National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination
CHAPTER 6. END-STAGE RENAL DISEASE FACILITIES

I. Introduction

The purpose of this chapter is to provide a guide to identify and prioritize efforts for the prevention and reduction of healthcare-associated infections (HAIs) in end-stage renal disease (ESRD) patients. This chapter is an addition to the original *HHS Action Plan to Prevent Healthcare-Associated Infections*[1] (Action Plan) and should serve as a platform by which federal and non-federal representatives affiliated with the nephrology, infection prevention, and public health communities define key areas of strategic focus for infection control processes, performance measurement, and data management. It should serve not only as a guide for future resources and efforts but should also translate into elements of an actionable plan for integration that will reduce and ultimately prevent HAIs in ESRD.

II. Background

HAIs are among the leading causes of morbidity and mortality in the United States and the most common type of adverse event in the field of healthcare today. They are defined as localized or systemic adverse events, resulting from the presence of an infectious agent or toxin, occurring to a patient in a healthcare setting. By this definition, these infections are not present or incubating in the patient at the time of entry into that healthcare setting unless related to a previous admission from the same healthcare facility.[2] At any given time, about one in every 20 patients has an infection related to their hospital care; the fiscal cost of these HAIs is steep, creating an additional $28 to $33 billion dollars in healthcare expenditures annually.[3]

The U.S. Department of Health and Human Services (HHS) along with partners at the U.S. Department of Defense and the U.S. Department of Veterans Affairs has been working to reduce the prevalence and incidence of HAIs. On March 31, 2008, the Government Accountability Office (GAO) released "Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections."[4] This report acknowledged the multiple HHS efforts in this area. However, it also reported that these efforts were often not sufficiently coordinated or collaborative in nature. From these findings, the GAO made

[1]Department of Health & Human Services. HHS Action Plan to Prevent Healthcare Associated Infections, 2009. Available at: http://www.hhs.gov/ophs/initiatives/hai/3-hai-plan-intro.pdf
[2] McKibben L, Horan T, Tokars JI, et al. Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee, 2005. *American Journal of Infection Control* 2005; 33:217-226.
[3] Klevens RM, Edwards J, Richards C, Horan T, Gaynes R, Pollock D, Cardo D. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports* 2007; 122:160-166.
[4] United States Government Accountability Office. 2008. Health-Care-Associated Infections in Hospitals: Leadership Needed from HHS to Prioritize Prevention Practices and Improve Data on These Infections, GAO-08-283, 2008. Available at: http://www.shea-online.org/Assets/files/GAO_Report_0308.pdf

recommendations to the Department calling for leadership in prioritizing HAI prevention guidelines and establishing databases that can link information not only across the Department but among healthcare facilities as well to improve data reliability. These priorities have been echoed in the Affordable Care Act of 2010 (PL 111-148), passed on March 23, 2010. The law charges the Secretary to develop requirements for health plans which "implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology…." PPACA Section 1001 (Adding new section 2717(a)(1)(C) to the Public Health Service Act); and PPACA Section 1311(g)(1)(C).[5]

In response to this call, the HHS Steering Committee for the Prevention of Healthcare-Associated Infections was formed. The committee was charged with developing a plan that systematically and continuously addresses afore mentioned issues including prioritizing infection control practices that are guided by scientific validity, economic, and operational feasibility. The Steering Committee initially focused on the HAIs determined to be most significant based on their prevalence, preventability, and potential for morbidity and mortality.

Phase I of the Action Plan was focused on the prevention of infections in the acute care hospital setting namely catheter-associated urinary tract infections (CAUTI), central-line associated bloodstream infections (CLABSIs), *Clostridium difficile* infection (CDI), methicillin-resistant *Staphylococcus aureus* (MRSA), surgical-site infections (SSIs), and ventilator-associated pneumonia (VAP).[6] Recognizing the need to coordinate prevention efforts across healthcare facilities, the Department began to move into Phase II of the Action Plan in late 2009. Phase II expands these prevention and reduction efforts outside of the acute care setting into outpatient facilities such as ambulatory surgical centers and ESRD Facilities, the latter being the focus of this chapter. Similar to its Phase I efforts, Phase II HAI reduction and prevention strategies expect to be executed through research and guideline development, implementation of national quality improvement initiatives at the provider level, and creation of payment policies that promote infection control and reduction in healthcare facilities.

Although it is recognized that HAIs are a significant issue for ESRD patients who receive the majority of their treatment in home settings, this chapter concentrates on HAI prevention and reduction recommendations for ESRD patients who regularly receive hemodialysis (HD) in an outpatient dialysis facility. Also, given that the terminology ESRD Facilities is the one most commonly used in the nephrology community as well as in government regulation, we use this term throughout the chapter for consistency. Again, however, for the purposes of this chapter in addressing HAIs in this setting, ESRD Facilities refers to those facilities which provide hemodialysis treatment for ESRD patients on a regular basis. We chose at this time to focus on HAIs related to vascular access and those HAIs associated with infection from Hepatitis B and Hepatitis C in order to prioritize our recommendations based on patient impact and the availability of

[5] Patient Protection and Affordable Care Act (PPACA) (PL 111-148) and Healthcare Education Reconciliation Act, Act, (PL111-152) March 2010
[6] Department of Health and Human Services. HHS Action Plan to Prevent Healthcare Associated Infections, 2009. Available at: http://www.hhs.gov/ophs/initiatives/hai/3-hai-plan-intro.pdf

evidence-based processes for HAI prevention and reduction. It is important to note that the chapter aims to prevent HAIs in ESRD patients. Providers in ESRD Facilities are crucial to this effort. However, transitions of care are common and the chapter recognizes the various provider types and care settings that influence the occurrence of HAIs in this population. This includes pre-ESRD care providers, surgeons, hospitals, long-term care facilities, and others. All of these entities plus other stakeholders (e.g., public health officials and infection preventionists) are viewed as having an essential role in HAI prevention in ESRD and considered active partners in this effort. As with all of the chapters in the Action Plan, this chapter is a living document and thus expected to evolve as HAI efforts targeting this patient population continue.

III. Healthcare-Associated Infections in ESRD

A. Epidemiology

Infection is a leading cause of morbidity and is second only to cardiovascular disease as the leading cause of death in the chronic uremic patient on HD. According to the United States Renal Data System, the total death rate due to infection is 76 per 1,000 patient-days with sepsis responsible for three quarters of these infection-related deaths.[7] In comparison to the general population, the incidence of sepsis in patients with ESRD disease can be up to 100 times higher.[8] Infections are a major reason for hospitalizations in this population, estimated to be responsible for as many as 20% of all inpatient admissions. These infections also confer a higher risk of mortality than in the general population with a diagnosis of septicemia carrying "a cumulative mortality rate of 43% at one year compared to 20% for the general population."[9] It has been predicted that the number of ESRD patients will increase approximately 1.5-fold by the year 2020, underscoring the importance for prevention efforts in this population to reduce the physical, emotional, and financial cost of infections.[10]

B. Pathogenesis

Multiple factors contribute to infectious morbidity and mortality in the ESRD patient on HD. ESRD patients are more susceptible to infection because of the process inherent in HD treatment which includes the need for long-term vascular access, including chronic central-line use. These patients also have multiple and frequent exposures to the healthcare environment and other patients which confers multiple opportunities to acquire infection. This exposure can take the form of patient-to-patient transmission of infection as well as indirect transmission from a contaminated source, such as environmental surfaces, equipment or supplies, and from the hands of the many

[7] National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. US Renal Data System, USRDS 2009 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, 2009.
[8] Bertrand LJ. Kidney International –Bacterial Infections in the Hemodialysis Patient: Pathogenesis and Prevention. *Kidney International* 2005; 67:2508–2519.
[9] Lafrance JP, Rahme E, Lelorier J, Igbal S. Vascular Access-Related Infections, Definitions, Incidence Rates, and Risk Factors. *American Journal of Kidney Disease* 2008; 52:982-993.
[10] National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. US Renal Data System, USRDS 2009 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, 2009.

healthcare providers these patients encounter. In addition, patients with ESRD are immunocompromised because of co-morbidities such as diabetes mellitus (DM) or from the uremic toxicity itself that characterizes their disease.

C. Vascular Access

Risk associated with device use in this population is arguably one of the most significant contributors to HAIs. HD treatment requires exogenous access to a patient's vascular system, usually obtained by either an arteriovenous fistula (AVF), an arteriovenous graft (AVG), or a central venous catheter (CVC). Access via a CVC confers the greatest risk for acquiring a vascular access infection; cumulative risk increasing with the duration of time that the catheter is present and/or in use. Dialysis catheter-related bloodstream infections arise mainly from either migration of the pathogen from the skin outside of the catheter into the bloodstream or directly from inoculation of a pathogen into the interior lumen of the catheter via the hub or infusion port. Less common routes include contamination of the lumen from a contaminated infusate solution, hematogenous seeding from a distant infection site, and rarely from dialysate back-flow into the extracorporeal circuit while priming on a dialysis machine with the waste handling option.[11,12,13,14,15] AVFs have the lowest associated rate of vascular-access infection.[16] AVFs confer a substantially lower risk of vascular-access related infection when compared to CVC use. Observed vascular access infection rates in patients with AVGs tend to be higher than those of AVFs. This is possibly because bacteria adhere more strongly to the synthetic material but might also reflect different underlying patient co-morbidities.

The most common pathogens responsible for access-related bloodstream infections in HD are gram-positive organisms with *Staphylococcus aureus* (*S. aureus*) and coagulase-negative staphylococcus (e.g., *S. epidermidis*) which account for an estimated 40-80% of cases.[17] The incidence of invasive MRSA infections in dialysis patients, most of which are bloodstream infections (BSIs), is 45 per 1,000 persons, or more than 100 times the incidence in the general population. This is in part likely due to the capability of the organism to form biofilm on the inner surfaces of indwelling medical devices such as a CVC. Gram-negative microorganisms account for

[11] Jochimsen EM, Frenette C, Delorme M, et al. A cluster of bloodstream infections and pyrogenic reactions among hemodialysis patients traced to dialysis machine waste-handling option units. *American Journal of Nephrology* 1998; 18:485-489.
[12] Arnow PM, Garcia-Houchins S, Negale MB et al. An outbreak of bloodstream infections arising from hemodialysis equipment. *The Journal of Infection Diseases* 1998; 178:783-791.
[13] Wang SA, Levine RB, Carson LA, Arduino MJ, Killar T, Grillo FG, Pearson ML, Jarvis WR. An outbreak of gram-negative bacteremia in hemodialysis patients traced to hemodialysis machine waste drain ports. *Infection Control and Hospital Epidemiology* 1999; 20:746-751.
[14] Block C, Backenroth R, Gershon E, Israeli R, Simhon A, Popovtzer M, Shapiro M. Outbreak of bloodstream infections associated with dialysis machine waste ports in a hemodialysis facility. *European Journal of Clinical Microbiology & Infectious Diseases* 1999; 18:723-5.
[15] Rao CY, Pachucki C, Cali S, Santhiraj M, Krankoski KL, Noble-Wang JA, Popli S, Brandt ME, Lindsley MD, Fridkin SK, Arduino MJ. Contaminated product water as the source of Phialemonium curvatum bloodstream infection among patients undergoing hemodialysis. *Infection Control and Hospital Epidemiology* 2009; 30:840-847.
[16] Centers for Disease Control and Prevention. Vital Signs: Central Line--Associated Blood Stream Infections --- United States, 2001, 2008, and 2009, *Morbidity and Mortality Weekly Report (MMWR)* 2001; 60(08): 243-248. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6008a4.htm?s_cid=mm6008a4_w
[17] Klevens RM, Edwards J, Richards C, Horan T, Gaynes R, Pollock D, Cardo D. Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002. *Public Health Reports* 2007; 122:160-166.

approximately 30-40% of BSIs in HD patients while infections of polymicrobial origin account for 10-20% of cases.[18]

Because vascular access infections are such a significant source of HAIs in the dialyzed patient and the potential for morbidity and mortality resulting from these infections is high, much attention has and should continue to be placed on infection prevention and reduction efforts among this sub-population of patients. Emphasis and incentives for early fistula placement, education on AVF maintenance and sustainability, highlighting catheters as a last option, and improving CVC maintenance practices should be high priorities in this arena.

D. Viral Hepatitis Infections in Hemodialysis Patients

Infections caused by hepatitis B virus (HBV) and hepatitis C virus (HCV) pose a particular clinical challenge for ESRD patients on HD, given the increased opportunity for exposure to other patients' blood during treatment when proper infection prevention precautions are not followed. Prevalence and incidence statistics for these infections vary widely between dialysis units and geographical location. However, a 2002 national survey of chronic hemodialysis centers revealed the prevalence of hepatitis B surface antigen (HBsAg) positivity among U.S. dialysis patients was approximately 1%, and the incidence 0.12%. Among the 63% of centers that reported they tested patients for HCV antibody (anti-HCV), the prevalence and incidence of anti-HCV in hemodialysis patients that same year was estimated at 7.8% and 0.34% respectively.[19]

It is encouraging to note that the incidence of HBV transmission in HD facilities has been steadily declining since the 1980's, a decline which is attributable to implementation of infection control practices in dialysis centers as well as the administration of the HBV vaccine in this population. In fact, the administration of the hepatitis B vaccine is recommended early in the course of progressive Chronic Kidney Disease (CKD) as the immunogenic response is likely to be more robust in the more immuno-competent pre-ESRD patient. Despite what is known about reducing transmission of HBV, outbreaks of HBV infection in ESRD Facilities have occurred.[20,21] "In 2002, 27.3% of centers reported one or more patients with HBV infection (HBsAg positivity) and 2.8% of facilities reported one or more patients with new infection,"[22] indicating that the risk for acquisition and spread (still) exists.[23] In many cases, the analyses of these occurrences reveal a breakdown in infection control practices or the presence of a significant segment of susceptible patients who have not

[18] Boyce JM. Epidemiology of MRSA Infection in Adults, 2010. [Online] Up to Date for Patients. Available at: http://www.uptodate.com/patients/content/topic.do?topicKey=~IjBrxetWTnKp3j
[19] Finelli L, Tokars J, Alter M, Arduino MJ. National Surveillance of Dialysis-Associated Diseases in the United States, 2002. *Seminars in Dialysis* 2005; 18:52– 61.
[20] Centers for Disease Control and Prevention. Outbreaks of Hepatitis B Virus Infection Among Hemodialysis Patients – California, Nebraska and Texas, 1994. *Morbidity and Mortality Weekly Report (MMWR)* 1996; 45:285-289.
[21] HutinYJF, Goldstein ST, Varma JK, O'Dair JB, Mast EE, Shapiro CN, Alter MJ. An Outbreak of Hospital-Acquired Hepatitis B Virus Infection Among Patients Receiving Chronic Hemodialysis. *Infection Control and Hospital Epidemiology* 1999; 20:731-735.
[22] Finelli L, Tokars J, Alter M, Arduino MJ. National Surveillance of Dialysis-Associated Diseases in the United States, 2002. *Seminars in Dialysis* 2005; 18:52– 61.
[23] Miller ER, Alter MJ, Tokars JI. Protective Effect of Hepatitis B Vaccine in Chronic Hemodialysis Patients. *American Journal of Kidney Diseases* 1999; 33:356-360.

been vaccinated. HBV infection in the dialyzed patient is particularly challenging as resultant morbidity and mortality rates are higher and the immunogenic response to vaccine is more likely to be non-protective or shorter in duration when compared with the general population.

The prevalence of HCV infection among hemodialysis patients is almost five times that of the general U.S. population.[24,25] It is difficult to know what impact the introduction of blood donor screening, general declines in acute HCV infection at the U.S. population level, and changes in infection control processes have had on the prevalence in the HD population because facilities do not universally screen patients. Multiple HCV infection outbreaks in dialysis centers have been reported in the U.S. in the past decade.[26,27] These investigational studies have shown the main mode of transmission to be healthcare-related, occurring among patients within dialysis facilities, and transmission has been attributed to failures to adhere to recommended infection control practices. In hemodialysis patients, studies have shown that HCV infection is related to the length of time one is on dialysis.[28,29]

HBV and HCV infection are, and should remain, key areas of focus for HD facilities due to higher prevalence and transmission rates among this vulnerable population, the increased risk of morbidity once infection is acquired,[30] and the preventability of transmission with adherence to the infection control recommendations discussed later in this chapter. In addition, screening for and administering the hepatitis B vaccine to all chronic hemodialysis patients is an Advisory Committee on Immunization Practices (ACIP) and Centers for Disease Control and Prevention (CDC)-recommendation and should continue to be practiced by dialysis facilities with consideration given to attaching incentives to immunization practice(s) in this setting.

IV. Prevention Priorities Recommendations in ESRD Facilities [31,32,33,34,35,36,37]

[24] [24] Finelli L, Tokars J, Alter M, Arduino MJ. National Surveillance of Dialysis-Associated Diseases in the United States, 2002. *Seminars in Dialysis* 2005; 18:52– 61

[25] Armstrong GL, Wasley A, Simard EP, McQuillan GM, Kuhnert WL, Alter MJ. The Prevalence of Hepatitis C Virus Infection in the United States, 1999 through 2002. *Annals of Internal Medicine* 2006; 144:705-14.

[26] Thompson ND Novak RT, Datta D, Cotter S, M Arduino M, Patel PR, Williams IT, Bialek SR. Hepatitis C virus transmission in the hemodialysis setting: The importance of infection control practices and aseptic technique. *Infection Control and Hospital Epidemiology* 2009;30:300-3.

[27] Centers for Disease Control and Prevention. Hepatitis C virus transmission at an outpatient hemodialysis unit — New York, 2001–2008. *Morbidity and Mortality Weekly Report* 2009;58(8):189-94.

[28] Fabrizi F, Takkouche B, Lunghi G, Dixit V, Messa P, Martin P. The impact of hepatitis C virus infection on survival in dialysis patients: meta-analysis of observational studies. *Journal of Viral Hepatitis* 2007; 14:697-703.

[29] Centers for Disease Control and Prevention. Recommendations for preventing transmission of infections among chronic hemodialysis patients. *Morbidity and Mortality Weekly Report (MMWR)* 2001; 50(RR05): 1-43. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm

[30] Fabrizi F, Takkouche B, Lunghi G, Dixit V, Messa P, Martin P. The impact of hepatitis C virus infection on survival in dialysis patients: meta-analysis of observational studies. *Journal of Viral Hepatitis* 2007; 14:697-703.

[31] Centers for Disease Control and Prevention. Recommendations for preventing transmission of infections among chronic hemodialysis patients. *Morbidity and Mortality Weekly Report (MMWR)* 2001; 50(RR05): 1-43. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm

[32] Centers for Disease Control and Prevention. The Guidelines for Environmental Infection Control in Health-Care Facilities. *Morbidity and Mortality Weekly Report (MMWR)* 2003; 52(RR10): 1-42. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm

[33] Centers for Disease Control and Prevention. Guidelines for the prevention of intravascular catheter-related infections. *Morbidity and Mortality Weekly Report (MMWR)* 2002; 51(RR10):1-26. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5110a1.htm

A. Overview

Multiple nationally recognized organizations have developed recommendations to prevent HAIs among hemodialysis patients. These include: CDC, the Healthcare Infection Control Practices Advisory Committee (HICPAC), the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI), Kidney Disease: Improving Global Outcomes (KDIGO), ACIP, and the Association for the Advancement of Medical Instrumentation (AAMI). This section reflects recommendations from each of these organizations that were prioritized for inclusion on the basis of burden of targeted HAI, expected impact of the recommended interventions, and supporting evidence.

Of the extensive prevention recommendations that exist, many are based upon observational studies, expert opinion, and/or documented lapses identified during outbreak investigations. In general, high quality infection prevention trials specifically conducted among hemodialysis patients are scarce. In some instances, strong evidence exists from trials conducted among other patient populations that can be presumed to apply to hemodialysis as well. Recently, the Centers for Medicare & Medicaid Services (CMS) incorporated various prevention recommendations into their required Conditions for Coverage (CfCs) for ESRD Facilities, thereby adding regulatory authority to many of these recommendations. Select regulatory requirements from the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) have also been included.

B. Methods

As in Phase 1 of the Action Plan, the implementation priorities included here are "based upon supporting scientific evidence that a practice is effective/beneficial, recognized gaps in current implementation…and potential impact." However, because of the limited number of infection prevention research trials conducted in this patient population, recommendations considered were not limited to only those meeting Category IA or Category IB level evidence. The level of evidence is indicated when available, along with organizations with guidance or regulation in support of the recommendation.

Of note, it is recommended that these prevention priorities be supported by a facility-level program of ongoing training, performance tracking and quality assurance to

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[34] Rutala W, Weber D, and the Healthcare Practices Control Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities. Centers for Disease Control. 2008 Available at: http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf

[35] Centers for Disease Control and Prevention. Guidelines for hand hygiene in healthcare settings, 2002 *Morbidity and Mortality Weekly Report (MMWR)* 2002; 51(RR-16):1-45. Available at: http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf

[36] Kidney Disease Improving Global Outcomes. Guideline 3: Preventing HCV transmission in hemodialysis units. *Kidney International* 2008; 73(Suppl 109):S46-S52. Available at: http://www.kdigo.org/guidelines/hepc/guide3.html

[37] National Kidney Foundation. KDOQI Clinical Practice Guidelines for Vascular Access 2006 Updates. *American Journal of Kidney Diseases* 2006; 48(Suppl 1):S176-S322. Available at: http://www.ajkd.org/issues/contents?issue_key=S0272-6386(06)X0213-5

ensure that, once incorporated, these skills and processes don't degrade over time, particularly as new staff is added.

C. Priority Recommendations

1. Prevention of Intravascular Infections

Vascular access infections, particularly BSIs, cause substantial morbidity and mortality in HD patients. Hemodialysis patients with CVCs have the highest rate and burden of BSIs. Interventions to reduce CVC-related BSIs also have the greatest evidence base. Therefore, priority recommendations in this category are primarily focused upon patients with CVCs.

Priority Module 1 – Selection of Vascular Access

- Use a fistula or graft instead of a CVC for permanent access for hemodialysis.
  HICPAC Category IA; NKF KDOQI

Priority Module 2 – Recommendations for Aseptic Insertion of Vascular Catheters

- Maintain aseptic technique for the insertion and care of intravascular catheters.
  HICPAC Category IA
- Use maximal sterile barrier precautions including the use of a cap, mask, sterile gown, sterile gloves, and a sterile full body drape, for the insertion of CVCs or guidewire exchange.
  HICPAC Category IB
- Prepare clean skin with a >0.5% chlorhexidine preparation with alcohol before CVC insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives.
  HICPAC Category IA; NKF KDOQI

Priority Module 3 – Recommendations for Appropriate Maintenance of Vascular Catheters

- Educate healthcare personnel regarding the indications for intravascular catheter use, proper procedures for the insertion and maintenance of intravascular catheters, and appropriate infection control measures to prevent intravascular catheter-related infections.
  HICPAC Category IA
- Perform hand hygiene before and after palpating catheter insertion sites as well as before and after inserting, replacing, accessing, repairing, or dressing an intravascular catheter. Palpation of the insertion site should not be performed after the application of antiseptic, unless aseptic technique is maintained.
  HICPAC Category IB
- Periodically assess knowledge of and adherence to guidelines for all personnel involved in the insertion and maintenance of intravascular catheters.
  HICPAC Category IA

- Promptly remove any intravascular catheter that is no longer essential.
  HICPAC Category IA
- Use polymyxin B/ bacitracin/ gramicidin (e.g., Polysporin® Triple) or povidone-iodine antiseptic ointment at the hemodialysis catheter exit site after catheter insertion and at the end of each dialysis session. Select an ointment that does not interact with the material of the hemodialysis catheter.
  HICPAC Category IB; NKF KDOQI
- Scrub the catheter access port with an appropriate antiseptic (chlorhexidine, povidone-iodine, or 70% alcohol) prior to accessing and access the port only with sterile devices.
  HICPAC Category IA

Priority Module 4 – Recommendations for Water and Dialysate Quality

- Product water used to prepare dialysate or concentrates from powder at a dialysis facility, or to process dialyzers for reuse, should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL.
  AAMI; CMS, HICPAC Category IA
- The action level for the total viable microbial count in the product water is 50 CFU/mL, and the action level for the endotoxin concentration is 1 EU/mL. If values above these action levels are observed in the product water, corrective measures should promptly be taken to reduce the levels.
  AAMI; CMS, HICPAC Category IA
- Conventional dialysate used to treat patients should contain a total viable microbial count lower than 200 CFU/mL and an endotoxin concentration lower than 2 EU/mL.
  AAMI; CMS, HICPAC Category IA
- The action level for the total viable microbial count of the dialysate bath is 50 CFU/mL, and the action level for the endotoxin concentration is 1 EU/mL. If values above these action levels are observed in the dialysate bath, corrective measures should promptly be taken to reduce the levels.
  AAMI; CMS, HICPAC Category IA
- Perform bacteriologic assays of water and dialysis fluids at least once a month and during outbreaks using standard quantitative methods.
  AAMI; CMS; HICPAC Category IA
- Disinfect water distribution systems in dialysis settings on a regular monthly schedule.
  AAMI; HICPAC Category IA
- Design and engineer water systems in dialysis settings to avoid incorporating joints, dead-end pipes, and unused branches and taps that can harbor bacteria.
  AAMI; HICPAC Category IA

2. Prevention of Bloodborne Pathogen Transmission

Due to the need for repeated vascular access and practice of treating other patients in close proximity, HD patients are at increased risk of acquiring infections caused by bloodborne pathogens, particularly HCV and HBV. OSHA requirements to protect dialysis healthcare personnel who have contact with potentially infectious blood in these environments are also included.

Priority Module 1 – Recommendations to Prevent Hepatitis B Virus and Hepatitis C Virus Infections

- Offer hepatitis B vaccine to all susceptible hemodialysis patients.
  CDC; ACIP; CMS
- Treat hemodialysis patients with active HBV infection at an isolation station with dedicated room, machine, supplies, and staff members.
  CDC; CMS
- For patients who respond to the hepatitis B vaccine series, check surface antibody titers annually and administer a booster dose when indicated.
  CDC; CMS, ACIP
- Perform baseline hepatitis B serology (HBsAg, anti-HBs and total anti-HBc) of patients and repeat HBsAg monthly for susceptible patients to identify new HBV infections.
  CDC; CMS
- Perform baseline HCV antibody screening of patients and repeat biannually for susceptible patients to identify new HCV infections.
  CDC; NKF KDOQI; KDIGO
- Offer hepatitis B vaccine to healthcare personnel to protect staff.
  HICPAC Category IA; ACIP; OSHA
- Conduct bloodborne pathogen training for all staff with occupational exposure to blood or other potentially infectious materials upon initial assignment and yearly thereafter.
  OSHA

Priority Module 2 – Recommendations for Safe Injection Practices

- Do not administer medications from single-dose vials or bags to multiple patients or combine leftover contents for later use.
  HICPAC Category IA; CMS
- Do not keep multidose vials in the immediate patient treatment area and store in accordance with the manufacturer's recommendations; discard if sterility is compromised or questionable.
  HICPAC Category IA; CMS
- Use aseptic technique to avoid contamination of sterile injection equipment.
  HICPAC Category IA; CMS

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Priority Module 3 – Recommendations for Cleaning and Disinfection

- After each patient treatment, clean and disinfect environmental surfaces at the dialysis station, including the external surfaces of the dialysis machine and prime waste containers.

CDC; NKF KDOQI; CMS

- Thoroughly clean and disinfect environmental and medical equipment surfaces on a regular basis using EPA-registered disinfectants in accordance with manufacturer's instructions.
  EPA; HICPAC Category IB, IC
- Follow proper procedures for site decontamination of spills of blood or blood-containing body fluids, using an appropriate disinfectant.
  HICPAC Category IC; CMS; OSHA

3. Prevention of Influenza and Pneumococcal Disease

Persons with chronic kidney disease are at increased risk of developing severe complications from influenza and pneumococcal disease. Although not all influenza and pneumococcal infections in this population are healthcare-associated, the preventability of these infections through immunization justifies their inclusion as a priority. For the recommendations below, the population to be vaccinated excludes those with a medical contraindication to the vaccine being addressed.

Priority Module 1 – Recommendations to Prevent Influenza and Pneumococcal Disease

- Offer influenza vaccine to hemodialysis patients on an annual basis.
  CDC; ACIP; CMS
- Offer influenza vaccine annually to healthcare personnel to protect staff, patients, and family members and to decrease staff absenteeism.
  HICPAC & ACIP Category IA
- Offer 1-dose of pneumococcal polysaccharide vaccine to adult dialysis patients and a one-time booster dose, for those vaccinated prior to age 65, after 5 years have elapsed.
  ACIP

4. Prevention Priority Implementation Bundles

Experts from the dialysis community have emphasized the importance of disseminating prevention recommendations in a format that promotes operational feasibility. As such, consideration should be given to incorporating recommendations into the daily routine of staff members who care for ESRD patients. This would include presenting infection control guidelines in the form of care bundles incorporated into the daily treatment flow sheet of each patient. In this way, infection control practices could be presented as easy-to-understand, concise checklists for recommended HAI prevention practices prior to, during, and after dialysis treatment. Examples of infection control protocols which could be presented in "bundle" format include steps for catheter maintenance, environmental cleaning, and methods for conducting HAI surveillance and reporting. As with all HAI prevention strategies, a bundle or checklist must be utilized in conjunction with a comprehensive program of infection control within an organizational culture that emphasizes and values safety for every patient every time.

5. Education and Training

Education and training of dialysis providers as well as ESRD patients and their caretakers is crucial to effective HAI control and prevention in this setting. Infection control priorities should be implemented in conjunction with a plan of appropriate education and training programs for all dialysis staff as well as vigorous methods to test staff competencies to help ensure consistency and sustainability of desired practices. In addition, a continual program for patient and caretaker education and training is a key requirement to promote self-care methods for infection prevention and to empower patients and families to report concerns about staff adherence to infection control practices

Opportunities to access and provide educational resources for dialysis staff and ESRD patients are available. Utilizing and adapting the expertise and educational programs developed by professional organizations such as the Association for Professionals in Infection Control, the Society for Healthcare Epidemiology of America and NKF, may allow dialysis organizations to adopt and implement comprehensive educational programs. However, there is likely a need for new development of continuing education and other training resources that address infection prevention issues specific to dialysis provider types. Infection control training and educational tools and collaborative opportunities may be available by leveraging the regional resources of ESRD networks. Ensuring that state survey and certification information is effectively communicated to regional quality improvement experts such as ESRD network representatives would serve as a method for recruitment and mobilization of such resources to facilities.

To further incorporate and sustain a culture of safety through infection control and prevention, it is imperative to ensure that the schools, accrediting organizations and post-graduate programs responsible for training providers and maintaining provider certifications are involved in this process at every level of staff education and training. Establishing and maintaining a dialogue with organizations such as the Accreditation Council for Graduate Medical Education, national nursing boards, technician certification groups, and state hospital associations among others, is an important step to promote evolving curricula, licensing and certification standards and competencies that reflect knowledge of recommended infection prevention priorities as well as an adequate level of skill for their execution.

Lastly, the changes in the "Welcome to Medicare" benefit which include the opportunity to receive "education, counseling and referral," during a one-time comprehensive examination (up to one year after Medicare, Part B enrollment), may be another resource by which dialysis facilities can offer individualized education for their ESRD patients.

V. Metrics and Evaluation

Note: The metrics proposed in this chapter are distinct from measures in the CMS ESRD Quality Incentive Program (QIP) and should not be considered part of the same process.

The following metrics and evaluation targets were developed to assess progress toward achieving HAI goals on a national level. They were not intended for measuring the performance of individual facilities. For this reason, case-mix adjustment of measures is unnecessary. This should be taken into consideration before attempting to apply the measures and targets in ways other than originally intended.

Presuming that the aforementioned processes represent the highest priority content in the management and prevention of HAIs in ESRD Facilities, we propose the following measures as indicators of progress in this arena.

Table 10. Five-Year National Metrics and Evaluation Targets

RECOMMENDED METRICS	DEFINITION (CALCULATION FORMULA)	(Proposed) EVALUATION TARGET	DATA SOURCE(S)	COMMENTS
All bloodstream infections stratified by access type	1. # of incident positive blood cultures in CVC patients/100 CVC patient-months 2. # of incident positive blood cultures in AVF patients/100 AVF patient-months 3. # of incident positive blood cultures in AVG patients/100 AVG patient-months	**1. Pooled mean < or = to 5.0** **OR** ***RIR > or = 40%** **2. n/a** **3. n/a**	NHSN **CrownWeb	We propose BSI rates for AVF and AVG as metrics for data collection and analysis although not enough data at this time for target setting
Access-related BSI stratified by access type	1. # of incident positive blood cultures with vascular access as suspected source or with unknown source in CVC patients/100 CVC	**1. RIR > or = 50%**	NHSN **CrownWeb	Including this as a metric would address the concern that not all BSIs in this population are access-related

	patient-months 2. # of incident positive blood cultures with vascular access as suspected source or with unknown source in AVF patients/100 AVF patient-months 3. # of incident positive blood cultures with vascular access as suspected source or with unknown source in AVG patients/100 AVG patient-months	 **2. n/a** **3. n/a**		but reinforce preventing serious access-related infection by reflecting in outcome metrics. Because of a lack of data, we do not recommend setting an evaluation target for AVF or AVG at this time.
<u>Seasonal influenza vaccination for ESRD patients</u>	# of ESRD patients who received seasonal influenza vaccination /all ESRD patients x 100	**greater or = to 90%**	Medicare Claims data, **CrownWeb, Kidney Care Quality Alliance (KCQA)	In line w/Healthy People 2020 goals. Influenza claims for ESRD patients would have to be cross-referenced across all care to capture or dialysis personnel would be required to note vaccination(s) done outside facility. This data would also be

				appropriate for capture in a renewed CDC-CMS survey initiative.
Facilities reporting to NHSN either manually or electronically or via data interoperability mechanism with CMS	# of ESRD Facilities that report to NHSN/all ESRD Facilities x 100	**greater or equal to 90%**	NHSN	
Any CVC use in patients on hemodialysis	# of hemodialysis patients with CVCs/# of hemodialysis patients x 100	**Absolute target: less or =to 20%; OR RIR greater than or = to 20%**	Fistula First NHSN **CrownWeb	The NHSN definition of "any CVC use" includes patients with temporary or permanent lines in order to include all CVC regardless of duration
Screening for Hepatitis C antibody	# of ESRD Facilities that screen all susceptible hemodialysis patients biannually/# of all ESRD Facilities x 100	**Greater than or = to 70%**	**CrownWeb	
Hepatitis B vaccine coverage in hemodialysis patients	#of hemodialysis patients who have ever received > or = to 3 doses of hepatitis B vaccine/all hemodialysis patients x 100	**greater or = to 90%**	Data from ESRD networks, **CrownWeb, Medicare Claims	In line with Healthy People 2020 goal Would be appropriate for renewed CDC-CMS survey.

*RIR – Relative Improvement Rate
**As CrownWeb has not yet been launched for national rollout at the time this chapter is being written, it could not be confirmed definitively as a source of data for the above metrics.

Priority Module 1: Bloodstream and Vascular Infection Rates and Care Processes

A. Process Measures

Reducing all CVC use is a recognized goal of the Fistula First Program, KDOQI, and CDC. The metric below has been used by these groups. CDC's National Healthcare Safety Network (NHSN) currently measures all CVC use and the CMS Vascular Access Database measures all CVC use as well as long term CVC use.

Any CVC Use = # of hemodialysis patients with CVC / all hemodialysis patients x 100

B. Outcome Measures

NHSN currently collects and reports several metrics relevant to vascular access infection. The metrics used in NHSN have been validated for surveillance and interventions have been shown to reduce measured outcomes. The metrics included here are specific to BSI, access-related BSI, and BSI in CVC patients, as these are most appropriate to target for prevention efforts.

All BSI stratified by access type =
a. Number of incident positive blood cultures in CVC patients per 100 CVC patient-months
b. Number of incident positive blood cultures in AVG patients per 100 AVG patient-months
c. Number of incident positive blood cultures in AVF patients per 100 AVF patient-months

Access-related BSI stratified by access type=
a. Number of incident positive blood cultures in CVC patients with vascular access or unknown suspected source per 100 CVC patient-months
b. Number of incident positive blood cultures in AVG patients with vascular access or unknown suspected source per 100 AVG patient-months
c. Number of incident positive blood cultures in AVF patients with vascular access or unknown suspected source per 100 AVF patient-months

Data Reporting:

Number of facilities reporting to NHSN either manually, electronically or via database interoperability mechanism to CMS= Number of ESRD Facilities reporting to NHSN/number of ESRD Facilities x 100

Priority Module 2: Hepatitis B and C

Although hepatitis B and C virus infections can represent HAIs in hemodialysis patients, neither incident nor prevalent infections in this population can be presumed to be HAIs without additional information. Truly prevalent infections represent the background rate of HBV and HCV infection in the community. Some proportion of incident infections will be related to healthcare exposures in dialysis versus other exposures; this proportion is currently unknown. For this reason, we will not propose HBV or HCV infection outcome measures are currently suggested as HAI metrics until after further investigations. However, it is well-documented that healthcare transmission of these infections does occur, requiring screening for detection, and can be prevented through actions such as appropriate vaccination and infection control measures.

Thus, these steps are reflected in process measures. Some, such as the measurement of hepatitis B vaccine coverage, are supported by Healthy People objectives. Anti-HCV screening, which is recommended by CDC, was included to highlight its importance to HAI prevention and reflect the opinions of public health, infection prevention, and nephrology leaders voiced at the stakeholder meeting.

A. Process Measures

Hepatitis B vaccine coverage = # of hemodialysis patients who have ever received ≥ 3 doses of hepatitis B vaccine / all hemodialysis patients x 100

Screening for new HCV infections = # of ESRD Facilities that screen susceptible hemodialysis patients biannually for hepatitis C antibody / ESRD Facilities x 100

Priority Module 3: Pneumococcal Disease, Seasonal Influenza

As with hepatitis B and C virus infections, not all pneumococcal and influenza illness in this ambulatory population represent HAIs. Most pneumococcal and influenza infections likely arise in the community. The intersection with healthcare through frequent dialysis treatments affords some opportunity for healthcare transmission, and also an opportunity to prevent both healthcare and community-based transmission in this high risk population. For these reasons, metrics in this section are focused on process, not outcome measures. The following vaccine coverage measure is supported by Healthy People objectives. A metric following seasonal influenza vaccination for healthcare workers in this setting is included in the HHS "Influenza in Healthcare Workers" chapter and thus was not repeated in this document.

Seasonal influenza vaccine coverage = # of ESRD patients who received seasonal influenza vaccine / all ESRD patients x 100

VI. Incentives and Challenges

A. Incentives

i. Federal Level

The CfCs for ESRD Facilities set minimum requirements that the facilities must meet in order to participate in Medicare. The standards set by the CfCs can be grouped into three broad categories: (1) patient safety; (2) patient care; and (3) administration. The CfCs can be found in the Federal Register at 42 CFR Part 494. Patient safety requirements address topics such as infection control and emergency preparedness. Patient care requirements address patient evaluation, care planning, and care implementation. Administration requirements address topics such as staff qualifications and data submission.

Facilities use the CfCs and related Interpretive Guidance to ensure that they are operating within the guidelines established by CMS. State Survey Agencies use the Interpretive Guidance when performing surveys of ESRD Facilities to determine compliance with the CfCs. If a facility is found to be out of compliance with any of the CfCs, the facility would be required to correct the deficiency within a certain time frame or, in a severe case, the facility might be forced to close. Since Medicare pays for the vast majority of maintenance dialysis treatments in the U.S., complying with CfC standards is necessary for almost all ESRD Facilities to remain in business.

At the HHS HAI meeting in September 2010, it was widely felt that these standards lend importance and credibility to the infection control practices required by them. In addition, the opportunity to use CfCs along with the Interpretive Guidance language accompanying them has the potential to serve as a powerful lever for adherence to infection prevention priorities and should be used as such.

Federal payment incentives include the ESRD QIP, mandated by The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) which was enacted on July 15, 2008 (Pub. L. 110-275). This legislation called for development of a value-based purchasing program for ESRD Facilities for services furnished on or after January 1, 2012. The statute calls for a payment reduction of up to 2% for facilities that do not meet or exceed a total performance score with respect to performance standards established with respect to certain specified measures.

ii. State/Network Level

Colorado recently became the first state to mandate reporting of HAIs from outpatient dialysis facilities. CMS has adopted a measure for the PY 2014 ESRD QIP under which facilities must enroll, train, and report at least three consecutive months of dialysis infection event data to NHSN.

B. Challenges

There are several challenges to implementing and sustaining efforts aimed at reducing healthcare-associated infections among ESRD patients. The challenges can be sorted by the level of the system that is most affected: the State/Network Level; the Facility/Provider Level; and the Patient Level.

i. State/Network Level

a. State Survey Agencies/Network

Prioritizing ESRD HAI prevention at the federal level dictates the need for focus on infection control processes, tools and education available for surveyors and facilities to implement them, and adherence to regulatory requirements for dialysis facilities across states. CMS and State Survey Agencies (SSA) align their regulatory mandates for infection control with CDC guidelines and Food and Drug Administration (FDA) device-related requirements. Enhanced communication and collaboration strategies between SSAs and the ESRD Networks are crucial to improve opportunities for information sharing and resource allocation to facilities with deficient practices.

Recommendations from the Preventing HAIs in ESRD Working Group strongly support efforts between CMS, Regional Offices, and the contractors they each oversee, e.g. State Survey Agencies and ESRD Networks, to coordinate activities that identify and correct lapses in ESRD infection control while promoting its sustainability through training, education, and any available HAI prevention tools.

b. State and Local Health Departments

In addition to SSA, other departments located in states and other jurisdictions play an important role in HAI prevention. Generally, departments within these health authorities have expertise in responding to HAI and other communicable disease outbreaks, and are responsible for surveillance of conditions with public health importance, including HAIs. Health department officials have historically had strong relationships with infectious disease providers and infection preventionists in hospital and community settings. For many health departments, outpatient dialysis providers remain a nontraditional partner and effective relationships have been more challenging to establish. Within state governments, HAI outbreak response efforts are often organizationally separated from healthcare licensing and certification functions, creating a potential challenge to communication and coordination between these groups with overlapping activities.

ii. Facility/Provider Level

a. Infection Control Resources – Most maintenance hemodialysis treatments occur in freestanding clinics outside of hospitals. Much like other outpatient

settings, these facilities typically lack dedicated resources for infection prevention and rarely have on-site personnel with infection prevention expertise. The ability to implement certain infection control practices can be hindered by financial pressures, staffing constraints, and lack of a clear understanding of and training in appropriate infection prevention practices. Currently, certificate programs to provide dialysis personnel specialized training in infection prevention are lacking. Also lacking are educational resources to address infection control practices specific to dialysis settings.

b. Transitions of Care – Hemodialysis patients undergo frequent hospitalization. Overlap also can occur for these patients with care provided in nursing homes, assisted living facilities, and other settings. These transitions represent a challenge to communication of information necessary for clinical care, as well as for HAI detection. It should be recognized that not all infections in hemodialysis patients represent events that can be attributed to hemodialysis care versus other settings, including the community. A comprehensive and coordinated effort between a host of providers including dialysis providers, vascular surgeons, primary care providers and hospitalists in the various array of settings where ESRD care takes place is essential for effective and efficient HAI prevention.

Other essential transitions involve care provided in the pre-ESRD period and vascular surgical care. Many ESRD providers feel limited in their ability to impact pre-ESRD and surgical care. This includes proper vascular access planning, permanent access placement, and prompt CVC removal to prevent HAIs. Other stakeholders through these various stages and transitions of care should be engaged in HAI prevention efforts. Efforts to incentivize and hold accountable hospitals, surgeons, and other non-ESRD providers should be explored as ways to improve vascular access planning and care to ultimately benefit patients.

c. Caution must be used when tying the public reporting of HAIs and associated incentives, particularly financial, to a main outcome measure, e.g., vascular access infections (VAI). When using an outcome measure as the yardstick by which success or failure of the facility to provide quality care is judged, the tendency is for the facility to focus solely on that measure. This focus often comes at the expense of other areas. Unintended consequences of this type of incentive and reporting might include under-testing or under-reporting of VAIs, and may even lead to antibiotic over-use as a preemptive effort to prevent infection. The use of outcome measures needs to be balanced with those measures that evaluate the root cause of the outcomes. These process measures, such as adherence to infection control practices or levels of staffing, offer a timely and straightforward way to measure the necessary components of a facility's care process that have been identified as directly affecting the outcomes of interest.

d. There is a lack of clarity in a standardized definition for vascular access infection, particularly access-associated bacteremia. FDA, CDC, and CMS are

operating under different definitions for vascular access infections. This presents the ESRD Facilities and providers with the challenge to as to which definition of VAI they are targeting. With a standardized definition across all entities, there can be alignment of research protocols, quality improvement initiatives, and payment rules.

e. Collecting and reporting data, be it outcome measures of infection, or process measures of infection control, needs to be balanced with the actual improvements in quality. The ability to acquire the data and the data themselves cannot be the sole drivers of change. Several things can impact the accuracy and precision of data including: lag times, often significant, between data acquisition and reporting, particularly for cultures; and depending on the time in the month that data are collected, facilities could have different results.

f. Improving the culture of safety in ESRD Facilities is necessary to ensure the uptake of practices aimed at eliminating HAIs.

iii. Patient Level

There is a need to increase patient involvement in HAI prevention efforts from the patient participating in their own care (e.g. washing access with soap and water prior to dialysis) to patient involvement in individual facility-level through state and network level activities. A growing body of literature suggests that patients, themselves, can participate in and monitor the quality of their care and can provide unique insight into its improvement.

a. There is literature to support the patients' involvement monitoring the safety of their care. ESRD patients are uniquely situated to assess whether or not required infection control practices are being followed, including objective measures of adherence to infection control practices. However, many patients feel uncomfortable questioning or challenging their care providers and might have concerns that doing so could negatively impact the care they receive.

The patient needs to be empowered to be an active member of the healthcare delivery team, and have the opportunity to engage in HAI-related efforts from the facility level through the network level. Focus on directly involving patients in their care, through education efforts[38] and opportunities to report their concerns in a safe environment, may help mitigate these concerns and can positively affect the quality of their care.

VII. Information Systems and Technology

A. Resources

[38] D'Agata E. Hospital-Acquired Infections in Chronic Hemodialysis Patients: Prevention and Control of HAI. [online] Medscape (Published June 2001). http://www.medscape.com/viewarticle/410166

Information systems supported by HHS Operating Divisions provide or will provide data with which to monitor HAIs among dialysis patients on the national level and assess progress in HAI reduction. As such, these systems are important resources for HAI prevention and can be used to help improve the quality of ESRD care and reduce associated costs. Concerted efforts are underway to leverage investments in HHS systems in ways that will enhance their value for analysis and action at all geographic levels.

NHSN is a web-based public health surveillance system that CDC's Division of Healthcare Quality Promotion (DHQP) and its partners in healthcare and public health use for surveillance of HAIs and processes of care designed to prevent and control those infections. Surveillance of select healthcare events and processes among dialysis patients is an integral part of NHSN: bloodstream infections, IV antibiotic administrations, and vascular access infections.[39]

The data requirements for these dialysis events and associated denominators are specified in the NHSN data collection protocol and in data collection forms developed and maintained by DHQP. Manual data entry into NHSN's web interface is the primary means of dialysis data collection. However, the technical design of the system enables importation of dialysis data in electronic form, and DHQP is moving forward with plans to enable dialysis facilities to report electronically. Participation by dialysis facilities in NHSN is voluntary, although one state – Colorado – requires facilities in its jurisdiction to participate. NHSN's analytic features enable dialysis facilities to analyze their own HAI data and compare their summary statistics to data aggregated and analyzed nationally by DHQP.

The Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) is a system under development by CMS that is designed to increase the efficiency of data collection and consolidate into one system several separate CMS systems currently used for reporting to the ESRD Program Management and Medical Information System. The legacy systems that will be consolidated by CROWNWeb are the Renal Information Management System, Standard Information Management System, and Vital Information System to Improve Outcomes in Nephrology also known as VISION. The existing information systems and databases will continue until their functions can be assumed by CROWNWeb. The technical design of CROWNWeb will enable ESRD Facilities to enter data manually into a web interface or electronically transmit data. CROWNWeb will receive and manage electronically-transmitted forms for ESRD patient registration (CMS-2728), ESRD clinical data (CMS-820 and CMS-821), and death notification (CMS-2746). ESRD Facilities will be able to retrieve summary information on their patients through CROWNWeb. Reporting to CROWNWeb will support ESRD facility compliance with CfCs. Plans call for HAI data to be included in CROWNWeb's data requirements and DHQP is working with CMS on the specifics of those requirements.

[39] Centers for Disease Control and Prevention. National Healthcare Safety Network: Dialysis Event (DE). Available at: http://www.cdc.gov/nhsn/psc_da_de.html

B. Integration of Systems

Integration of CDC and CMS systems for monitoring HAIs among dialysis patients can yield important operational benefits for reporting, analyzing, and using HAI data. A single HHS system interface for reporting data, or even a single set of specifications for submitting HAI data electronically to separate HHS systems, would streamline reporting and enable a merger of resources and user support for HAI reporting and data analysis. Use of standard analytic methods and tools would be facilitated, and, in turn, results from these analyses would be applied more readily to HAI prevention and quality improvement as common strategies for translating data into action are refined and put into practice as widely as possible through joint efforts. The challenge is accomplishing systems integration in the first place, but a relatively unique opportunity is presented by the efforts underway to enable electronic reporting to NHSN and to launch CROWNWeb in a phased approach that leverages the advanced information capabilities at many dialysis facilities and increases the user base with each phase.

Barriers to information systems integration are challenging, both within and across agencies. Programmatic, technological, resource, and regulatory issues need to be considered. CDC and CMS staff are actively engaged in an analysis and initial response to these issues as they pertain to a proposed integration of systems across the two agencies for monitoring HAIs among dialysis patients.

VIII. Future Directions

A. Emerging Infections

This chapter did not recommend a specific focus on preventing and reducing vancomycin-resistant enterococcus (VRE) at this time. Although this pathogen has the potential for high mortality rates, especially in the chronically dialyzed patient, its prevalence has remained low relative to other pathogens. That does not mean that the prevalence and incidence figures for this pathogen should not be monitored. Outbreaks of VRE infection have been described with associated mortality rates reaching 60%.[32] When hospitalized, ESRD patients are 11 times more likely to be treated with vancomycin during their stay than the non-hemodialyzed patient. Compounding the challenges to find appropriate treatments for antimicrobial-resistant pathogens in HD patients is the potential risk of cross-transmission to others in the facility and the community. The higher rates of mortality in these immunocompromised patients and the reality of transfer of antimicrobial-resistant genes to other organisms such as *S. aureus* remains a concern. Since 2002, there have been eleven cases of vancomycin-resistant *Staphylococcus aureus* or VRSA reported to the CDC.[40] The first of these occurred in a hemodialysis patient.

[40] CDC Reminds Clinical Laboratories and Healthcare Infection Preventionists of their Role in the Search and Containment of Vancomycin-Resistant Staphylococcus aureus (VRSA). [online] Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/ncidod/dhqp/ar_vrsa_labUpdate.html

Perhaps more striking than the infection itself, VRE and the existence of other such pathogens, represent a need for HHS to highlight the importance of developing and implementing strategic processes for appropriate antimicrobial selection and use in this patient population. Difficulties may exist in coordination of these efforts across dialysis units given the presence of multiple prescription formularies, treatment by multiple providers, and varied hospital protocols for antimicrobial use. However, these issues should serve as a platform by which we address and institute an infection control program that promotes using the most narrow-spectrum antibiotics for the shortest duration as clinically appropriate in this setting.

Important to remember as well is that there is an entire community of patients that undergo peritoneal dialysis at home who are subject to their own set of infection risks, usually in the form of peritonitis. While it is out of the scope of this chapter, opportunities to address HAIs in this population should be strongly considered as these efforts evolve.

B. Research Directions

The goal to eliminate HAIs in this setting will require a continuous infusion of strong evidenced-based data that serves to validate, improve upon, or refocus the strategic processes used to attain it.

i. Antimicrobial resistance – Because HD patients are so frequently hospitalized, the outpatient transmission dynamics of antimicrobial resistant (AR) organisms in this population is not well understood. Studies are needed to determine whether transmission of AR organisms occurs in outpatient dialysis settings and, if so, whether current recommendations for infection prevention in hemodialysis settings are sufficient to control their spread without implementation of more aggressive precautions. Development and implementation of best practices for judicious antimicrobial use in outpatient dialysis settings also is warranted to prevent antimicrobial resistant infections.

ii. Prevention through access care – Most CLABSI prevention research to date has focused on central line insertion practices. For patients who have long-term accesses, including central lines, the preventability of BSIs through optimal CVC maintenance practices is not as well defined. Furthermore, almost no studies have examined infectious outcomes of AV fistula and graft cannulation or maintenance practices. Research is needed to provide evidence to support best maintenance practices as the primary means of preventing access-related infections in this population.

iii. Viral hepatitis epidemiology – The current epidemiology of HCV and HBV infections in HD patients is not known, including prevalence and incidence, variability by facility, and the extent to which new infections in this population represent HAIs.

iv. Role of the environment – More research is needed to understand the role of environmental surfaces in transmission of pathogens in HD settings to facilitate better intervention strategies.

v. Engineering solutions and processes – Engineering solutions that can help to improve practices without relying upon behavior modifications should be pursued. These solutions should be specific to dialysis processes and/or challenges to infection control encountered in these settings given space, time, and other constraints.

vi. New medications and devices – In addition, the need for ongoing study and monitoring of new devices for hemodialysis access should be recognized. For example, devices for HD patients with conditions such as central venous outflow obstruction who may otherwise require a tunneled CVC for permanent dialysis access have been developed with evidence to date showing lower rates for bacteremia and hospitalizations when compared to CVCs. However, such studies are limited by the small number of patients who use it for access. This underscores the need for further monitoring in terms of HAI rates and other clinical outcomes associated with this and other new devices as they are released to the market.[41]

Antimicrobial catheter lock solutions have not been approved by FDA for prevention of catheter related BSIs; however, anecdotally their off-label use for prevention of catheter related BSIs appears to be widespread. Some lock solutions show promise as a means of preventing BSI in catheter consigned patients. Others might predispose to antimicrobial resistance or other adverse events that have not yet been fully assessed in studies. In addition to assessing the additive effect of antimicrobial lock solutions over and above currently recommended best practices, identifying a catheter lock agent that is safe for frequent patient use, effectively prevents BSI, and does not lead to resistance should be a research priority.

vii. Improvement in catheter polymers that retard/prevent the formation of biofilm.

viii. Other approaches – Peritoneal dialysis and home hemodialysis also should be examined to determine the benefits in terms of HAI and other outcomes when compared to in-center hemodialysis.

C. Reducing HAIs in ESRD Facilities by Reducing ESRD: A Focus on Early and Effective Treatment of Chronic Kidney Disease

It is important to note that ESRD patients, defined as those with a glomerular filtration rate <15 ml/min/1.73m^2 and/or who require dialysis, represent only 3.5% of the estimated 19.5 million Americans with CKD. Translated, this means that patients on hemodialysis account for only the very top of the pyramid and that "there are significantly more people with less severe CKD who need to be appropriately managed

[41] Nasser G. Long-Term Performance of the Hemodialysis Reliable Outflow (HeRO) Device: The 56-Month Follow-Up of the First Clinical Trial Patient. *Seminars in Dialysis* 2010; 23: 229-232.

to prevent an alarming increase in the number of people with ESRD."[42] In preventing HAIs in HD patients, concurrent Departmental efforts in reducing the progression to ESRD itself are in existence and should continue to be developed and pursued. The kidney disease education services benefit is an example of the type of program that could be used to educate patients that are at risk. Additional initiatives which promote identification and risk modifications for individuals with a family history of ESRD, predisposing conditions such as hypertension or DM and/or those in certain high-risk minority groups are essential in these at-risk populations and should be identified at each level including those provided in the community setting in order to expand reach. Early vascular access planning and immunization pre-ESRD can help to prevent HAIs and associated morbidity once patients initiate dialysis. These practices as well as collaboratives that educate and disseminate clinical practice guidelines for early nephrology referrals, dietary recommendations, and control of comorbid disease states could be seen as an appropriate if not necessary extension of this chapter.[43]

D. Expansion of Emerging Infection Program

The Preventing HAIs in ESRD Working Group is utilizing funds provided by the Office of the Secretary/Office of the Assistant Secretary for Health/Office of Healthcare Quality to expand a pilot project within the Emerging Infections Program (EIP), headed by the CDC. This program supports data collection at dialysis facilities by the use of EHR data to identify bloodstream infections in dialysis patients. This project aims to validate use of data collected at dialysis facilities and available in EHR data is a feasible and valid means of capturing HAI information. Additional potential exists for the outcomes of this project to augment and feed into the CMS initiative involving CROWNWeb and potentially be expanded to dialysis centers nationwide.

IX. Summary of Recommendations

Recommendation #1: Vascular Access

- Continued priority should be given to initiatives that promote the early placement and use of AVFs as well as the concept of CVCs as a last option for permanent dialysis access.
- Consider further investigation into policies that may unintentionally discourage early fistula placement.
- Follow evidence-based recommendations for CVC insertion and maintenance practices and appropriate aseptic technique for all vascular access care to prevent access-related infections.

Recommendation #2: Healthcare-Associated Infection Type

[42] Nasser G. Long-Term Performance of the Hemodialysis Reliable Outflow (HeRO) Device: The 56-Month Follow-Up of the First Clinical Trial Patient. *Seminars in Dialysis* 2010; 23: 229-232.
[43] St Peter WL, Schoolwerth AC, McGowen T, McClellan WM. Chronic Kidney Diseases: Issues and Establishing Programs and Clinics for Improved Patient Outcomes. *American Journal of Kidney Diseases* 2003; 41: 903-904.

- Recommend that efforts largely be placed on vascular-access related, hepatitis B and hepatitis C virus infection at this time because of higher prevalence and/or incidence rates of these infections in hemodialysis, their potential for significant morbidity and mortality in the ESRD population as well as demonstrated impact in infection rates with proper adherence to infection control processes and in the case of HBV, use of vaccination.

Recommendation #3: Immunization & Screening Practices

- Immunize all susceptible patients against hepatitis B, screen hemodialysis patients annually for evidence of vaccine-induced immunity and encourage immunization with the HBV vaccine for those susceptible to HBV;
- Screen susceptible ESRD patients on hemodialysis for Hepatitis C antibody in accordance with CDC and NKF-KDOQI recommended guidelines;
- Offer seasonal influenza vaccination as well as appropriate administration of the pneumococcal vaccine to all adult ESRD patients;
- Offer seasonal influenza vaccination to healthcare personnel in dialysis facilities. Also offer hepatitis B vaccine to susceptible healthcare personnel in dialysis facilities; and,
- Consider linking incentives to recommended immunization practices within dialysis facilities.

Recommendation #4: Prevention Priorities

- Prevention initiatives should target the most significant risk factors for acquisition and transmission of the aforementioned HAIs;
- Efforts should also target identified gaps and underutilized recommended practices in HD facilities as referenced in Section IV of this chapter;
- Identification and dissemination of best practice tools and other strategies to implement recommendations are needed;
- Increase staff training and educational opportunities and resources, targeting infection prevention needs specific to dialysis settings; and,
- Recommend quality improvement strategies that address and facilitate ESRD patient-centered efforts such as education programs and patient feedback processes to help reduce and prevent HAIs in this setting.

Recommendation #5: Metrics and Evaluation

- Recommend that proposed metrics and evaluation targets align where possible with the HAI prevention priorities as detailed in this chapter;
- Recommend that metrics and corresponding evaluation targets be accompanied by methods of data capture and data validation where possible; and,
- Recommend continued coordinated efforts between HHS and experts in the ESRD and infectious disease community to establish standardized definitions

and nomenclature for HAIs, not only pertinent to the ESRD Facilities but across settings that enhance clarity across all entities, improve alignment of research and quality improvement strategy and promote consistency in practice requirements, data monitoring and reporting as well as goal-setting.

Recommendation #6: Incentives and Challenges

- Recommend exploration of incentives for various stakeholders, including ESRD providers, hospitals, surgeons, and others to align practices with HAI prevention goals;
- Recommend emphasis on strategies that continue and further efforts linking survey and certification results with quality improvement resources such as those of the ESRD networks and other professional organizations; and,
- Recommend continued use of conditions for coverage and accompanying interpretive guidance as a strong lever to embed infection control priorities in ESRD Facilities.

Recommendation #7: Information Systems and Technology

- Recommend further investigation into the barriers that continue to hinder interdepartmental data system interface accompanied by solution development in order to develop HHS departmental interoperability and eliminate the potential data reporting burden of reporting to multiple databases; and,

X. Conclusion

HAIs disproportionately affect individuals receiving services in ESRD Facilities, with infection second only to cardiovascular disease as the leading cause of death. With an estimated 1.5-fold increase in these patients by 2020, renewed and strengthened efforts for prevention in these facilities is paramount. The priority recommendations take into account the best thinking on ESRD infection control and prevention, and highlight those with the strongest evidence base and the most promise for significantly reducing bloodstream infections, hepatitis B and C, influenza, and pneumococcal disease. These actionable prevention priorities will guide infection prevention and protect patient lives.

TABLE 11. HHS Ongoing Collaborative Projects Related to Reducing HAIs in ESRD Facilities

Project Title	Description of Project	Lead Agencies	Timeline	Ongoing/Projected	Contact
Fistula First	Launched in May 2007, initiative lead and overseen by CMS in partnership with physician groups, dialysis centers, patient advocacy groups and other major stakeholders, to increase the rates of AVF placement and use to NKF-DOQI target of 50% with maintenance of AVF in 40% of HD patients. (Contract through ESRD networks).	CMS/OCSQ through the ESRD Network	2003	Ongoing	
Clinical Performance Measures	Multiphase project where clinical performance measurements are being developed with long-range goal to expand quality measures for dialysis treatment and potentially future data reporting	CMS/QMHAG, ESRD Networks *and* CDC/NHSN	Ongoing	Ongoing CPM development is underway with strong encouragement for CDC-CMS collaboration, including use of NHSN for vascular access infection prevention QI projects. Currently 14 NQF Endorsed measures where CMS is the steward. CMS is convening a Technical Expert Panel in spring 2012 to develop measures covering 30-day hospital readmissions, pediatric peritoneal dialysis	Thomas Dudley (CMS, Lead) Renee Henry (CMS, Alternate)

Project Title	Description of Project	Lead Agencies	Timeline	Ongoing/Projected	Contact
				adequacy, anemia management, and preventive care.	
Annual Survey	Survey of outpatient dialysis facilities. In the past, had been annual or biennial. Survey includes information on infection control policies, practices, immunization rates & viral hepatitis prevalence and incidence	CDC and CMS (Survey and Certification)	Currently administered through NHSN; Last national survey was 2002, used to be administered in conjunction with CMS facility survey		

Project Title	Description of Project	Lead Agencies	Timeline	Ongoing/Projected	Contact
National Opportunity to Improve Infection Control in ESRD (NOTICE) [formerly titled: Improving Infection Control Practices in ESRD Facilities]	Multiyear project which serves to develop an infection control checklist and comprehensive unit based safety program (CUSP) for ESRD facilities. Additionally, a draft infection control audit tool will serve as the basis for future development of a comprehensive infection control worksheet for use by surveyors. Long-range goal aims to reduce infection and hospitalization rates for ESRD patients through adherence to strategies outlined in the checklist and worksheet.	AHRQ and CMS (Survey & Certification)) and CDC	Project began in 2010 and anticipated to run until 2013	Further optional work will include implementing and testing a Comprehensive Unit-based Safety Program (CUSP) that incorporates the checklist together with an education and training element that addresses the needs of the specific facilities	*K. Hall, AHRQ/CQuIPS*
Emerging Infections Program	Population-Based Surveillance for invasive MRSA infections in approximately 9 US geographic regions to track invasive MRSA rates among dialysis patients using USRDS denominator data	CDC, EIP Program	1995	Ongoing+	

Project Title	Description of Project	Lead Agencies	Timeline	Ongoing/Projected	Contact
A Regional Approach to HAI Reduction in the Hemodialysis Population	To apply improvement methods, including applications of LEAN and Positive Deviance techniques from the 'MRSA Reduction Collaborative in Outpatient Settings' specifically to ESRD facilities.	AHRQ and 2 Fresenius dialysis units based at Maine Medical Center.	Project to be completed May 2012.	Ongoing	*D. Gray , AHRQ/CQuIPS*
Safe and Timely Immunization Coalition (STIC)	STIC has developed immunization measures, immunization tracking tools, patient and provider tools and immunization guidelines for CKD patients for HBV, influenza and pneumovax	CDC, CMS, Southeastern Kidney Council	Initiative began August 2005 to the present	Ongoing	
Immunization in Dialysis Facilities	It has been proposed that offering influenza vaccination be a condition of participation for certain IPPS facilities including dialysis facilities. Final rule pending.	CMS: CSG		Projected	

Project Title	Description of Project	Lead Agencies	Timeline	Ongoing/Projected	Contact
Dialysis BSI Prevention Collaborative	A group of motivated dialysis facilities working together, utilizing a uniform measurement system, and implementing evidence-based best practices to prevent BSI.	CDC, dialysis facilities and ESRD Networks		Ongoing	
Viral Hepatitis Surveillance	State Health Departments are performing routine surveillance for viral hepatitis; risk factors such as HD are assessed	CDC and State Health Departments		Ongoing	
Colorado Mandated Reporting to NHSN	State-mandated reporting of dialysis events, including BSI	CDC and State Health Departments	Reporting began in March 2010	Ongoing	
Medicare Conditions for Coverage (CfC)	Existing COPs require that dialysis facilities cooperate with the ESRD network corresponding to its geographical area to implement priorities as defined in the 10th SOW.	CMS (OCSQ/CSG)	New contract began August 1, 2011.	Ongoing	*Lauren Oviatt, CMS/CSG*

Project Title	Description of Project	Lead Agencies	Timeline	Ongoing/Projected	Contact
MIPPA 153(c): Quality Incentive Program	Value-based purchasing program that rewards ESRD Facilities for meeting or achieving a total performance score based on their performance on specified measures. Failure to meet or achieve the total performance score could mean a loss of up to 2% of Medicare reimbursement under the ESRD PPS for ESRD Facilities. Under the PY 2014 program, ESRD facilities will be required to attest that they have successfully reported at least 3 consecutive months of dialysis infection event data to the NHSN.	CMS, QIG	Most recent final rule published November 10, 2011. This program will go through rulemaking every year.	Ongoing	Teresa Casey, CMS
ESRD Network Scope of Work (SOW)	A new SOW contract is in development between CMS and the ESRD networks	CMS, OCSQ	Projected for July 2012	In development	Teresa Casey, CMS