I. Statement of the Problem
Infections, including bloodstream infections (BSIs) and localized infections of the vascular access site, are a major cause of hospitalization and are among the leading causes of death in patients undergoing hemodialysis.\(^1\) Optimal prevention and control of infections among outpatient hemodialysis patients requires active collection and use of surveillance data to identify potential reservoirs of infection and to focus prevention efforts.\(^2\) The majority of hemodialysis patients receive treatment in outpatient dialysis facilities; therefore, a plan for establishing, expanding, and supporting surveillance and prevention activities for infections in outpatient hemodialysis settings is needed.\(^3\)

II. Background and Justification
Patients receiving hemodialysis treatment in outpatient dialysis facilities are at excessive risk for infection.\(^1\)–\(^3\) Hemodialysis patients’ increased risk for infection, including those caused by antimicrobial resistant pathogens, is related to multiple risk factors,\(^2\)–\(^5\) such as the need for repeated vascular access through central venous catheters or arteriovenous grafts or fistulae, frequent hospital visits, and frequent receipt of antimicrobial drugs. In 2009, the Centers for Disease Control and Prevention estimated there were 37,000 central line related bloodstream infections (CLABSI) among U.S. hemodialysis patients, a magnitude of burden similar to that of US hospital inpatients (41,000 CLABSI).\(^6\) The importance of this issue to public health and quality medical care led the United States Department of Health and Human Services to target outpatient dialysis facilities providing treatment to hemodialysis patients in Phase 2 of the National Action Plan to Prevent Healthcare-Associated Infections (HAI).\(^3\) The plan includes recommended metrics for increasing the number of facilities that report to the National Healthcare Safety Network (NHSN) and decreasing rates of BSI and vascular-access BSI stratified by access type.

Engagement in prospective surveillance, as part of a quality improvement initiative, has been demonstrated to reduce BSI, access-related BSI, and other events (antimicrobial use, hospitalizations, use of catheters) in hemodialysis patients.\(^7\) A collaborative involving 17 outpatient hemodialysis facilities adopted NHSN dialysis event surveillance and recommended interventions for BSI and access-related BSI. Between the pre- and post-intervention periods, these facilities were able to significantly decrease BSI by 32% and access-related BSI by 54%.\(^8\)

Generating standardized and actionable surveillance data about infections among hemodialysis patients requires use of a common reporting platform such as that provided by NHSN. The End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) is an ongoing Centers for Medicare & Medicaid Services (CMS) effort to improve the quality of care provided to patients receiving outpatient maintenance hemodialysis in the United States.\(^9\) The CMS QIP is a value-based purchasing program that supports quality improvement efforts among providers and makes available healthcare quality information to enable patients to make informed decisions about the health care they receive. Under QIP, facility reimbursement by CMS is contingent on the reporting of data on a range of quality of care measures. In January 2012, the CMS QIP began requiring participating outpatient dialysis facilities nationwide to report dialysis event surveillance data through NHSN, thus establishing a standard for reporting of infection data for outpatient dialysis facilities. Subsequent to the adoption of the NHSN infrastructure for QIP reporting, NHSN experienced rapid increases in the number of dialysis facilities reporting to NHSN: during 2012, the number enrolled increased from 410 to 5,438 facilities.
However, not all dialysis facilities in the US are required to report dialysis event data to NHSN through the QIP, despite the fact that patient populations served by these facilities experience similar risks for infection. ESRD facilities operated by the Department of Veterans Affairs, small CMS-certified facilities (10 or fewer patients), and facilities that are not CMS-certified, are all excluded.

NHSN is a secure, internet-based surveillance system that collects HAI process and outcome data for reporting facilities. NHSN also provides public health departments and facilities an array of high quality services, such as online training, surveillance definitions, data analysis features, and regular conference calls that provide technical assistance and opportunities for user input. NHSN data are used to improve patient safety at the facility, local, state, and national levels. Participating facilities retain real-time access to reported data and structured analytic tools; group administrators, such as state health departments, can analyze NHSN data in their jurisdictions and support local facilities accordingly; and the CDC uses NHSN data to establish benchmarks for disease control and to focus prevention activities at the national level. CDC publishes NHSN surveillance data to characterize the national burden of HAIs; local users and facilities can compare their experience to these benchmarks.

Outpatient dialysis facilities face significant challenges in performing complete and accurate surveillance for dialysis events, including: the burden of performing manual data collection and data entry; limited access to dedicated infection control or surveillance staff; and difficulties obtaining information on positive blood cultures drawn outside the facility. To date, however, only a few states (AR, CO, CT, GA, HI, MS, UT, TN) have, or are in the process of establishing, mandates for reporting of dialysis event data to NHSN. Given the wealth of existing experience working in other healthcare settings, state health departments are in a unique position to support outpatient dialysis facilities to evaluate the completeness and accuracy of the NHSN reporting, understand and interpret facility-, regional- and state-level HAI data, implement prevention strategies, and accelerate the process to achieve the goals of the HHS National Action Plan to Prevent HAIs.

III. Statement of the desired action(s) to be taken

1. CSTE recommends use of NHSN surveillance definitions, case identification and classification, and denominator collection methods for outpatient dialysis events and recommends that any State or Territory conducting surveillance for this condition use these standard methods. This entails sharing of case information with CDC through NHSN using established procedures for such reporting. [Note: if NHSN includes more than one surveillance option for this condition, recommended standardized surveillance methods should be detailed below.]

2. CSTE recommends that CDC publish data on outpatient dialysis events as appropriate in MMWR and/or other venues such as the National and State Healthcare-associated Infections Progress Report. Local and state health departments also are encouraged to publish their jurisdiction-specific data.

3. CSTE recommends that all States and Territories consider enacting laws (statute or rule/regulation, as appropriate) to make outpatient dialysis events reportable through NHSN in their jurisdiction, under circumstances defined in Section VII. (Jurisdictions may also elect to go beyond these circumstances). Doing so will assure the jurisdiction access to reported data, with full functionality of NHSN tools and analysis through the NHSN group function. [Note: This is not a recommendation to add the condition to the Nationally Notifiable Conditions List, but to enable standardized reporting, and standardized regional reporting, with access to data by regional public health authorities].

4. CSTE recognizes outpatient dialysis events as important to public health, and anticipates a need to periodically review and revise surveillance and prevention plans as resources and priorities permit. The current vision and proposed strategies to reduce disease burden are discussed in Section VIII.
5. CSTE recommends that reported outpatient dialysis events be validated to ensure the completeness and consistency of data across facilities and jurisdictions, and those validation methods be described in national or local data reports.

6. CDC and CMS should coordinate to ensure that adequate resources are available to validate dialysis event data and to train facilities to use NHSN.

7. CSTE recommends that state and local health departments engage in partnerships with regional ESRD Networks and/or state quality improvement organizations to assure data quality through data validation activities.

IV. Goals of Surveillance
To provide vascular access type-specific, event type-specific, and facility-specific, rate information to facilities for internal quality improvement; to provide vascular access type-, event type-, facility-, and jurisdiction-specific, rate information and analytic tools imbedded in NHSN to public health jurisdictions for transparent situational awareness and public health planning and prevention activities, for exploration of data quality, and (in some cases) for public reporting as required by law; to provide vascular access type-, event type-, facility-, jurisdiction-specific, and national rate information to Federal agencies on the temporal, geographic, demographic, device-, and pathogen- specific occurrence of dialysis events to facilitate prevention and control of outpatient dialysis events.

V. Methods for Surveillance:
NHSN methods and definitions for outpatient dialysis event reporting are located at: http://www.cdc.gov/nhsn/PDFs/pscManual/8pscDialysisEventcurrent.pdf. No modifications are recommended.

VI. Case-and denominator definitions, or risk-adjustment dialysis events:
NHSN methods and definitions for outpatient dialysis event reporting are located at: http://www.cdc.gov/nhsn/PDFs/pscManual/8pscDialysisEventcurrent.pdf. No modifications are recommended.

VII. Proposed Circumstances for Standardized Surveillance and Reporting of Outpatient Dialysis Events

A. Narrative and Justification: Description of recommended circumstances where standardized surveillance of case- and denominator events should be conducted using NHSN, including justification (e.g.: meaningful gaps in existing surveillance and populations currently at risk because of these gaps).

Bloodstream infections in hemodialysis patients are of significant epidemiological importance. Among 32 outpatient hemodialysis providers who voluntarily reported adverse events to NHSN in 2006, the pooled mean rates of BSIs were 0.5, 0.9, 4.2, and 27.1 per 100 patient-months among patients with arteriovenous fistulas, grafts, permanent and temporary central venous catheters, respectively. However, a 2009 CDC study showed that significant decreases in BSI rates can be achieved through implementation of a bundle of evidence-based prevention initiatives, including feedback of data captured via NHSN.

As of 2014, approximately 5,800 outpatient dialysis facilities nationwide were reporting dialysis events via NHSN, in part due to CMS requirements as part of the ESRD QIP. Beginning in 2012, facilities were required to enroll in NHSN and submit three or more consecutive months of dialysis event data to NHSN, and in 2014 this requirement was expanded to include 12 months of data. Additionally, at least three groups of ESRD facilities (which represent the minority of ESRD facilities in the US) are excluded from CMS QIP reporting: facilities with 10 or fewer patients that are therefore exempt from NHSN reporting under QIP; Veteran’s
Despite widespread reporting, state health departments have limited access to dialysis event data, as only eight states (AR, CO, CT, GA, HI, MS, UT, TN) have mandated reporting from outpatient dialysis settings. The 18 ESRD Networks, responsible for each U.S. state, territory, and the District of Columbia under direction of CMS, request access to these data via the NHSN group function from their constituent facilities.

Currently, serious concern exists regarding the quality of dialysis event data being reported to NHSN. For example, on-site validation conducted in 25 Colorado dialysis facilities in 2012 uncovered significant data quality issues, including 28% under-reporting of dialysis events, as well as issues with appropriate denominator data collection methods. A comprehensive data validation toolkit, developed by CDC with input from state partners, is available to state health departments, ESRD Network personnel, as well as healthcare facility staff. However, state health departments should consider partnering with their local ESRD Network staff to minimize burden of validation efforts and maximize resources while ensuring high-quality actionable surveillance data.

B. Tables of circumstances where standardized surveillance through NHSN of Dialysis Events should be conducted and reported to public health in all jurisdictions.

Table VII-B.
Circumstances where standardized surveillance through NHSN of Dialysis Events should be conducted and reported to public health in all jurisdictions

<table>
<thead>
<tr>
<th>Type of facility</th>
<th>Type of location</th>
<th>Time frame</th>
<th>Exceptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient Hemodialysis Facilities Participating in CMS ESRD QIP</td>
<td>All outpatient</td>
<td>2015</td>
<td>None</td>
</tr>
<tr>
<td>Outpatient Hemodialysis Facilities Not Participating in CMS ESRD QIP, including:</td>
<td>All outpatient</td>
<td>2016</td>
<td>None</td>
</tr>
<tr>
<td>- Non-CMS certified facilities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- CMS-certified facilities that are exempt from QIP reporting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Veterans' Administration ESRD facilities</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

VIII. Narrative: Public Health Surveillance Vision, Proposed Priorities, and Strategy for Future Expansion or Decrease in Surveillance for Dialysis Events Reporting via NHSN
While all hemodialysis patients can benefit from the implementation of known best practices and resources for prevention of BSIs and other NHSN Dialysis Events, the proposed surveillance methods can focus and prioritize the implementation of practices to those at higher relative risk for these events. Tracking infections
can profile which outpatient hemodialysis patients are at risk or which facilities need improvement for focused improvement.

Surveillance data can guide prioritization of evidence-based prevention activities. Such data include both process measures, such as the number of catheters and fistulas used, and outcomes, such as infections. This information can be used to evaluate and improve performance locally, statewide, and nationally. In addition, surveillance allows CDC to determine and monitor national trends and direct prevention efforts for the country.

NHSN is configured to gather the needed surveillance data for prevention. NHSN incorporates and provides a variety of analysis tools and options including line listings, rate tables, and control charts, which can be used to better inform quality improvement decisions and track performance. CMS published a final rule in 2012 encouraging all ESRD facilities to track quality indicators through NHSN by following the dialysis event protocol. Facilities must comply with the rule to receive full payment through the CMS Prospective Payment System (PPS) ESRD QIP. Though CMS currently requires dialysis centers to report for QIP, there will be benefits of public reporting through state health departments, including increased public transparency, and state health department assistance with NHSN reporting and validation. The fact that the QIP has encouraged NHSN enrollment and reporting for dialysis centers to increase from 86 facilities in 2010 to 5,800 facilities in 2014 affords an opportunity, as state health departments do not need to expend the considerable resources that otherwise would be necessary to recruit dialysis centers in the absence of the CMS incentive. Dialysis event surveillance provides an opportunity for ESRD Networks and state health departments to develop important partnerships. State health departments have expertise in NHSN protocols, data collection, analysis and validation, and the ESRD Networks are trusted by the ESRD community; they have critical subject matter technical expertise in hemodialysis, and decades of experience working with patients and the dialysis provider community. These partnerships can guide improvement in facility-level surveillance programs, data validation projects, prevention activities, and communications.

Because the number of ESRD patients continues to increase, and they are at risk for developing HAIs, especially infections caused by multidrug-resistant organisms (MDROs), we can anticipate that in time, dialysis event measures will be included in both the nation’s HAI Action Plan and Healthy People objectives. Until these measures are established and the burden of HAIs significantly decreases in this population, we anticipate that dialysis event surveillance will need to continue, and not decrease.

IX. Data sharing/release and print criteria
NHSN maintains confidentiality of individuals and reporting facilities. Facilities reporting to NHSN are required to sign data use agreements that allow CDC to share aggregate de-identified data with CMS. CDC calculates aggregate pooled mean rates for each event type by combining rates from all participating facilities. State health departments and facilities can compare individual facility and aggregate state rates with the aggregate rates using NHSN analysis rate table or run chart output options. Reports should be shared with facilities prior to publication.

In addition, consumers of health information have different needs and healthcare literacy levels. Reporting of complex data such as dialysis events requires thoughtful consideration about the intended audience(s) and ways to make the data accessible, understandable, relevant and actionable to the audience.

X. References


XI. Coordination

**Agencies for Response**

1. Centers for Disease Control and Prevention (CDC)
   - Thomas Frieden MD, MPH
   - Director
   - 1600 Clifton Road, NE
   - Atlanta, GA 30333
   - 404-639-7000
   - tf2@cdc.gov

**Agencies for Information:**

1. US Department of Health and Human Services (HHS)
   - Sylvia Mathews Burwell
   - Secretary
   - 200 Independence Avenue SW
   - Washington, DC 20201
   - 877-696-6775

2. Centers for Medicare and Medicaid Services (CMS)
   - Kate Goodrich, MD, MHS
   - Director, Quality Measurement and Health Assessment Group
   - Center for Clinical Standards and Quality
   - 7500 Security Boulevard
   - Baltimore, MD 21244-1850
   - 410-786-7828
   - kate.goodrich@cms.hhs.gov

3. U.S. Department of Veterans Affairs
   - Robert L. Jesse, MD, PhD
   - Principal Deputy under Secretary for Health
   - 810 Vermont Avenue, NW
   - Washington, DC 20420
   - 202-461-7008
   - robert.jesse@va.gov

4. Association of State and Territorial Health Officials (ASTHO)
   - Paul Jarris, MD
   - Executive Director
   - 2231 Crystal Drive
   - Suite 450
   - Arlington, VA 22202
   - 202-371-9090
   - pjarris@astho.org
(5) National Association for County and City Health Officials (NACCHO)
Robert Pestronk, MPH
Executive Director
1100 17th Street, NW
Seventh Floor
Washington, DC 20036
202-783-5550
rpestronk@naccho.org

(6) Association for Professionals in Infection Control and Epidemiology (APIC)
Katrina Crist, MBA
Chief Executive Officer
1275 K Street, NW
Suite 1000
Washington, DC 20005-4006
202-789-1890
kcrist@apic.org

(7) Society for Healthcare Epidemiology of America (SHEA)
Eve Humphreys, MBA, CAE
Executive Director
1300 Wilson Boulevard
Suite 300
Arlington, VA 22209
703-684-1006
ehumphreys@shea-online.org

(8) The Forum of ESRD Networks
Andrew Howard, MD, FACP
President, Board of Directors
Post Office Box 203
Birchwood, Wisconsin 54817
715-354-3735
kidneedok@aol.com
XII. Submitting Author:

(1) Meredith Kanago, MSPH
    Epidemiologist, Healthcare Associated Infections Program
    Tennessee Department of Health
    710 James Robertson Parkway
    Andrew Johnson Tower, 3rd Floor
    Nashville, TN 37243
    615-532-6833
    meredith.kanago@tn.gov

Co-Author:

(1) ☑ Active Member  ☐ Associate Member
    Richard Melchreit, MD
    Healthcare Associated Infections Program Coordinator
    Connecticut Department of Public Health
    410 Capitol Avenue
    P.O. Box 340308
    Hartford, CT 06134
    860-509-7833
    richard.melchreit@ct.gov

(2) ☑ Active Member  ☐ Associate Member
    Marion Kainer, MD, MPH
    Director, Healthcare Associated Infections and Antimicrobial Resistance Program
    Tennessee Department of Health
    710 James Robertson Parkway
    Andrew Johnson Tower, 3rd Floor
    Nashville, TN 37243
    615-741-7247
    marion.kainer@tn.gov