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 health care-associated infections (HAIs) in end-stage renal disease (ESRD) patients. This chapter should serve as a platform by which federal and nonfederal 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 also serve as a guide for resources and initiatives that will be needed in the future 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 health care 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 health care setting. By this definition, these infections are not present or incubating in the patient at the time of entry into that health care setting unless related to a previous admission from the same health care facility.[1] At any given time, about one in every 20 hospitalized patients has an HAI, while over one million HAIs occur across the U.S. health care system every year; the fiscal cost of these HAIs is steep, creating an additional $28 billion to $33 billion in health care expenditures annually.[2]

The U.S. Department of Health & 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."[3] 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 recommendations to HHS calling for leadership in prioritizing HAI prevention guidelines and establishing databases that could link information not only across the department but among U.S. health care facilities as well to improve data reliability. A call for actions that support safe and quality health care priorities are also echoed in the Affordable Care Act of 2010 (P.L. 111-148), which was passed on March 23, 2010. One such example includes the legislative charge for the Secretary of HHS to develop requirements for health plans which "implement activities to

[1] 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.
[2] Klevens RM, Edwards J, Richards C, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public Health Reports* 2007; 122:160-166.
[3] 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

improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology. …" (Patient Protection and Affordable Care Act [PPACA] Section 1001, adding section 2717[a][1][C] to the Public Health Service Act), and PPACA Section 1311(g)(1)(C).[4]

In response, the Federal Steering Committee for the Prevention of Health Care-Associated Infections was formed in 2008. The committee was tasked with developing a plan that systematically and continuously addresses the aforementioned issues, including prioritizing infection control practices that are guided by scientific validity and economic and operational feasibility. The Steering Committee initially focused on those HAIs determined to be most significant based on their prevalence, preventability, and potential for morbidity and mortality.

Phase One of the *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination* (HAI Action Plan) was focused on the prevention of infections in the acute care hospital setting ─ specifically, catheter-associated urinary tract infections (CAUTIs), central-line associated bloodstream infections (CLABSIs), *Clostridium difficile* infection (CDI), methicillin-resistant *Staphylococcus aureus* (MRSA), surgical-site infections (SSIs), and ventilator-associated events (VAE).[5] Recognizing the need to coordinate prevention efforts across health care facilities, the department began to move into Phase Two of the HAI Action Plan in late 2009. Phase Two 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 One efforts, Phase Two HAI reduction and prevention strategies are expected 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 the control and reduction of infections in health care facilities.

Although it is recognized that HAIs might be a significant issue for those ESRD patients who receive the majority of their treatment in home settings, this chapter concentrates on recommendations to prevent HAIs and reduce their number among ESRD patients who regularly receive hemodialysis in an outpatient dialysis facility. Also, given that the term "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. More specifically, the term ESRD facilities will always refer in this chapter to those facilities that provide outpatient hemodialysis treatment for ESRD patients. In this chapter, we will also focus on HAIs related to vascular access and those HAIs associated with infection from the hepatitis B virus (HBV) and hepatitis C virus (HCV). In doing so, we seek to prioritize our recommendations based on patient impact and the availability of evidence-based processes for the prevention and reduction of HAIs in this setting.

Recognizing that ESRD patients may encounter multiple providers and access care in multiple health care settings is crucial to infection control and prevention efforts. This chapter addresses the various provider types and care settings that can influence the occurrence of HAIs in the

[4] Patient Protection and Affordable Care Act (PPACA) (P.L. 111-148) and Healthcare Education Reconciliation Act, Act (P.L. 111-152), March 2010.
[5] Department of Health and Human Services. HHS Action Plan to Prevent Health Care-Associated Infections, 2009. Available at: http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html

ESRD population. These include the various 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 are considered active partners in this effort. As with all of the chapters in the HAI Action Plan, this chapter is a living document and thus is expected to evolve as HAI efforts targeting this patient population continue.

III. HEALTH CARE-ASSOCIATED INFECTIONS IN ESRD

A. Epidemiology

In the chronic uremic patient on hemodialysis, infection is a leading cause of morbidity and second only to cardiovascular disease as a cause of death. According to the United States Renal Data System (USRDS), the total death rate due to infection is 76 per 1,000 person-years at risk, with sepsis responsible for three-quarters of these deaths.[6] In comparison with the general population, the incidence of sepsis in patients with ESRD can be up to 100 times as high.[7] Infections are a major reason for hospitalizations in this population, estimated to be responsible for as many as 20% of their inpatient admissions. These infections confer a higher risk of mortality in the ESRD patient than they do in the general population, with a diagnosis of septicemia carrying a cumulative mortality rate of 43% at one year, versus 20% for the general population.[8] 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.[9]

B. Pathogenesis

Multiple factors contribute to infectious morbidity and mortality in the ESRD patient on hemodialysis. First, ESRD patients are more susceptible to infection because of the processes inherent in hemodialysis, which include the need for long-term vascular access, including chronic use of central lines. These patients also have multiple and frequent exposures to the health care environment and to other patients, conferring multiple opportunities to acquire an infection. These exposures 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 health care providers these patients encounter. In addition, patients with ESRD are frequently immunocompromised because of comorbidities such as diabetes mellitus or from the uremic toxicity that characterizes their disease.

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[6] 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.
[7] Bertrand LJ. Bacterial infections in the hemodialysis patient: pathogenesis and prevention. *Kidney International* 2005; 67:2508-2519.
[8] 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.
[9] 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.

C. Vascular Access

Risk associated with device use in this population is arguably one of the most significant contributors to HAIs. Hemodialysis 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). A CVC accesses the central circulation, the superior vena cava, or right atrium through one of the large veins. Providers may rely on temporary access through a CVC while an AVF, a more permanent access site, is ready for use. Also, CVCs may be used for the longer term in patients where previous AVG or AVF surgery has been unsuccessful or when a patient has refused surgery to have an alternate access site placed. An AVG is a bridge between an artery and vein created with the use of a synthetic graft implanted under the skin. An AVF is a surgical anastomosis between an artery and a vein. It cannot be used for access immediately after being place because of the time it takes to mature. Over time, the vein becomes larger and stronger due to continued exposure to high blood flows in the artery making repeated access easier. The AVF is considered to be the best access site for patients on long-term hemodialysis.[10]

Access via a CVC confers the greatest risk for acquiring a vascular-access infection (VAI); cumulative risk increases with the amount of time the catheter is present and/or in use. Dialysis catheter-related bloodstream infections (BSIs) 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 backflow into the extracorporeal circuit while the dialysis machine is being primed with the waste-handling option.[11,12,13,14,15] AVFs have the lowest associated infection rate of vascular access,[16] and AVFs confer a substantially lower risk of VAI than does the use of CVCs. Observed VAI 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 comorbidities.

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[10] http://kidney.niddk.nih.gov/kudiseases/pubs/vascularaccess/#graft

[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, et al. 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, et al. Outbreak of bloodstream infections associated with dialysis machine waste ports in a hemodialysis facility. *European Journal of Clinical Microbiology & Infectious Diseases* 1999; 18:723-725.

[15] Rao CY, Pachucki C, Cali S, et al. 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)* 2011; 60(08): 243-248. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6008a4.htm?s_cid=mm6008a4_w

The pathogens most commonly responsible for access-related bloodstream infections in hemodialysis are gram-positive organisms, with *Staphylococcus aureus* (*S. aureus* and coagulase-negative staphylococcus [e.g., *S. epidermidis*]) accounting for an estimated 40-80% of cases.[17] The incidence of invasive MRSA infections in dialysis patients, most of which are BSIs, is 45 per 1,000 persons, or more than 100 times the incidence in the general population. This high rate 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 approximately 30-40% of BSIs in hemodialysis patients, while infections of polymicrobial origin account for 10-20% of cases.[18]

Because VAIs are such a significant source of HAIs in the dialyzed patient, and because the potential for morbidity and mortality resulting from these infections is high, much attention has been and should continue to be placed on preventing infection or reducing its incidence among this sub-population of patients. Emphasis and incentives for early fistula placement, education on AVF maintenance and sustainability, making catheters 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 HBV and HCV pose a particular clinical challenge for ESRD patients on hemodialysis, given the increased opportunity for exposure to other patients' blood during treatment when proper precautions to prevent infection are not followed. Prevalence and incidence statistics for these infections vary widely between dialysis units and geographic locations. Regardless, a 2002 national survey of chronic hemodialysis centers revealed the prevalence of hepatitis B surface antigen (HBsAg) positivity among U.S. dialysis patients to be approximately 1%, and incidence was 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 hemodialysis facilities has been declining steadily since the 1980s, a decline attributable to implementation of infection control practices in dialysis centers as well as the administration of the HBV vaccine in this population. In fact, administration of the HBV 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 immunocompetent 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,

[17] Klevens RM, Edwards J, Richards C, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. *Public Health Reports* 2007; 122:160-166.
[18] Boyce JM. Epidemiology of MRSA infection in adults, 2012. [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.

27.3% of the centers reported one or more patients with HBV infection (HBsAg positivity), and 2.8% of the 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 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 nonprotective or to last a shorter time than is the case in the general population, where the prevalence of HBV is 0.27%.[24]

The prevalence of HCV infection among hemodialysis patients is almost five times that of the general U.S. population, where the prevalence of HCB is 1.6%.[25,26,27] 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 of HCV infection in the hemodialysis 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.[28,29] These investigational studies have shown the main mode of transmission to be health care-related, occurring mainly within dialysis facilities, and transmission has been attributed to failures to adhere to recommended infection control practices. In studies of hemodialysis patients, researchers have shown that HCV infection is related to the length of time the patient is on dialysis.[30,31]

HBV and HCV infection are, and should remain, key areas of focus for hemodialysis facilities because of the higher prevalence and transmission rates among the vulnerable population treated there, the increased risk of morbidity once infection is acquired,[32] and the preventability of transmission if there is adherence to the infection control recommendations discussed later in this

[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.
[24] Wasley A, Kruszon-Moran D, Kuhnert W, Simard EP, Finelli L, McQuillan G, Bell B. The prevalence of hepatitis B virus infection in the United States in the era of vaccination. *Journal of Infectious Diseases* 2010 Jul 15; 202(2):192-201.
[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] 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.
[27] 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.
[28] Thompson ND Novak RT, Datta D, Cotter S, 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.
[29] 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):189-194.
[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] 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.

chapter. In addition, screening for HBV and administering the HBV 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. RECOMMENDATIONS FOR PREVENTION PRIORITIES IN ESRD FACILITIES [33,34,35,36,37,38,39]

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 includes recommendations from each of these organizations that have been prioritized for inclusion on the basis of burden of targeted HAI, expected impact of the recommended interventions, and supporting evidence. The decision not to include certain recommendations from this prioritized list should not prevent providers from implementing other evidence-based recommendations in their practices to prevent infections.

Of the extensive recommendations for prevention that exist, many are based upon observational studies, expert opinion, and/or documented lapses identified during investigations of outbreaks. In general, high-quality trials of infection prevention conducted specifically among hemodialysis patients have been 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, Centers for Medicare & Medicaid Services (CMS) incorporated various recommendations for prevention in its required Conditions for Coverage (CfCs) for ESRD facilities. Select regulatory

[33] 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
[34] 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
[35] 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
[36] Rutala W, Weber D, and the Healthcare Practices Control Advisory Committee. Guideline for disinfection and sterilization in healthcare facilities. Centers for Disease Control and Prevention, 2008. Available at http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
[37] Centers for Disease Control and Prevention. Guidelines for hand hygiene in healthcare settings. *Morbidity and Mortality Weekly Report (MMWR)* 2002; 51(RR-16):1-45. Available at http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf
[38] 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
[39] 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

requirements from the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) have also been included. Therefore, while the guidelines in this specific document are considered priority recommendations, we have tried to maximize their alignment with current regulations where they exist.

B. Methods

As in Phase One of the HAI Action Plan, the implementation priorities included here are based upon scientific evidence that a practice is effective/beneficial, recognize gaps in current implementation, and consider potential impact. However, because of the limited number of research trials on preventing infection conducted in this population, the recommendations considered were not limited to those meeting Category IA or Category IB levels of evidence. The level of evidence is indicated when available, along with organizations that have guidance or regulations 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 ensure that, once incorporated, these skills and processes do not degrade over time, particularly as new staff are added.

C. Priority Recommendations

Prevention of Intravascular Infections

Vascular-access infections (VAIs), particularly BSIs, cause substantial morbidity and mortality in hemodialysis patients. Hemodialysis patients with CVCs have the highest rate and burden of BSIs. Interventions to reduce CVC-related BSIs have the largest evidence base, and thus 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 to obtain permanent access for hemodialysis.
Sources: 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.
  Source: 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.
  Source: 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.
  Sources: HICPAC (Category IA), NKF KDOQI.

Priority Module 3

Recommendations for Appropriate Maintenance of Vascular Catheters and Arteriovenous Fistulas and Grafts

- Educate health care 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.
  Source: 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.
  Source: HICPAC (Category IB).
- Periodically assess knowledge of and adherence to guidelines among all personnel involved in the insertion and maintenance of intravascular catheters.
  Source: HICPAC (Category IA).
- Assess for need and promptly remove any intravascular catheter that is no longer essential.
  Source: 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 constituent materials of the hemodialysis catheter.
  Sources: HICPAC (Category IB), NKF KDOQI.
- Scrub the catheter access port with an appropriate antiseptic (chlorhexidine, povidone-iodine, or 70% alcohol) prior to accessing this port and access it only with sterile devices.
  Source: HICPAC (Category IA).
- 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.
  Source: HICPAC (Category IA).
- Use aseptic technique to avoid contamination of sterile injection equipment.
  Sources: HICPAC (Category IA), CMS.

Priority Module 4

Recommendations for the Quality of Water and Dialysate

- 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 (colony-forming units)/mL and an endotoxin concentration lower than 2 EU (endotoxin units)/mL.
  Sources: 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 be taken promptly to reduce the levels.
  Sources: 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.
  Sources: 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 be taken promptly to reduce the levels.
  Sources: 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.
  Sources: AAMI, CMS, HICPAC (Category IA).
- Disinfect water distribution systems in dialysis settings on a regular monthly schedule.
  Sources: 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.
  Sources: AAMI, HICPAC (Category IA).

Prevention of Bloodborne Pathogen Transmission

Because of the need for repeated vascular access and the practice of treating other patients on dialysis in close proximity, hemodialysis patients are at increased risk of acquiring infections caused by bloodborne pathogens, particularly HCV and HBV. Although not directly related to prevention of HAIs in patients, OSHA requirements to protect dialysis health care personnel who have contact with potentially infectious blood in these environments are also included here, because these requirements might overlap logistically with the implementation of efforts to prevent patient HAIs.

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

- Offer HBV vaccine to all susceptible hemodialysis patients.
  Sources: CDC, ACIP, CMS.
- Treat hemodialysis patients with active HBV infection at an isolation station with dedicated room, machine, supplies, and staff members.
  Sources: CDC, CMS.
- For patients who respond to the HBV vaccine series, check surface antibody titers annually and administer a booster dose when indicated.
  Sources: CDC, CMS, ACIP.
- Perform baseline HBV serology (HBsAg, anti-HBs [hepatitis B surface antibody] and total anti-HBc [hepatitis B core antibody]) of patients and repeat HBsAg monthly for susceptible patients to identify new HBV infections.
  Sources: CDC, CMS.
- Perform baseline anti-HCV screening of patients and repeat every six months for susceptible patients to identify new HCV infections.
  Sources: CDC, NKF KDOQI, KDIGO.

- Offer HBV vaccine to health care personnel to protect staff.
  Sources: HICPAC (Category IA), ACIP, OSHA.
- Conduct training in bloodborne pathogens for all staff with occupational exposure to blood or other potentially infectious materials upon initial assignment and yearly thereafter.
  Source: 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.
  Sources: HICPAC (Category IA), CMS.
- Do not keep multi-dose vials in the immediate patient treatment area and store them in accordance with the manufacturer's recommendations; discard if sterility is compromised or questionable.
  Sources: HICPAC (Category IA), CMS.
- Use aseptic technique to avoid contamination of sterile injection equipment.
  Sources: HICPAC (Category IA), CMS.

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.
  Sources: CDC, NKF KDOQI, CMS.
- Thoroughly clean and disinfect environmental and medical equipment surfaces using EPA-registered disinfectants in accordance with manufacturer's instructions.
  Sources: EPA, HICPAC (Categories IB, IC).
- Follow proper procedures for site decontamination of spills of blood or blood-containing body fluids, using an appropriate disinfectant.
  Sources: HICPAC (Category IC), CMS, OSHA.

Prevention of Influenza and Pneumococcal Disease

Patients with CKD are at increased risk of developing severe complications from influenza and pneumococcal disease. Although not all influenza and pneumococcal infections in this population are health care-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.
  Sources: CDC, ACIP, CMS.

- Offer influenza vaccine annually to health care personnel to protect staff, patients, and family members and to decrease absenteeism among staff.
  Sources: HICPAC, ACIP (both Category IA).
- Offer one dose of pneumococcal polysaccharide vaccine to adult dialysis patients and a one-time booster dose after five years has elapsed.
  Source: ACIP.

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 that 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 used in conjunction with a comprehensive program of infection control within an organizational culture that emphasizes and values safety for every patient every time.

Education and Training

The 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, and vigorous methods to test staff competencies should be used to help ensure the consistency and sustainability of desired practices. In addition, a continuous 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 the adherence of staff to infection control practices. Patient education should include general hygiene, vascular-access care and maintenance, recognition of the signs and symptoms of infection, understanding the risks associated with catheters, and the importance of having a permanent access placed, if the patient is eligible.

Opportunities to both access and provide educational resources for dialysis staff and ESRD patients are available. Using and adapting the expertise and educational programs developed by professional organizations such as the Association for Professionals in Infection Control (APIC), the Society for Healthcare Epidemiology of America, and NKF may allow dialysis organizations to 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 the type of dialysis provider. Examples of such training materials include CDC's continuing education course "Infection Prevention in Dialysis Settings" and APIC's "Infection Prevention in Hemodialysis Settings" course. In

addition, training in infection control and educational tools and collaborative opportunities may become available by leveraging the regional resources of ESRD Networks. Ensuring that information from state surveys and certification processes 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 postgraduate 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 promoting evolving curricula, licensing and certification standards, and competencies that reflect knowledge of recommended priorities for preventing infection as well as an adequate skill level for their execution.

Lastly, the changes made 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 enrollment in Medicare, Part B), may be another resource by which dialysis facilities can offer individualized education for their ESRD patients.

V. METRICS AND EVALUATION

A. Overview

Note: Although a continued effort is being made in this HAI Action Plan to align recommended measures with those of various programs across HHS, the metrics proposed in this chapter are distinct from those of the CMS ESRD Quality Incentive Program (QIP) and should not be considered part of that regulatory process.

The metrics and evaluation targets shown in Table 9 and described below were developed by the Steering Committee to assess progress toward achieving HAI goals on a national level. These metrics 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 presented here 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 measures presented in Table 9 as indicators of progress in this arena.

Table 9. Five-Year National Metrics and Evaluation Targets

Recommended Metrics	Definition (Calculation Formula)	(Proposed) Evaluation Target	Data Source(s)	Comments
All bloodstream infections (BSIs) stratified by access type	1. Number of incident-positive blood cultures in CVC patients/100 CVC patient-months 2. Number of incident-positive blood cultures in AVF patients/100 AVF patient-months 3. Number of incident-positive blood cultures in AVG patients/100 AVG patient-months	1. Pooled mean ≤5.0 or ***RIR ≥40 %** 2. n/a 3. n/a	NHSN **CROWN Web	We propose BSI rates for AVF and AVG as metrics for data collection and analysis, although there is not enough data at this time for setting targets.
Access-related BSIs stratified by access type	1. Number of incident-positive blood cultures with vascular access as suspected source or with unknown source in CVC patients/100 CVC patient-months 2. Number of incident-positive blood cultures with vascular access as suspected source or with unknown source in AVF patients/100 AVF patient-months 3. Number of incident-positive blood cultures with vascular access as suspected source or with unknown source in AVG patients/100 AVG patient-months	1. RIR ≥50% 2. n/a 3. n/a	NHSN **CROWN Web	Including this as a metric would address the concern that not all BSIs in this population are access-related but reinforces the issue of preventing serious access-related infection by reflecting that problem in outcome metrics. Because of a lack of data, we do not recommend setting an evaluation target for AVF or AVG at this time.

Recommended Metrics	Definition (Calculation Formula)	(Proposed) Evaluation Target	Data Source(s)	Comments
Seasonal influenza vaccination for ESRD patients	Number of ESRD patients who received seasonal influenza vaccination /all ESRD patients x 100	**≥ 90%**	Medicare claims data, **CROWN Web, Kidney Care Quality Alliance (KCQA)	In line with Healthy People 2020 goals. Influenza claims for ESRD patients would have to be cross-referenced across all care to capture all patients, 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 the NHSN either manually or electronically or via data-interoperability mechanism with CMS	Number of ESRD facilities that report to the NHSN/all ESRD facilities x 100	**≥ 90%**	NHSN	
Any CVC use in patients on hemodialysis	Number of hemodialysis patients with CVCs/number. of hemodialysis patients x 100	**Absolute target: ≥20% or RIR ≥20%**	Fistula First NHSN **CROWN Web	The NHSN definition of "any CVC use" includes patients with temporary or permanent lines in order to include all CVC use regardless of duration.
Screening for hepatitis C antibody	Number of ESRD facilities that screen all susceptible hemodialysis patients every 6 months/ number. of all ESRD facilities x 100	**≥70%**	**CROWN Web	
Hepatitis B vaccine coverage in hemodialysis patients	Number of hemodialysis patients who have ever received ≥3 doses of hepatitis B vaccine/all hemodialysis patients x 100	**≥ 90%**	Data from ESRD Networks, **CROWN Web, Medicare claims	In line with Healthy People 2020 goal. Would be appropriate for renewed CDC-CMS survey. Hepatitis B vaccine should be administered at appropriately timed intervals.

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

B. Priority Recommendations

Bloodstream and Vascular Infection Rates and Care Processes

Priority Module 1
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 all three 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 = number of hemodialysis patients with CVC/all hemodialysis patients x 100.

Outcome Measures: NHSN currently collects and reports several metrics relevant to VAI. 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 problems are most appropriate to target for prevention efforts.

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

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

Hepatitis B and C

Priority Module 2
Although HBV and HCV 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 should be used to represent the background rate of HBV and HCV infection in the community. Some proportion of incident infections will be related to health care exposures in dialysis versus other exposures, but this proportion is currently unknown. For this reason, we will not propose HBV or HCV infection outcome

measures as HAI metrics until further investigations are conducted. However, it is well-documented that health care transmission of these infections does occur, thus requiring screening for detection, and can be prevented through actions such as appropriate vaccination and infection control measures.

Thus, two of these steps (vaccination, screening) are reflected in the process measures below. One, the measurement of HBV vaccine coverage, is supported by Healthy People objectives.[40] Screening for anti-HCV, 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.

Process Measures: HBV vaccine coverage = Number of hemodialysis patients who have ever received ≥3 doses of HBV vaccine/all hemodialysis patients x 100

Screening for new HCV infections = Number of ESRD facilities that screen susceptible hemodialysis patients every 6 months for hepatitis C antibody/ESRD facilities x 100

Pneumococcal Disease, Seasonal Influenza

Priority Module 3

As with HBV and HCV infections, not all pneumococcal and influenza illness in this ambulatory population represent HAIs. In fact, most pneumococcal and influenza infections likely arise in the community. The intersection with health care through frequent dialysis treatments affords some opportunity for health care transmission and also an opportunity to prevent both health care and community-based transmission in this high-risk population. For these reasons, metrics in this section are focused on process, not outcome measures. The measure of vaccine coverage below is supported by Healthy People objectives. A metric that follows seasonal influenza vaccination for health care workers in this setting is included in the Influenza Vaccination of Health Care Personnel Chapter of the HAI Action Plan and thus was not repeated in this chapter.

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

[40] http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23

VI. INCENTIVES AND CHALLENGES

A. Incentives

Federal Level

The CfCs for ESRD facilities set minimum requirements that they must meet to participate in Medicare, requirements that can be grouped in 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, while 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 Guidelines to ensure that they are operating within the guidelines established by CMS. State Survey Agencies (SSAs) use the Interpretive Guidelines 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, it would be required to correct the deficiency within a certain time frame or, in a severe case, might be forced to close. Because 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, many attendees agreed that these standards lend importance and credibility to the infection control practices they require. In addition, the opportunity to use CfCs along with the Interpretive Guidelines 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) and enacted on July 15, 2008 (P.L. 110-275, Section 153(c)). This law calls for the development of a value-based purchasing program for ESRD facilities for services furnished on or after January 1, 2012. The statute also calls for a payment reduction of up to 2% for facilities that do not meet or exceed a total performance score on performance standards established for certain specified measures. In November 2011, CMS released its final rule for the 2012 ESRD QIP with requirements that affect payment in 2014. Included is a measure by which facilities must enroll facilities and train personnel, and report at least three consecutive months of data on dialysis infection events to the NHSN during 2012.

State/Network Level

Colorado recently became the first state to mandate the reporting of HAIs from outpatient dialysis facilities.

B. Challenges

There are several challenges to implementing and sustaining efforts aimed at reducing HAIs among ESRD patients. The challenges can be sorted by the level of the system that is most affected: state/network, facility/provider, or patient.

State/Network Level

State Survey Agencies/Networks
Prioritizing ESRD HAI prevention at the federal level dictates the need for a focus on infection control processes, the tools and education available for surveyors and facilities to implement these processes, and adherence to regulatory requirements for dialysis facilities across states. CMS and the SSAs 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 the SSAs and the ESRD Networks are crucial to improve opportunities for information sharing and the allocation of resources to facilities with deficient practices.

Recommendations from the Federal Steering Committee for the Prevention of HAIs ESRD Working Group strongly support efforts between CMS, regional offices, and the contractors they each oversee, e.g., the SSAs and the 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.

State and Local Health Departments
In addition to the SSAs, certain departments located in the states and other jurisdictions play an important role in HAI prevention. Generally, departments within these health authorities have expertise in responding to HAIs and other outbreaks of communicable disease 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, however, and effective relationships have been more challenging to establish with them. Within state governments, efforts to respond to HAI outbreaks are often organizationally separate from health care licensing and certification functions, creating a potential challenge to communication and coordination between these groups.

Facility/Provider Level

Infection Control Resources
Most maintenance hemodialysis treatments are given 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 expertise in this area. Furthermore, the ability to implement certain infection control practices can be hindered by financial pressures, staffing constraints, and the lack of a clear understanding of (and training in) appropriate infection prevention practices. Currently, certificate programs to

provide dialysis personnel with specialized training in infection prevention are lacking. Also lacking are educational resources to address infection control practices specific to dialysis settings.

Transitions of Care

Hemodialysis patients undergo frequent hospitalization. Overlap in the responsibility for these patients can occur because care is provided in nursing homes, assisted living facilities, and other settings as well. These transitions between settings represent a challenge to the 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 as opposed to 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 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 affect pre-ESRD and surgical care. This includes planning for proper vascular access, 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. In addition, working toward ensuring that data always follows the patient supports the patient-centric model of care and the essential need for coordinated transitions of care.

Culture of Safety

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

HAI Data

Caution must be used when tying the public reporting of HAIs and associated incentives, particularly financial, to a main outcome measure, e.g., VAIs. 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 such use of incentives and reporting might include under-testing or underreporting of VAIs, and may even lead to antibiotic overuse as a preemptive effort to prevent infection. Thus, 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 those necessary components of a facility's process of care that have been identified as directly affecting the outcomes of interest.

Currently, it is not clear what the accepted definition for VAI should be, particularly for access-associated bacteremia. FDA, CDC, and CMS are operating under different definitions for VAIs. This presents the ESRD facilities and providers with the challenge of deciding

which definition of VAI they will be targeting. With a standardized definition across all entities, there could be an alignment of research protocols, quality improvement initiatives, and payment rules.

Collecting and reporting data, whether that involves outcome measures of infection or process measures of infection control, needs to be balanced with actual improvements in quality. Neither the ability to acquire the data nor the data themselves can be the sole drivers of change. Among the things that can affect the accuracy and precision of data are the lag times, often significant, between data acquisition and reporting, particularly for cultures, and the fact that the same facilities could have different results depending on the time in the month that data are collected.

For HAI data to be credible and useful for evaluating progress towards the elimination of HAIs it is necessary that it undergo robust validation procedures. A variety of methods will be needed to ensure data accuracy and completeness, methods that should include a system of both internal and external validation. This should include attention to data validation at the facility or the place where the data is entered as well as a system of validating HAI data that is received at the state or federal level. Stakeholders at the HAI Data Summit held in May 2012 concurred, sharing their opinion that data validation, in particular, was an issue for all dialysis organizations, regardless of their size, although some larger organizations do have the resources to do their own validation. Even when validation exists in organizations, consistency across organizations is an issue that stakeholders believe should be undertaken by HHS and its partnering stakeholders in the ESRD community. Both internal and external validation methodologies developed by various organizations, including state health departments, should be examined for their potential applicability on a wider scale.

Patient Level

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

- There is a substantial literature to support the involvement of patients in monitoring the safety of their own care. ESRD patients are uniquely situated to assess whether required infection control practices are being followed (which could include looking at objective measures of adherence to infection control practices). However, many patients feel uncomfortable in questioning or challenging their care providers and might have concerns that doing so could negatively affect the care they receive.

- The patient needs to be empowered to be an active member of the health care delivery team and have the opportunity to engage in HAI-related efforts from the facility level through the network level. A focus on directly involving patients in their care, through

education efforts[41] and the creation of 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

Information systems supported by HHS operating divisions currently provide, or should provide in the near future, 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 under way 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 health care and public health use for surveillance of HAIs and the processes of care designed to prevent and control those infections. Surveillance of selected health care events and processes among dialysis patients is an integral part of NHSN, including BSIs, administrations of intravenous (IV) antibiotics, and VAIs.[42]

The data requirements for these dialysis events and associated denominators are specified in NHSN data collection protocol and in data collection forms developed and maintained by DHQP. Manual entry into NHSN's web interface is the primary means of collecting data on dialysis. 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 was voluntary prior to the November 2011 release of the ESRD QIP. One state – Colorado – requires all of the ESRD 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.

In June 2012, the Consolidated Renal Operations in a Web-enabled Network (CROWNWeb) system underwent national release for use by all ESRD facilities. This system is designed to increase the efficiency of data collection and consolidate into one system several separate CMS legacy systems used by CMS 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, the last one also known as VISION. The existing information systems and databases will continue until their functions can be fully assumed by CROWNWeb. The technical design of CROWNWeb will enable ESRD facilities to

[41] D'Agata E. Hospital-acquired infections in chronic hemodialysis patients: prevention and control of HAI. Medscape (published June 2001). Available at http://www.medscape.com/viewarticle/410166.
[42] Centers for Disease Control and Prevention. National Healthcare Safety Network: Dialysis Event (DE). Available at: http://www.cdc.gov/nhsn/psc_da_de.html

enter data manually into a web interface or to 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 the compliance of ESRD facilities with CfCs. Plans currently call for HAI data to be included in CROWNWeb's data requirements, and DHQP is working with CMS on the specifics of those requirements.

B. Integration of Systems

The 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. The 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 special opportunity is presented by the efforts under way 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 the integration of information systems 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. The need for continued emphasis on efforts to develop system capabilities that allow for data sharing, promote the standardization of measures, and reduce the HAI data reporting burden was echoed by multiple stakeholders from the ESRD community who attended the HAI Data Summit in May 2012.

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 that of other pathogens. That does not mean that the prevalence and incidence figures for this pathogen should not be monitored. In fact, outbreaks of VRE infection have been described with associated mortality rates reaching 60%.[43] When hospitalized, ESRD patients are 11 times as likely to be treated with vancomycin during their stay as is the non-hemodialyzed

[43] 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

patient. Compounding the challenges of finding appropriate treatments for antimicrobial-resistant pathogens in hemodialysis 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 the transfer of antimicrobial-resistant genes to other organisms, such as *S. aureus,* remain concerns. Since 2002, there have been 11 cases of vancomycin-resistant *S. aureus* (VRSA) reported to CDC.[44] The first of these occurred in a hemodialysis patient.

Perhaps more striking than the infection itself is the fact that VRE and 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, however, 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 who undergo peritoneal dialysis at home and are subject to their own set of infection risks, usually in the form of peritonitis. While it is beyond 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 of eliminating HAIs in the hemodialysis setting will require a continuous infusion of strong evidenced-based data that serve to validate, improve upon, or refocus the strategic processes used to attain this goal.

Antimicrobial Resistance

Because hemodialysis patients are so frequently hospitalized, the outpatient transmission dynamics of antimicrobial-resistant organisms in this population are not well understood. Studies are needed to determine whether the transmission of antimicrobial-resistant 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. Further study regarding the prevention and transmission of infection with multidrug-resistant organism is needed. Development and implementation of best practices for judicious use of antimicrobials in outpatient dialysis settings also is warranted to prevent antimicrobial-resistant infections.

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

Prevention through Care for the Access

Most research to date on CLABSI prevention has focused on practices for inserting central lines. 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 AVF (i.e., 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.

Epidemiology of Viral Hepatitis

The current epidemiology of HCV and HBV infections in hemodialysis patients is not known, whether that be the dimensions of prevalence and incidence, variability by facility, or the extent to which new infections in this population represent HAIs.

Role of the Environment

More research is needed to understand the role of environmental surfaces in the transmission of pathogens in hemodialysis settings to facilitate better intervention strategies. Improved guidance may also be needed to achieve environmental decontamination objectives. For example, use of the term "patient zone" from the World Health Organization's 5 Moments for Hand Hygiene may be helpful for describing any potentially contaminated area that requires cleaning and disinfection between patients. This zone would include the dialysis treatment chair, the dialysis machine, and all surfaces touched directly by the patient or potentially contaminated during the care of the patient (for example, keyboards, Hoyer Lifts, wheelchairs). Additional strategies and guidance might be needed to address difficult-to-disinfect items such as keyboards.

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.

New Medications and Devices

The need for ongoing study and monitoring of new devices for hemodialysis access should be recognized. For example, devices for hemodialysis patients who have conditions such as central venous outflow obstruction and may otherwise require a tunneled CVC for permanent dialysis access have been developed, with evidence to date showing lower rates for bacteremia and hospitalizations among patients with these new devices in comparisons with patients having CVCs. However, such studies have been limited by the small number of patients who use these new devices for access. This fact underscores the need for further

monitoring in terms of HAI rates and other clinical outcomes associated with these and other new devices as they are released to the market.[45]

Antimicrobial catheter lock solutions have not been approved by FDA for prevention of catheter-related BSIs, but anecdotal information indicates that their off-label use for prevention of catheter-related BSIs is widespread. Some lock solutions show promise as a means of preventing BSI in catheter-consigned patients. Other lock solutions 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 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.

Catheter Polymers

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

Other Approaches

Peritoneal dialysis and home hemodialysis should be examined to determine the benefits in terms of preventing HAI and other undesirable outcomes in comparisons with 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 many more people with less severe CKD who need to be managed appropriately to prevent a huge increase in the number of people with ESRD.[46] In preventing HAIs in hemodialysis patients, concurrent HHS efforts in reducing the progression to ESRD itself are under way and should continue to be developed and pursued. The educational services on kidney disease included in the Welcome to Medicare benefit are an example of the type of program that could be used to educate at-risk patients. Additional initiatives that promote identification and risk modification for individuals with a family history of ESRD, predisposing conditions such as hypertension or diabetes mellitus, or membership in certain high-risk minority groups, are essential in these at-risk populations and should be identified at each level, including initiatives provided in the community setting in order to maximize the impact reach of the initiatives. Early planning for vascular access and immunization before the patient is determined to have 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

[45] 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.
[46] 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.

for early nephrology referrals, dietary recommendations, and control of comorbid disease states could be seen as an appropriate if not a necessary extension of this chapter.[47]

D. Expansion of Emerging Infection Program

The Federal Steering Committee for the Prevention of HAIs ESRD Working Group is using funds provided by the Office of the Secretary of HHS/Office of the Assistant Secretary for Health to expand a pilot project within the Emerging Infections Program (EIP) headed by CDC. This program supports data collection at dialysis facilities through the use of electronic health record (EHR) data to identify BSIs in dialysis patients. This project aims to validate the use of data collected at dialysis facilities and available in EHRs and 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 to potentially be expanded to dialysis centers nationwide.

IX. SUMMARY OF RECOMMENDATIONS

A. 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 that CVCs are a last option for permanent dialysis access.
- Consider further investigation into policies that may unintentionally discourage the early placement of fistulas.
- Follow evidence-based recommendations for CVC insertion and maintenance practices and appropriate aseptic technique for all vascular-access care to prevent access-related infections.

B. Recommendation 2: Health Care-Associated Infection Type

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

C. Recommendation 3: Immunization and Screening Practices

- Immunize all susceptible patients against HBV, screen hemodialysis patients annually for evidence of vaccine-induced immunity, and encourage immunization with the HBV vaccine for those susceptible to HBV.

[47] 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.

- Screen susceptible ESRD patients on hemodialysis for HCV antibody in accordance with CDC and NKF-KDOQI recommendations.
- Offer seasonal influenza vaccination as well as appropriate administration of the pneumococcal vaccine to all adult ESRD patients.
- Offer seasonal influenza vaccination to health care personnel in dialysis facilities. Offer HBV vaccine to susceptible health care personnel in dialysis facilities.
- Consider linking payment incentives to recommended immunization practices within dialysis facilities.

D. 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 underused recommended practices in hemodialysis facilities as referenced in Section IV of this chapter.
- Both identification and dissemination of best-practice tools and other strategies to implement recommendations are needed.
- Increase staff training and educational opportunities and resources, targeting needs for infection prevention that are specific to dialysis settings.
- Recommend quality improvement strategies that address and facilitate ESRD patient-centered efforts such as educational programs and patient feedback processes to help reduce and prevent HAIs in this setting.

E. Recommendation 5: Metrics and Evaluation

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

F. Recommendation 6: Incentives and Challenges

- Recommend exploration of incentives for various stakeholders, including ESRD providers, hospitals, surgeons, and other health care providers to align practices with HAI prevention goals.
- Recommend emphasis on strategies that link survey and certification results with quality improvement resources such as those of the ESRD Networks and other professional organizations.
- Recommend continued use of Conditions for Coverage (i.e., CfCs) and accompanying interpretive guidance as a strong lever to embed infection control priorities in ESRD facilities.

G. Recommendation 7: Information Systems and Technology

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

X. CONCLUSION

HAIs disproportionately affect individuals receiving services in ESRD facilities, with infection second only to cardiovascular disease as the leading cause of death in this setting. With a predicted 1.5-fold increase in these patients by 2020, renewed and strengthened efforts for preventing HAIs in these facilities are of paramount importance. The priority recommendations in this chapter take into account the best thinking on ESRD infection control and prevention, and they 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 10. 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, an initiative led 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 the NKF-DOQI target of 50% with maintenance of AVF in 40% of hemodialysis patients. (Contract through ESRD Networks.)	CMS/CCSQ through the ESRD Networks	2003	Ongoing	
Clinical Performance Measures	Multiphase project in which clinical performance measurements are being developed with a long-range goal to expand quality measures for dialysis treatment and potentially for future data reporting.	CMS/QMHAG, ESRD Networks, *and* CDC/NHSN	Ongoing	Ongoing CPM development is under way with strong encouragement for CDC-CMS collaboration, including use of NHSN for QI projects in preventing vascular-access infection. Currently 14 NQF-endorsed measures where CMS is the steward. CMS convened a technical expert panel in spring 2012 to develop measures covering 30-day hospital readmissions, pediatric peritoneal dialysis adequacy, anemia management, and preventive care.	*Thomas Dudley* (CMS, lead) Renee Henry (CMS, alternate)
Annual Survey	Survey of outpatient dialysis facilities. In the past, these had been annual or biennial. Survey includes information on infection control policies, practices, immunization rates and viral hepatitis prevalence and incidence.	CDC and CMS (Survey and Certification)	Currently administered through NHSN. Last national survey was 2002, formerly 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 that serves to develop an infection control checklist and comprehensive quality improvement change package for ESRD facilities. Long-range goals aim to reduce infection and hospitalization rates for ESRD patients through adherence to strategies outlined in the checklist and change package.	AHRQ, CMS, and CDC	Project initiated in 2010, with testing of change package to be completed in 2014.	The development, implementation, and testing of the quality improvement change package has begun. The change package incorporates the checklist together with education, training, and patient/family engagement modules that address the needs of the facilities	*K. Hall, AHRQ/CQuIPS*
Emerging Infections Program	Population-based surveillance for invasive MRSA infections in approximately nine US geographic regions to track invasive MRSA rates among dialysis patients by using USRDS denominator data.	CDC, EIP	1995	Ongoing+	
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 two Fresenius dialysis units based at Maine Medical Center.	Project concluded in May 2012.	Ongoing	*D. Gray, AHRQ/CQuIPS*
Safe and Timely Immunization Coalition (STIC)	The 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 and continues to the present	Ongoing	
Immunization in Dialysis Facilities	It has been proposed that offering influenza vaccination be a Condition of Participation for certain Medicare participating providers, including dialysis facilities. Final rule pending.	CMS: CSG	Proposed rule published April 2011. Final rule in development.	Projected	*Lauren Oviatt, CMS/CSG*

Project Title	Description of Project	Lead Agencies	Timeline	Ongoing/Projected	Contact
Dialysis BSI Prevention Collaborative	A group of motivated dialysis facilities working together, using 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 hemodialysis 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 CfCs require dialysis facilities to minimize the transmission of infectious agents. Facilities must report policies, procedures, and outcomes as required.	CMS (CCSQ/CSG)		Ongoing	*Lauren Oviatt, CMS/CSG*
MIPPA 153(c): Quality Incentive Program	Value-based purchasing program that rewards ESRD facilities for meeting or exceeding a total performance score based on their performance on specified measures. Failure to meet or exceed the total performance score could mean a loss of up to 2% of Medicare reimbursement under the ESRD PPS for ESRD facilities. Under the FY 2014 program, ESRD facilities will be required to attest that they have successfully reported at least three consecutive months of data on dialysis infection events to NHSN.	CMS/CCSQ/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/CCSQ/ QIG	Released July 2012	Ongoing	*Teresa Casey, CMS*