increases 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.[9-13] AVFs have the lowest associated rate of vascular-access infection. AVGs 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 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.3 The incidence of invasive methicillin-resistant *S. aureus* (MRSA), one of the pathogens most commonly implicated in HAI in HD patients, can be up to 100-fold higher or 45 per 1,000 patients when compared to that of the general population. This is again 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 HAIs in HD patients while infections of polymicrobial origin account for 10-20% of cases.[14]

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 standardizing definitions for more cohesive practice and data reporting 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 and the immunocompromised state of hemodialysis patients. 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.[15]

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 directly 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 non-dialyzed patient. Despite what is known about reducing transmission of HBV, outbreaks of HBV infection in ESRD facilities have

HHS Action Plan to Prevent Healthcare-Associated Infections: End-Stage Renal Disease Facilities

I. Introduction

The purpose of this module 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) facilities. The module is an addition to the original "HHS Action Plan to Prevent Healthcare-Associated Infections"[1] and should provide a platform by which federal representatives and the nephrology community 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 facilities.

II. Background

Healthcare-associated infections (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] An epidemiologic study by the Centers for Disease Control and Prevention (CDC) revealed that HAIs accounted for 1.7 million infections annually and were associated with 99,000 deaths in 2002. The fiscal cost is steep as well creating an additional $28 to $33 billion dollars in healthcare expenditures annually.[3]

Multiple agencies within the U.S. Department of Health and Human Services (HHS) have 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. From these findings, the GAO made 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.[4] These priorities have been echoed in the Patient Protection and 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.

The first phase (Phase I) of the HHS Action Plan to Prevent Healthcare-Associated Infections (Action Plan) was focused on the prevention of infections in the acute care hospital setting namely surgical-site infections (SSIs), central-line associated bloodstream infections (CLABSIs), ventilator-associated pneumonia (VAP), catheter-associated urinary tract infections, *Clostridium difficile* infection (CDI), and methicillin-resistant *Staphylococcus aureus* (MRSA).[1] Recognizing the need to coordinate prevention efforts across healthcare facilities, the Department began to move into the second phase (Phase 2) of the Action Plan in late 2009. Phase 2 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 module. Similar to its Phase 1 efforts, Phase 2 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.

III. Healthcare-Associated Infections in ESRD Facilities

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 hemodialysis (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.[6] In comparison to the general population, the incidence of sepsis in patients with end-stage renal disease can be up to 100 times higher.[7] 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."[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.[6]

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/supplies, and from the hands of the many healthcare providers these patients encounter. In addition, patients with ESRD are immunocompromised because of co-morbidities such as diabetes mellitus (DM) and anemia of chronic disease 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 vascular catheter (CVC). Access via a CVC confers the greatest risk for acquiring an HAI and

increases 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.[9-13] AVFs have the lowest associated rate of vascular-access infection. AVGs 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.

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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 standardizing definitions for more cohesive practice and data reporting should be high priorities in this arena.

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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 directly 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 non-dialyzed patient. Despite what is known about reducing transmission of HBV, outbreaks of HBV infection in ESRD facilities have

occurred.[16, 17] "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,"[15] indicating that the risk for acquisition and spread (still) exists.[18] In many cases, the root cause 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 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 prevalence.[19] 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 hemodialysis population because facilities do not universally screen patients. Multiple HCV infection outbreaks in dialysis centers have been reported in the United States in the past decade.[20,21] 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.[22,23]

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,[24] and the preventability of transmission with adherence to the infection control protocols discussed later in this module. In addition, screening for and administering the hepatitis B vaccine to all patients with ESRD is an Advisory Committee on Immunization Practices (ACIP) and 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 for Infection Control Recommendations in ESRD Facilities [25-31]

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 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 HHS 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 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 bloodstream infections (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 also have the greatest evidence base. Therefore, priority recommendations in this category are primarily focused upon patients with CVC.

***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 IA
- Prepare clean skin with a >0.5% alcohol-based chlorhexidine preparation 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
- Assess knowledge of and adherence to guidelines periodically for all persons who insert and manage 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 IA; 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, hemodialysis 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

***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

- Follow proper procedures for site decontamination of spills of blood or blood-containing body fluids, using an appropriate disinfectant. HICPAC Category IC; CMS; OSHA

- 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

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 after 5 years have elapsed. ACIP

V. Metrics and Evaluation

The metrics written in this module are for discussion purposes. They have not been adopted by CMS at this time and the bloodstream infection metrics have not been endorsed by the National Quality Forum (NQF).

The effectiveness of the recommendations presented in this module can only be ascertained through methodical measurement. These metrics serve as important indicators of the quality of healthcare provided to ESRD patients. Presuming that the aforementioned processes represent the highest priority content in the management and prevention of HAIs in ESRD facilities, we propose consideration of the following measures as indicators of quality performance in this arena.

In accordance with each of the aforementioned Priority Modules, we suggest defining an appropriate HAI outcome of interest (i.e., bloodstream and vascular access infection rates; hepatitis, pneumococcal, and influenza infection rates). Collection methods for these outcome events must be developed, tested, and validated. Similarly, methods must be developed to assess the actual performance of each module. Finally, it will be important to assess the effect of module implementation on subsequent infection rates. Further consideration must be given to the appropriateness and necessity of case-mix adjustment to account for differences in patient populations between facilities.

Measures should abide by four criteria; the measures should 1) address a problem of importance; 2) be evidence-based with scientifically

acceptable characteristics; 3) be feasibly collected and transmitted electronically; and 4) be publicly reportable. Measures developed as indicators of quality must specify cases of interest (numerator) relative to the sample at risk, with clearly defined exclusions of potentially confounding conditions or characteristics. Considerable effort should be extended to develop measures that represent staff, facility, network, and community.

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

A. **Process Measures**

Reducing all CVC use and long-term CVC use are recognized goals of the Fistula First Program, KDOQI, and CDC. The following metrics have been used by one or more of 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

Long term CVC use = # of hemodialysis patients with CVC ≥ 90 days / 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 = Positive blood cultures per 100 patient-months

Access-related BSI = Positive blood culture with vascular access or unknown suspected source per 100 patient-months

BSI in patients with CVC = Positive blood cultures per 100 CVC patient-months

Access-related infection in patients with CVC = Positive blood culture with vascular access or unknown suspected source per 100 CVC patient-months

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, no HBV or HCV infection outcome measures are currently suggested as HAI metrics without further investigation. However, it is clear healthcare transmission of these infections does occur, requires 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. Others are proposed for discussion, including HCV screening that is recommended by CDC, but not required by

CMS.

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

Hepatitis B admission status = # of hemodialysis patients who were tested on facility admission for hepatitis B serology / all hemodialysis patients x 100

Screening for new HBV infections = # of susceptible hemodialysis patients tested monthly for surface antigen / susceptible hemodialysis patients x 100

Isolation room use = # of facilities with dedicated isolation room / # of facilities that treat HBsAg positive patients x 100

Hepatitis C admission status = # of hemodialysis patients tested on facility admission for hepatitis C antibody / all hemodialysis patients x 100

Screening for new HCV infections = # of susceptible hemodialysis patients tested biannually for hepatitis C antibody / susceptible hemodialysis patients x 100

Medication room use = # of facilities with separate clean medication preparation room / all facilities x 100

Staff hepatitis B vaccine coverage = # of hemodialysis healthcare personnel who have received ≥ 3 doses of hepatitis B vaccine / all hemodialysis healthcare personnel x 100

Priority Module 3: Pneumococcal, 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 measures are supported by Healthy People objectives.

Influenza vaccine coverage = # of hemodialysis patients who received seasonal influenza vaccine / all hemodialysis patients x 100

Pneumococcal vaccine coverage = # of adult hemodialysis patients who received at least one dose of pneumococcal vaccine / all adult hemodialysis patients x 100

Staff influenza vaccine coverage = # of hemodialysis healthcare personnel who received seasonal influenza vaccine / all hemodialysis healthcare personnel x 100

Prior to implementation for purposes such as quality improvement, incentive payment and/or public reporting, quality measures are

reviewed through a systematic and transparent process by panels of experts and subjected to a consensus development process such as NQF that includes public comment.

VI. Incentives and Challenges

A. Incentives

i. Federal Level

The Conditions for Coverage (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 CfCs when performing surveys of ESRD facilities. 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 United States, complying with CfC standards is necessary for almost all ESRD facilities to remain in business.

The Medicare Improvements for Patients and Providers Act (MIPPA), signed into law on July 15, 2008 (PL 110-275), called for development of a value-based purchasing program for ESRD facilities for services furnished on or before January 1, 2012. The specifics of the program are still being developed by CMS, but the statute calls for a reduction in payment to facilities by up to 2% that do not meet certain performance measures developed by the Secretary.

ii. State/Network Level

Colorado recently became the first state to mandate reporting of HAIs from outpatient dialysis facilities. These facilities are required to conduct surveillance and report event data to NHSN. Once validated, some part of these data will be reported publicly. Colorado and other states are partnering with their corresponding ESRD Networks to promote HAI surveillance and prevention activities in dialysis facilities.

B. Challenges

There are several challenges to implementing and sustaining efforts aimed at reducing healthcare-associated infections acquired during care in ESRD facilities. 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 infection control practices on a federal level dictates the need for alignment between expectations for these processes, tools available for facilities to implement them, and accreditation requirements for dialysis facilities across states. State survey agencies align their regulatory mandates for infection control with the recommendations of CDC and for device-related considerations with the Food and Drug Administration (FDA). Attention to continued refinement of communication and collaboration strategies between state survey agencies and the ESRD networks is crucial to minimize missed opportunities for information sharing so that resources are allocated to facilities most in need of them. Also important to note is that ESRD network resources available to mitigate problems or infection control lapses identified by state survey agencies may be limited by funding allowances still governed by a statutory mandate that was established by the Omnibus Budget Reconciliation Act of 1986 (PL 99-509).

Recommendations from the Preventing HAIs in ESRD Facilities Working Group strongly support efforts between CMS and Survey and Certification Regional Offices (and the contractors they each oversee) to coordinate their activities that identify and correct lapses in infection control procedures while promoting sustainability in this area through training, education, and other HAI prevention tools available through the State Survey Agencies/Network.

b. **State and Local Health Departments**

Health departments located in states and other jurisdictions play an important role in HAI prevention. 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 and staffing constraints.

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 verses other settings, including the community.

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.

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. The use of prescription of antibiotics as a measure of infection is fraught with issues. First, there is variability among providers as to which patients receive antibiotics and the threshold at which they are started. Facilities can reliably report intravenous antibiotic use, as long as it was administered by that facility, but may not consistently be able to report oral use. If the facility or provider is not the entity prescribing the antibiotic, it is very difficult to track.

f. Positive blood cultures are difficult to track if the culture was not performed by the facility or provider. Linking lab data and medication starts from potentially multiple sources puts a burden on already overwhelmed ESRD facilities.

g. 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.

iii. **Patient Level**

There is a need to increase patient involvement in HAI prevention efforts. A growing body of literature suggests that patients, themselves, can 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 facility 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. Focus on directly involving patients in their care, through education efforts[32] 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

Information systems supported by HHS agencies 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 hospitalizations.[33]

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 (PMMIS). The legacy systems that will be consolidated by CROWNWeb are the Renal Information Management System (REMIS), Standard Information Management System (SIMS), and VISION (Vital Information System to Improve Outcomes in Nephrology). 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.

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.

However, even if these issues cannot be resolved in a timely way, progress can be made on other fronts. Of potential would be the incorporation of the Health Information Technology for Economic and Clinical Health (HITECH) initiative to facilitate and/or enhance data capture, reporting, and transfer in ESRD facilities. This initiative authorized by the American Reinvestment and Recovery Act of 2009(PF 111-5), allows CMS to provide incentive payments to certain eligible professionals for efforts to adopt and meaningfully use certified electronic health records (EHR) technology."[34] While not yet eligible for this initiative, inclusion of dialysis providers should be given strong consideration as a means to improve the data sharing process.

VIII. Future Directions

A. Emerging Infections

This module 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 *Staphylococcus aureus (S. aureus)* remains a concern. Since 2002, there have been eleven cases of vancomycin-resistant *Staphylococcus aureus* or

VRSA reported to the CDC.[35]

Perhaps more striking than the infection itself, VRE and the existence of other such pathogens, represents 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 although outside the scope of this module, there is an entire community of patients that undergo peritoneal dialysis at home who are subject to their own set of infection risk, usually in the form of peritonitis.

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 hemodialysis patients are so frequently hospitalized, the 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 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 hemodialysis 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 the hemodialysis 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, the HeRO device has been approved by the FDA for ESRD patients with conditions such as central venous outflow obstruction who may otherwise require a tunneled CVC for permanent dialysis access. The studies that have been done to date on this device show improved rates for bacteremia and hospitalizations when compared to CVCs, however, 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.[36]

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.

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 (GFR) 15 ml/min/1.73m^2 and/or who require dialysis, represent only 3.5% of the estimated 19.5 million Americans with Chronic Kidney Disease (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 to prevent an alarming increase in the number of people with ESRD."[36] 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. Initiatives which promote identification and risk modifications for individuals with a family history of ESRD, predisposing conditions such as hypertension (HTN) or diabetes mellitus (DM) and/or those in certain high-risk minority groups are essential in these at-risk populations. In particular, early vascular access planning and immunization pre-ESRD can help to prevent HAIs 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 module.[37]

D. **Expansion of Emerging Infection Program**

The Preventing HAIs in ESRD Facilities Working Group is utilizing funds provided by the Office of the Secretary/Office of Public Health and Science/Office of Healthcare Quality to expand the Emerging Infection Program, 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 will help determine if EHR data is a feasible and valid measure to capture 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; and,
- Consider further investigation into policies that may unintentionally discourage early fistula placement.

Recommendation #2: Infection Type

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

Recommendation #3: Immunization

- Immunize all patients against hepatitis B, screen ESRD patients for HBsAg positivity annually and encourage immunization with the HBV vaccine for those susceptible to HBV (CDC, APIC);
- Offer annual influenza vaccination as well as appropriate administration of the pneumococcal vaccine to all adult ESRD patients;
- Offer annual 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 module; 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 module;

- Proposed metrics that should be considered are vascular access infection rates and immunization protocols, as well as those that align with Healthy People 2020. These metrics should be accompanied by methods of data capture and validation where possible; and,
- Metrics that target bloodstream infections that have not been NQF-endorsed nor validated by CMS at this time.

Recommendation #6: Incentives and Challenges

- Recommend continued coordinated efforts between HHS and external experts in the ESRD and infection control fields to develop a more standardized definition for vascular-access infection to enhance clarity across all entities and improve alignment of research protocol, quality improvement strategies, evaluation targets, and payment rules;
- Recommend emphasis on strategies that continue and further coordinate efforts between ESRD networks and state survey agencies; 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 #7: Information Systems and Technology

- Recommend further investigation into the barriers that continue to hinder interdepartmental data system interface accompanied by solution development; and,
- Recommend further consideration into how system of "meaningful use" for EHR development or enhancement can be utilized in dialysis facilities for improvement in data collection, reporting, and transfer.

TABLE 1. 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,	CMS/OCSQ through the ESRD Network	2003	Ongoing	

	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).				
Clinical Performance Measures	Multiphase project where clinical performance measurements are being developed with long-range goal to expand quality measures for HD treatment and potentially future data reporting	CMS/QMHAG, ESRD Networks *and* CDC/NHSN	April 2008 to present: Currently 26 NQF Endorsed. Additional CPMs being developed with 34 potential measures scheduled for NQF submission in the fall 2010.	Ongoing CPM development is underway with strong encouragement for CDC-CMS collaboration, including use of NHSN for vascular access infection prevention QI projects	
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		
Improving Infection Control Practices in ESRD Facilities	Multiyear project which serves to survey existing, required and best practice infection control processes	AHRQ and CMS (QIG/CMSO)	Project to start in 2010 and anticipated to run until 2013	Further optional work will include developing and implementing a Comprehensive Unit-Based	*K. Hall, AHRQ/CQuIPS*

	in dialysis facilities and develop a comprehensive infection control worksheet or tool for providers and surveyors. Long-range goal aims to reduce hospitalization rates for ESRD patients through adherence to strategies outlined in the worksheet.			Program (CUSP) that incorporates an education and training element and modifications in addition to standardized worksheet that address needs of specific facilities	
Emerging Infections Program	Population-Based Surveillance for invasive MRSA infections from facilities at approximately 9 US geographic regions to track invasive MRSA rates for these facilities using USRDS denominator data	CDC, EIP Program	1995	Ongoing+	
A Regional Approach to HAI Reduction in the Hemodialysis Population	To apply the improvement methods from the 'MRSA Reduction Collaborative in Outpatient Settings' specifically to ESRD facilities including applications of the LEAN and Positive Deviance techniques.	AHRQ and 2 local HD facilities from Fresenius	Plans to run through February 2011	Ongoing	*C. Palmer, AHRQ/CDOM*
Safe and Timely Immunization Coalition (STIC)	STIC has developed immunization measures, immunization tracking tools, patient and provider tools and immunization	CDC, CMS, Southeastern Kidney Council	Initiative began August 2005 to the present	Ongoing	

	guidelines for CKD patients for HBV, influenza and pneumovax				
Immunization in Dialysis Facilities	A proposal is being considered to require HD facilities to offer influenza vaccinations to its patients	CMS: CSG		Projected	
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 and external dialysis facilities		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	
ColoradoMandated Reporting to NHSN	State-mandated reporting of dialysis events, including BSI	CDC and State Health Departments	Goal of full reporting from Colorado would be Spring-Summer 2010	Ongoing	
Data Integration Effort	To work to populate NHSN HAI and HD facility data into upcoming mandatory Dialysis data reporting	CMS Information Systems Technology	Goal would be to implement this pilot project for 2011	Proposed	

	system, CROWNWeb which does not currently have HAI data elements for reporting	Group (ISG) *and* CDC (NHSN)			
ESRD Disease Management Demonstration for Managed Care Plans	Voluntary enrollment for Managed Care Plans and their beneficiaries who have ESRD. These plans would be evaluated on multiple quality indicators (NKF-DOQI, Fistula First) and a pay-for-performance system set up whereby up to 5% of managed care plan (depending on no. of beneficiaries) payment would be held with ability to 'earn' that payment back by meeting targets related to above indicators	CMS: Office of Research and Development (ORDI)	This is last year of the demonstration.	Ongoing	*M. Siddar, CMS/ORDI*
Medicare Conditions of Participation (COPs)	Existing COPs require that dialysis facilities cooperate with the ESRD network corresponding to its geographical area to implement priorities as defined in the 9th SOW.	CMS (OCSQ/CSG)	Until July 31st, 2011 when the next SOW will become effective.	Ongoing	*Lauren Oviatt, CMS/CSG*
MIPPA 153c: Quality Incentive Rule	Payment program based on performing on certain performance score in ESRD	CMS, QIG	Implementation January 2012	Projected	

Payment	facilities for specified clinical performance measures. Performing at an effort below the standard could mean a loss of up to 2% of Medicare reimbursement for ESRD facilities					

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