

Dialysis Event Surveillance Protocol

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I. Introduction

Approximately 500,000 patients are treated with maintenance hemodialysis in the United States. 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 non-tunneled 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/>

II. Reporting Instructions

Location: NHSN requires that facilities map each patient care area in their facility to one or more locations, as defined by NHSN, in order to report surveillance data collected from these areas. For the Dialysis Event Module, facilities should choose one of the following locations to report their surveillance data:

- Outpatient Hemodialysis Clinic (OUT: NONACUTE: CLINIC: DIAL)
- Outpatient Hemodialysis Clinic-Acute Kidney Injury (OUT: NONACUTE: CLINIC: DIAL_AKI)

NHSN forms and/or the definitions in this protocol should be used to collect required data. Each form has a corresponding table of instructions (TOI) that can be located on the NHSN Dialysis website.

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 following the NHSN surveillance protocol, in its entirety, for each data type selected on the plan. A Monthly Reporting Plan must be completed before data can be entered into NHSN for that month.

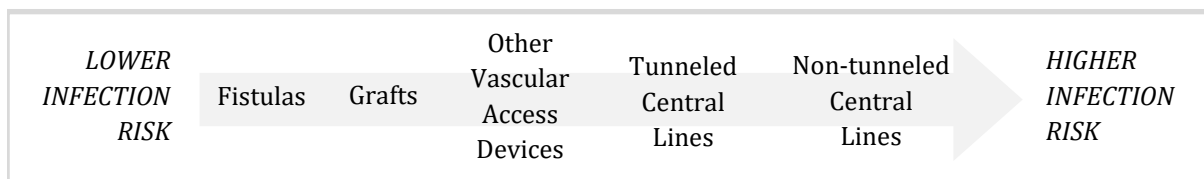
- To indicate the facility is reporting in accordance with this protocol, save a Monthly Reporting Plan with the "DE" checkbox selected for the 'outpatient hemodialysis clinic' and 'outpatient hemodialysis clinic-AKI' locations, under the Events section, for each month that the facility is participating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

If your facility is not following any protocols for the Dialysis Component modules for a particular month (e.g., the facility was closed), select "Not Participating in NHSN this 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 and their hemodialysis 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-Census 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 a patient has multiple vascular accesses, record that patient once, reporting only their vascular access type with the highest risk of infection (note: this might not be the vascular access currently in use for dialysis). Definitions of each type of vascular access lines can be found under the Dialysis Event Surveillance section.



The *Tables of Instructions (TOIs)*, located on the *NHSN Dialysis website*, provide an explanation of each field of the *Denominators for Dialysis Event Surveillance-Census Form*.

Working Days: The first two “working days” of the month should provide the opportunity to capture all patients who received hemodialysis at the center during those days.

- 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	2	3	4	5	6	7
Facility closed	Working day 1	Working day 2				

- For facilities that provide nocturnal hemodialysis, working days should include nocturnal hemodialysis patients.
- Working days are shift/schedule dependent.
- 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 any 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 Surveillance Event* form if a hemodialysis outpatient has one or more of the following:

- Positive Blood Culture
- IV Antimicrobial Start
- Pus, Redness, or Increased Swelling at the vascular access site

Multiple Dialysis Events: If multiple dialysis events occur together, **for a single patient**, the events 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 are recorded together on one form. When reporting multiple dialysis events together, the “date of event” is always the date that the first event occurred. Do not report unrelated dialysis events on the same form. Events are considered related if fewer than 21 days have passed since the last reported event of the same type. Refer to an explanation of the “21-day rule”.

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-Census Form* to confirm that no events of that type occurred during the month.

III. 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 for which there is risk of healthcare-associated infection. Throughout the entire month, any and all outpatients who receive hemodialysis at the facility are monitored for three National Healthcare Safety Network (NHSN)-defined dialysis events, which are: 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 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: In-Center Hemodialysis outpatients.

The facility who is currently providing treatment should report all events in NHSN, regardless of permanent or temporary patient status.

- Include transient patients: A patient was temporarily admitted for treatment at your facility for a short time at the time of the event (fewer than 30 days or 13 treatments) due to vacation, emergency, or other short-term displacement. A patient is transient from the time they receive treatment at the temporary facility to the first treatment at their home facility. For example: Patient has treatment at their home facility. The next treatment is done at a temporary facility and completed. If an event happens after treatment is done at the temporary facility the event will be attributed to the temporary facility and the patient will be considered a transient patient. If an event happens after they receive treatment at their home facility, then the event will be attributed to the home facility.
- Include peritoneal dialysis patients or transplant patients undergoing temporary hemodialysis
- Include outpatients with acute kidney injury (AKI): Patients with AKI are defined by the following criteria:
 - a. No diagnosis of “End Stage Renal Disease’ or “ESRD” in the patient medical record, or through the ESRD Medical Evidence Form (Form [CMS-2728-U3](#)), AND
 - b. Physician-diagnosis of “Acute Kidney Injury” or “AKI” listed in the patient medical record (e.g., nephrologist consult or referral form), AND
 - c. No more than 6 months has passed since the patient-initiated outpatient hemodialysis.

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 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 by event type.

IV antimicrobial start: Report **all** starts of intravenous (IV) antibiotics or antifungals administered in the reporting outpatient dialysis facility, regardless of the reason for administration (e.g., include IV antimicrobial starts unrelated to vascular access infection) and regardless of the duration of treatment. A start is defined as a single outpatient dose or first outpatient dose of a course. Do not report IV antiviral starts. Report outpatient starts that are continuations of antimicrobial treatment initiated outside of the reporting outpatient dialysis facility.

- 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.
- **21-day rule:** There must be 21 or more days from the **end** of one reported 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.
 - **Example:** Patient A begins IV Vancomycin while in the hospital on 1/8. The patient is discharged from the hospital on 1/12 and returns to the dialysis facility on 1/13 and is administered the IV Vancomycin by the dialysis clinic to continue the course. The course ends on 1/22. Patient A later begins a new course of IV Antimicrobials for a different illness on 2/10, administered by the dialysis clinic. Because the end of the first course (1/22) and the beginning of the second course (2/10) are less than 21 days apart, the second course does not need to be reported in NHSN.

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.

- Suspected source of the positive blood culture: Indicating one of four suspected sources of a positive blood culture is required. Consider the following suspected sources sequentially, starting with “Vascular access”.
 - 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) 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 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 can include (but are not limited to): 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. For a full list of Common Commensal organisms, refer to the

Common Commensal tab of the NHSN organism list
(<https://www.cdc.gov/nhsn/xls/master-organism-com-commensals-lists.xlsx>).

- **Uncertain:** Choose “Uncertain” only if there is insufficient evidence to decide among the three previous suspected source categories.
- **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 two positive blood cultures (the first of which is reported) occur less than 21 days apart, the second positive blood culture is NOT considered a new dialysis event and therefore, is not reported. If different organisms grow from the subsequent positive blood cultures, add the new organisms to the first reported event.

Pus, redness, or increased Swelling at the vascular access site:

Report each new outpatient episode where the patient has one or more symptoms of the following, at any vascular access site, regardless of whether the patient receives treatment for infection. Indicate the vascular access site(s) where the symptom(s) occurred that is suspicious for infection.

- **Pus**
- **Redness**
- **Greater than expected swelling** .

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 a reported 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 event.
- **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.

All Vascular Access Types Present

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. Do not include peritoneal dialysis catheters in vascular access type reporting.

- **Non-tunneled 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 (e.g., triple lumen catheters or temporary dialysis catheter).
- **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)
- **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 a permanent 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 vascular 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 report vascular accesses that are grafts, central venous catheters or fistulas. Do not use this field to report peritoneal dialysis catheters.

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 device²).

Access Used for Dialysis at the Time of the Event

Identify the vascular access used for dialysis at the time of the dialysis event from the list above in the All Vascular Accesses Types Present section. Please select only one. If more than one access was used for the dialysis treatment, please indicate the access with the higher risk of infection.

IV. Data Quality

Facilities are responsible for reporting complete and accurate data. Reviewing the alerts, data reminders in NHSN, and any email correspondence sent by NHSN will assist facilities in data collection reminders. Facilities should log into NHSN regularly to review data and ensure the facility information and staff are up to date. Facilities are encouraged to follow up on all hospitalizations to determine if a positive blood culture was collected within one calendar day of admission.

Additional information on implementing data quality checks and evaluations:

- <https://www.cdc.gov/nhsn/pdfs/dialysis/3-steps-to-review-de-data-2014.pdf>

V. Data Analyses

The NHSN application offers a variety of analytic reports that can be used to evaluate data quality by calculating rates for various types of dialysis events. 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 data 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 dialysis event rates. The formula to calculate the dialysis event rates is shown below:

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

The above formula is applicable to the following measurements via the rate table reports:

- IV Antimicrobial Start Rate
- IV Vancomycin Start Rate
- Local Access Site Infection Rate
- Bloodstream Infection Rate
- Access-Related Bloodstream Infection Rate
- Vascular Access Infection Rate

Additionally, the NHSN BSI in Hemodialysis Outpatients Measure is the standard for evaluating the number of positive blood cultures observed by a facility. Although other dialysis event types are reported to NHSN and calculated from the data, the BSI measure only assesses the number of positive blood cultures reported by a facility using a standardized infection ratio (SIR). The standardized infection ratio (SIR) is a ratio of the number of infections that are observed at a facility versus the number of infections that are predicted for that facility. The predicted values are based on national aggregate data. If a facility reports an observed number of BSIs exactly equal to their predicted number of BSIs, the SIR is equal to 1. If a facility observed more BSIs than were predicted, the SIR is greater than 1. If a facility observed fewer BSIs than were predicted, the SIR is less than 1.

$$SIR = \frac{Number\ of\ Observed\ BSI}{Number\ of\ Predicted\ BSI}$$

Regular reviewing of data and running of analysis reports should be done on a regular basis and at least once before the QIP reporting period deadline to ensure facility data is correct.

Additional resources and information on analysis can be found:

<https://www.cdc.gov/nhsn/pdfs/dialysis/dialysis-analysis-manual.pdf>.

VI. Additional Resources

Dialysis Event Module Training, getting to know the NHSN Dialysis Event Module and training guides:
<https://www.cdc.gov/nhsn/training/roadmap/dialysis-roadmap.html>

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

Analysis example: <https://www.cdc.gov/nhsn/pdfs/dialysis/APPENDIX-1-4-NHSN.pdf>

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