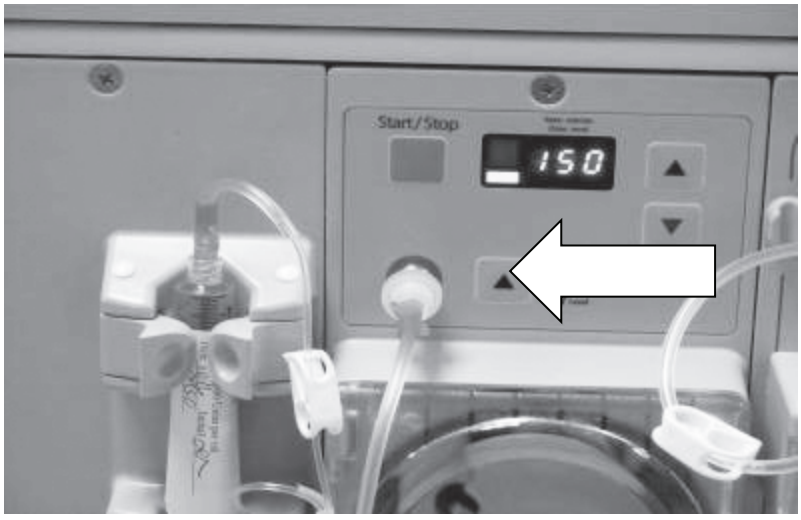
Background

HD equipment includes HD machines, dialyzers, water supply/treatment/distribution systems, component parts such as tubing and filters, acid and bicarbonate concentrate solutions, and instruments including blood pressure cuff, stethoscope, hemostats, scissors, and clamps. Sterile and clean supplies are also integral to the provision of HD. Infections caused by contamination of supplies/equipment with bloodborne viruses and pathogenic bacteria have been reported. Cleaning and disinfection of equipment and proper handling of reusable and disposable supplies is critical to the safety of patients in this high risk area.

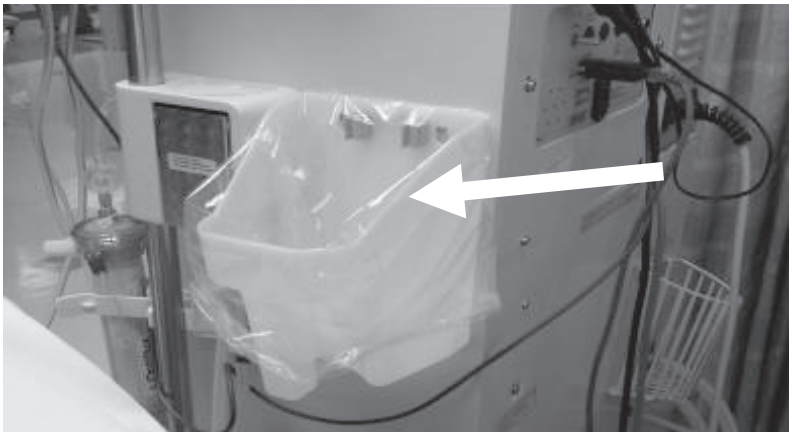
The following pictures are offered as examples only. They are not representative of equipment used in every dialysis center. For instance, some dialysis centers use machines with a waste handling option. This requires extreme care not to cross contaminate, as well as maintenance and testing of check valves. Others use one-time use containers (sometimes called "urinals") to prevent cross-contamination from priming waste buckets.



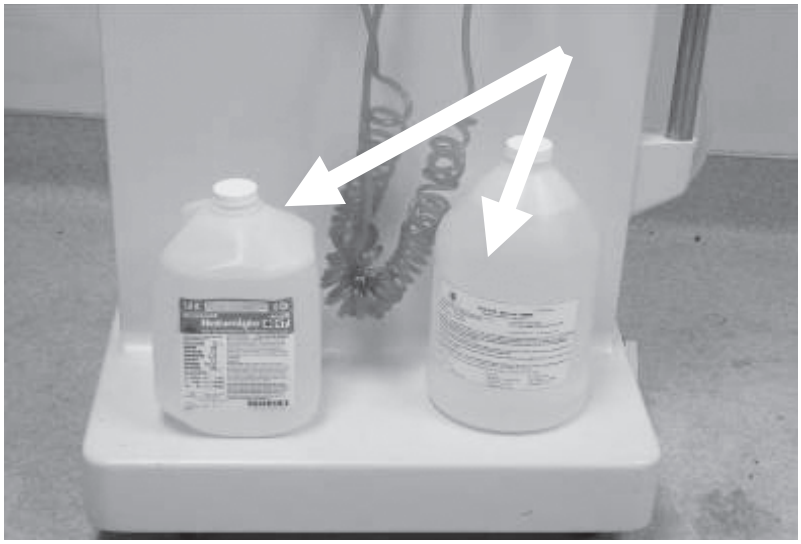
Transducer Protector—Internal



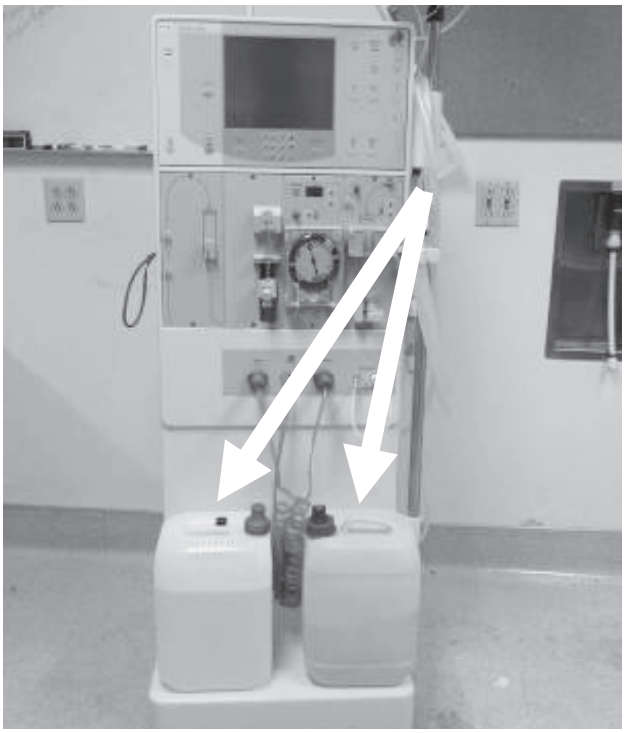
Transducer Protector—External



Priming Bucket



Disposable Acid and Bicarb Jugs



Reusable Acid and Bicarb Containers

Key principles related to equipment cleaning/disinfection that should be adhered to in order to reduce the risk of cross-contamination in HD settings follow.

- Items taken into an individual HD patient station should be disposed of after use, dedicated for use on a single patient, or cleaned and disinfected before being taken to a common clean area or used on another patient.
- Non-disposable items that cannot be comprehensively cleaned and disinfected (e.g., adhesive tape, cloth-covered blood pressure cuffs) should be dedicated for use on a single patient.
- External venous and arterial pressure transducer filters/protectors should be changed after each patient treatment, and should not be reused. Internal transducer filters do not need to be changed routinely between patients.
- When reprocessing or disposing of dialyzers, dialyzer ports should be capped and tubing clamped. The used dialyzer should be placed in a leak proof container for transport from the patient station to the reprocessing area. Gloves should be worn at a minimum. Gowns are required if there is any risk of contamination of clothing.
- All equipment, including the front of the dialysis machine, should be considered contaminated after a patient dialysis session.
- Non-disposable instruments (scissors, hemostats, clamps, etc.) which have no contact with sterile tissue or mucous membranes may become contaminated during the procedure. To facilitate thorough cleaning of the hinges and joints, these instruments should be first submerged and cleaned (e.g., with enzymatic detergent, rinsed thoroughly, then soaked in an appropriate disinfectant according manufacturer's instructions—typically low level disinfectant unless visibly contaminated with blood—then tuberculocidal disinfectant). The alternative would be to send the instruments to the Sterile Processing Department, if available, for reprocessing. Wiping with a cloth saturated with disinfectant may not be adequate to thoroughly clean hinged or jointed instruments.

Exterior Cleaning and Disinfection of Dialysis Machine

Exterior (surface) cleaning and disinfection of dialysis machine can be accomplished between each treatment using any approved EPA-registered disinfectant labeled for use in healthcare settings and in accordance with facility policy and procedure. In a typical HD setting, dialysis technicians and registered nurses generally perform the process of cleaning of the patient station between dialysis sessions. Dialysis schedules and pace must accommodate comprehensive cleaning between patient treatments.

Interior Disinfection of Dialysis Machine

Disinfection of the internal pathways of the dialysis machine between patient uses is not required. Dialysis machines are engineered so that the pathways segregate blood and dialysate. The pathways further segregate clean (affluent) dialysate from effluent dialysate (that which has passed through the dialyzer). The term used to describe the flow schematic of HD machines is "single-pass." This means that the dialysate solution passes through the hemodialyzer once, where it picks up renal waste from the blood through a one way membrane, and then is routed to drain without contaminating any fresh dialysate being introduced into the hemodialyzer. When a single machine is used in succession by patients, cross-contamination via the internal pathways of the machine is prevented by the single-pass feature of the HD machine. The exception is if a blood leak event occurs. In the event of a blood leak outside of the blood pathway, the CDC recommends internal disinfection before the dialysis machine is used on a successive patient. A blood leak results when the hemodialyzer fiber membrane is compromised and allows blood to enter the dialysate pathway. In this event, disinfection of this pathway must be performed prior to use of the HD machine on a successive patient.

There are two methods of disinfecting the dialysate pathways (internal) of the HD machine: heat and chemical. The standard as recommended by HD machine manufacturers is to perform disinfection of the dialysate pathways at the end of each treatment day using heat disinfection. Heat disinfection is an auto-cycle that subjects the pathway to an 80°+ centigrade water temperature for approximately 30 minute exposure time. The process is convenient and excludes the use of any chemicals to achieve disinfection for the purpose of bacterial control. Alternatively, chemical disinfection can be accomplished using a variety of solutions including sodium hypochlorite (bleach) and peroxyacetic acid (compound comprised of peracetic acid and hydrogen peroxide). When using a chemical disinfectant, it is important to follow the manufacturer's recommendation regarding concentration and dwell time. In the acute setting where dialysis may not be performed on a daily basis, HD machines may be inactive for prolonged periods of time and could potentially develop bacterial growth. In this situation, inactive machines must be chemically disinfected prior to patient use.

Monitoring Dialysis Machine Disinfection

The effectiveness of disinfection for the internal pathways of the dialysis machine can be validated by routine bacteriologic and endotoxin analysis. Testing of HD machine dialysate and reverse osmosis (RO) water (a central system) for bacteria and endotoxin assay are required at least monthly. This should involve testing of at least two HD machines each month. The sampled machines must be rotated so that each machine in the facility is tested at least annually. Testing of dialysate should be performed at the end of the treatment day. The process of sampling versus testing all machines each month is practiced for two reasons. First, the testing of every machine every month can be labor intensive and costly. Secondly, since all outpatient machines receive the same water via a single distribution loop and each machine is disinfected on the same frequency and same procedure, testing two machines randomly on a rotating basis provides a comprehensive testing model. Dialysate testing for a dialysis machine using portable RO or in a home setting should be performed on a quarterly basis at a minimum.

The maximum allowable level for dialysate bacteria is 200 colony forming units (CFU)/mL, with an action level of 50 CFU/mL. An action level of 50 CFU/mL has been established so that corrective measures are performed to

prevent bacteria proliferating to higher levels. The maximum allowable level for dialysate endotoxin is 2 endotoxin unit (EU)/mL, with an action level of 1 EU/mL. As with bacteria, the action level for endotoxin has been established so that corrective measures are performed as an early intervention, preventing endotoxin proliferating to the maximum allowable levels. A decision tree that is published in AAMI RD52 is attached and can be used to guide the analysis and action taken in response to test results.

Auxiliary Equipment

Additional or auxiliary equipment in an HD setting can include jugs for acid concentrate, sodium bicarbonate concentrate, a priming bucket, and the transducer protector (disposable). Bicarbonate powder can be mixed with processed water in a centralized vat, in individual jugs, or via automated process on the individual machines (e.g., BiCART, Gambro, Lakewood, CO). All disposable equipment is to be used for only one patient and then must be discarded. Acid concentrate and sodium bicarbonate concentrate can be delivered to the dialysis machine via a distribution loop similar to the RO water loop. Acid, because of its high salt concentration and low pH, is not conducive to bacterial growth and therefore this system would not require routine bacterial control strategies. Sodium bicarbonate can support bacterial growth, and this system (which includes the mixing tank, distribution tank, pipe loop, and outlet connectors) must be disinfected at least weekly, using the same process as that used for the RO loop. For facilities that do not use central delivery for concentrate solutions, the use of disposable or reusable jugs is the alternative. For these facilities, each dialysis treatment would utilize two jugs: one for acid and one for sodium bicarbonate. Disposable jugs must be discarded after each use. "Topping off" or adding additional sodium bicarbonate solution to single use jugs is not permitted. The growth of bacteria can occur with prolonged use of the sodium bicarbonate solution in an opened container. Consequently, sodium bicarbonate jugs should not be used 24 hours or more after opening.

Reusable jugs for sodium bicarbonate must be treated as all other reusable dialysis equipment and subjected to cleaning and disinfection (exterior of jug) prior to removal from the machine after each patient session. With the acid concentrate, it is not necessary to empty, rinse, clean, and disinfect the jug. Sodium bicarbonate reusable jugs must be emptied and rinsed with AAMI quality water (RO water) after use. Tap water should not be used for the cleaning and rinsing of the container. Water that is of AAMI quality water (dialysis quality) should be used. Disinfection of the inside of the sodium bicarbonate jugs must be performed at least weekly. The new CMS regulation references the use of bleach at 1:100 dilution as an example of an acceptable disinfectant for this purpose.

Priming buckets are containers that can be attached to the side of some HD machines. This container serves to collect the solution used for preparing the extracorporeal system (blood lines and dialyzer). The procedure for use of the priming buckets may vary from facility to facility. Consequently, the initiation of the dialysis session may or may not introduce blood into the priming bucket. Regardless of the procedure, the priming bucket should be emptied, cleaned, and disinfected after the initiation of each treatment. Cleaning and disinfection of the priming bucket should follow the same procedure used for the sodium bicarbonate jug.

The arterial segment of the blood line is connected to the patient's arterial access and removes blood from the patient. The venous segment of the bloodline is connected to the patient's venous access and returns blood to the patient. The transducer is a component within the electronic modules of the dialysis machine which monitors the condition of these blood pathways by measuring the flow pressure in both venous and arterial segments of the pathway in the dialysis machine. Transducer protectors serve as an additional barrier between the dialysis machine and the patient's blood. Internal transducer filters do not need to be changed routinely between patients. External transducer protectors need to be changed after each dialysis session. In addition, during the dialysis session, if the external transducer protector filter becomes wet with blood or fluid, it must be replaced immediately and the

transducer inspected. If blood or fluid is visible on the side of the filter that connects to the machine, inspection of the internal hardware of the dialysis machine must be performed prior to use on subsequent patients. A qualified biomedical engineer or a trained and qualified dialysis HCW must inspect the external and internal hardware for blood or fluid intrusion. If the equipment has been contaminated with either blood or fluid, the internal lines and filter must be replaced and the external machine connector port disinfected with an intermediate-level disinfectant such as 1:100 bleach solution.

Reprocessing and Reuse of Hemodialyzer

The practice of reusing dialyzers (for the same patient) has been performed in the U.S. since the 1960s. The U.S. Food and Drug Administration (FDA) published "Guidance for Hemodialyzer Reuse Labeling" on October 6, 1995. The document requires that dialyzers labeled for multiple uses must include instructions for their safe and effective reuse. This means that instructions for cleaning, rinsing, disinfecting, and testing the dialyzer as well as instructions for preparation before use (priming) must be included in the labeling package (package insert). Warnings must be included regarding the use of any reprocessing agents or processes known to adversely affect the manufacturer's dialyzer. The percentage of centers practicing reuse declined after 1997 to 63% in 2002,[1] and in 2005, it was estimated that 61% of patients were being treated with single-use dialyzers.

The terms reprocessing and reuse have often been used interchangeably within the dialysis community. In fact, the two terms describe different aspects of the multiple use practice. Reprocessing is the act of cleaning, testing, and filling dialyzer with germicidal solution. This is performed outside of the dialysis treatment area. Reuse is performed in the treatment area and refers to verification of germicide, rinsing and testing to ensure the comprehensive removal of all germicide, and "reusing" the reprocessed dialyzer for the designated (same) patient. Reuse and reprocessing must follow all applicable AAMI standards to receive CMS reimbursement.

See Appendices for details.

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Hand Hygiene

Hand hygiene is the single most important intervention in preventing infections in healthcare. The challenge, however, is to achieve compliance. Poor hand hygiene compliance has been well documented across the continuum of care, including dialysis facilities.[1,2] There are a number of factors that affect compliance. The large number of times that hand hygiene must be performed is one impediment. Other challenges include frequent movement of dialysis staff between patients and between machines and the urgency associated with patient incidents and machine alarms.

It is important to make hand hygiene as simple and expeditious as possible to encourage compliance. The use of alcohol-based hand sanitizer (i.e., gels, wipes, or foams with an alcohol concentration of greater than 60%) for hand hygiene is preferred over hand washing with soap and water, unless the caregiver's hands are visibly soiled. This is because of the superior efficacy of alcohol sanitizer over soap and water, as well as less time required for use. Dispensers can and should be placed at each patient station so that the caregiver can quickly and easily perform hand hygiene without having to leave the chairside to walk to a sink. Sinks with soap dispensers should be available as well, as alcohol sanitizer should supplement instead of replace soap and water washing.

The most critical times for performance of hand hygiene are just before touching a patient and before leaving a patient station. Other important times include after gloves are removed; after touching blood, body fluids, secretions, excretions, and contaminated items (including front of the HD machine); and before accessing or restocking supplies.

Fingernails should be kept short and clean for several critical reasons, including that the subungual region (underside portion of nail that extends beyond fingertip) harbors the majority of microorganisms found on the hand. Removing debris from fingernails requires vigorous cleaning and running water. Additional effort is necessary for longer nails. Also, the risk of tearing gloves increases if fingernails extend past the fingertips, and long fingernails may scratch or gouge patients during patient care.

CDC states that artificial nails are prohibited for direct patient care providers. Bacteria, viruses, and fungus adhere more readily to the material used to make artificial nails. Consequently, artificial nails may harbor organisms which may remain despite hand hygiene. Studies report higher number of Gram-negative microorganisms on artificial finger nail surfaces, both before and after handwashing, and infection transmission has been reported in inpatient environments. Although there have been no studies specific to the HD setting, the method of contamination described in inpatient accounts would theoretically create the same risk in any patient care setting including HD.

Patients must also be instructed in the importance of hand hygiene including before and after dialysis sessions.

Glove use is an integral aspect of hand hygiene. Gloves must be worn in HD facilities whenever caring for a patient or touching the patient's medical equipment, handling lab specimens or used dialyzers, cleaning machines, cleaning stations, and wiping up blood or other body fluid spills. They must be changed whenever moving from one patient or machine to another. Gloves must be changed after cannulation. Clean disposable gloves are provided for this type of routine use. Sterile gloves must also be available and used during procedures requiring aseptic technique such as central line insertion.

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Patient Immunizations and TB Screening

For reasons illuminated previously, HD patients are at increased risk for a variety of infections including TB and a number of vaccine preventable diseases. The immunizations that should be a component of standard care for HD patients include (many of the recommended vaccines and schedules below apply to adults, not other age groups):

- **Tetanus:** a dose of dT should be given every 10 years; a single dose of dT with acellular pertussis vaccine (Tdap) can be substituted for those under 65 years of age. This assumes the patient has completed a primary series. If not, this should be done.
- **Pneumovax:** an initial dose should be given when the diagnosis of CKD is made; a single booster should be given 5 years to complete the lifetime series.
- **Influenza:** yearly immunization is required.
- **Shingles:** all dialysis patients over 60 should be evaluated for Zostavax (Merck & Co. Inc., Whitehouse Station, NJ).
- **HBV:** full series of three vaccinations (HBV vaccine may be a four dose series rather then three dose series, depending on the vaccine preparation being provided). Serologic testing of HD patients is recommended 1–2 months after administration of the final dose of the primary vaccine series to determine the need for revaccination. For HD patients, the need for HBV vaccine booster doses should be assessed by annual testing for antibody to HBV surface antigen (anti-HBs). A booster dose should be administered when anti-HBs levels decline to less than 10 mIU/mL.

Note: Tetanus and shingles vaccine may not be billable in the outpatient dialysis setting.

Additional Detail: HBV Vaccination

All new patients should receive a full course of HBV vaccine. A higher dose than normal is recommended (Table 1) since the immune response is impaired in ESRD patients and both the antibody response and the rate of seroconversion in these patients is lower than in non-ESRD population.[1] Patients should receive HBV vaccine in the predialysis phase when the immune response is better preserved. This practice maybe uncommon, often because the patient has not seen a nephrologist prior to initiation of maintenance dialysis.

In the case of failure of the patient to reach the desired titer of antibody (≥10 mIU/mL), a repeated course is recommended. If the patient still does not respond, he or she should be considered susceptible and screened monthly for HBsAg. No additional doses of vaccine are warranted for those who do not respond to a full second series.

HD centers must be careful not to send blood for testing for HBsAg within 2–3 weeks of HBV vaccine administration, as during this time HBsAg may be detected. This is referred to as transient antigenemia, which can lead to an erroneous diagnosis of acute HBV infection and unnecessary concern. Additionally, there is potential risk to the patient if they are inappropriately treated in an HBV isolation area.

Although sufficient time must be allowed between the vaccine administration and the testing of the surface antigen, it is imperative not to skip the monthly antigen blood draw. Ideally, the monthly blood is drawn immediately before giving the vaccine. This way, no matter what dose of the vaccine in the series is administered, sufficient time will have been allowed avoiding transient antigenemia.

Table 1. Doses and Schedules: Hepatitis B Vaccines for Hemodialysis Patients

Group	Recombivax HB			Engerix B		
	Dose	Volume	Schedule	Dose	Volume	Schedule
≥20 years of age: predialysis*	10 μg	1.0 mL	Three doses at 0, 1, and 6 months	20 μg	1.0 mL	Three doses at 0, 1, and 6 months
≥20 years of age: dialysis-dependent	40 μg	1.0 mL†	Three doses at 0, 1, and 6 months	40 μg	Two 1.0 mL doses at one site	Four doses at 0, 1, 2, and 6 months
<20 years of age‡	5 μg	0.5 mL	Three doses at 0, 1, and 6 months	10 μg	0.5 mL	Three doses at 0, 1, and 6 months

*Immunogenicity might depend on degree of renal insufficiency.
†Special formulation.
‡Doses for all persons aged <20 years approved by the U.S. FDA. For HD patients, higher doses might be more immunogenic.

Note: All doses should be administered in the deltoid by the intramuscular route.

Adapted from CDC. Recommendations for preventing transmission of infections among hemodialysis patients. *MMWR* 2001;50(RR-5):Table 3.

Patients who do achieve the anti-HBs level of at least 10 mIU/mL should be screened annually, since patients with ESRD tend to lose their protective level at a much higher rate than normal. If the anti-HBs level falls below 10 mIU/mL, the patient should be given a booster dose of vaccine. Patients who are both anti-HBs and anti-HBc positive do not require such follow-up screening.[2]

TB Screening

It is critical to ensure that screening for latent TB infection in patients with renal failure occurs at a very early stage. CDC recommends (and CMS requires) that all HD patients be screened for TB at baseline and whenever exposure is suspected. Screening can be by tuberculin skin test or blood test. Patients with ESRD are at high risk for progression from latent TB to active TB disease. Those who come from areas of the world where TB is endemic are especially at risk. For those with positive tests, latent TB infection should be considered. Although the sensitivity of TB skin testing is substantially reduced in the setting of chronic renal failure with rates of anergy in excess of 30%, this should not preclude its use as a screening tool because specificity is unaltered. Also, since these patients are frequently hospitalized, the potential for transmission to other patients and HCWs is significant. Because of the high incidence of anergy in this population, patient and staff education should include symptoms of TB in order to support timely diagnostic work-up, which should not replaced by total dependence on the tuberculin test.

There is a growing body of evidence suggesting potential improved sensitivity of the QuantiFeron TB Gold blood test (Cellestis Limited, Carnegie, Vistoria, Australia) in HD patients compared to tuberculin skin test. The potential role of QuantiFeron TB Gold in HD population is an evolving subject.

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Medication Safety and Injection Practices

Background

The transmission of bloodborne viruses and other pathogens during routine healthcare procedures continues to occur. Root causes include improper injection, infusion, and medication vial practices within various clinical settings throughout the U.S. Over 35 outbreaks of hepatitis have occurred in a wide range of settings in the U.S. in the past 10 years because of these and other unsafe practices. These outbreaks have resulted in the transmission of hepatitis B or C to more than 500 patients. The unsafe practices that were reported in these outbreaks include:

- Syringe reuse between patients during medication administration;
- Contamination of medication vials or IV bags; and
- Failure to follow basic injection safety practices when preparing and administering parenteral medications to multiple patients such as "scrub the hub."

General Principles

The following general principles are recommended in all patient care settings, including HD, in order to reduce the risk of infection transmission between patients and between employees and patients.

Aseptic Technique

- Perform hand hygiene prior to accessing supplies, handling vials and IV solutions, and preparing or administering medications.
- Use aseptic technique during all aspects of parenteral medication administration, medication vial use, injections, and glucose monitoring procedures.
- IV medications should be prepared in a clean area away from the patient treatment area to avoid contamination.
- Discard all opened vials, IV solutions, and prepared or opened syringes that were used in an emergency situation.

IV Solutions

- Never use IV solution containers (e.g., bags or bottles) for the purpose of IV flush solutions (or other purposes) for more than one patient.
- Never use infusion supplies such as needles, syringes, flush solutions, administration sets, or IV fluids on more than one patient.
- Complete infusion of lipid containing solutions within 24 hours, lipid emulsions with 12 hours, and blood/blood products within 4 hours.
- Disinfect IV ports prior to accessing, using friction and 70% alcohol, iodophor, or chlorhexidine/alcohol agent. Allow to dry prior to accessing.

Flushing

- Use single-dose containers for flush solutions.[1]

Syringes

- Never use medication in a syringe for more than one patient even if the needle is changed between patients. Changing the needle but not the syringe is unacceptable.
- Utilize sharps safety devices whenever possible.
- Discard syringes, needles, and cannulas after used on a patient or in the IV administration system.
- Dispose of used needles at the point of use in an approved, puncture resistant sharps container.

Vials

- Use single-use or single-dose vials whenever possible.
- Always use a sterile syringe and needle/cannula when entering a vial.
- Never enter a vial with a syringe or needle/cannula that has been used on a patient.
- Cleanse the access diaphragm of vials using friction and 70% alcohol. Allow to dry before inserting a device into the vial.
- Discard single-dose vials after use. Never reuse for another patient.
- Use multidose medication vials for a single patient whenever possible and access all vials using a new sterile syringe and needle/cannula with adherence to aseptic technique. The risk of transmission posed by multidose vials has been clearly demonstrated and mandates a practice of one vial per one patient whenever possible. Infection transmission risk is reduced when multidose vials are dedicated to a single patient.
- Never store vials in clothing or pockets.
- Never pool or combine leftover contents of vials for later use.
- Never leave a needle or cannula inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination.
- Dispose of opened multidose medication vials 28 days after opening.[2] Date vial to reflect date opened and date of expiration. CDC Immunization Program states vaccines are to be discarded per manufacturer's expiration date.
- Examine the vial for any particulate matter, discoloration, or turbidity. If present, do not use and discard immediately.
- All vials used during an emergency should be discarded as sterility cannot be guaranteed.
- Do not use medication carts to transport medications to patient stations in HD settings

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Patient and Employee Education

Staff education and oversight of compliance with infection prevention practice is mandatory in all direct care areas including HD settings (see Appendix "Infection Control Training and Education" extracted from the CDC 2001 Recommendations). HD facilities should designate an individual responsible for oversight of the Infection Prevention program under the supervision of the medical director. This role could be fulfilled by the clinic manager or other designee. The scope of this position must include education of employees and patients related to infection prevention and control in the HD setting. Most of the care in the dialysis facility is delivered by patient care technicians who are under the supervision of registered nurses. In some states, prior to the new Conditions for Coverage (CfC) implemented by CMS in October 2008, there were no required qualifications for patient care technicians. Some states such as Arizona, Oregon, and Ohio required patient care technician certification prior to the new CfC and certified clinical HD technician certifications. Most HD facilities have always had defined training programs in place. As a result of frequent turnover among HD caregivers, training of new staff can be particularly challenging. HD staff assigned to be in charge of infection prevention and control typically do not have experience in this area. HD facilities should consider seeking assistance from a certified IP to assist with education and training of staff.

Patient involvement in any effective infection prevention and control program is critical. Dialysis staff should ensure patients are involved and understand their role in the infection prevention and control program. This can be supported via education regarding the patient role in infection prevention and control including hand hygiene, access and wound cleaning, respiratory etiquette, and understanding/reporting signs and symptoms of infection. Caregivers and patients should be educated by HD staff regarding what infection prevention measures they should expect to see taken by their dialysis team. An informed patient can make an important contribution to infection prevention efforts.

The following site provides a great resource for patient education for all aspects of CKD and HD: http://www.dialysispatients.org/resources.

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Presurgical (HD Access) Infection Prevention

HD access-associated surgery can be performed on an inpatient or outpatient basis. Dialysis patients are often more immunocompromised than other preoperative patients, so guidelines for surgical infection prevention should be strictly followed.

Preoperative Showers/Bathing

Patients typically arrive at the surgical center or hospital the same day as the scheduled surgery, and should have performed preoperative antiseptic bathing/shower(s), focusing on cleansing of the access extremity, according to their physician's instructions prior to arrival. Preoperative bathing or showering with an antiseptic agent such as CHG has been shown in a number of studies to reduce the risk of postoperative surgical site infection, though this evidence does not rise to the level of Category I. However, there is ample evidence that CHG effectively reduces the bacterial load on the skin. Based on the most current published evidence, the most promising agent and delivery method appears to be CHG-impregnated bathing cloths used to bath the entire body with special focus on the preoperative surgical site the night before and morning of surgery.

Hair Removal

Once the patient is admitted to the surgical center or hospital, any excess hair removal at the surgical site may also be performed. The national standard for preoperative hair removal is that hair should only be removed if absolutely essential, and then it should be performed with clippers instead of razors. This is because of an increased risk of infection associated with microabrasions resulting from razor use. Hair removal should be performed immediately prior to the surgical procedure and outside of operating room so that clipped hair does not contaminate the operating room environment.

Vascular Access Protection

It is also very important to avoid IV line placements and phlebotomy in the arm where the dialysis vascular access is going to be placed. This is a critical action that not only helps prevent infection, but also maintains the integrity of the vasculature near the operative site.

Active Surveillance Screening for MRSA and Decolonization

Although there is not Category I level evidence regarding efficacy, some medical centers are culturing patients preoperatively for MRSA. For those who test positive, nasal mupirocin is applied to decolonize the nasal passages before surgery as an additional measure to reduce postoperative infection risk.

Postsurgical Care

After surgery, primary patient care goals include keeping the vascular access working and preventing infection. A temporary catheter is generally used for HD while the permanent access is maturing. Since temporary catheters are associated with a greater risk of infection and associated hospitalization than permanent access (fistula/graft), the goal is to remove the temporary catheter as soon as possible.

Hospitalizations for Vascular Access Infections by Access Type

Fistula	Graft	Catheter
1.1%	2.6%	15.2%

Source: Collins AJ, Foley RN, Herzog C, et al. United States Renal Data System 2008 Annual Data Report Abstract. *Am J Kidney Dis* 2009;53(1 Suppl):vi–vii, S8–374.

Since prevention is the preferred strategy in access care, the following information should provide the basis for patient education postsurgery. Patients should be taught to contact the surgeon if any of the following is noted after any type of vascular access surgery.

1. The incision is swollen, red, warm, or there is the presence of pus
2. Stitches comes apart
3. Bandage becomes soaked with blood
4. Development of a fever
5. Absence of thrill in a fistula or graft (A thrill or bruit must be present to ensure that the vascular access is working. Thrill is defined as a rhythmic vibration that can be felt over a fistula or graft. A bruit is a sound that is heard when listening to the vascular access with a stethoscope.)
6. New bulging of the access
7. Fingers becomes blue, cold, or numb
8. Severe pain in the access site.

Postsurgical Care of an HD Access (Temporary or Permanent)

In addition to possible signs of adverse outcomes, the patient should also be informed regarding actions they can take to reduce the risk of postoperative infection, including the following.

- Hand hygiene must be performed before donning gloves, prior to wound care or vascular access.
- The patient should be reminded not to touch the skin at the site where the catheter enters the skin or where the fistula/graft has been placed.
- The area around the new access should be covered with a clean, dry dressing.
- The patient's clothes should not impede or compromise the access.
- The patient and nurse must wear a mask when a catheter (not fistula or graft) is connected or disconnected from the blood lines during dialysis.

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Standard Precautions

Standard Precautions (formerly Universal Precautions) refers to the practices that are designed to prevent transmission of infection by contact with bodily fluids. The concept of Standard Precautions is based on the principle that *all* blood, body fluids, secretions, and excretions of *all* patients may contain transmissible infectious agents, and involves the use of PPE such as masks, face shields, gowns, and gloves. In HD settings, in addition to Standard Precautions, more stringent measures are recommended because of the increased potential for contact with blood and bloodborne pathogens including HIV, HBV, and HCV. The risk of exposure is increased because accessing the bloodstream is required during the dialysis session, there is close proximity of patients, and staff have frequent contact with numerous patients and equipment. Exposure to blood and potentially contaminated items can be routinely expected during the process of HD. As a result, dialysis healthcare personnel must take more rigorous steps to protect their patients as well as themselves, as follows.

- **Use dedicated equipment:** A risk of transferring infectious material between patients is created when moving equipment or disposables from patient station to station. Any single-use disposable item must be used for only one patient and then discarded. Items such as adhesive tape should be dedicated for use on a single patient and discarded. Blood pressure cuffs should be made or covered with a material that can be cleaned and disinfected between patient uses. Items such as pillows and blankets are sometimes supplied by the facility and sometimes the patient. Patients bringing items from home to the unit for each treatment must take them home afterwards to prevent use by other patients. Unused medications or supplies (e.g., syringes, alcohol swabs) taken to the patient's station should not be returned to a common clean area or used on other patients.
- **Prohibit use of shared mobile supply or medication carts.**
- **Gloves must always be worn** for any contact with the patient or a patient's equipment.
- **Isolation of HBsAg-positive** patients (see HBV Isolation/Precautions)

PPE Guidelines for Standard Precautions in HD Settings

The following guidelines for PPE use should be followed for all patients in all HD settings.

Patients

1. Wear a mask during initiation and discontinuation of dialysis treatment if vascular access is a catheter.
2. Wear a mask in an HD facility when experiencing symptoms of an upper respiratory illness.

Employees

1. Lab-style cover coats:
   - Regular cotton, non-fluid resistant lab coats are *not* considered PPE and should be removed or worn under an isolation or fluid resistant gown when needed.
   - Fluid resistant lab coats *are* considered PPE.
   - Either type of lab coat must be removed if it becomes soiled or wet.
   - Either type of lab coat must be removed prior to leaving the unit and for breaks and lunch.
2. Full isolation or fluid resistant gowns should:
   - Be worn when caring for an isolation patient with HBV.
   - Cover arms and be closed in front.

- Be worn when there is likelihood of blood contact, especially when initiating and removing patients from dialysis.
- Be worn when there is a likelihood of body fluid contact especially with diarrheal illnesses, uncontrolled secretions, draining wounds, stool incontinence, and ostomy tubes and bags.
- Be worn during reprocessing of dialyzers.

3. Gloves should be:
   - Worn whenever caring for a patient.
   - Worn when touching the patient's medical equipment or handling lab specimens or used dialyzers.
   - Worn when cleaning machines, cleaning stations, or wiping up blood or other body fluid spills.
   - Changed whenever moving from one patient or machine to another.
   - Changed when moving from a dirty to a clean site/task on the same patient (i.e., new gloves should be donned after touching the HD machine, prior to touching the same patient's vascular access)
   - Changed after cannulation.
   - Removal of gloves should always be followed with hand hygiene.
4. Mask should be:
   - Worn if experiencing mild cold or cough illness in order to protect patients and other employees.
5. Face protection (mask with eye protection [goggles, face shield]) should be:
   - Worn during initiation and discontinuation of dialysis.
   - Worn during reprocessing dialyzers or cleaning equipment in a sink.
   - Worn when within 6 feet of an unmasked coughing patient.
   - Discarded between patients or if reusable, cleaned and disinfected between uses as indicated.

HBV Isolation/Precautions

Introduction

In addition to Standard Precautions, isolation (separate room) for HBsAg positive patients is standard of practice in HD facilities, for several reasons:

1. Environmental stability: HBV can persist on surfaces and equipment and remain infectious at ambient room temperature for up to 7 days. HBsAg has been detected on clamps, machine control surfaces, doorknobs, and other surfaces in dialysis facilities. These blood-contaminated surfaces can serve as a reservoir for HBV transmission, creating the potential for contamination of healthcare personnel hands, equipment, and supplies.
2. High viral titer: Persons with HBV infection tend to have high concentrations of virus in their blood. This, along with its environmental stability, makes the risk of HBV transmission from blood contaminated items in this setting greater than would be expected for other common bloodborne viruses.

While HCV and HIV also pose potential infection risk to employees and patients, the risk is significantly less than that related to HBV:

- HIV infection from an exposure occurs at a rate of 0.2%–0.4%.
- HCV infection from an exposure occurs at a rate of less than 1%.
- HBV infection from an exposure occurs at a rate of up to 30%.

Note: The relative risk of HIV/HCV infection is significantly less than that of HBV for both HCWs and patients, though the rates above reflect only HCW conversions.

HBV Isolation/Precautions

- Patients are placed in a private room or segregated area.
- Dedicated dialysis machine is used for HBV-positive patients.
- Dialyzers are discarded in biomedical waste after treatment.
- Dialyzers can not be reprocessed/reused.
- Gown and gloves are required for each entry into room.
- Mask with eye protection is required for cannulation and decannulation.
- Staff caring for HBV patients cannot care for HBV susceptible patients at the same time.[1,2]
- Staff caring HBV patients should be HBV-immune.
- Required when the surface antigen is positive and not required when the surface antigen is not detectable.

Since the introduction of universal HBV vaccination in 1991 in the U.S., the prevalence of chronic HBV infection in the general population including dialysis patients has decreased. In the 1999–2004 *National Health and Nutrition Examination Survey (*NHANES),[3] the prevalence was reported to be 0.27%. However, it must be remembered that certain racial groups have much higher prevalence of positivity. A survey of the general population in Rochester County, Minnesota, showed a prevalence of 2.1% among Asians, 1.9% among African-Americans, and 0.02% among Caucasians. A total of 86% of the population with chronic HBV infection were born outside the U.S.[4] Other groups at high risk include men who have sex with men and IV drug users.[5]

Risk Factors for HBV Infection in HD Units

It should be emphasized that outbreaks of HBV infection in dialysis facilities in the U.S. and other developed countries occur as a result of clear violations of standard practice.[6] In a review of outbreaks with patient-to-patient transmission between 1992 and 2007 in the U.S. and Europe, 30% of 33 outbreaks occurred in HD facilities, the largest single setting identified.[7] Risk factors for HBV infection in HD facilities include the presence of HBsAg-positive patients within the dialysis unit, the use of the same dialysis machines for HBsAg positive and negative patients (i.e., HBsAg patients not being isolated), a relatively low prevalence of HBV vaccination in unit patients, and multiple entries into single or multidose medication vials. The preparation of injectable medications within the HD treatment area has also been associated with a higher incidence rate for HBV infection compared to centers that used a dedicated medication room (2002 incidence rates of 0.27% and 0.06%, respectively).[8]

It is important to note that a negative HBsAg test does not preclude the presence of occult HBV infection (HBsAg-negative, HBV DNA positive). In a study from a Canadian dialysis center, 2 of 241 patients were HBsAg positive, while nine (3.8%) of the 239 HBsAg negative patients were positive for HBV DNA in the serum by real-time polymerase chain reaction,[9] and in a study of 188 HD patients from Turkey overt HBV infection was found in 25 patients (13.3%) and occult HBV infection in 5 (2.7%).[10] Transmission of occult HBV infection in dialysis settings has not been demonstrated; however, transmission of HBV infection in nondialysis patients by liver transplantation or by blood transfusion from donors with occult HBV infection has been reported.[11]

HIV Positive Patients

Standard Precautions recommended for all HD patients (see Appendix: Recommended Practices) are sufficient to prevent HIV transmission between patients. HIV-infected patients do not have to be isolated from other patients or dialyzed separately on dedicated machines. In addition, they can participate in dialyzer reuse programs. Because HIV is not transmitted efficiently through non–sharps-associated exposures, reprocessing dialyzers from HIV-positive patients should not place staff members at increased risk for infection.

HCV Positive Patients

Standard Precautions recommended for all HD patients are sufficient to prevent HCV transmission between patients. Patients who are anti-HCV positive (or HCV RNA positive) do not have to be isolated from other patients or dialyzed separately on dedicated machines. According to CDC recommendations, dialyzers can be reused (for same patient) with HCV infection.[1] Case series have not shown that the risk of transmission is higher in centers that practice such reuse.[12] HCV is not transmitted as efficiently as HBV, and the HCV conversion rate for HD patients is low. In one report, the rate of seroconversion of known negative patients was 0.34%.

However, this disease still remains a risk to HD patients and employees since there is no vaccine to confer immunity, and the prevalence of persons with chronic HCV infection is currently much higher than that of HBV infection. Adding to the severity of the risk is that the incidence of chronic persistent infection after an acute episode of HCV is high: 80%–100% of patients remain HCV-RNA positive, and 60%–80% have persistently elevated liver enzymes. Data derived from NHANES suggest that the prevalence of HCV infection in the general population is only about 1.6%. The prevalence of anti-HCV in patients in the various ESRD networks during the last National Surveillance of Dialysis-Associated Diseases in the United States in 2002 ranged from 5.5% to 9.8%,[8] significantly higher than in the general population.

The CDC and the Kidney Disease Outcome Quality Initiative (KDOQI) recommends screening HD patients for anti-HCV at 6-month intervals; however, CMS does not reimburse for this. Fortunately, there is a very low conversion rate of patients to HCV positivity when Standard Precautions are rigorously followed.

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Respiratory Hygiene/Cough Etiquette

Respiratory illnesses which cause coughing include but are not limited to influenza, upper/lower respiratory illnesses, pertussis, strep throat, and MRSA pneumonia. To prevent the transmission of all respiratory infections in HD settings, the following measures should be implemented year-round at the first point of contact with a coughing or potentially infected person. HD facilities should have adequate signage and supplies (tissue, waterless alcohol hand sanitizer(i.e., gels, wipes, or foams with an alcohol concentration of greater than 60%) to support the following prevention efforts.

1. Cover the nose/mouth when coughing or sneezing with tissues or masks to contain respiratory secretions and dispose of them in the nearest waste receptacle after use.
2. Persons unable or unwilling to use tissue or wear a mask should be spatially separated from others by at least 6 feet.
3. HCWs who care for individuals who are coughing or have a respiratory illness should don a mask with eye protection when within 6 feet of the individual (microorganism contact with conjunctiva can cause illness).
4. Patients and HCWs should perform hand hygiene after having contact with respiratory secretions and contaminated objects/materials.

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Transmission-Based Precautions

Transmission-Based Precautions are recommended in addition to Standard Precautions by the CDC when the route(s) of transmission is (are) not completely interrupted using Standard Precautions alone. There are three categories of Transmission-Based Precautions: Contact Precautions, Droplet Precautions, and Airborne Precautions.

1. **Airborne Precautions:** Transmissible airborne illnesses include varicella, disseminated varicella, TB, and measles. Microorganisms can remain airborne for up to 2 hours.
   - **Inpatient Setting**: Patients are placed in a negative airflow room. Respirators are required for TB and for anyone not immune to varicella, measles, or other airborne disease. It is recommended that those individuals who are not immune be reassigned to prevent exposure to vaccine preventable diseases. Hospital policies should be followed.
   - **Ambulatory Setting**: Patient identified with a suspected airborne disease should be masked immediately and geographically separated from other patients, preferably in a single room. Arrangements should be made for HD treatments at a facility that can provide a negative pressure isolation room.
2. **Droplet Precautions:** Illnesses transmitted by large respiratory droplets include pertussis, influenza, mumps, strep throat, rubella, diphtheria, Mycoplasma pneumonia, adenovirus, Neisseria meningitidis, Haemophilus influenzae type b, and acute respiratory infections with MRSA/VRE/other MDRO.
   - **Inpatient:** Hospital policies should be followed.
   - **Ambulatory Setting:** Respiratory Hygiene/Cough Etiquette Precautions should be followed. If hospitalization is required, the patient should be spatially separated by at least 6 feet from other patients and a mask worn until transport can be arranged. In HD facilities, dialysis center exposure management and follow-up policies should be followed in the event of a vaccine preventable disease exposure or meningitis. Only immune staff should care for patients with a vaccine preventable disease (i.e., mumps, rubella, diphtheria).
3. **Contact Precautions:** Illnesses transmitted via contact include *C. difficile*, adenovirus, rotavirus, impetigo, scabies, pediculosis, and MDROs (e.g., MRSA, vancomycin intermediate–resistant *S. aureus*, VRE, and other MDROs).
   - **Inpatient Setting:** Hospital policy should be followed.
   - **Ambulatory Setting**: Routine contact precautions are not required in HD units for patients infected or colonized with pathogenic bacteria for several reasons. First, although contact transmission of pathogenic bacteria is well-documented in hospitals, similar transmission has not been well-documented in HD centers. Transmission might not be apparent in dialysis centers, possibly because it occurs less frequently than in acute-care hospitals or results in undetected colonization rather than overt infection. Also, because dialysis patients are frequently hospitalized, determining whether transmission occurred in the inpatient or outpatient setting is difficult. Second, contamination of the patient's skin, bedclothes, and environmental surfaces with pathogenic bacteria is likely to be more common in hospital settings (where patients spend 24 hours a day) than in outpatient HD centers (where patients spend approximately 10 hours a week). Third, the routine use of infection control practices recommended for HD units (gloves for all patient and environmental contact), which are more stringent than the Standard Precautions routinely used in hospitals, should prevent transmission by the contact route.

When Additional Precautions are Recommended for MDRO in HD Facilities

Infection prevention and control precautions recommended for all HD patients (see above and also Appendices "Recommended Practices at a Glance") are presumed adequate to prevent transmission for most patients infected or colonized with pathogenic bacteria, including antimicrobial-resistant strains. However, additional infection control precautions should be considered for treatment of patients who might be at increased risk for transmitting pathogenic bacteria. Such patients include those with either an infected skin wound with drainage that is not contained by dressings (the drainage does not have to be culture positive for VRE, MRSA, or any specific pathogen) or fecal incontinence or diarrhea uncontrolled with personal hygiene measures. For these patients, consider using the following additional precautions: a) staff members treating the patient should wear a separate gown over their usual clothing and remove the gown when finished caring for the patient, and b) dialyze the patient at a station with as few adjacent stations as possible (e.g., at the end or corner of the unit). *Note*: These additional measures would be taken if the patient was considered at high risk for transmission in order to prevent transmission.

Overview: HCW and Patient PPE Guidelines for HD Facilities

Task	Gloves	Lab coats/ scrub	Gown or apron	Mask with eye protection or full face shield
HCW				
Patient set-up	X		X	X
Cannulation	X		X	X
Decannulation	X		X	X
Central line connection, disconnection	X		X	X
Providing snack		X		
Adjusting dialysis machine—no patient contact	X	X		
Transporting and pouring chemicals	X		X gown	X
Reprocessing equipment and dialyzers	X decontamination gloves (used once)		X gown	X
HBV isolation	X		X gown	determined by task
Central line insertion	Full sterile barriers (sterile gown/gloves/barriers; full face protection)			
Central line removal	X		X	X
Patient				
During cannulation or decannulation			barrier over clothing	
Central line connection, disconnection/dressing change				X
Visitors	X		X	

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Vascular Access—Infection Prevention During Insertion and Care

Overview

The primary risk factor for infection in HD patients is vascular access with CVCs. Unlike patients in other areas of the continuum of healthcare where the goal is to discontinue the vascular access when no longer indicated, access for HD patients is in most cases needed for life. Consequently, the goal (when possible) is to provide permanent vascular access, since the risk of infection is less with permanent than with temporary access. Infection rates with tunneled dialysis catheters (temporary access) are roughly 10 times that of fistulas or grafts (permanent access). In turn, grafts are associated with a higher infection rate than fistulas. There is an organized effort underway in the U.S. to promote early placement of fistulas to eliminate the need for a CVC when the patient initiates dialysis. The National Kidney Foundation KDOQI provides recommendations on types of temporary access prior to starting dialysis therapy. See Appendices (Planning for Dialysis Access) for details.

Types of Vascular Access

1. Catheter: A narrow tube percutaneously or surgically inserted into a vein in the neck, chest, or leg near the groin. The catheter has two chambers permitting a two-way flow of blood. There are two types of catheters: tunneled and non-tunneled. Tunneled (surgically inserted) cuffed catheters can be used for a longer time (months to years), and non-tunneled (percutaneously inserted) catheters are used for short periods (1–2 weeks). Because they protrude through skin incisions and have external connectors, catheters have a significantly higher risk and rate of infection than the AVF or AVG, which are buried beneath the skin and are only accessible by cannulation.
2. Fistula (also called AVF): A surgically performed connection of a vein and an artery under the skin in the arm. After the vein and artery are connected, the pressure inside the vein increases, making the vein larger and stronger over time. A good AVF can take 8–12 weeks to mature sufficiently for HD use.
3. Graft (also called AVG): A synthetic plastic tube which serves as a conduit placed between an artery and a vein surgically implanted under the skin in the arm. Grafts do not require as much time to mature as fistulas because the graft does not need time to enlarge before using. In most cases, a graft can be used about 2–6 weeks after placement.

Temporary Access: Indwelling Catheters (Cuffed or Uncuffed) and Port Catheters

Cuffed and uncuffed catheters used for dialysis vascular access are central lines with an external exit site, and therefore by design are at greater risk of infection than a fistula or graft. The access for port catheters is under the skin. Cuffed catheters with a balloon-type barrier near the skin opening are associated with a slightly reduced risk of associated infection when compared with uncuffed catheters. All types of catheters require meticulous skin preparation and strict aseptic technique. The KDOQI guidelines provide specific infection prevention/control measures for dialysis access catheters and focus on insertion and care.

Catheter Insertion

A number of steps designed to reduce the risk of catheter-related bloodstream infection (CRBSI) have been identified for percutaneous insertion of uncuffed CVCs, including the following.

- A checklist should be employed to support reliable and consistent practice and adherence to aseptic technique.

- Scrupulous hand hygiene should be performed prior to insertion using either an alcohol-based hand sanitizer (i.e., gels, wipes, or foams with an alcohol concentration of greater than 60%) or antimicrobial soap and water.
- Use of the femoral vein should be avoided in adults.
- Maximal sterile barrier precautions (including mask, cap, sterile gown, and sterile gloves) should be used by the catheter inserter.
- The patient should be covered with a large sterile drape.
- For patients older than 2 months, a skin preparation solution containing greater than 0.5% chlorhexidine gluconate and 70% isopropyl alcohol should be applied to the insertion site and allowed to dry before the skin is punctured.

Catheter Care

A number of practices designed to reduce the risk of CRBSI have been identified for care of percutaneously inserted uncuffed CVCs, including the following.

- The catheter exit site should be examined for proper position of the catheter and absence of infection by experienced personnel before accessing the bloodstream at each HD session.
- Aseptic technique should be used to prevent contamination of the catheter system, including the use of a surgical mask for staff and patient and clean gloves for all catheter system connect, disconnect, and dressing procedures.
- The hub of HD catheters can be soaked in povidone-iodine solution or wrapped with gauze saturated with povidone-iodine solution for 5 minutes prior to removing the caps.[1]
- A mask should be worm by the patient and a mask with eye protection should be worn by the employee during the entire time that the catheter is being manipulated—a face shield alone will not suffice and a mask must be worn under the face shield.
- A fresh pair of disposable gloves should be worn for the connection procedure (dialysis session initiation).
- After removing the cap, the hub should be wiped with CHG, alcohol, or povidone-iodine.
- The catheter hub should be connected immediately to limit exposure to air.
- This procedure should also be followed at the time the patient is disconnected at the end of dialysis session or for any other reason.
- Catheter manipulation should be kept to an absolute minimum; if there are flow problems they must be definitively addressed as quickly as possible.
- Exit-site care: The catheter exit-site dressing should be changed every 3 days (after each HD session) if gauze/tape, or every 7 days if transparent dressing is used in addition to whenever the dressing is wet or soiled.
- The catheter insertion site should be cleaned/disinfected at the time of the dressing change with CHG/alcohol or povidone-iodine solution; ointment should be applied (povidone-iodine or triple antibiotics).
- CHG-impregnated exit-site dressing can be applied

Skin Antiseptics for Exit-Site Care

There are numerous studies indicating that a chlorhexidine/alcohol prep solution reduces the risk of infection when compared to povidone-iodine as a precatheter insertion site preparation. A prep solution containing chlorhexidine in a concentration greater than 0.5% in 70% isopropyl alcohol is the standard in inpatient settings for insertion and care of central venous devices, though not in the HD setting. There are no randomized trials of routine exit-site cleansing with HD catheters which provide similar guidance. One nonrandomized sequential trial found that using CHG for cleansing reduced the incidence of CRBSI but not exit-site infection. Both groups received

Table 2 Considerations for Accessing Catheters and Cleansing Catheter Exit Sites

Prepare procedure site using dialysis precautions.
Conduct procedures using aseptic technique (correct handwashing, masks for patient and staff, "no-touch" technique, and disposable clean gloves).
CHG greater than 0.5% with 70% alcohol is the preferred solution for cleansing of long-term catheter sites.* For patients with sensitivities to CHG greater than 0.5% with 70% alcohol, CHG aqueous* may be used instead. For patients with sensitivities to CHG aqueous, povidone solution† may be used.
Skin cleansing should include the following steps. • Apply solution/swab in a circular motion working from catheter exit site outwards. • Cover an area 10 cm in diameter. • Repeat this step twice. Do not rinse of or blot excess solution from skin. • Allow solution to dry completely before applying dressing.
To cleanse the connection between any CVC hub and cap, use two swabs: • Grasp connection with one swab. • Use second swab to clean from catheter connection up catheter for 10 cm. • Cleanse hub connection site and cap vigorously with the first swab. Discard swab. • Do not drop and connection site once it is cleaned.
To cleanse the section of the catheter that lies adjacent to the skin, gently swab the top and undersides of the catheter starting at the exit site and working outwards.
a) Check catheter manufacturer's warnings about effect of disinfectants on catheter material. b) Use according to manufacturer's directions.

Source: 2006 KDQOI recommendations

CHG-impregnated sponges at the exit site, so the significance of the outcome is unclear.[2] KDOQI[3] guidelines recommend using CHG based on the literature with other vascular catheters.[4] CHG is the standard preparation product used in inpatient settings for both insertion and care of central venous access devices. However, it must be remembered that there are practical differences between general use CVCs and tunneled CVC used for HD, not least of which is the prolonged use seen with the latter, often for weeks, months, or even years. It would seem logical to prefer CHG to povidone-iodine given its rapid and persistent antimicrobial activity.

CHG sensitivity and allergy may occur in the HD patient population, perhaps because of the more prolonged use in this group. Povidone-iodine is a reasonable alternative if the patient develops sensitivity or becomes allergic to CHG.

See the "Unresolved Issues" section for discussion of bleach containing skin antiseptic solutions.

Exit-Site Dressings and Ointment

The use of a dry dressing changed after each treatment or a transparent dressing changed weekly seem to give equal results in preventing exit-site infection. Many HD facilities apply a dry dressing after each treatment, which typically occurs three times per week. In the inpatient setting, published guidelines recommend changing the dressing every 3 days for gauze and every 7 days for transparent.

The Guidelines for the Prevention of Intravascular Catheter-Related Infections published by the CDC in 2002[5] recommend that povidone-iodine antiseptic ointment be used at the HD catheter exit site after catheter insertion and at the end of each dialysis session if this ointment does not interact with the material of the HD catheter.

A prospective, randomized, placebo-controlled trial of exit-site care with povidone-iodine ointment in non-tunneled subclavian catheters in patients with either acute or chronic renal failure requiring HD demonstrated a marked reduction in both CRBSI and in exit-site infection.[6] Two additional randomized prospective trials have studied the benefit of treating the exit site with mupirocin. The first reported a marked reduction in *S. aureus* exit-site infection and CRBSI but did not report the incidence of infection with other pathogens.[7] The second also demonstrated a marked reduction in both CRBSI and in exit-site infection.[8] *S. aureus* CRBSI was eliminated in the treatment group, and there was a low incidence of infection with organisms not sensitive to mupirocin. However, a subsequent publication from the same institution noted that 2% of the *S. aureus* isolates were mupirocin resistant.[9]

A prospective, randomized, placebo-controlled trial of triple antibiotic ointment (bacitracin, gramicidin, polymyxin B) demonstrated a significant reduction in the incidence of both CRBSI and exit-site infection.[10]

Applying povidone-iodine ointment to the exit site of HD catheters is the recommended practice per the CDC. Mupirocin use should be limited because of the risk of increasing incidence of *S. aureus* resistance. Additionally, mupirocin is not effective against Gram-negative organisms. Based on the published evidence related to infection risk reduction, the choice between povidone-iodine and triple antibiotic ointment (neomycin, polymyxin B, bacitracin) would seem equal and should be based on local preference. Both are available over the counter. Staining can be an issue with povidone-iodine, and intrinsic contamination has been reported. Triple antibiotic ointment may provide a better barrier to water than povidone-iodine ointment which could be important in reducing the risk of waterborne organism contamination. CDC guidelines recommend that ointment should be applied at the time of insertion and with each subsequent dressing change for the duration of catheter use.

There is only one reported trial of the CHG-impregnated insertion site dressing in HD catheters. This was a nonrandomized trial in children on HD using tunneled cuffed catheters in which exit-site care using povidone-iodine and a transparent dressing were compared to the results when a CHG-impregnated exit-site patch was applied and covered with a transparent dressing. There was a significant decrease in exit-site infection but no difference in the rate of CRBSI.[2] Since it is generally accepted that CHG is a more effective agent than povidone-iodine for exit-site care and because the trial was not randomized, the results are inconclusive.

In a recent randomized trial of non-tunneled venous and arterial catheters in the intensive care unit (with a mean catheter use of only 6 days), there was a 75% reduction in CRBSI from a low baseline 0.6 versus 1.4 episodes per 1000 catheter days associated with CHG-impregnated site patch. However, the control group was given exit-site care with povidone-iodine.[11] The same criticism can be made of the last two studies in that there was a poor choice of the control product.

A meta-analysis which did not include the studies outlined above looked at eight studies using a CHG-impregnated site dressing/patch on a variety of catheters—epidural and intravascular—and concluded that the CHG-impregnated patch significantly reduced the risk of exit-site bacterial colonization, and that there was a trend toward a reduction in bloodstream or central nervous system, infection (2.2 versus 3.8%, $P = 0.11$).[12] It should be noted that the control patients were treated with inactive dressings in seven of the eight studies. Furthermore, the largest trial entered into the meta-analysis and which dominates the data has only been published in abstract form,[13] and it is the only study which showed a statistically significant decrease in CRBSI, and so has a distorting effect on the overall result.

It should be emphasized that there are no reported trials in which the use of a CHG-impregnated site dressing is compared to standard exit site care using CHG/alcohol solutions. Since it is accepted that the latter is more effective than povidone-iodine, which has been used in the control group in the reported studies, it is difficult

to justify the added cost of CHG-impregnated site dressing in HD until a comparison with CHG/alcohol exit-site care demonstrates a benefit. Milstone et al.,[14] in a review of the use of CHG in infection control, similarly concluded the following: "Although these data consistently find decreased colonization of CVCs, few published data demonstrate decreases in catheter-associated BSIs to support widespread chlorhexidine-impregnated dressing use. This is a promising area for further research."

Permanent Access: Fistulas/Grafts

Overview

The following principles support reduction of infection risk and should be included in education for dialysis staff and patients.

- Patients with a fistula should be taught fistula exercises to encourage fistula development. The sooner the fistula develops, the fewer days of infection risk for the patient who may also have a noncuffed HD catheter.
- The skin around the access area should be kept clean and dry. Once dialysis is started, the fistula or graft must be cleansed with soap and water prior to each dialysis treatment.
- Patients should be encouraged to check the access daily, especially feeling for presence of a "thrill."
- Tight clothes or jewelry should not be worn in the access arm.
- Sleeping on the access arm should be avoided.
- Taking blood pressure, drawing blood, or putting IVs in the access arm should be prohibited.
- Lifting heavy objects or putting pressure on the access arm should be avoided.
- Extra care must be taken by the patient in order not to bump or cut the fistula or graft.

Permanent Access (AVF or AVG)

For the vascular access that is permanently implanted beneath the patient's skin, a large cannulation needle (usually 15 gauge) is used. Infection prevention efforts are those which are required for any venipuncture procedure, including cleaning and disinfection of the cannulation site, and sterile technique when handling the needle. For AVGs and most AVFs, the technique of "rotating sites" is used, where the needle insertions must be made at least an inch apart to avoid damaging the vessel or graft, and possibly creating aneurysms and other complications which could leave the patient susceptible to infection.

In addition, with the AVF there is another cannulation technique called "same site" or "buttonhole" technique. This technique, used exclusively with AVFs (*not* AVGs), is designed to support the development of a needle track between the skin and vessel lumen over time (3–5 weeks), similar to a pierced ear. After each cannulation, a protective scab develops over the skin opening, and in order to continue supporting healthy development of this tract, the scab must be removed *using aseptic technique* prior to the next cannulation. If not performed properly, scab removal can contribute to infection risk, permitting a portal of entry for infectious organisms. Use of this technique requires special instruction for staff and patients, since identical techniques and angles of needle insertion are paramount to developing a single needle tract, and not multiple adjoining tracts. There is a growing body of anecdotal evidence for this technique being used successfully in a number of settings, but controlling infection risk through aseptic technique is still critical.

Cannulation of AVFs

Appropriate cannulation methods and the use of aseptic technique are essential in the prevention of vascular access infection. The 2006 KDQOI recommendations follow (Table 3). **For all vascular access including cannulation, aseptic technique should be used.**

Table 3 Skin Preparation Technique for Subcutaneous Arteriovenous Accesses

- Locate, inspect, and palpate the needle cannulation sites prior to skin preparation. Repeat preparation if the skin is touched by the patient or staff once the skin preparation has been applied, but the cannulation not completed.
- Wash access site using an antibacterial soap or scrub and water.
- Cleanse the skin by applying CHG greater than 0.5% /70% isopropyl alcohol or 70% alcohol and/or 10% povidone-iodine as per manufacturer's instructions for use.

Notes:

- 0.5% CHG/70% isopropyl alcohol has a rapid and persistent antimicrobial activity on the skin. Higher concentrations of CHG have demonstrated persistence on the skin of up to seven days. Apply the solution using back and forth friction scrub per manufacturer's instructions. Allow the area to dry. Do not blot the solution.
- Alcohol has a short bacteriostatic action time and should be applied in a rubbing motion for 1 minute immediately prior to needle cannulation.
- Povidone-iodine needs to be applied 2–3 minutes for its full bacteriostatic action to take effect and must be allowed to dry prior to needle cannulation.
- Clean gloves should be worn by the dialysis staff for cannulation. Gloved should be changed if contaminated at any time during the cannulation procedure.
- New, clean gloves should be worn by the dialysis staff for each patient with proper infection control measures followed between each patient.

Source: 2006 KDQOI recommendations

Cannulation of AVGs

Grafts generally should not be cannulated for at least 2 weeks after placement to ensure adequate healing and reduction in swelling. One type of graft, the composite polyurethane graft, can be cannulated earlier, but not for at least 24 hours after placement and not until swelling has subsided so that palpation of the course of the graft can be performed. Rotation of cannulation sites is particularly important in AVGs to avoid pseudoaneurysm formation.

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Water Treatment and Testing

Bacteriology of Water and Dialysate

The new CfC document from CMS was published on April 25, 2008. Within this document, the maximum allowable bacteriologic and endotoxin levels for water and dialysate are provided. As previously mentioned, CMS reflects AAMI's RD52[1] and RD62[2] for these maximum allowable levels (RD52, section 4.1.2):[1] "Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse shall contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL. The action level for the total viable microbial count in the product water shall be 50 CFU/mL, and the action level for the endotoxin concentration shall be 1 EU/mL." "Action level" indicates that once these are measured in the product water, corrective measures shall promptly be taken to reduce the levels of bacteria/endotoxin.

Fluid	Bacteria CFU/mL	Endotoxin EU/mL
Water used for dialysate, reprocessing of hemodialyzer, germicide production	200/50 action level	2/1 action level
Dialysate	200/50 action level	2/1 action level
Minimum frequency	monthly	monthly

Bacteriologic and endotoxin assay are performed to validate the adequacy of the dialysis machine disinfection process and frequency, not to determine when disinfection is needed. If an HD facility's monthly testing results are below the action levels and disinfection frequency is monthly, this suggests that process and frequency of dialysis machine disinfection is effective. If monthly testing results are above acceptable levels for bacteria/endotoxin, this would suggest that either the machine disinfection process or frequency is not sufficient to control bacterial growth. An adjustment to the frequency or process of disinfection would be indicated in order to keep bacteria/endotoxin below action levels.

When Bacteria and Endotoxin Levels are Exceeded

Measures must be performed promptly when results exceed the action level or the maximum allowable level. Dialysis may continue when bacteria/endotoxin is found to be at the action level, but retesting and/or disinfection of the system should be performed promptly. "Promptly" has been defined by CMS regulation as within 48 hours of receiving the report.[3] For bacteria/endotoxin levels exceeding the maximum allowable levels, the medical director must determine the course of action. The medical director must assess the impact to the patient and determine which option would result in a more detrimental outcome for the patient: not receiving the treatment or using a dialysate which contains greater than the allowable CFU and EU limits. When limits exceed the maximum allowable, regulations require that cultures be performed weekly for at least a month until a stable trend has been reestablished demonstrating control of the bacteria/endotoxin levels which does not exceed the maximum allowable.

The sampling source has also been defined within the new regulations for *central* RO systems (RO that produces and supplies product water for three or more dialysis machines) and *individual* portable RO systems (mobile

systems that produce and supply product water for one or two machines and are typically used in home or acute settings). For central RO systems, the recommended sampling location for bacteria/endotoxin samples are the first point of use, last point of use, and an auxiliary point such as the reprocessing machine or concentrate mixing system. The recommended sampling frequency is monthly, when repairs to the RO system result in intrusion to the membrane and dialysate pathways, and when pyrogenic reactions are suspected. For portable systems, the recommended sampling frequency is quarterly, when repairs are performed and during suspected pyrogenic reactions. (*Note: There are portable systems that have been developed which incorporate an exchangeable cartridge that produces RO water. Testing frequently for these systems are the same as for portable systems.*)

Bacteriologic Monitoring of Water and Dialysate

The bacteriologic levels permitted for dialysate is very low. Consequently, the sensitivity of the culturing methods used must be sufficient to detect bacteria at these low levels. Testing can be done through an accredited laboratory or on site at the dialysis facility using commercially available dip samplers. Water samples should be collected directly from outlet taps. Sample taps should be flushed for at least 60 seconds before the sample is collected. Collection containers must be sterile/endotoxin-free. All new sterile plasticware is endotoxin-free because of the high temperatures involved in the manufacturing process. Disinfection of the sample taps is not recommended as residual disinfectant may contaminate the sample and affect the result. If users insist on disinfecting the sample taps, sterile gauze saturated with alcohol may be used. Caution must be followed so that collection of the sample is performed after sufficient time has elapsed that would ensure that alcohol has evaporated so as to leave no disinfectant residual in the sample. Bleach or other disinfectant solutions should not be used. A minimum of 50 mL of water, or the volume specified by the laboratory performing the test, should be collected.

According to the regulations and AAMI recommendations,[1,2] samples that cannot be cultured within 1 to 2 hours can be refrigerated for up to 24 hours. Membrane filtration technique is the reference method used. The method involves a known volume or sample or diluted sample filtered through a 0.45 μm membrane filter; the membrane filter is transferred aseptically to the surface of an agar plate. Trypticase soy agar is the medium of choice for culturing water and dialysate. Other acceptable media include standard methods agar and plate count agar (also know as TGYE). Blood and chocolate agars are not appropriate because of the high nutrient content. The spread plate technique may also be used but with a restriction that calibrated loop should not be used as a means of applying sample to the plate. This is because a standard calibrated loop transfers 0.001 mL of sample, so that the minimum sensitivity of the assay is 1000 CFU/mL. When commercially available, dip samplers are used; they should be used only in conjunction with a quality assurance program. The quality assurance program should include staff training in areas such as the correct methods of inoculation, incubation, interpretation, and verification involving duplicate samples sent to a certified laboratory on at least an annual basis.

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Surveillance Methodology for Dialysis Infections

Background

Surveillance has been defined as the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding health-associated events and is used to reduce morbidity and mortality and to improve health. Surveillance involves process measures (adherence to protocols) and/or outcome measures (infection rates, death, hospitalization rates and length of stay, costs, etc.).

Major components of a healthcare-associated infection surveillance system include the following.

- Standardized definitions
- Monitoring of population at risk for infection
- Statistical analysis
- Feedback of results to primary caregivers
- Feedback to managers and senior leadership

These activities mirror steps of the quality improvement process, with ongoing monitoring of patients using specific, defined indicators, collection and analysis of data, seeking trends, developing corrective or improvement actions based on data results, and reporting to appropriate clinical staff and leadership.

The 2008 ESRD Medicare CfC[1] require dialysis facilities, either hospital-based or free-standing, to include infection prevention/control as a formal part of the quality assurance and performance improvement program (QAPI) by:

- Analyzing and documenting infections to identify trends, and establishing baseline information on incidence.
- Developing recommendations and action plans to minimize infection transmission, promoting immunization, and taking actions to reduce future incidents.

Monitoring the Dialysis Population

To adequately meet the requirements for monitoring and surveillance of dialysis infections, selection of metrics and development of documentation forms are essential steps in the process. Metrics (or measures) to track in dialysis include both process and outcome indicators. Outcome indicators (infection rates) form the basic data for most surveillance and quality improvement activities. Until 2002, CDC collected dialysis facility data and issued reports on an annual basis, including numbers of patients with HBV, HCV, MRSA, and VRE. CDC now has a "dialysis event" module as part of the National Healthcare Safety Network program, which contains a voluntary internet-based surveillance system for collection of dialysis infection data (see www.cdc.gov/nhsn). A data collection tool, used by Kaiser Permanente Southern California, is included as an appendix. Ultimately, dialysis facilities are accountable for managing their internal surveillance and using the data to direct quality improvement activities. In addition to outcome data, process compliance (how things are done) can be assessed using observational checklists based on key procedures and tracked via compliance rates over time.

Calculating outcome (infection) rates for surveillance indicators in a dialysis setting is different from an acute care hospital setting. In acute healthcare facilities with large mixed populations, denominators are often expressed as a number of "line days" (for catheters) or "patient days" (e.g., 1000 or 10,000), and are compared across a number of units, departments, or service areas. Dialysis units have a defined population, all of whom are potentially "at risk," so the denominators can be simpler (e.g., total population, patients with CVCs, patients with fistulas, etc.) and time periods can be generally monthly, quarterly, or annually, depending on the particular metric.

Table 4 illustrates examples of infection-associated process and outcome metrics for HD. Outcome metrics have numerators and denominators to calculate rates. Process metrics data could be comprised of "yes/no" responses and a compliance percentage such as the number of "yes" responses/total = compliance percentage.

Table 4 Infection-Associated Process and Outcome Metrics for HD

Areas of Care/Service	Outcome Metrics (rates)	Process Metrics (compliance)
Environmental cleaning/disinfection	• Trended results of environmental cultures (dialysis machines, tubing, surfaces) and/or water/dialysate testing • **Numerator:** Number of positive results, cultures or outliers • **Denominator:** Total number of tests or observations	• Tracking logs (for applicable cultures and tests) are up to date • Policies and procedures on handling infectious waste and cleaning equipment are followed
HBV conversions (newly infected patients)	• HBV rate results trended per patient and per facility • **Numerator:** Number of positive antibody or antigen results • **Denominator:** Total number of patients	• Susceptible patients undergo monthly HBsAg testing to identify conversions • All patients with negative antibodies for HBV are followed-up (for vaccination), with documentation in medical record • Patients with positive HBsAg are placed in appropriate isolation
Patient immunization	• Vaccination rate results trended per patient and per facility • **Numerator:** Number of patients immunized • **Denominator:** Total number of patients	• Vaccination status for all eligible patients reviewed at least annually • Vaccination is offered to all eligible patients
Effective infection prevention and control practices by clinical staff	• Vascular access device (VAD) and/or other infection rates trended per patient and per facility • **Numerator**: Number of confirmed infections **Denominator**: Total number of patients • **Numerator**: Number of VAD removal due to infection • **Denominator**: Total number of patients	• Staff use Standard Precautions consistently Policies and procedures on hand hygiene followed consistently† • Chlorhexidine/alcohol prep with greater than 0.5% chlorhexidine used for catheter care‡ • Consistent use of disposable equipment covers, and single-dose vials for medications prepared in a "clean" area
Antibiotic usage*	• Appropriate antibiotics used for treating diagnosed infections • **Numerator**: Number of appropriate antibiotic doses (recommended antibiotic from culture and sensitivity report) • **Denominator**: Total number of antibiotic doses per time period (e.g., month or quarter)	• Unit policies and procedures include matching recommended antibiotics (from culture and sensitivity reports) with appropriate pathogen

*Not a required area.[1]
†See example of CDC Hand Hygiene technique (see Appendices)
‡See example of Institute of Healthcare Improvement CHG skin antisepsis (from Central Line Bundle) (see Appendices)

Surveillance Tools

Metrics are typically tracked using manually written logs or electronic files. Infection tracking tools on individual patients can be included as part of the medical record or kept in a separate database or hard copy record (see Appendices). Basic demographic data commonly included on patient-specific infection report forms might include the following.

- Patient identification
- Date of infection (diagnosis)
- Site of infection/location
- Organism identification and antibiotic susceptibility
- Skin prep used
- Antibiotic(s) used—dosage and timeframe

Additional information that could be added to assist in root cause analysis includes type of vascular access, cannulation method (same site or rotating site), number of days hospitalized, dialysis station, and machine number.

Facility-wide documentation should be maintained on dialysis-associated infections and other adverse events trended over time (CABSIs at a minimum), as well as associated performance improvement goals and interventions (see Appendices and www.fistulafirst.org).

Analysis and Reporting

Outcome trend charts (e.g., number of infections over given time period) provide a quick way to visually assess the status of patient safety for the HD facility. Clinical staff and leadership can see whether trends are positive or negative over time, and dialysis QAPI/infection prevention and control committees can use this data to inform the direction of the quality improvement program and/or epidemiological investigation if an outbreak is suspected. The HD facility surveillance plan should include "trigger points" above which an action plan would be indicated.

In the outpatient dialysis setting, many facilities do not have access to sophisticated statistical programs. In this case, a basic run chart can serve as a trending tool. If a statistical package (e.g., SPSS) is available, formal control charts (with means and standard deviations) can be used. Examples of each with the same basic data can be found below.

In the prior examples, the trigger point for action (i.e., investigation and intervention) could be identified by an HD facility as an upward trend sustained for 3 months on the run chart, or possibly a certain level above the upper control limit (e.g., two standard deviations above the mean). These types of decisions should be determined by the infection prevention/control and quality improvement committees.

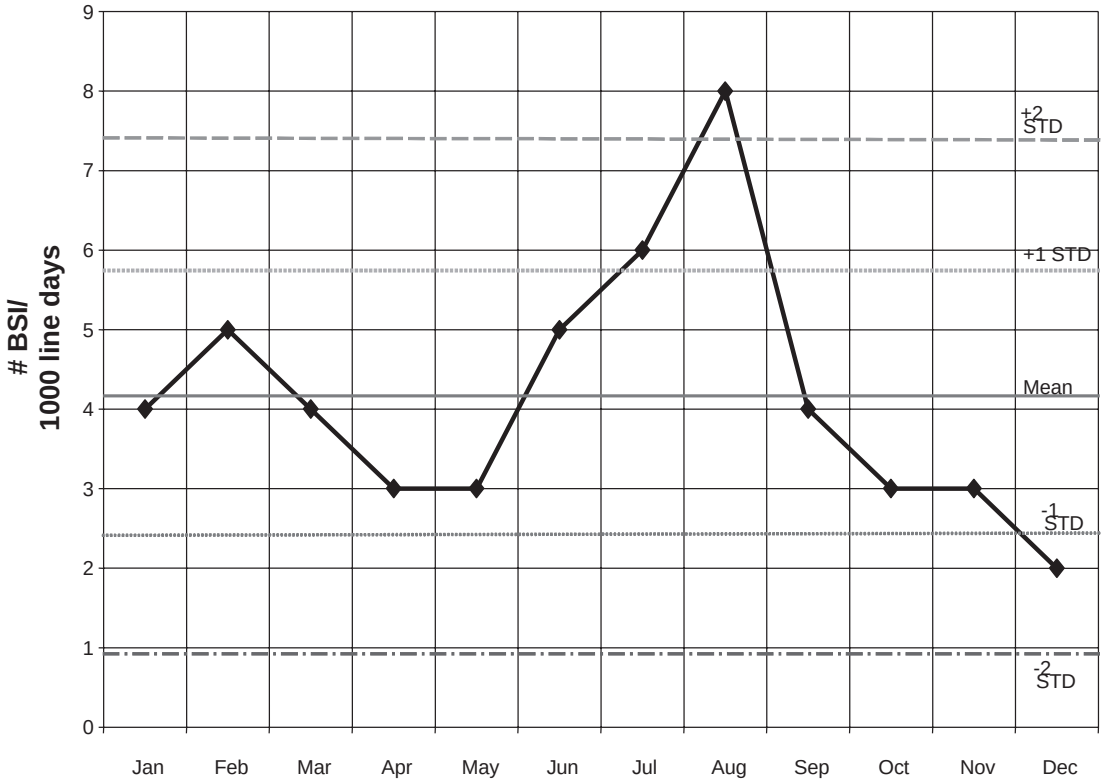
Ongoing monitoring and surveillance of infection-associated metrics is not only an important activity for patient care and safety, but is now also a formal requirement for facility licensure and certification. Each dialysis center will need to determine how to monitor these metrics, which data collection tools to use, how to develop appropriate intervention plans, and finally how to fit these important activities into the daily workflow.

There are three different types of infections associated with catheters, as defined by the KDOQI clinical practice guidelines which are among those available as outcome metrics for HD facilities:

- **Exit-site infection:** Inflammation confined to the area surrounding the catheter exit site, not extending superiorly beyond the cuff if the catheter is tunneled, with positive exudate culture.
- **Tunnel infection:** The catheter tunnel superior to the cuff is inflamed, painful, and may have drainage through the exit site that is culture positive.
- **Catheter-associated bacteremia:** Blood cultures are positive for the presence of bacteria with or without accompanying fever. This is the most serious type of catheter infection, and can result not only in loss of the catheter, but in serious morbidity and mortality.

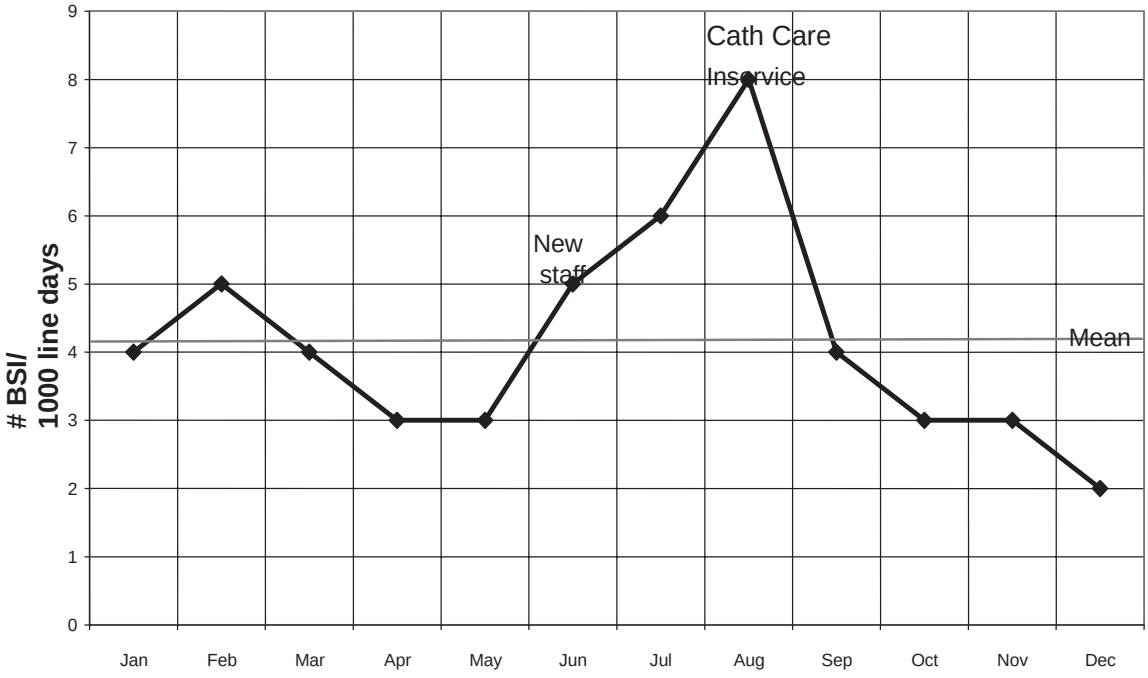
Statistical Control Chart With Standard Deviations

BSI Rate 2008



Run Chart With Notations

BSI Rate 2008



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Employee Health Considerations

Transmission of the common cold, influenza, and other respiratory infections from employees to patients can be prevented primarily via covering coughs (respiratory etiquette) with tissue, elbow, or mask (see Appendices). Additionally, these infections can be prevented with hand hygiene performed on a regular basis. Influenza can be prevented via annual vaccination and can be prevented from spreading to others by staying home when ill. When working to optimize vaccination rates in an HD facility, it is important to help employees understand that it is possible to transmit influenza to this vulnerable patient population even in the absence of obvious symptoms. Vaccination can reduce this risk.

Beyond the flu, there are a number of vaccine preventable diseases which can pose a risk to patients unless HD staff are immunized. These include HBV, chickenpox (varicella), measles, mumps, rubella, pertussis, diphtheria, and tetanus. MMR is required by law for all employees with patient contact. Offering HBV vaccine to employees with patient contact is mandatory. The other vaccinations are recommended but not mandated by law.

TB screening of employees should also be performed in all HD facilities according to local regulation; this is commonly a two-step test on hire and then on an annual basis for any employee with direct patient contact.

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Unresolved Infection Prevention Issues and Measures

Active *S. aureus*/MRSA Surveillance Testing/Decolonization

Infection is the second most common cause of death after cardiovascular disease in patients on HD, and *S. aureus* is the most common pathogen associated with these infections.[1] As in the general population, infection is usually produced by the strain the patient carries in their nose and other body sites (endogenous). Patients on HD have about twice the rate of *Staphylococcus* carriage as the general population, and this explains in part the high incidence of *Staphylococcus* infection, including bacteremia. In one report,[2] monthly nasal swabs were performed in 101 HD patients over a 27-month period. Forty-seven (46.5%) patients had one or more positive *S. aureus* cultures. The incidence of *S. aureus* bacteremia was greater in patients with two or more positive cultures ($P = 0.030$).

S. aureus bacteremia in the HD patient has severe consequences, with an in-hospital mortality rate of 13.5%, compared to 3.8% for bacteremia due to other organisms.[3] Hospital stay and therefore cost is also significantly greater, with more than 20% of patients developing major complications such as endocarditis and osteomyelitis.

In the majority of episodes of *S. aureus* bacteremia, the vascular access is found to be the root cause of the infection.

Elimination of nasal carriage by topical mupirocin may be a potential strategy to reduce *S. aureus* carriage and infections for HD patients. This intervention has been shown in published studies to reduce surgical site infections in general surgical patients. In addition, intranasal mupirocin has been shown in clinical trials to reduce the incidence of *S. aureus* bacteremia in HD patients.[4,5] However, the patient on maintenance HD may be repeatedly exposed to *S. aureus* in both the HD unit and during frequent hospitalizations, and relapse with the original endogenous strain is common after ceasing treatment.[6] The long-term benefit of removing *S. aureus* from the nose with mupirocin is not clear, since nasal carriage is often accompanied by carriage in the perineum and axilla, as well as the intestine. It is well described that most reacquisition of *S. aureus* is because of relapse with the original strain, although in the HD facility where both patients and staff are often carriers, reinfection with a different strain is also common.[7]

A major concern with decolonization is the emergence of mupirocin resistance, which occurs more frequently with long-term use.[8] Of special concern are reports of outbreaks of mupirocin-resistant MRSA in hospitals following widespread mupirocin use.[9–11] Therefore, the benefit of either short-term or long-term treatment with intranasal mupirocin must be considered very cautiously. The safest approach may be to use mupirocin eradication of *S. aureus* nasal carriage for the individual HD patient for a single incident of elective surgery only.

Antibiotic Locks

It is generally believed that there are two major routes of infection reaching the bloodstream: extraluminal via the catheter tunnel and intraluminal resulting from hub contamination during the HD process. Routine treatment of the exit site with antimicrobial ointment (povidone-iodine or triple antibiotic) markedly reduces the rate of CRBSI, presumably by reducing infection via the extraluminal route, although it is possible that reducing bacterial growth at the exit site also reduces the risk of hub contamination.

Colonization of intravascular catheters is a universal phenomenon and occurs within hours or days of catheter placement. The presence of sessile bacteria in the resulting biofilm makes eradication by systemic antibiotics more

difficult, and CRBSI is clearly a likely result.[12] Prophylactic antimicrobial locks have been introduced via clinical trials with the goal of preventing intraluminal colonization and biofilm formation and hence CRBSI.

Antibiotic locks have also been used in the treatment of patients with known or suspected CRBSI in order to eliminate catheter colonization and so obviate the need to remove the catheter. This strategy has not had universal success, and there is an especially high failure rate with *S. aureus* infections.[13]

Heparin as a catheter lock between dialysis sessions is effective at preventing clotting but has no antibacterial activity. Since the catheter lock by definition excludes neutrophils and antibodies from the catheter lumen, locking with heparin provides a protected site which bacteria can colonize. Heparin has been demonstrated in vitro to promote biofilm formation by *S. aureus* in a dose-dependent fashion.[14] Conversely, sodium citrate has been shown by the same group to inhibit biofilm formation in concentrations higher than 0.2%.[15]

Three recent meta-analyses have examined the efficacy of antimicrobial locks in preventing bacteremia in patients utilizing CVCs for HD.[16–18] All come to similar conclusions: antimicrobial locks are very effective in reducing the rate of CRBSI, but longer studies are needed to determine whether antimicrobial resistance will result.

An obvious concern with antimicrobial locks is the fact that the lock can only be expected to deal with intraluminal colonization of the catheter and will not eliminate any colonization on the external surface. Therefore, treatment of the exit site with an antimicrobial ointment is a logical companion intervention to an antimicrobial lock. The combination of a gentamicin 320 μg/mL in 4% sodium citrate used as a catheter lock and triple antibiotic applied to the exit site was demonstrated to be very effective in preventing CRBSI.[19] It should be noted that there are currently no FDA-approved antimicrobial catheter locking solutions.

Environmental Cleaning/Disinfection

- **Contact time—label claim versus 60 seconds**: The 2008 CDC Guideline for Disinfection and Sterilization in Healthcare Facilities states that,

  > Most Environmental Protection Agency (EPA)-registered disinfectants have a 10-minute label claim. In seeming direct conflict with the label claim requirement, the CMS Conditions for Coverage permit cleaning of hemodialysis stations before the patient is removed and the next brought in. This practice can contribute to transmission of infection from patient to patient, as well as exposure of patients to chemicals used to disinfect the environment/equipment.
  >
  > In addition, multiple investigators have demonstrated the effectiveness of these disinfectants against vegetative bacteria (e.g., Listeria, *Escherichia coli*, Salmonella, vancomycin resistant *Enterococci*, methicillin-resistant *Staphylococcus aureus*), yeasts (e.g., Candida), mycobacteria (e.g., Mycobacterium tuberculosis), and viruses (e.g., poliovirus) at exposure times of 60 seconds.
  >
  > Even though there is scientific evidence showing that contact time of 60 seconds is sufficient (Rutala, Weber 2008), federal law requires all applicable label instructions on EPA-registered products be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use, disposal). If the user selects exposure conditions (e.g., exposure time) that differ from those on the EPA-registered products label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[20]

  If an HD facility follows the scientific evidence with regard to environmental disinfection (60 second contact time), it would be advisable to have a copy of the Rutala, Weber reference available for surveyors (see Appendices).
- **One- versus two-step process**: CDC Guidelines[21] direct that for some environmental disinfectants, physical cleaning should always be performed prior to application of a surface disinfectant. The surface disinfectant

should then be kept wet for the prescribed contact time (e.g., 10 minutes) in order to achieve low-level disinfection. Many germicides on the market are a combined cleaner/disinfectant. Some manufacturer's label instructions include a one-step cleaning/disinfection process when the surface is not visibly soiled and a two-step (clean first then rewipe to disinfect) process for those surfaces that have visible soil or body substances present. In practice, one-step cleaning/disinfection is often performed in the absence of visible soiling. This practice is supported by the APIC text.

HD Reliable Outflow (HeRO) VAD (Graft/Catheter)

In 2009, a new type of VAD was introduced to the dialysis community, termed HeRO. It was developed to provide an alternative for patients who have exhausted the usual permanent access sites in the extremities, and do not want to have an external catheter. This device consists of two main sections, and is part catheter and part AVG. One section, known as the venous outflow component, is a catheter-type extension, with the tip resting in the inferior vena cava and the opposite end attached to the second section. The second section, known as the graft component, is made from polytetrafluoroethylene material and resides in the upper or lower arm near the brachial artery. This is the section used for HD cannulation. The two connected components reside in a tunnel beneath the skin to minimize infections. Infection is listed as a potential complication, and time will tell if there are lower bacteremia rates for this device when compared to catheters, AVGs, and AVFs.

PPE

- **Use of lab coat as PPE for cannulation/decannulation:** In some HD facilities, a regular cotton, nonimpervious lab-style cover coat instead of a disposable isolation gown is worn during cannulation and decannulation. In some of these facilities, the practice is not to change the lab coat after cannulation or decannulation. These activities can contaminate the lab coat and result in the potential for transmission of pathogens to other patients. A disposable isolation gown would provide an effective protective barrier, and if disposed of prior to leaving the patient station would not contribute to infection transmission risk.
- **Contact isolation/HBV isolation in HD facilities:** In some HD facilities, isolation gowns may be used for MRSA+ patients and HBV+ patients. However, the practice is sometimes to wear one isolation gown for the patient for the entire day. When this practice is in place, the gown is removed before moving to another patient station, and re-donned on return to resume care of the patient. Since there are typically no hangers in the patient station, the gown is laid down somewhere within the patient area between uses. The re-donning can result in contamination of clothing and the potential for transmission of pathogens to other patients/patient environment.

Postoperative Antiseptic Dressing

Postsurgical wounds, including post-fistula and -graft placement, are susceptible to bacterial invasion by skin flora that can result in surgical site infections and sepsis if untreated. Gauze dressing is the most commonly used wound dressing for postsurgical wounds. Because of its porous structure, gauze is not a barrier to external bacterial penetration.

There are a number of antimicrobial dressings on the market, containing silver, polyhexamethylene biguanide (PHMB), a bacteria-killing polymer, iodine, or 2-octyl cyanoacrylate. There are no large randomized controlled trials (RCTs) that have evaluated the efficacy of antimicrobial dressings in the prevention of surgical site infection. However, there have been a number of small studies and unpublished abstracts presented during professional conferences, including APIC.

One small RCT (N = 67) found improved pain ratings, comfort, exudate management, wound healing, and safety for a silver-impregnated dressing versus povidone-iodine, and another small trial (N = 21) reported reduction in bacterial counts for PMHB gauze versus usual care gauze for wounds that required packing. A few small case series and controlled trials have reported improved healing and reduced bacterial count for surgical sites treated with antimicrobial dressings.

There are three unpublished meeting abstracts reporting on surgical site infection rates at baseline and after implementation of postoperative antimicrobial surgical dressings throughout the hospital. All three observed a reduction in surgical site infection with antimicrobial dressing used postoperatively.

Although the available evidence is of only fair quality, the results have been consistently positive in favor of antimicrobial dressing as prophylaxis to reduce the risk surgical site infection. There is also no reported harm to patients with this "plus" measure.

Skin Antisepsis

Sodium Hypochlorite

Bleach use as a skin antiseptic came into existence during World War I when Dr. Dakins used a diluted solution to clean wounds. Dakins' solution has been on the market since that time. It appeared to have effectiveness in treating infection but there were no studies supporting the clinical use. In 2002, bleach-based skin antiseptic solution in a 1100 ppm 10% electrolytic chloroxidizing formulation was brought to market. Bleach is well know for its antibacterial properties and is used extensively as an environmental disinfectant.

Current published studies *do not* provide Category I level evidence supporting the efficacy of bleach as a skin antiseptic for use in care of vascular access exit sites. *Small* studies have been published including the following. This does not provide sufficient evidence that bleach can be safely used as a skin antiseptic.

- Nephrology Nursing Journal includes the findings of a 2005 randomized clinical trial (N = 121) comparing effectiveness of a bleach solution marketed as a skin antiseptic to CHG in reducing colonization (not infection).[22]
- Mishkin[23] published a study where a total of 44 HD catheter lumens were evaluated assessing tensile strength after exposure to commonly used disinfectants.

The lack of evidence supporting product efficacy in addition to reports of respiratory irritation associated with bleach use argues against the use of bleach for skin antisepsis in HD settings. In addition, the vendor providing the most commonly used bleach skin antiseptic solution also produces a bleach solution for environmental disinfection. The containers for the two solutions are the same shape and are only distinguishable by a difference in label color. This could create a potential risk of inappropriate product use, especially if the containers are stored next to each other.

Medihoney for Exit Site Care

A randomized trial comparing mupirocin ointment with honey (Medihoney, Derma Sciences, Inc., Bay of Plenty, New Zealand) showed similar efficacy to mupirocin in reducing CRBSI[24] while avoiding the problem of emerging mupirocin resistance. Of note, Medihoney is not available in the United States.

Ultrapure Dialysate

Patients treated with HD have been observed to maintain an inflammatory chronic condition and as a result may show any of the following symptoms: anemia, reduction of erythropoiesis, epoetin resistance, amyloidosis with

arthropathy and carpal tunnel syndrome, malnutrition, atherosclerosis, low-albumin and low-cholesterol synthesis, decrease of iron stores and transferring iron stores, and increase in C-reactive protein production, protein A, and ferritin.

The use of ultrapure dialysate (sterile and pyrogen-free) can potentially reduce this condition. This is defined as dialysate with bacterial level of 0.1 CFU/mL and endotoxin level of 0.03 EU/mL.[25] The use of ultrapure dialysate is not currently required in the HD community. Although dialysate preparation and distribution techniques have improved markedly, bacterial contamination of dialysate fluid remains a continuing problem in the HD environment. The ability of the dialyzer membrane to function as a barrier to restrict the transverse introduction of bacteria into the patient's bloodstream has been one of empirical reliance and controversy. The widespread use of bicarbonate dialysate, which is a good bacterial culture medium, and the increasing use of high-efficiency and high-flux dialyzers warrants further investigation into the potential transfer of bacteria from the dialysate into the patient's blood.

The AAMI has developed the standards and recommended practice for dialysis that have been incorporated as reference to the federal regulations for the ESRD program. The committee is currently working on a Technical Information Report (TIR) that addresses ultrapure dialysate. A TIR is developed as a community reference.

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Conclusion—Putting it All Together

HD patients have unique vulnerability to healthcare-associated infections. This is because of a number of human, environmental, and procedural factors related to the HD setting, in addition to a multitude of patient comorbidities. Establishing an infection prevention and control program which includes a bundle of strategies and interventions that are consistently performed will reduce the risk for both employees and patients. These include the following.

1. Environmental cleaning/disinfection
2. Equipment cleaning/disinfection
3. Hand hygiene
4. Immunizations and screening for patients and employees
5. Medication/injection safety
6. Patient/family/employee education
7. Pre-/postsurgical infection prevention
8. Standard/Transmission-Based Precautions
9. Vascular access—infection prevention during insertion and care
10. Water treatment/testing
11. Infection surveillance
12. Quality improvement program

Unfortunately, most outpatient HD facilities are not staffed with a resident IP. Consequently, the APIC organization has undertaken the development of this guide to serve as a road map for those responsible for infection prevention and control in these facilities.

Appendices

Unless otherwise noted, all resources will be available at www.apic.org/eliminationguides.

General Appendices

Infection Prevention and Control checklist for HD Facilities—Sample	Sample HD Site Checklists
Basic and Plus measures	1. Infection prevention measures at a glance for HD 2. Sample protocol : promoting transition from catheters to fistulas 3. Fistula first permanent access algorithm 4. CDC Cover your Cough poster in multiple languages : http://www.cdc.gov/flu/protect/covercough.htm 5. Society for Healthcare Epidemiology of America central line insertion checklist 6. CVC insertion guidelines 7. CVC insertion checklist 8. Compendium of infection prevention: http://www.shea-online.org/about/compendium.cfm 9. ACIP vaccine recommendations: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm 10. CDC guidelines excerpt—Employee IP training for HD facilities
Environmental cleaning and disinfection	One minute contact time for environmental disinfection Disinfection defined
Equipment cleaning and disinfection	Acid/bicarbonate jug cleaning guidelines Rutala web site disinfection and sterilization: http://disinfectionandsterilization.org/ Reprocessing dialyzers:
Water treatment and testing	Detail on water treatment: Algorithm for analysis of water/dialysate test results
Presurgical infection prevention	Preoperative antiseptic shower or bath nurse/physician instructions
Postsurgical infection prevention	AJIC 2008 study AMD reduces SSI
Surveillance methodology and definitions	Infection flow sheet Sample infection tracking tool National Safety Healthcare Network infection form Excerpt from KDOQI guidelines

Employee health	Link to the CDC Employee Health Guideline 1998: http://www.cdc.gov/ncidod/dhqp/gl_hcpersonnel.html Link to other CDC Employee Health documents: http://www.cdc.gov/ncidod/dhqp/wrkr_occHealth.html Immunization Action Coalition. *Healthcare Personnel Vaccination Recommendations*. 2007. Available online at www.immunize.org/catg.d/p2017.pdf.
Types of vascular access	Information on planning for dialysis access:
Unresolved issues	HeRO graft info: MRSA testing preopetative protocol Arrow catheter compatibility letter 2002 Medcomp catheter compatibility letter 2006 Tyco Healthcare/Kendall Dialysis Catheter Antiseptics
Regulations	Overview of associated regulations

Patient Teaching Tools

1. Living with MRSA-multiple languages: http://www.doh.wa.gov/Topics/Antibiotics/MRSA.htm
2. Prevention and control of dialysis-associated infections: http://www.cdc.gov/ncidod/dhqp/dpac_dialysis_pc.html
3. Frequently asked questions on surgical site infections from healthcare-associated infection prevention compendium:
4. MRSA testing preoperatively—patient communication:
5. CHG preoperative bath patient instructions
6. "Clean Care is Safer Care"

Nephrology Resources

Emergency Preparedness: http://www.kcercoalition.com/

Kidney Community Emergency Response Coalition: Information available on this site may be useful when creating HD Facility Emergency Preparedness Plan

General Information

CDC guide for immunizations in patients with kidney disease: http://www.cdc.gov/vaccines/pubs/downloads/b_dialysis_guide.pdf

CDC interim H1N1 guidance for dialysis: http://www.cdc.gov/h1n1flu/guidance/hemodialysis_centers.htm

http://www.nursesource.org/nephrology.htmL

Nephrology Nursing Journal: http://www.annanurse.org/cgi-bin/WebObjects/ANNANurse.woa/wa/viewSection?ss_id=536873785&s_id=1073744615

American Nephrology Nurses' Association's official journal and newsletter (both are bimonthly): www.annanurse.org

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