Dialysis Event Protocol

Introduction

In 2011, more than 395,000 patients were treated with maintenance hemodialysis in the United States.[13] Hemodialysis patients require a vascular access, which can be a catheter, or a graft or an enlarged blood vessel that can be punctured to remove and replace blood. Bloodstream infections and localized infections of the vascular access site cause substantial morbidity and mortality in hemodialysis patients. Hemodialysis vascular access types, in order of increasing risk of infection, include arteriovenous fistulas created from the patient's own blood vessels; arteriovenous grafts typically 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 is located at http://www.cdc.gov/dialysis/

Dialysis Event Surveillance

Overview: Each month, facilities report the number of hemodialysis outpatients who were dialyzed in the facility on the first two working days of the month, using the *Denominators for Dialysis Event Surveillance* form. This count is used to estimate the number of patient-months that there is risk of healthcare-associated infection. Throughout the entire month, any and all outpatients who receive maintenance hemodialysis at the facility are monitored for three National Healthcare Safety Network (NHSN)-defined dialysis events, which include IV antimicrobial starts, positive blood cultures, and evidence of local access site infection. 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 this protocol by saving a *Monthly Reporting Plan* and selecting "DE." 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. If other patients (e.g., inpatients, peritoneal dialysis patients) are present, exclude them from Dialysis Event numerator and denominator reporting.

Population: Hemodialysis outpatients.

- Include transient patients
- Include peritoneal dialysis patients or transplant patients undergoing temporary hemodialysis

[13] *U.S. Renal Data System, USRDS 2013 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, 2013.* (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 participating facilities. Report available data to NHSN within 30 days to 60 days of the end of the month for which they were collected. If additional data become available after that period, users are expected to report the additional information retrospectively to ensure NHSN data are complete and accurate. This may involve reporting additional dialysis events and/or editing existing event records.

Event Definitions and Key Terms

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. The following measures are also generated from the reported data: bloodstream infection (BSI), local access site infection (LASI), access-related bloodstream infection (ARBSI), and vascular access infection (VAI).

21 day rule: An event reporting rule which reduces reporting of events that are likely to be related to the same patient problem. The rule is that 21 or more days must exist between two dialysis events of the *same* type for the second occurrence to be reported as a separate dialysis event. If fewer than 21 days have passed since the last reported event of the same type, the subsequent event of the same type is NOT considered a new dialysis event and therefore, it is not reported. The 21 day rule applies across calendar months. Refer to each event definition for instructions on applying the 21 day rule for each specific event type.

IV antimicrobial start: Report **all** starts of intravenous (IV) antibiotics or antifungals administered in an outpatient setting, regardless of the reason for administration (i.e., include IV antimicrobial starts unrelated to vascular access problems) and regardless of the duration of treatment. A start is defined as a single outpatient dose or first outpatient dose of a course. Report all IV antibiotic starts, not just vancomycin. Do not report IV antiviral starts. Report outpatient starts that are continuations of inpatient antimicrobial treatment.

- 21 day rule: There must be 21 or more days from the **end** of one IV antimicrobial course to the **beginning** of a second IV antimicrobial start for two starts to be reported as separate dialysis events, even if different antimicrobials are used. If IV antimicrobials are stopped for fewer than 21 days and then restarted, the second start is NOT considered a new dialysis event and therefore, is not reported.

- For outpatient IV antimicrobial starts that are continuations of inpatient antimicrobial treatment, consider the start day to be the first day of outpatient administration.

- Inter-facility patient transfers: If a patient at a dialysis facility has an IV antimicrobial start and then transfers to another facility (as a transient or permanent patient) where the antimicrobial is continued, the second facility would report the IV antimicrobial start in their facility as well.

Positive blood culture: Report **all** positive blood cultures from specimens collected as an outpatient or collected within one calendar day after a hospital admission. One calendar day after hospital admission includes positive blood cultures collected on the day of or the day following admission to the hospital. Positive blood cultures meeting the criteria above should be reported regardless of whether or not a true infection is suspected or whether the infection is thought to be related to hemodialysis.

- 21 day rule: 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 is NOT considered a new dialysis event and therefore, is not reported. However, if different organisms grow from these subsequent positive blood cultures, add the new organisms to the reported event.

- Suspected source of the positive blood culture: indicating one of four suspected sources of a 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 nurse manager to be a contaminant. Contamination is more likely if the organism is a common commensal and is isolated from only one of several blood cultures. Examples of common commensals include: diphtheroids [*Corynebacterium* spp., not *C. diphtheriae*]; *Bacillus* spp. [not *B. anthracis*]; *Propionibacterium* spp.; coagulase-negative staphylococci [including *S. epidermidis*]; viridans group streptococci; *Aerococcus* spp.; and *Micrococcus* spp.

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

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 any vascular access site, regardless of whether the patient received treatment for infection. Pus is always reportable. Report redness or swelling if it is greater than expected and suspicious for infection. Indicate the vascular access site(s) where the symptom(s) occurred.

- 21 day rule: There must be 21 or more days between the **onset** of one episode and the **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 of the first onset, the recurrence is NOT considered a new dialysis event and therefore, is not reported.

Measure Definitions

- Bloodstream infection (BSI): Any positive blood culture.
- Access-related bloodstream infection (ARBSI): Positive blood culture with the suspected source reported as the vascular access or uncertain.
- Local access site infection (LASI): Pus, redness, or increased swelling of the vascular access site and access-related bloodstream infection is not present.
- Vascular access infection (VAI): Either a local access site infection or an access-related bloodstream infection.

Vascular Access Types

Consider all vascular accesses for hemodialysis and all central venous catheters that are present at the time of the event in Dialysis Event reporting, even if they are not used for dialysis and even if they are abandoned/non-functional.

- Nontunneled central line: a central venous catheter that is fixed in place at the point of insertion and 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 entering a vein, and terminates at or close to the heart or one of the great vessels (e.g., Hickman® or Broviac® catheters[14]).
- Graft: a surgically created connection between an artery and a vein using implanted material (typically synthetic tubing) to provide a permanent vascular access for hemodialysis.
- Fistula: a surgically created direct connection between an artery and a vein to provide vascular access for hemodialysis.
    - Buttonhole: a cannulation technique where a blunt needle (cannula) is inserted into the fistula at the same location each time using an established track. Report the way in which a patient is primarily cannulated.
- Other access device: includes catheter-graft hybrid vascular access devices, ports, and any other vascular access devices that do not meet the above definitions. Do not use this field to

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

report vascular accesses that are grafts, central venous catheters or fistulas. Do not use this field to report peritoneal dialysis accesses.

- Catheter-graft hybrid: a subcutaneous surgical implant with both a catheter and a graft component that provides blood flow directly from the target artery to the heart, bypassing the patient's central venous system (e.g., HeRO® vascular access device[15]).

REPORTING INSTRUCTIONS

NHSN forms and/or the definitions in this protocol should be used to collect required data. Each form has a corresponding table of instructions.

Complete a Survey Annually: Upon enrollment and annually thereafter, complete the *Outpatient Dialysis Center Practices Survey* (CDC 57.500). After enrollment, the data for the dialysis survey should be collected and reported in February.

Complete Monthly Reporting Plans: The *Monthly Reporting Plan* (CDC 57.501) is used by NHSN facilities to inform CDC that they are committed to following the NHSN surveillance protocol, in its entirety, for each data type selected on the plan. These data are referred to as "in-plan." A Monthly Reporting Plan must be completed before data can be entered into NHSN for that month.

- To indicate the facility is reporting in accordance with this protocol, save a Monthly Reporting Plan with the "DE" checkbox selected for the 'outpatient hemodialysis clinic' location, under the Events section, for each month that the facility is participating in Dialysis Event Surveillance.

Do **not** select "No NHSN Reporting this Month." Selection of this checkbox indicates the facility did not follow any NHSN Dialysis Component surveillance protocols that month (e.g., the facility was closed that month).

Report Denominator Data Monthly: The denominators are counts of patients by vascular access type used to estimate the number of patient-months considered at risk for dialysis events. To report denominator data, each month, report the number of hemodialysis outpatients with each vascular access type who received hemodialysis at the center during the first two working days of the month on the *Denominators for Dialysis Event Surveillance* form (CDC 57.503).

Report all hemodialysis outpatients, including transient patients. Exclude non-hemodialysis patients and exclude inpatients. Report denominator data each month, regardless of whether any dialysis events occur. Count each patient only once; if the patient has multiple vascular accesses, record that patient once, reporting only their vascular access with the highest risk of infection (note: this might not be the vascular access currently in use for dialysis).

HIGHER INFECTION RISK	Nontunneled Central Lines	Tunneled Central Lines	Other Access Devices	Grafts	Fistulas	*LOWER INFECTION RISK*

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

Working Days: The first two "working days" of the month should provide the opportunity to capture all regularly scheduled shifts and patients.

- For example, if a facility dialyzes patients 6 days a week, Monday through Saturday, and the first day of the month falls on a Sunday, then Monday and Tuesday would be the first two working days of the month for that facility.

Sun	Mon	Tues	Wed	Thurs	Fri	Sat
1 Facility closed	2 Working day 1	3 Working day 2	4	5	6	7

- For facilities that provide nocturnal hemodialysis, working days should include nocturnal hemodialysis patients.

- Working days are shift/schedule dependent – the actual patient census is **not** a criterion for determining a working day.

- If the facility was closed the entire month, do not complete a denominator form.

Report Numerator Data Monthly: The numerators are the number of dialysis events that occur during a defined time period. To report numerator data, complete one *Dialysis Event* form (CDC 57.502) per occurrence of event(s) among all patients who received hemodialysis at the facility during that month. If there are no dialysis events to report, access that month's denominator form to "Report No Events."

Report Events: Any patient who receives outpatient hemodialysis treatment at your facility is monitored for dialysis events, even if they were not counted on the denominator form. Include transient patients at your facility who have a dialysis event. Complete a *Dialysis Event* form only if a 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.

Multiple Dialysis Events: If multiple dialysis events occur together, **as a part of the same patient problem**, they should be reported on the same *Dialysis Event* form. 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, the "date of event" is always the date that the first event occurred. Refer to dialysis event definitions for the 21 day rule. Do not report unrelated dialysis events on the same form.

Event Type	Date of Event Criterion
IV antimicrobial start	Date of first outpatient dose of an antimicrobial course
Positive blood culture	Date of specimen collection
Pus, redness or increased swelling at vascular access site	Date of onset
Combination	Earliest date of the three types

Report *No* Events: Each dialysis event type needs to be accounted for every month. Either (a) the event type is reported on one or more *Dialysis Event* forms, or (b) the "report no events" box for that event type is checked on the *Denominators for Dialysis Event Surveillance* form to confirm that no events of that type occurred during the month.

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 aggregate pooled mean rates for each event type by combining rates from all participating facilities. Facilities can compare their rates with the aggregate rates using NHSN analysis rate table or run chart output options. Facilities are strongly encouraged to analyze the data they report and provide regular feedback to staff about patient outcome event rates.

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

Reporting Resources

Data collection and reporting resources are available on the NHSN Dialysis Event website: http://www.cdc.gov/nhsn/dialysis/dialysis-event.html.

Please direct questions to the NHSN Helpdesk at nhsn@cdc.gov and include "dialysis" in the subject line.