Dialysis Event Protocol

Introduction

In 2009, more than 370,000 patients were treated with maintenance hemodialysis in the United States.[1] Hemodialysis patients require a vascular access, which can be a catheter or a graft or enlarged blood vessel that can be punctured to remove and replace blood. Bacteremias and localized infections of the vascular access site are an important cause of morbidity and mortality in hemodialysis patients. Hemodiaylsis vascular access types, in order of increasing risk of infection, include arteriovenous fistulas created from the patient's own blood vessels; arteriovenous grafts often constructed from synthetic materials; tunneled central lines; and nontunneled central lines. Other access devices, such as catheter-graft hybrid devices, also exist. Because of frequent hospitalizations and receipt of antimicrobial drugs, hemodialysis patients are also at high risk for infection with antimicrobial-resistant bacteria. Measuring and tracking rates of infection and utilizing this information is an important part of prevention.

Infection prevention information can be located at http://www.cdc.gov/dialysis/

Dialysis Event Surveillance

Summary: Each month, facilities report the number of maintenance hemodialysis outpatients who were dialyzed on the first two working days of the month, using the *Denominators for Outpatient Dialysis* form. This point prevalence is used to estimate the number of patients at the facility who are at risk of healthcare-associated infection. Throughout the entire month, any and all outpatients who receive maintenance hemodialysis at the facility are monitored for dialysis events, which include IV antimicrobial starts, positive blood cultures, and evidence of local access site infection. Each month, facilities use a *Dialysis Event* form to report the details of each dialysis event that occurred among these patients. Before data can be reported, facilities must indicate that they are reporting according to protocol by saving a *Patient Safety Monthly Reporting Plan.* Completion of an *Outpatient Dialysis Center Practices Survey* is required annually.

Setting: Surveillance occurs in outpatient hemodialysis centers. These centers may be attached to or affiliated with a hospital, but should serve hemodialysis outpatients.

Population: Maintenance hemodialysis outpatients.

[1] U.S. Renal Data System, USRDS 2011 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2010. (http://www.usrds.org/adr.htm)

Requirements: Participating facilities are required to report data according to this protocol, using the NHSN definitions described herein, to ensure data are uniformly reported across participants. A minimum of 6 months of Dialysis Event (DE) **s**urveillance at an outpatient hemodialysis facility, indicated on the *Patient Safety Monthly Reporting Plan* (CDC 57.106), is required by CDC[2]. Data must be reported to NHSN within 30 days of the end of the month for which they were collected (e.g., patient census information from September must be reported no later than October 30).

Definitions of Dialysis Events

Dialysis Event: Three types of dialysis events are reported by users: IV antimicrobial start; positive blood culture; and pus, redness, or increased swelling at the vascular access site. An additional four types of dialysis events are calculated from the reported data: bloodstream infection, local access site infection, access-related bloodstream infection, and vascular access infection.

IV antimicrobial start: Report **all** outpatient intravenous (IV) antibiotic and antifungal starts, regardless of the reason for treatment (i.e., include IV antimicrobial starts unrelated to vascular access problems) and regardless of the duration of treatment. Report all IV antibiotic starts, not just vancomycin. Do **not** report IV antiviral starts. Report outpatient starts that are continuations of inpatient treatment.

There must be 21 or more days from the **end** of the first IV antimicrobial start to the beginning of a second IV antimicrobial start for two starts to be considered separate dialysis events, even if different antimicrobials are used. If IV antimicrobials are stopped for less than 21 days and then restarted, the second start is NOT considered a new dialysis event. To apply the 21 day rule to outpatient IV antimicrobial starts that are continuations of inpatient treatment, consider the start day to be the first day of outpatient treatment.

Positive blood culture: Report **all** positive blood cultures collected as an outpatient or collected within 1 calendar day after a hospital admission, regardless of whether or not the patient received treatment. The date of a blood culture result is based on the date the blood specimen was collected, not the date the laboratory reported the result.

There must be 21 or more days between positive blood cultures for each positive blood culture to be considered a separate dialysis event, even if organisms are different. If positive blood cultures occur less than 21 days apart, the second positive blood culture(s) is NOT considered a new

[2] Other organizations (e.g., your ESRD Network or State Health Department) may require additional months of reporting. Participants reporting to meet the Centers for Medicare and Medicaid (CMS) End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) rule requirements may report as few as three consecutive months of data in 2012.

dialysis event: add new organisms from these subsequent positive blood cultures to the first report.

Pus, redness, or increased swelling at the vascular access site: Report each new outpatient episode where the patient has one or more symptoms of pus, greater than expected redness or greater than expected swelling at a vascular access site, regardless of whether the patient received treatment. There must be 21 or more days between the onset of a first episode and onset of a second episode of pus, redness, or increased swelling at a vascular access site to be considered separate dialysis events. If an episode of pus, redness, or increased swelling at a vascular access site resolves and then recurs within 21 days, the recurrence is NOT considered a new dialysis event.

Bloodstream infection: Any positive blood culture.

Local access site infection: Pus, redness, or swelling of the vascular access site and bloodstream infection is not present.

Access-related bloodstream infection: Positive blood culture with the suspected source identified as the vascular access site or uncertain.

Vascular access infection: Either a local access site infection or an access-related bloodstream infection.

Vascular Access Types

All vascular accesses are included in Dialysis Event reporting, even if they are not used for dialysis and even if they have been abandoned and/or are non-functional.

- Nontunneled central line: a central venous catheter that travels directly from the skin entry site to a vein and terminates close to the heart or one of the great vessels, typically intended for short term use.

- Tunneled central line: a central venous catheter that travels a distance under the skin from the point of insertion before terminating at or close to the heart or one of the great vessels (e.g., Hickman® or Broviac® catheters[3]).

- Graft: a surgically created connection between an artery and a vein using implanted synthetic tubing for the purpose to provide a permanent vascular access.

[3] Use of trade names and commercial sources is for identification only and does not imply endorsement.

- Fistula: a surgically created direct connection between an artery and a vein to provide vascular access.

- Other access device: includes hybrid access devices (e.g., HeRO® vascular access device[3]), ports, and any other central vascular access devices not meeting the above definitions.

REPORTING INSTRUCTIONS

NHSN forms should be used to collect required data, using the definitions outlined in this protocol. Each form has corresponding instructions which define all fields on the form.

Complete a Survey Annually: Upon enrollment and annually thereafter, complete the *Outpatient Dialysis Center Practices Survey* (CDC 57.104). Annual surveys can be completed for the year as early as the second week of January and are due on or before April 1 of the same year.

Patient Safety Monthly Reporting Plan: The *Patient Safety Monthly Reporting Plan* (CDC 57.106) is used by NHSN facilities to inform CDC which Patient Safety modules are used during a given month. There must be a Monthly Reporting Plan completed before data are entered into NHSN for that month. Facilities participating in Dialysis Event surveillance indicate "DE" for their 'outpatient hemodialysis clinic' location, under the Device-Associated section for each month that they will be doing Dialysis Event surveillance.

For months that a facility is not participating in any Patient Safety surveillance, a monthly reporting plan should still be completed, but the checkbox "No NHSN Patient Safety Modules Followed this Month" is selected.

Report Denominator Data Monthly: Each month, report the number of maintenance hemodialysis patients with each vascular access type who received hemodialysis at the center during the first two working days of the month on the *Denominators for Outpatient Dialysis* form (CDC 57.119). Report all maintenance hemodialysis outpatients, including transient patients. Exclude non-hemodialysis patients and exclude inpatients. Report denominator data each month, regardless of whether any dialysis events occur. Each patient is counted only once; if the patient has multiple vascular accesses, record that patient once, reporting their highest infection risk vascular access type only. See tables of instructions for an explanation of each field on the *Denominators for Outpatient Dialysis* form.

Report Numerator Data Monthly: Each month, complete one *Dialysis Event* form (CDC 57.109) per event among all patients who received hemodialysis at the facility during that month. If a transient patient has a dialysis event during the time he or she is receiving hemodialysis treatment at your facility, report the dialysis event. If no dialysis events occurred during a given month, select 'Report No Events' on the *Denominators for Outpatient Dialysis* form. Complete a Dialysis Event form only if a maintenance hemodialysis outpatient has one or more of the following:

- IV antimicrobial start
- Positive blood culture
- Pus, redness or increased swelling at the vascular access site

See tables of instructions for an explanation of each field of the *Dialysis Event* form.

Reporting multiple dialysis events for a single patient: Dialysis Event surveillance definitions include IV antimicrobial start; positive blood culture; and pus, redness, or increased swelling at the vascular access site. If multiple dialysis events occur together, **as a part of the same patient problem**, they should be reported as one dialysis event. For example, if a patient has a positive blood culture and begins IV antimicrobials, these two events would be recorded together on one form. When reporting multiple dialysis events together, always use the date from the first event that occurred. Refer to dialysis event definitions for the 21 day rule. Do not report unrelated dialysis events on the same form.

Suspected source of the positive blood culture: When reporting a positive blood culture, indicating one of four suspected sources of the positive blood culture is required.

Vascular access: Choose "Vascular access" if there is objective evidence of vascular access infection and the vascular access is thought to be the source of the positive blood culture.

A source other than the vascular access: Choose "A source other than the vascular access" if either (a) or (b) is true:

a) a culture from another site (e.g., infected leg wound, urine) shows the same organism found in the blood and the site is thought to be the source of the positive blood culture
b) there is clinical evidence of infection at another site which is thought to be the source of the positive blood culture, but the site was not sampled for culture

Contamination: Choose "Contamination" if the organism isolated from the blood culture is thought by the physician, infection preventionist, or head nurse to be a contaminant. Contamination is more likely if the organism is a common commensal and is isolated from only one blood culture.

Examples of some common commensals include:

- diphtheroids [*Corynebacterium* spp., not *C. diphtheriae*]
- *Bacillus* [not *B. anthracis*] spp.
- *Propionibacterium* spp.
- coagulase-negative staphylococci [including *S. epidermidis*]
- viridans group streptococci
- *Aerococcus* spp.
- *Micrococcus* spp.

Uncertain: Choose "Uncertain" only if there is insufficient evidence to decide among the three previous suspected source categories.

Data Analyses: Dialysis event rates are stratified by vascular access type and expressed per 100 patient-months. Rates are calculated by dividing the number of events by the number of patient-months and multiplying the result by 100. CDC calculates pooled mean rates for each event type by combining rates from all participating facilities. Facilities can compare their rates with the pooled mean rates using NHSN analysis rate table output options. Facilities are strongly encouraged to analyze the data they report and provide regular feedback to staff about performance.

$$rate = \frac{Dialysis\ Events\ (numerator)}{Patient\ Census\ (denominator)} \times 100$$

Reporting Resources

Data collection and reporting resources, including Frequently Asked Questions (FAQs), are available on the NHSN Dialysis Event website, http://www.cdc.gov/nhsn/psc_da_de.html

Please direct questions to the NHSN Helpdesk at nhsn@cdc.gov