

## Dialysis Event Surveillance Manual

**Visit the Dialysis Event Homepage** http://www.cdc.gov/nhsn/dialysis/dialysis-event.html

NHSN Helpdesk nhsn@cdc.gov

February 2013





### **NHSN Dialysis Event Surveillance Manual**

The definitions and instructions used in this manual are the only criteria to be used to identify and report National Healthcare Safety Network (NHSN) Dialysis Event Surveillance. While some participants may not agree with all reporting criteria, it is important that NHSN participants consistently use them for reporting, so that metrics between facilities can be appropriately compared.

Dialysis event surveillance is part of the Device-Associated Module in the Patient Safety Component of NHSN. For information about other NHSN surveillance, please refer to <a href="http://www.cdc.gov/nhsn/">http://www.cdc.gov/nhsn/</a>

Direct questions about this manual to the NHSN Helpdesk at <a href="mailto:nhsn@cdc.gov">nhsn@cdc.gov</a>

The findings and conclusions in this document are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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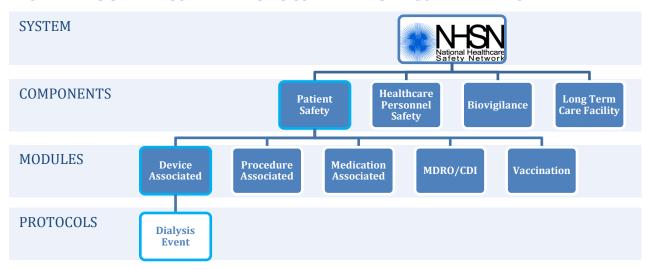
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#### **NHSN Structure**

The National Healthcare Safety Network (NHSN) is a secure, internet-based surveillance system open to all types of healthcare facilities in the United States. Various surveillance options are available to applicable facility types, each with an NHSN surveillance protocol that provides instructions for data collection and reporting. NHSN surveillance is categorized into components and modules.

#### HOW DIALYSIS EVENT SURVEILLANCE IS CURRENTLY CATEGORIZED IN NHSN



### **Getting Started in NHSN**

There is a process to getting started in NHSN which includes:

- 1. Completing required training
- 2. Enrolling the facility in NHSN
- 3. Completing set-up
- 4. Implementing a data collection process in your facility
- 5. Reporting data to NHSN

NHSN enrollment is not included in this manual; please refer to <a href="http://www.cdc.gov/nhsn/dialysis/dialysis-event.html">http://www.cdc.gov/nhsn/dialysis/dialysis-event.html</a> to get started in NHSN.

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### **User Roles and Rights**

Each person with access to NHSN has a unique user profile, which is linked to their digital certificate by email address. A person may have access to more than one NHSN facility/group using a single digital certificate, as long as the same email address is used each time. User roles are facility/group specific, and therefore may differ across facilities. User rights are both facility and component specific, and therefore may differ both across facilities and within a facility across components (e.g., in a given facility, a user may have rights to enter data under the Patient Safety Component, but not the Healthcare Personnel Safety Component).

#### **Facility User Requirements**

It is recommended that each NHSN facility have at least two users with administrative rights to simplify issues related to staff turnover. All NHSN users who no longer require NHSN access should be deactivated immediately (e.g., if they no longer work for the facility).

To ensure data quality, at least one staff member <u>at the facility</u> should be trained in and knowledgeable of how to report dialysis event data to NHSN. This is required regardless of whether electronic (clinical document architecture [CDA]) or manual methods are used to submit data.<sup>1</sup>

#### **Facility Component Primary Contacts**

Each component has a primary contact person designated during enrollment. This contact should be the person who interacts most closely with NHSN for the component. If the facility is participating only in Dialysis Event Surveillance, then only a Patient Safety Primary Contact Person is required.

Primary contacts are not mutually exclusive from NHSN roles. For example, the NHSN Facility Administrator and the Patient Safety Primary Contact Person may be the same.

Primary contacts assigned during enrollment are not necessarily NHSN users unless they are also the NHSN Facility Administrator, or they are added as a user following enrollment completion.<sup>2</sup>

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<sup>&</sup>lt;sup>1</sup> CMS requires that at least one staff member <u>at the facility</u> is trained in and knowledgeable of how to report dialysis event data to NHSN.

<sup>&</sup>lt;sup>2</sup> In summer 2013, the NHSN system will be modified so that primary contacts created during enrollment are also added as users.



### **Facility Roles**

- NHSN Facility Administrator: The user who enrolls a facility in NHSN is designated as the NHSN Facility Administrator. Following facility enrollment, he or she is responsible for adding additional users and assigning their user rights. The NHSN Facility Administrator will remain in the role unless they reassign the role to an existing facility user.
- Facility User: All other users with access to the facility in NHSN aside from the NHSN Facility Administrator. Their user rights determine their role(s) in NHSN. They may be assigned administrator rights.

#### **Facility User Rights**

Category	Activity	Facility Administrator	Facility User with Administrator Rights	Facility User
Patients	View/add patients	X	X	X
	Edit/delete patients not shared across components	X	X	X
	Edit/delete patients shared across components	X		
Data Entry	View monthly reporting plan	X	X	X3
	Add/edit monthly reporting plan	X	X	X4
	View NHSN data	X	X	X <sup>3</sup>
	Add, edit, delete NHSN data	X	X	X <sup>4</sup>
Import/Export	Import or export NHSN data	X	X	X <sup>4</sup>
Analysis	Analyze data, create NHSN reports	X	X	X5
Annual Survey	View/add/edit survey data	X	X	
Users	View facility users and user rights	X	X	X <sup>6</sup>
	Add/edit/deactivate facility user	X	X	
	Add/edit facility user rights	X	X	
Facility	Customize data collection forms	X	X	
	View/edit facility contact information and identifiers	X	X	
	Reassign NHSN Facility Administrator role	X		
	Activate/reactivate components	X		
	Deactivate components	X	X	
	View/add locations	X	X	
	Edit/delete locations not shared across components	X	X	
	Edit/delete locations shared across components	X		
	View/add/edit/delete surgeons	X	X	
Group	Confer rights to share facility data with a group	X	X	
	Join a group	X	X	
	Leave a group	X	X	
	Nominate a group	X	X	

<sup>&</sup>lt;sup>3</sup> If assigned "View Data" or "All Rights" on the Edit User Rights screen

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<sup>&</sup>lt;sup>4</sup> If assigned "Add, Edit, Delete" or "All Rights" on the Edit User Rights screen

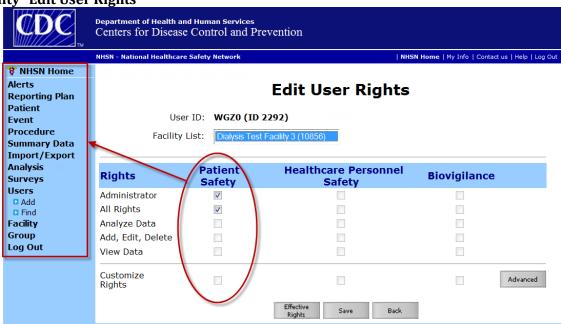
<sup>&</sup>lt;sup>5</sup> If assigned "Analyze Data" or "All Rights" on the Edit User Rights screen

<sup>&</sup>lt;sup>6</sup> A facility user may view only their own user rights under the "My Info" link



A facility user's rights determine which options appear on the NHSN navigation bar.

Facility "Edit User Rights"



#### **Group Roles**

- NHSN Group Administrator: The NHSN Group Administrator is selected when a group is nominated in NHSN. Once the NHSN Group Administrator has access to NHSN, they are responsible for adding additional group users and assigning their user rights. The NHSN Group Administrator remains in their role, unless they reassign the role to another user.
- **Group User**: All other users with access to the group aside from the NHSN Group Administrator. Their user rights determine their role(s) in NHSN. Their rights to facilities that belong to the group may be limited to a specific subset, as determined on the "Edit Users Rights" screen. They may be assigned administrator rights for the facilities to which they have access.

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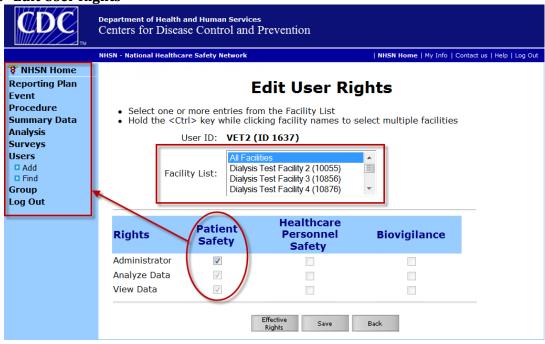
### **Group User Rights**

A group's access to a facility's data is determined solely by what that facility has agreed to share by conferring rights. An individual group user's rights can only further restrict access to these data.

Category	Activity	NHSN Group Administrator	Group User with Administrator Rights	Group User
Data	View facility's monthly reporting plans	X	X	<b>X</b> <sup>7</sup>
	View NHSN facility data	X	X	<b>X</b> <sup>7</sup>
Analysis	Analyze facility data, create NHSN reports	X	X	X8
<b>Annual Survey</b>	View Facility Survey	X	X	<b>X</b> <sup>7</sup>
Users	View group users and user rights	X	X	X <sup>9</sup>
	Add/edit/deactivate group users	X	X	
	Add/edit group user rights	X	X	
Group	View/edit Group Information	X	X	
	Reassign NHSN Group Administrator role	X		
	Set Joining Password	X	X	
	Evict Members	X	X	
	Define Rights	X	X	
	Rights Acceptance Report	X	X	

A group user's rights determine which options will appear on the NHSN navigation bar.

Group "Edit User Rights"



<sup>&</sup>lt;sup>7</sup> If assigned "View Data" on the Edit User Rights screen

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<sup>&</sup>lt;sup>8</sup> If assigned "Analyze Data" on the Edit Users Rights screen

<sup>&</sup>lt;sup>9</sup> A group user may view only their own user rights under the "My Info" link



### **Required Training**

Training is required to orient users to the system and ensure data are collected and reported to NHSN correctly. Please visit the NHSN Dialysis Event Homepage for current training materials at <a href="http://www.cdc.gov/nhsn/dialysis/dialysis-event.html">http://www.cdc.gov/nhsn/dialysis/dialysis-event.html</a>

Training requirements vary based upon user roles:

Training Title	Required For	Description
NHSN Enrollment for Outpatient Dialysis Facilities Video (23:20 minutes)	<ul> <li>Persons without access to NHSN who will enroll a dialysis facility in NHSN<sup>10</sup></li> <li>Group users who will be assisting facilities with the enrollment process</li> </ul>	Review of the 5-step enrollment process: training and preparation; register, request and install a digital certificate; submit forms electronically, and sign and send consent.
Enrolling Multiple Outpatient Dialysis Facilities in NHSN Slides (self-study)	<ul> <li>Users with existing access to NHSN who need to enroll a facility in NHSN</li> <li>Group users who will be assisting facilities with the enrollment process</li> </ul>	Review of the enrollment process for users who have access to NHSN, but need to enroll an additional facility in NHSN.
NHSN Set-up for Outpatient Dialysis Facilities Video (13:29 minutes)	<ul> <li>NHSN Facility Administrators</li> <li>Users with administrator rights</li> <li>Group users who will be assisting facilities with the set-up process</li> </ul>	Review of the set-up process including NHSN navigation and organization, adding users, adding a reporting location, adding monthly reporting plans, and introduction to patient data import and groups for data sharing.
Understanding Surveillance Requirements Video (29:38 minutes)	<ul> <li>All facility users (regardless of user rights/roles)</li> <li>Non-users who are involved in data collection</li> <li>Group users who will be assisting facilities with reporting or who will be analyzing facility data</li> </ul>	Review the purpose of surveillance, describe the Dialysis Event Protocol, describe reporting requirements, including: survey, monthly reporting plans, Denominators for Outpatient Dialysis form, and Dialysis Event form, as well as define dialysis events.  Examples of how to apply surveillance definitions.

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<sup>&</sup>lt;sup>10</sup> Most existing outpatient dialysis facilities are already enrolled in NHSN: check with the NHSN Helpdesk (nhsn@cdc.gov) to determine if your facility needs to be enrolled.



Training requirements vary based upon user roles: (continued)

Training Title	Required For	Description
NHSN Dialysis Event Protocol  Document	<ul> <li>All facility users (regardless of user rights/roles)</li> <li>Non-users who are involved in data collection</li> </ul>	Provide brief context for infection surveillance in outpatient dialysis settings. Provide exact definitions for dialysis events, the 21 day rule, and
(self-study)	<ul> <li>Group users who will be assisting facilities with reporting or who will be analyzing facility data</li> </ul>	vascular access type categories. Detail reporting instructions.
Joining a Group and Conferring Rights for Outpatient Dialysis Slides (self-study)	<ul> <li>NHSN Facility Administrators</li> <li>Users with administrator rights who will join their facility to a group</li> <li>Group users who will be assisting facilities with joining their group</li> </ul>	Describe the Group function used to share data. Outline steps for joining a group and introduce the Confer Rights screen that specifies which data are shared with the group, review elements specific to Dialysis Event data sharing.

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### **Locations for Dialysis Event Reporting**

Each NHSN facility must have at least one location where surveillance occurs. Each surveillance location is "mapped" to a corresponding CDC Location Description, which is a CDC-defined designation given to a patient care area with patients who have similar disease conditions or who are receiving care from similar medical or surgical specialties.

A reporting location is added and assigned a code and label by an administrative user, following facility activation as part of the NHSN Set-Up process. Required training for set-up is available at <a href="http://www.cdc.gov/nhsn/Training/dialysis/index.html">http://www.cdc.gov/nhsn/Training/dialysis/index.html</a>

Dialysis Event surveillance data are reported to the "Outpatient Hemodialysis Clinic" location.

CDC Location Description	Definition	NHSN Location Code	CDC Location Code
Outpatient Hemodialysis Clinic	An outpatient setting where maintenance hemodialysis patients are evaluated and dialyzed.	1153-6	OUT:NONACUTE:CLINIC:DIAL
Home Hemodialysis <sup>11</sup>	Hemodialysis performed by a patient (and/or the patient's caregiver) at home.	1262-1	COMM:NONACUTE:HOME:DIAL

**Other Locations:** In addition to the locations in the above table, dialysis facilities have the option to add other locations which are used for different types of surveillance, such as the Healthcare Personnel Safety Component. Visit <a href="https://www.cdc.gov/nhsn">www.cdc.gov/nhsn</a> for information on other surveillance options.

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<sup>&</sup>lt;sup>11</sup> Reporting for home hemodialysis patients is <u>currently being pilot tested</u>. If you are interested in participating in the pilot test, or if you have questions, please contact the NHSN Helpdesk at <a href="mailto:nhsn@cdc.gov">nhsn@cdc.gov</a>. Do NOT include home hemodialysis patients when reporting for maintenance hemodialysis outpatients in your Outpatient Hemodialysis Clinic location.



### **Monthly Reporting Plan**

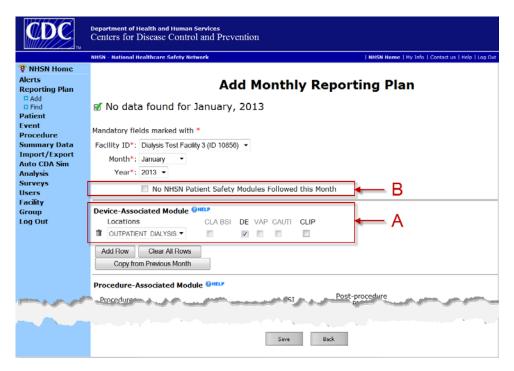
NHSN uses the Monthly Reporting Plan to identify which data have been reported according to an NHSN surveillance protocol. Only data reported according to an NHSN protocol are combined to generate national statistics used for inter-facility comparisons.

A monthly reporting plan must be saved before data can be submitted for that month. If a new plan is added, the message "No data found for *month*, *year*" will display. Otherwise, the existing plan will display, which may be edited.

**A.** To indicate your facility will submit data according to the NHSN Dialysis Event **Protocol**, navigate to the "Device-Associated module" section of the reporting plan. From the "Locations" drop-down menu, select the code for the outpatient hemodialysis clinic. If the location has been appropriately mapped to the correct CDC Location Description, a checkmark automatically appears in the "DE" box. Any Dialysis Event surveillance data reported this month are referred to as "in-plan" and will be included in CDC analyses.

Indicate on the plan any other surveillance<sup>12</sup> the facility is participating in; otherwise, leave remaining sections blank, scroll to the bottom of the screen and click "Save".

**B.** To indicate your facility will not submit data according to any NHSN surveillance protocols select the "No NHSN Patient Safety Modules Followed this Month" checkbox and "Save" the plan. Any Dialysis Event surveillance data reported this month are referred to as "out-of-plan" and will be excluded from CDC analyses.



<sup>&</sup>lt;sup>12</sup> Refer to the Patient Safety Manual, Chapter 14, (Tables of Instructions, Table 1) for instructions on completing a plan that includes other surveillance. Some dialysis facilities may be interested in Central Line Insertion Practices (CLIP), Multidrug-Resistant Organism (MDRO) LabID Event Reporting, and the Patient Vaccination module.

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Up to a year of Monthly Reporting Plans can be saved in advance. Saved plans can be edited, if needed. If any incomplete "out-of-plan" data exists, then all applicable existing records must be completed before the Monthly Reporting Plan can be edited to change the records to "in-plan".

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### **Dialysis Event Protocol**

#### Introduction

In 2010, more than 380,000 patients were 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 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 maintenance hemodialysis outpatients who were dialyzed in the facility on the first two working days of the month, using the *Denominators for Outpatient Dialysis* form. This count 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 three NHSN-defined 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. If other patients (e.g., inpatients, peritoneal dialysis patients) are present in this setting, exclude them from Dialysis Event reporting.

<sup>&</sup>lt;sup>13</sup> U.S. Renal Data System, USRDS 2012 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, 2011. (http://www.usrds.org/adr.htm)
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**Population:** Maintenance hemodialysis outpatients.

**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. A minimum of 6 months of Dialysis Event (DE) surveillance at an outpatient hemodialysis facility, indicated on the *Patient Safety Monthly Reporting Plan* (CDC 57.106), is required by CDC<sup>14</sup>. 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**

<u>Dialysis Event</u>: 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 generated from the reported data: bloodstream infection (BSI), local access site infection (LASI), access-related bloodstream infection (ARB), and vascular access infection (VAI). The numbers of the different dialysis event types are used as the numerator for the calculation of dialysis event rates.

<u>IV antimicrobial start</u>: Report **all** occurrences where intravenous (IV) antibiotics or antifungals are 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. Report all IV antibiotic administrations, not just vancomycin. Do **not** report IV antiviral starts. Report outpatient starts that are continuations of inpatient treatment.

• 21 day rule: There must be 21 or more days from the **end** of the first IV antimicrobial course that was started in an outpatient setting to the **beginning** of a second IV antimicrobial start in an outpatient setting for two starts to be reported as 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 and therefore, not reported. For outpatient IV antimicrobial starts that are continuations of inpatient treatment, consider the start day to be the first day of outpatient administration.

<u>Positive blood culture</u>: Report **all** positive blood cultures from specimens collected as an outpatient or collected within one calendar day after a hospital admission, regardless of whether or not the patient received treatment. The date of a blood culture result is based

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<sup>&</sup>lt;sup>14</sup> 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.



on the date the blood specimen was collected, not the date the laboratory reported the result.

• 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(s) 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 first report.

<u>Pus, redness, or increased swelling at the vascular access site</u>: 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.

• 21 day rule: There must be 21 or more days between the **onset** of a first 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.

<u>Bloodstream infection (BSI):</u> Any positive blood culture.

<u>Access-related bloodstream infection (ARB):</u> Positive blood culture with the suspected source reported as the vascular access or uncertain.

<u>Local access site infection (LASI)</u>: Pus, redness, or swelling of the vascular access site and access-related bloodstream infection is not present.

<u>Vascular access infection (VAI)</u>: Either a local access site infection or an access-related bloodstream infection.

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### **Vascular Access Types**

Include all vascular accesses in Dialysis Event reporting, even if they are not used for dialysis and even if they are abandoned and/or are non-functional.

- <u>Nontunneled central line</u>: 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.
- <u>Tunneled central line</u>: 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<sup>15</sup>).
- <u>Graft</u>: a surgically created connection between an artery and a vein using implanted material (typically synthetic tubing) to provide a permanent vascular access for hemodialysis.
- <u>Fistula</u>: a surgically created direct connection between an artery and a vein to provide vascular access for hemodialysis.
- Other access device: includes hybrid access devices (e.g., HeRO® vascular access device<sup>15</sup>), ports, and any other central vascular access devices that do not meet the above definitions.

#### REPORTING INSTRUCTIONS

NHSN forms should be used to collect required data, using the definitions outlined in this protocol. 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 57.104). After enrollment, the data for the dialysis survey should be collected in January, but are due in NHSN by April 1 each 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. To indicate the facility is reporting as defined by this protocol, save a Monthly Reporting Plan with "DE" selected for the 'outpatient hemodialysis clinic' location, under the Device-Associated section for each month that they will be doing Dialysis Event surveillance.

 $<sup>^{15}</sup>$  Use of trade names and commercial sources is for identification only and does not imply endorsement. February 2013 page 16/55



**Report Denominator Data Monthly:** Each month, report the number of maintenance hemodialysis outpatients with each vascular access type who received hemodialysis at the center during the <u>first two working days of the month</u> 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. 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. See tables of instructions for an explanation of each field of the *Denominators for Outpatient Dialysis* form.

HIGHER RISK	Nontunneled Central Lines	Tunneled Central Lines	Other Access Devices	AV Grafts	AV Fistulas	LOWER RISK
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**Report Numerator Data Monthly:** Each month, complete one *Dialysis Event* form (CDC 57.109) per occurrence of event(s) among all patients who received hemodialysis at the facility during that month. 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.

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.

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.

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<u>Suspected source of the positive blood culture</u>: indicating one of four suspected sources of a positive blood culture is required.

- <u>Vascular access</u>: 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.
- <u>Contamination:</u> 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 blood culture. Examples of 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.; and *Micrococcus* spp.
- <u>Uncertain:</u> 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 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.

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

### **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.

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### **Forms and Instructions**

Refer to the Dialysis Event Protocol for reporting instructions, including when each of the following forms are completed. Accompanying form instructions provide an explanation for each data collection field.

- Outpatient Dialysis Center Practices Survey
  - o Form: CDC 57.104 (6 pages)
  - o Instructions for the Outpatient Dialysis Center Practices Survey
- Denominators for Outpatient Dialysis
  - o Form: CDC 57.119 (1 page)
  - o Instructions for the Denominators for Outpatient Dialysis Form
- Dialysis Event
  - o Form: CDC 57.109 (4 pages)
  - o Instructions for the Dialysis Event Form

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Complete this survey as indicated by the Dialysis Event Protocol.

**Instructions:** Complete one survey per facility. Surveys are completed for the current year. It is strongly recommended to complete the survey in January of each year. The survey should be completed by someone who works in the facility and is familiar with current practices. Complete the survey based on the actual practices at the facility, not necessarily the facility policy, if there are differences.

Page 1 of 6 \*required for saving

Facil	Facility ID#: *Survey Year:				
A. Fa	acility Information				
*1.	Ownership of your dialysis center (choo	,	·		
	☐ Government	☐ Not for profit	☐ For profit		
*2.	Location/hospital affiliation of your dialy	rsis center:			
	☐ Freestanding	☐ Hospital based	☐ Freestanding b	ut owned by	a hospital
*3.	Types of dialysis services offered (selection	ct all that apply):			
	☐ In-center hemodialysis	☐ Peritoneal dialysis	☐ Home hemodia	llysis	
*4.	Number of in-center hemodialysis static	ons:			
*5.	Is your facility part of a group or chain of a. If Yes, owned by:			□ Yes	□ No
	b. If Yes, managed or operated I	oy:			
*6.	Do you (the person primarily responsible patient care in the dialysis facility?	le for collecting data for this s	urvey) perform	□ Yes	□ No
*7.	<ul><li>□ Dialysis nurse or nurse r</li><li>□ Dialysis facility administr</li><li>□ Dialysis education special</li></ul>	nis person? (if >1 person in cler infection control practitione nanager eator or director	harge, select all that r comes to our unit	□ Yes apply)	□ No
*8.	Is there a dedicated vascular access nu facility?	urse/coordinator (either full or	part-time) at your	□ Yes	□ No
*9.	Does your facility have capacity to isola	ite hepatitis B?			
	☐ Yes, use hepatitis B isolation roo	m ☐ Yes, use hepatitis B	isolation area	No hepatitis	B isolation
*10.	Indicate any other conditions that are ro	outinely isolated or cohorted f	or treatment within yo	our facility:	
	☐ None	☐ Hepatitis C		Tuberculos	is (TB)
	☐ Methicillin-resistant Staphylococo	cus aureus (MRSA)	Other, specify:		<del></del>
collecte	ance of Confidentiality: The voluntarily provided informated with a guarantee that it will be held in strict confidence, it of the individual, or the institution in accordance with Sec	will be used only for the purposes stated,	and will not otherwise be disc	losed or released	I without the
source not req aspect	reporting burden of this collection of information is estimate s, gathering and maintaining the data needed, and comple uired to respond to a collection of information unless it disp of this collection of information, including suggestions for r PRA (0920-0666).	ting and reviewing the collection of inform plays a currently valid OMB control number	ation. An agency may not coler. Send comments regarding	nduct or sponsor this burden estir	, and a person is nate or any other
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A. Fa	cility Information (continued)			
*11.	Please indicate whether the following types of records are facility (select all that apply):		le to staff or an admir	nistrator in your
		Yes, available	Yes, available electronically	Not available
	Local hospital microbiology lab results (i.e., for cultures sent to hospital lab or patients during hospitalization)			
	Hemodialysis station & machine assignment			
	Staff immunizations			
Pleas	se respond to the following questions based on records	from vour faci	lity for the first weel	k of January
(appli	es to current or most recent January relative to current date			<u> </u>
B. Pa	tient and staff census			
*12.	How many MAINTENANCE, NON-TRANSIENT dialysis Proveed of January?  Of these, indicate the number who received:  a. In-center hemodialysis:  b. Home hemodialysis:  c. Peritoneal dialysis:	ATIENTS were a	assigned to your cent	er during the first
*13.	How many PATIENT CARE staff (full time, part time, or affi week of January? Include only staff who had direct contact Specify the number of persons by category:  a. Nurse/nurse assistant:  b. Dialysis patient-care technician:  c. Dialysis biomedical technician:  d. Social worker:	e. Dietitian f. Physicia	tients or equipment: _:: : ns/physician assistar	
C. Va	ccines			
*14.	Of the <u>patients</u> counted in question 12, how many received a. At least 3 doses of hepatitis B vaccine (ever)? b. The influenza (flu) vaccine for <u>this</u> flu season (Se c. The pneumococcal vaccine (ever)?		)?	
*15.	Of your MAINTENANCE, NON-TRANSIENT hemodialysis received at least 3 doses of hepatitis B vaccine (ever)?		uestion 12 (12a +12b)	), how many
*16.	Of the patient care <u>staff members</u> counted in question 13, a. At least 3 doses of hepatitis B vaccine (ever)? b. The influenza (flu) vaccine for this flu season (Se			
*17.	Does your facility use standing orders to allow nurses to a physician order?  ☐ Yes, for some or all vaccines ☐ No, not for any vaccines	dminister vaccin	es to patients withou	t a specific
*18.	Indicate whether your facility offers the following immunizate a. Influenza vaccine offered to patients  b. Influenza vaccine offered to patient care staff c. Pneumococcal vaccine offered to patients	tions:	Yes	<b>No</b>



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D. Hepatitis B and C								
*19.	Of your MAINTENANCE, NON-TRANSIENT in-center <a href="hemodialysis">hemodialysis</a> PATIENTS from question 12a:  a. How many were hepatitis B surface <b>ANTIGEN</b> (HBsAg) positive in the first week of January?  b. How many converted from hepatitis B surface ANTIGEN (HBsAg) negative to positive in the prior 12 months (i.e., had newly acquired hepatitis B virus infection, not as a result of vaccination)? Do not include patients who were antigen positive before they were first dialyzed in your center:  c. How many were hepatitis B surface ANTIGEN (HBsAg) positive on arrival to your center?							
*20.	Of the patients counted in question 12a, were all or almost all tested for hepatitis B surface    Yes    No ANTIBODY (anti-HBs) in the past 12 months?  a. If Yes, how many were positive in the first week of January?							
*21.	Does your facility routinely test hemodialysis patients for <b>hepatitis C</b> antibody (anti-HCV)?							
	to your center?   No admission testing done							
E. Dia	ysis Policies and Practices							
*22.	Does your facility reuse dialyzers for some or all patients? ☐ Yes ☐ No f Yes,							
	<ul> <li>a. What method is used to disinfect the majority of these dialyzers?  \[ \triangle \tri</li></ul>							
	d. Are dialyzers refrigerated before reprocessing? ☐ Yes ☐ No							
	<ul> <li>e. How is dialyzer header cleaning performed? (select all that apply)</li> <li>Automated machine (e.g., RenaClear® System)</li> <li>Spray device (e.g., ASSIST® header cleaner)</li> <li>Insertion of twist-tie or other instrument to break up clots</li> <li>Disassemble dialyzer to manually clean</li> <li>Other, specify:</li> </ul>							
	<ul> <li>□ No separate header cleaning step performed</li> <li>f. Is there a limit to the number of times a dialyzer is used?</li> <li>□ Yes (indicate number):</li> <li>□ No limit as long as dialyzer meets certain criteria (e.g., passes pressure leak test, etc.)</li> </ul>							



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E. Di	alysis Policies and Practices (c	ontinued)					
*23.	Does your facility use hemodialy	sis machine Waste I	landling Opti	on (WHO) ports?	□ Yes	□ No	
*24.	Are any patients in your facility "I or almost reach the prime waste		,	e blood is allowed to re	each □ Yes	□ No	
*25.	What form of erythropoiesis stim  ☐ Single-dose vial  a. Is ESA from a single-dose	☐ Multi-dose vial	☐ Pre-pac	ckaged syringe		□ No	
*26.	6. Where are medications most commonly drawn into syringes to prepare for patient administration?  ☐ At the individual dialysis stations ☐ On a mobile medication cart within the treatment area ☐ At a fixed location within the patient treatment area ☐ At a fixed location removed from the patient treatment area (not a room) ☐ In a separate medication room ☐ N/A						
*27.	Do technicians administer any IV	medications (e.g., h	eparin, salin	e)?	☐ Yes	□ No	
*28.	a. Have a written policy on a b. Formulary restrictions c. Antibiotic use approval pr d. Automatic stop orders for	antibiotic use	g means to re Yes  □ □ □ □	estrict or ensure approp  No  □  □  □  □	oriate antibiotic	use:	
*29.							
*30.	. Do you follow CDC-recommended Core interventions to prevent bloodstream infections in hemodialysis patients?  ☐ Yes ☐ No ☐ Don't know						
*31.		rs, is antimicrobial of	ntment routir	nely applied to the exit s	site during dres	sing	
	For <b>peritoneal dialysis catheters</b> , is antimicrobial ointment routinely applied to the exit site during dressing change?  \[ Yes						



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	Scular Access	
*32.	Of your MAINTENANCE, NON-TRANSIENT hemodialysis patients from question received hemodialysis through each of the following access types during the first va. AV fistula  b. AV graft  c. Tunneled central line  d. Nontunneled central line  e. Other access device (e.g., graft-catheter)	
For a	teriovenous (AV) grafts or fistulas:	
*33.	Before prepping the area for puncture, the area is most often <u>cleansed</u> with:  ☐ Soap and water ☐ Alcohol-based hand rub ☐ Both	th □ Neither
*34.	Before puncture of a graft or fistula, the area is most often prepped with:  Alcohol Chlorhexidine (e.g., Chloraprep®) Povidone-iodine (or tincture of iodine) Sodium hypochlorite solution (e.g., ExSept®) Other, specify: Nothing a. Indicate the form of skin antiseptic used to prep fistula/graft sites: Multiuse bottle (e.g., poured onto gauze) Pre-packaged swab or pad Other, specify: Other, specify:	
*35.	Is buttonhole cannulation performed on any fistula patients in your facility? If Yes,	□ Yes □ No
	a. Indicate for what patients:  ☐ Home hemodialysis ☐ In-center hemodialysis ☐ Both  ☐ Both  ☐ Both	th
	b. Buttonhole cannulation is most often performed by:  ☐ Nurse ☐ Patient (self-cannulation) ☐ Technician ☐ Oth ————————————————————————————————————	ner, specify:
For h	emodialysis catheters:	
*36.	Before access of the hemodialysis catheter, the <b>catheter hubs</b> are prepped with (used):  Alcohol Chlorhexidine (e.g., Chloraprep®) Povidone-iodine (or tincture of iodine) Sodium hypochlorite solution (e.g., ExSept®, Alcavis) Other, specify: Nothing a. Indicate the form of antiseptic/disinfectant used to prep the catheter hubs: Multiuse bottle (e.g., poured onto gauze) Pre-packaged swab or pad	



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F. Va	scular Access (continued)
*37.	When the catheter dressing is changed, the exit site (i.e., place where the catheter enters the skin) is prepped with (select the one most commonly used):
	☐ Alcohol
	☐ Chlorhexidine (e.g., Chloraprep®)
	☐ Povidone-iodine (or tincture of iodine)
	☐ Sodium hypochlorite solution (e.g., ExSept®, Alcavis)
	☐ Other, specify:
	□ Nothing
	a. Indicate the form of antiseptic/disinfectant used at the exit site:
	☐ Multiuse bottle (e.g., poured onto gauze) ☐ Other, specify:
	□ Pre-packaged swab or pad
*38.	Are antimicrobial lock solutions used to prevent hemodialysis catheter infections in your facility?
	$\square$ Yes, for all catheter patients $\square$ Yes, for some catheter patients $\square$ No
	If Yes,
	a. Indicate the lock solutions used (select all that apply):
	□ Sodium citrate □ Taurolidine
	☐ Gentamicin ☐ Ethanol
	☐ Vancomycin ☐ Other, specify:
	<ul> <li>Of your maintenance hemodialysis patients with a central line in Question 32 (32d + 32e), how many received prophylactic antimicrobial lock in the first week of January?</li> </ul>
*39.	For <b>hemodialysis catheters</b> , is antimicrobial ointment routinely applied to the exit site during dressing change?
	a. If Yes, what type of ointment?
	☐ Bacitracin/gramicidin/polymyxin B (Polysporin Triple) ☐ Mupirocin
	☐ Bacitracin/polymyxin B (e.g., Polysporin®) ☐ Povidone-iodine
	☐ Bacitracin/neomycin/polymyxin B (triple antibiotic) ☐ Other, specify:
*40.	Are closed connector luer access devices used on hemodialysis catheters? $\ \square$ Yes $\ \square$ No If Yes,
	a. Indicate what kind: ☐ Tego® ☐ Q-Syte™ ☐ Other, specify:
	b. Indicate for what patients: ☐ Home hemodialysis ☐ In-center hemodialysis ☐ Both
*41.	Are any of the following used for hemodialysis catheters (select all that apply)?  □ Antimicrobial-impregnated hemodialysis catheters □ Chlorhexidine dressing (e.g., Biopatch®, Tegaderm™ CHG) □ Other antimicrobial dressing (e.g., silver-impregnated) □ Antiseptic-impregnated catheter cap □ None of the above
*42.	Job classification of staff members who <u>primarily</u> perform hemodialysis catheter care (i.e., access catheters or change dressing) (select one):
	LINUISE LIEUTITUIAIT



### **Instructions for the Outpatient Dialysis Center Practices Survey**

These instructions address common questions about the dialysis survey (CDC 57.104). For additional clarification on any survey question, contact the NHSN Helpdesk at <a href="mailto:nhsn@cdc.gov">nhsn@cdc.gov</a>

**Instructions:** Complete one survey per facility for the current year. It is strongly recommended to complete the survey in January of each year. The survey should be completed by someone who works in the facility and is familiar with current practices. Complete the survey based on the actual practices at the facility, not the facility policy, if there are differences.

### A. Facility Information

- 10. "Indicate any other conditions that are routinely isolated or cohorted for treatment within your facility."
  - Select only the organisms for which positive patients are segregated. If additional criteria are used to isolate some positive patients, but not others (e.g., active diarrhea, draining wounds), do not select this organism on the survey.
  - Do not select patient conditions that your facility will not admit (e.g., active TB); indicate which conditions your facility will admit and would isolate if the patient was positive for the condition on admission.

#### B. Patient and staff census

- 13. "How many **PATIENT CARE** staff (full time, part time, or affiliated with) worked in your facility during the first week of January? *Include only staff who had direct contact with dialysis patients or equipment*"
  - The first week of January refers to the first 7 calendar days of the year.
  - Count each person as 1, even if they work part-time. If a person works at more than one facility, they are counted as 1 at each facility.
  - Include physicians who see patients in the facility.
  - Include patient care staff who are normally present, but are absent this week due to vacation or other leave.
  - Include per diem staff if they are consistently part of your facility staff.

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#### C. Vaccines

- 14. a. "Of the <u>patients</u> counted in question 12, how many received: at least 3 doses of hepatitis B vaccine (ever)?"
  - Do not count patients who are in the process of completing the series.
  - Include all patients who received ≥3 doses, even if the brand of hepatitis B vaccine being used requires four doses.
  - Include patients who have documentation of having a complete hepatitis B vaccine series, even if not received at your facility.
- 14. b. "Of the <u>patients</u> counted in question 12, how many received: the influenza (flu) vaccine for <u>this</u> flu season (September or later)?"
  - This refers to the flu season that begins in the year preceding the survey year. For example, if the survey year is 2013, count flu vaccinations for the 2012-2013 flu season.
  - Include patients who report having received a flu vaccination this season (or for whom there is documentation) even if not received at your facility.
- 16. a. "Of the patient care <u>staff members</u> counted in question 13, how many received at least 3 doses of hepatitis B vaccine (ever)?"
  - Do not count staff members who are in the process of completing the series.
  - Include all staff members who received ≥3 doses, even if the brand of hepatitis B vaccine being used requires four doses.
  - Include patient care staff members who report having received at least 3 doses of hepatitis B vaccine (or for whom there is documentation) even if not received at your facility.
- 16. b. "Of the patient care <u>staff members</u> counted in question 13, how many received the influenza (flu) vaccine for this flu season (September or later)?"
  - This question refers to the flu season that precedes the survey year. For example, if the survey year is 2013, count flu vaccinations for the 2012/2013 flu season.
  - Include patient care staff members who report having received a flu vaccination this season (or for whom there is documentation) even if not received at your facility.

### D. Hepatitis B and C

Complete this section even if your facility does not treat hepatitis B surface antigen (HBsAg) positive patients.

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### **E. Dialysis Policies and Practices**

- 22. "Does your facility reuse dialyzers for some or all patients?"
  - Facilities that use non-disposable dialyzers for more than one patient treatment should answer "yes" to this question.
  - All facilities with a dialyzer reuse program would answer "yes" to this question.
- 28. "Indicate whether your facility uses any of the following means to restrict or ensure appropriate antibiotic use."
  - Select "Yes" only for the practices implemented for the purpose of appropriate antimicrobial use. If the antimicrobials are restricted for another purpose only (e.g., cost management), select "No".
- 32. "Of your MAINTENANCE, NON-TRANSIENT hemodialysis patients from question 12 (12a +12b), how many received hemodialysis through each of the following access types during the first week of January?"
- The first week of January refers to the first 7 calendar days of the year. Note that this question counts patients differently than the Denominators for Outpatient Dialysis form.

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### **Denominators for Outpatient Dialysis**

Census Form - completed once per month

Complete this form as indicated by the Dialysis Event Protocol Instructions for this form are available at: http://www.cdc.gov/nhsn/forms/instr/57\_119.pdf

\*required for saving Page 1 of 1 Reporting to "Outpatient Hemodialysis Clinic" Location: Record the number of patients who received maintenance hemodialysis at your center on the first two working days of the month, including transient patients. A patient must be physically present for in-center maintenance hemodialysis on one of these days to be counted on this form (exclude patients who are hospitalized). Record each patient only once. If a patient has more than one vascular access, record the access type with highest risk for infection. Facility ID #: \*Location Code: \*Month: \*Year: \*Number of \*Vascular Access Type Maintenance **Hemodialysis Patients** Number of these Fistula Patients who undergo Fistula **Buttonhole Cannulation** Graft Tunneled central line Nontunneled central line Other access device (e.g., hybrid access) \*Total patients (sum of all patients listed above) Custom Fields: Label Data

Assurance of Confidentiality: The voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 6 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Reports Clearance Officer, 1600 Clifton Rd., MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0666).

CDC 57.119 Rev 4, v7.1



# **Instructions for the Denominators for Outpatient Dialysis Form** (CDC 57.119)

\* Indicates a required field when reporting in-plan.

Data Field	Instructions for Data Collection
Facility ID #	The NHSN-assigned facility ID will be auto-entered by the computer.
*Location code	<b>Required</b> . Enter the location code for the outpatient hemodialysis clinic
	location from which you will collect data about dialysis events.
*Month	<b>Required</b> . Enter the month during which the data were collected for this location.
*Year	<b>Required</b> . Enter the 4-digit year during which the data were collected for this location.
*Number of Maintenance Hemodialysis Patients by Vascular Access Type	<b>Required</b> . For each type of vascular access listed, enter the number of patients who received maintenance hemodialysis at this location on the first two working days of the month, including transient patients. Consider all vascular accesses the patient has, even if they are not used for dialysis and even if they are abandoned and/or are non-functional. A patient must be physically present for in-center maintenance hemodialysis on one of these days to be counted on this form (exclude patients who are hospitalized). Record each patient <b>only once</b> . If a patient has more than one vascular access, record the access type with highest risk for infection, using the following hierarchy:
	Lower Risk  Fistula Graft Other access device (e.g., hybrid access device) Tunneled Central Line Nontunneled Central Line Higher Risk  For example, if a patient has a fistula and a tunneled central line, count this patient under the category of tunneled central line. If the patient has a
	fistula and a "jump graft" record the patient as having a graft. If the patient
Number of these Fistula	has only a catheter-graft hybrid or a port, record as "other access device".
Patients who undergo	Conditionally required. Out of the fistula patients counted above, how many undergo buttonhole cannulation.
Buttonhole Cannulation	under go buttonnoie tannuation.
*Total patients	<b>Required</b> . The sum of all patients listed above will enter automatically.
Custom fields	Optional. Up to 50 alphanumeric, numeric, and/or date fields may added to this form for local use.
	<b>NOTE:</b> Each custom field must be added in advance. Within NHSN, select "Facility," then "Customize Forms," and then follow on-screen instructions. The Form Type is "CDC-Defined – PS – Summary Data" and form is "DIAL – Outpatient Dialysis Census Form".

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Complete this form as indicated by the Dialysis Event Protocol

Complete this form as indicated by the Dialysis Event Protocol

Instructions for this form are available at http://www.cdc.go	ov/nhsn/forms/instr/57_109.pdf Page 1 of 4
*required for saving	F ID #
Facility ID:	Event ID #:
*Patient ID:	Social Security #:
Secondary ID #:	Medicare #:
Patient Name, Last:	First: Middle:
*Gender: F M Other	*Date of Birth:
Ethnicity (Specify):	Race (Specify):
*Event Type: DE – Dialysis Event	*Date of Event:
*Location:	
Was the patient admitted/readmitted to the dial	lysis facility on this dialysis event date? ☐ Yes ☐ No
Risk Factors	
*Vascular accesses: (check all that apply)	*Access placement date (mm/yyyy):
□ Fistula	/
Buttonhole? ☐ Yes ☐ No	
☐ Graft	/ □ Unknown
☐ Tunneled central line	/
☐ Nontunneled central line	/
☐ Other access device specify:	/
Is this a catheter-graft hybrid? □	Yes □ No
Vascular access comment:	
Other Patient Information	
*Transient Patient ☐ Yes ☐ No	
Event Details	
*Specify Dialysis Event: (check at least one)	
*Specify Dialysis Event: (check at least one)  □ IV antimicrobial start	
*Specify Dialysis Event: (check at least one)	used for this start? □ Yes □ No
*Specify Dialysis Event: (check at least one)  □ IV antimicrobial start  *Was vancomycin the antimicrobial u	used for this start?
*Specify Dialysis Event: (check at least one)  IV antimicrobial start  *Was vancomycin the antimicrobial u  Positive blood culture (*specify organis	sm and antimicrobial susceptibilities on pages 2-3)
*Specify Dialysis Event: (check at least one)  IV antimicrobial start  *Was vancomycin the antimicrobial u  Positive blood culture (*specify organis  *Suspected source of positive blood or	sm and antimicrobial susceptibilities on pages 2-3) culture (check one):
*Specify Dialysis Event: (check at least one)  IV antimicrobial start  *Was vancomycin the antimicrobial u  Positive blood culture (*specify organis  *Suspected source of positive blood of the color o	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access   Contamination   Uncertain
*Specify Dialysis Event: (check at least one)  IV antimicrobial start  *Was vancomycin the antimicrobial u  Positive blood culture (*specify organis  *Suspected source of positive blood of the color o	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
*Specify Dialysis Event: (check at least one)  IV antimicrobial start  *Was vancomycin the antimicrobial u  Positive blood culture (*specify organis  *Suspected source of positive blood of the color o	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
*Specify Dialysis Event: (check at least one)  IV antimicrobial start  *Was vancomycin the antimicrobial use.  Positive blood culture (*specify organise	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
*Specify Dialysis Event: (check at least one)    IV antimicrobial start   *Was vancomycin the antimicrobial uses   Positive blood culture (*specify organises   *Suspected source of positive blood   Vascular access   A source   Pus, redness, or increased swelling at   *Check the access site(s) with pus, redness   Fistula   Graft   Tunneled	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
*Specify Dialysis Event: (check at least one)  IV antimicrobial start  *Was vancomycin the antimicrobial use.  Positive blood culture (*specify organis)  *Suspected source of positive blood of the compositive blood of the	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
*Specify Dialysis Event: (check at least one)    IV antimicrobial start   *Was vancomycin the antimicrobial uses   Positive blood culture (*specify organises   *Suspected source of positive blood   Vascular access   A source   Pus, redness, or increased swelling at   *Check the access site(s) with pus, redness   Fistula   Graft   Tunneled	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
*Specify Dialysis Event: (check at least one)  IV antimicrobial start  *Was vancomycin the antimicrobial use.  Positive blood culture (*specify organis)  *Suspected source of positive blood of the compositive blood of the	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
*Specify Dialysis Event: (check at least one)  □ IV antimicrobial start  *Was vancomycin the antimicrobial use. □ Positive blood culture (*specify organise.  *Suspected source of positive blood of the vascular access. □ A source. □ Pus, redness, or increased swelling ate.  *Check the access site(s) with pus, received. □ Fistula. □ Graft. □ Tunnele.  *Specify Problem(s): (check one or more). □ Fever ≥37.8°C (100°F) oral. □ Wound (NOT related to vascular access).	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
*Specify Dialysis Event: (check at least one)  □ IV antimicrobial start  *Was vancomycin the antimicrobial use. □ Positive blood culture (*specify organise.  *Suspected source of positive blood of the compositive blood o	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
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*Specify Dialysis Event: (check at least one)  □ IV antimicrobial start  *Was vancomycin the antimicrobial use. □ Positive blood culture (*specify organise.  *Suspected source of positive blood of the compositive blood o	sm and antimicrobial susceptibilities on pages 2-3) culture (check one): ce other than the vascular access
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*Specify Dialysis Event: (check at least one)  □ IV antimicrobial start  *Was vancomycin the antimicrobial uses a vancomycin to vascular access and a vancomycin the vancomycin that a vancomycin the vancomycin that a vancomycin the vancomycin that a vancomycin tha	culture (check one):  ce other than the vascular access

collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 16 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Reports Clearance Officer, 1600 Clifton Rd., MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0666).

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Pathogen	Gram-positive C	)rganisms								Page 2 of 4	
# 	Staphylococcus coagulase-negati (specify):	VA	NC R N								
	Enterococcus spp.( specify):	<b>AMP</b> SIRN	CIPRO/LE	VO/MOXI	<b>DAPTO</b> S NS N	<b>DOXY/MINO</b> SIRN	<b>GENTHL</b> <sup>§</sup> S R N	<b>LNZ</b> SIRN			
		STREPHL <sup>§</sup> SRN		<b>TETRA</b> SIRN	<b>TIG</b> S NS N	VANC SIRN					
	Enterococcus faecium	<b>AMP</b> SIRN	CIPRO/LE	VO/MOXI	<b>DAPTO</b> S NS N	<b>DOXY/MINO</b> SIRN	<b>GENTHL</b> <sup>§</sup> S R N	<b>LNZ</b> SIRN			
		<b>QUIDAL</b> SIRN	STREPHL <sup>§</sup> SRN	ì	TETRA SIRN	TIG S NS N	VANC SIRN				
	Staphylococcus aureus	CHLOR SIRN	CIPRO/LE	VO/MOXI	CLIND SIRN	<b>DAPTO</b> S NS N	<b>DOXY/MINO</b> SIRN	<b>ERYTH</b> SIRN	<b>GENT</b> SIRN		
		LNZ SRN	OX/CEFOX	(/METH	<b>QUIDAL</b> SIRN	<b>RIF</b> SIRN	TETRA SIRN	<b>TIG</b> S NS N	TMZ SIRN	<b>VANC</b> SIRN	
Pathogen #	Gram-negative Organisms										
	Acinetobacter spp. (specify):	AMK SIRN	AMPSUL SIRN	<b>AZT</b> SIRN	<b>CEFEP</b> SIRN	<b>CEFTAZ</b> SIRN	CIPRO/LEVO SIRN		COL/PB SIRN		
		<b>GENT</b> SIRN	IMI MERO/DORI SIRN SIRN		<b>PIP/PIPTAZ</b> SIRN	TETRA/DOXY/MINO SIRN					
		TMZ SIRN	TOBRA SIRN								
	Escherichia coli	<b>AMK</b> SIRN	<b>AMP</b> SIRN	<b>AMPSUL</b> SIRN	/AMXCLV	<b>AZT</b> SIRN	<b>CEFAZ</b> SIRN	<b>CEFEP</b> SIRN	CEFOT/O	CEFTRX	
		<b>CEFTAZ</b> SIRN	CEFUR SIRN	CEFOX/C SIRN	CETET	CHLOR SIRN	CIPRO/LEVO/ SIRN	MOXI	COL/PB SIRN		
		<b>ERTA</b> SIRN	<b>GENT</b> SIRN	IMI SIRN	MERO/DO SIRN	RI	<b>PIPTAZ</b> SIRN	TETRA/D SIRN	OXY/MINO	)	
		TIG SIRN	TMZ SIRN	TOBRA SIRN							
	Enterobacter spp. (specify):	<b>AMK</b> SIRN	<b>AMP</b> SIRN		/AMXCLV	<b>AZT</b> SIRN	<b>CEFAZ</b> SIRN	<b>CEFEP</b> SIRN	CEFOT/O	CEFTRX	
		<b>CEFTAZ</b> SIRN	<b>CEFUR</b> SIRN	CEFOX/C SIRN	CETET	CHLOR SIRN	CIPRO/LEVO/ SIRN	MOXI	COL/PB SIRN		
		<b>ERTA</b> SIRN	<b>GENT</b> SIRN	IMI SIRN	MERO/DO SIRN	PRI	<b>PIPTAZ</b> SIRN	TETRA/D SIRN	OXY/MINC	)	
		TIG SIRN	TMZ SIRN	TOBRA SIRN							
	Klebsiella spp. (specify):	<b>AMK</b> SIRN	<b>AMP</b> SIRN	<b>AMPSUL</b> SIRN	/AMXCLV	<b>AZT</b> SIRN	<b>CEFAZ</b> SIRN	<b>CEFEP</b> SIRN	CEFOT/O	CEFTRX	
		<b>CEFTAZ</b> SIRN	<b>CEFUR</b> SIRN	CEFOX/O	CETET	CHLOR SIRN	CIPRO/LEVO/ SIRN	MOXI	COL/PB SIRN		
		<b>ERTA</b> SIRN	<b>GENT</b> SIRN	IMI SIRN	MERO/DO SIRN	PRI	<b>PIPTAZ</b> SIRN	TETRA/D SIRN	OXY/MINO	)	
		TIG SIRN	TMZ SIRN	TOBRA SIRN							



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Pathogen #	Gram-negative Organisms (continued)									
	Serratia marcescens	<b>AMK</b> SIRN	<b>AMP</b> SIRN	AMPSUL/A SIRN	MXCLV	<b>AZT</b> SIRN	<b>CEFAZ</b> SIRN	<b>CEFEP</b> SIRN	<b>CEFO</b> SIRN	T/CEFTRX
		<b>CEFTAZ</b> SIRN	<b>CEFUR</b> SIRN	CEFOX/CE	TET	CHLOR SIRN	CIPRO/LEVO/I	MOXI	COL/F SIRN	
		<b>ERTA</b> SIRN	<b>GENT</b> SIRN	IMI SIRN	MERO/D SIRN	ORI	<b>PIPTAZ</b> SIRN	TETRA/ SIRN	DOXY/MIN	0
		<b>TIG</b> SIRN	TMZ SIRN	<b>TOBRA</b> SIRN						
	Pseudomonas aeruginosa	<b>AMK</b> SIRN	<b>AZT</b> SIRN	<b>CEFEP</b> SIRN	<b>CEFTAZ</b> SIRN		CIPRO/LEVO SIRN	COL/PE SIRN		
		IMI SIRN	MERO/DO SIRN	ORI	PIP/PIPT SIRN	AZ	TOBRA SIRN			
	Stenotrophomoi maltophilia	nas	<b>LEVO</b> SIRN	TETRA/MIN SIRN	10	TICLAV SIRN	<b>TMZ</b> SIRN			
Pathogen #	Fungal Organis	sms								
	Candida spp. (specify):	<b>ANID</b> SIRN	<b>CASPO</b> S NS N	FLUCO S S-DD R N	I	FLUCY SIRN	ITRA S S-DD R N	MICA S NS N	<b>VORI</b> S S-DI	D R N
Pathogen #	Other Organism	ns								
	Organism 1 (specify)	Drug 1 S I R N	Drug 2 S I R N	Drug 3 S I R N	Drug 4 S I R N	Drug 5 S I R N	Drug 6 S I R N	Drug 7 S I R N	Drug 8 S I R N	Drug 9 S I R N
	Organism 1 (specify)	Drug 1 S I R N	Drug 2 S I R N	Drug 3	Drug 4 S I R N	Drug 5 S I R N	Drug 6 S I R N	Drug 7	Drug 8 S I R N	Drug 9 S I R N
	Organism 1 (specify)	Drug 1 S I R N	Drug 2 S I R N	Drug 3 S I R N	Drug 4 S I R N	Drug 5 S I R N	Drug 6 S I R N	Drug 7	Drug 8 S I R N	Drug 9 S I R N

### **Drug Codes:**

AMK = amikacin	CEFTRX = ceftriaxone	ERYTH = erythromycin	MICA = micafungin	STREPHL = streptomycin – high level test
AMP = ampicillin	CEFUR= cefuroxime	FLUCO = fluconazole	MINO = minocycline	TETRA = tetracycline
AMPSUL = ampicillin/sulbactam	CETET= cefotetan	FLUCY = flucytosine	MOXI = moxifloxacin	TICLAV = ticarcillin/clavulanic acid
AMXCLV = amoxicillin/clavulanic acid	CHLOR= chloramphenicol	GENT = gentamicin	OX = oxacillin	TIG = tigecycline
ANID = anidulafungin	CIPRO = ciprofloxacin	GENTHL = gentamicin –high level test	PB = polymyxin B	TMZ = trimethoprim/sulfamethoxazole
AZT = aztreonam	CLIND = clindamycin	IMI = imipenem	PIP = piperacillin	TOBRA = tobramycin
CASPO = caspofungin	COL = colistin	ITRA = itraconazole	PIPTAZ = piperacillin/tazobactam	VANC = vancomycin
CEFAZ= cefazolin	DAPTO = daptomycin	LEVO = levofloxacin	QUIDAL = quinupristin/dalfopristin	VORI = voriconazole
CEFEP = cefepime	DORI = doripenem	LNZ = linezolid	RIF = rifampin	
CEFOT = cefotaxime	DOXY = doxycycline	MERO = meropenem		
CEFOX= cefoxitin	ERTA = ertapenem	METH = methicillin		
CEFTAZ = ceftazidime				

 $<sup>\</sup>frac{Result\ Codes}{S = Susceptible\ \ I = Intermediate\ \ R = Resistant\ \ NS = Non-susceptible\ \ S-DD = Susceptible-dose dependent\ \ N = Not\ tested$  § GENTHL and STREPHL results: S = Susceptible/Synergistic and R = Resistant/Not Synergistic



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Custom Fields	
Label	Label
<del></del>	
	·
A	
Comments	



### **Instructions for the Dialysis Event Form**

(CDC 57.109)

Complete a dialysis event form for IV antimicrobial starts; positive blood cultures; and onsets of pus, redness or increased swelling at vascular access sites, according to definitions and reporting instructions in the Dialysis Event Protocol.

\* = required field when reporting in-plan

Patient Data				
Data Fields	Instructions for Completion			
Facility ID #	NHSN-assigned facility ID will be auto-entered by the computer.			
Event ID #	Event ID# will be auto-entered by the computer.			
*Patient ID #	<b>Required</b> . Enter the alphanumeric patient ID number. This is the			
	patient identifier assigned by the healthcare facility and may consist			
	of any combination of numbers and/or letters.			
Social Security #	Optional. Enter the 9-digit numeric patient Social Security Number.			
Secondary ID #	Optional. Enter the alphanumeric ID number assigned by the			
	facility.			
Medicare #	Optional. Enter the patient's Medicare number.			
Patient Name	Optional. Enter last, first and middle name of the patient.			
*Gender	<b>Required</b> . Select "Female", "Male", or "Other" to indicate the gender			
	of the patient.			
*Date of Birth	<b>Required</b> . Enter the patient's date of birth using this format:			
	mm/dd/yyyy.			
Ethnicity (specify):	Optional. Specify whether patient is Hispanic or Latino.			
Race (specify)	Optional. Specify all of the following that identify the patient's race:			
	American Indian/Alaska Native; Asian; Black or African American;			
	Native Hawaiian/Other Pacific Islander; and White.			

General Event Information						
*Event Type	Required. Select "DE – Dialysis Event".					
*Date of Event	Required. Date depends on event type:					
	<ul> <li>For IV antimicrobial starts, enter the date the outpatient IV</li> </ul>					
	antimicrobial administration was started.					
	<ul> <li>For positive blood cultures, enter the date the blood</li> </ul>					
	specimen was collected.					
	<ul> <li>For pus, redness, or increased swelling at the vascular acc</li> </ul>					
	site, enter the onset date.					
	<ul> <li>If reporting more than one type of dialysis event, using the</li> </ul>					
	above criteria select the earliest event date.					
	Enter date of the event using this format: mm/dd/yyyy.					
*Location	<b>Required</b> . Enter the location code of the "outpatient hemodialysis					
	clinic" that is collecting Dialysis Event information.					

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General Event Information (continued)		
Was the patient	Optional. Select 'yes' if the dialysis event occurred on the same	
admitted/readmitted to	date the patient was admitted or readmitted to your facility. (e.g.,	
the dialysis facility on this	following a hospitalization).	
dialysis event date?		

Risk Factors			
Data Fields	Instructions for Completion		
*Vascular accesses	<b>Required</b> . Select all vascular accesses that the patient had present at the time of the dialysis event. Include all central		
	vascular accesses, not only those being used for dialysis.		
Fistula	Indicate if the patient has a surgically created connection between an artery and a vein for hemodialysis.		
Buttonhole	Conditionally required for patients with fistulas. Select "yes" if the patient's fistula is regularly accessed via buttonhole cannulation technique where a blunt needed (cannula) is inserted into the fistula at the same location each time using an established track.  Select "no" if the patient's fistula is regularly accessed by rope ladder method.		
Graft	Indicate if the patient has a surgically created connection between an artery and a vein created with implanted material (often synthetic tubing) for hemodialysis.		
Tunneled central line			
Nontunneled central line	Indicate if the patient has 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.		
Other access device	Indicate if the patient has a hybrid access device (e.g., HeRO®), port, or any other vascular access device not meeting definitions for fistula, graft, tunneled central line, or nontunneled central line. 16		
Is this a catheter-graft hybrid?			
*Access Placement Date	<b>Required</b> . For each access type present, indicate the date (mm/yyyy) the access was placed or check the box if placement date is unknown. If the patient has more than one access of the same type (e.g., two grafts), indicate the access placement date of the access in use, or most recently in use, at the time of the event.		

 $<sup>^{16}</sup>$  Use of trade names and commercial sources is for identification only and does not imply endorsement.

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Risk Factors (continued)		
Vascular access comment	Optional. Use this field to add any additional information about	
	the patient's vascular access(es) that would help you to interpret	
	your surveillance data, such as recent surgical revisions, etc. CDC	
	typically does not analyze these data.	

Other Patient Information		
*Transient Patient	<b>Required.</b> Select "Yes" if this patient was temporarily admitted	
	for treatment at your facility for a short time (fewer than 30 days	
	or 13 treatments) due to vacation, emergency, or other short-	
	term displacement.	
	Select "No" if this patient is part of your regular patient census.	

Event Details			
Data Fields	Instructions for Completion		
Specify Dialysis Event	Required. Select all that apply:		
IV antimicrobial start	Report <b>all</b> occurrences where intravenous (IV) antibiotics or antifungals are 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. Report all IV antibiotic administrations, not just vancomycin. Do <b>not</b> report IV antiviral starts. Report outpatient starts that are continuations of inpatient treatment.  21 day rule: There must be 21 or more days from the <b>end</b> of the first IV antimicrobial course that was started in an outpatient setting to the <b>beginning</b> of a second IV antimicrobial start in an outpatient setting for two starts to be reported as 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 and therefore, not reported. For outpatient IV antimicrobial starts that are continuations of inpatient treatment, consider the start day to be the first day of outpatient administration.		
Was vancomycin the antimicrobial used for this start?	Conditionally required for IV antimicrobial start dialysis events. Indicate whether IV vancomycin was started by selecting "Yes" or "No."		

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Event Details (continued)		
Positive blood culture	Report <b>all</b> positive blood cultures from specimens collected as an outpatient or collected within one 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.	
	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(s) 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 first report.	
Specify pathogen and antimicrobial susceptibilities	Conditionally required for a positive blood culture. See the following section for additional instructions.	

Pathogens and Antimicrobial Susceptibilities		
Data Fields	Instructions for Completion	
Pathogen # for gram- positive organisms, gram- negative organisms, and for fungal organisms	Enter pathogens 1 through 3 depending on the number of microorganisms identified in the positive blood culture: no specific order of microorganisms is required for dialysis event positive blood cultures.	
	If the species is not indicated on the lab report or is not listed in the NHSN pathogen dropdown list, then select the "spp" choice for the genus (e.g., <i>Bacillus natto</i> is not on the list so it would be reported as <i>Bacillus</i> spp.).	
Antimicrobial agent and susceptibility results	<ul> <li>Conditionally required if ≥1 pathogen is identified.</li> <li>For organisms shown on the back of the event form, susceptibility results are required only for the antimicrobial agents listed.</li> <li>For organisms that are not listed on the back of an event form, susceptibility result are optional.</li> <li>Users have the option to report additional antimicrobials and susceptibility results, up to a maximum of 20 antimicrobials per microorganism.</li> </ul>	

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Pathogens and Antimicrobial Susceptibilities (continued)

Antimicrobial agent and susceptibility results (continued)

Circle the microorganism's susceptibility result for each antimicrobial agent.

Susceptibility codes include:

S – Susceptible I – Intermediate R – Resistant

N – Not Tested NS- Non-susceptible

S-DD- Susceptible-dose dependent

For gentamicin and streptomycin high level tests only, use:

S – Susceptible/Synergistic R – Resistant/Not Synergistic

See antimicrobial drug codes and definitions below.

#### **Antimicrobial Drug Code Table**

AMK = amikacin GENT = gentamicin

AMP = ampicillin GENTHL = gentamicin – high level test

AMPSUL = ampicillin/sulbactam IMI = imipenem AMXCLV = amoxicillin/clavulanic acid ITRA = itraconazole ANID = anidulafungin LEVO = levofloxacin AZT = aztreonam LNZ = linezolid CASPO = caspofungin MERO = meropenem CEFAZ= cefazolin METH = methicillin CEFEP = cefepime MICA = micafungin CEFOT = cefotaxime MINO = minocycline

CEFOX= cefoxitin

CEFTAZ = ceftazidime

CEFTRX = ceftriaxone

CEFUR= cefuroxime

MOXI = moxifloxacin

OX = oxacillin

PB = polymyxin B

PIP = piperacillin

CETET= cefotetan PIPTAZ = piperacillin/tazobactam CHLOR= chloramphenicol QUIDAL = quinupristin/dalfopristin

CIPRO = ciprofloxacin RIF = rifampin

CLIND = clindamycin STREPHL = streptomycin – high level test

COL = colistin TETRA = tetracycline

DAPTO = daptomycin TICLAV = ticarcillin/clavulanic acid

DORI = doripenem TIG = tigecycline

DOXY = doxycycline TMZ = trimethoprim/sulfamethoxazole

ERTA = ertapenem TOBRA = tobramycin ERYTH = erythromycin VANC = vancomycin FLUCO = fluconazole VORI = voriconazole

FLUCY = flucytosine

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#### **Event Details (continued)**

# Suspected source of positive blood culture

Conditionally required for positive blood culture dialysis events. Select one suspected source of the positive blood culture:

- <u>Vascular access</u>: 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 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.
- <u>Contamination</u>: 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 blood culture. Examples of some common commensal include: diphtheroids [Corynebacterium spp., not C. diphtheriae], Bacillus [not B. anthracis] spp., Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridians group streptococci, Aerococcus spp., Micrococcus spp.
- <u>Uncertain</u>: Choose "Uncertain" only if there is insufficient evidence to decide among the three previous 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.

21 day rule: There must be 21 or more days between the **onset** of a first 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.

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	Event Details (continued)	
Check the access site(s)	Conditionally required if there is pus, redness, or increased	
with pus, redness, or	swelling at the vascular access site. Select vascular access site(s)	
increased swelling:	with these findings.	
*Specify Problem(s)	<b>Required.</b> Indicate which problems are present.	
Fever	Select if fever ≥37.8°C (100°F) oral is present.	
Chills or rigors	Select if chills or rigors are present.	
Drop in Blood Pressure	Select if abnormal drop in blood pressure is present.	
Wound (NOT related to	Select if a wound that is unrelated to the vascular access site has	
vascular access) with pus or increased redness	pus or increased redness is present.	
Cellulitis	Select if cellulitis is present at a site other than the vascular	
	access and without open wound.	
Pneumonia or respiratory	Select if pneumonia or respiratory infection is present.	
infection		
Other Problem	Select if other problem related to the IV antimicrobial start;	
	positive blood culture; and/or pus, redness, or increased swelling	
	at vascular access site is present. Specify the problem.	
None	Select "none" if there are no problems.	
*Outcome(s)	Required.	
Hospitalization	Select "Yes" if the patient was hospitalized related to the event(s)	
	or problem(s). Check "No" if patient was not hospitalized. Select	
	"Unknown" if uncertain about whether or not the patient was	
	hospitalized.	
Death	Select "Yes" if the patient died related to the event(s) or	
	problem(s).	
	Select "No" if patient did not die. Check "Unknown" if uncertain	
	about whether or not the patient died.	

Custom Fields		
Custom fields	Optional. Up to 50 alphanumeric, numeric, and/or date fields	
	may added to this form for local use.	
	<b>NOTE:</b> Each custom field must be added in advance. Within	
	NHSN, select "Facility," then "Customize Forms," and then follow	
	on-screen instructions. The Form Type is "CDC-Defined – PS –	
	Event" and form is "DE – Dialysis Event."	

Comments		
Comments	Optional. Use this field to add any additional information about the dialysis event that would help you to interpret your	
	surveillance data. CDC typically does not analyze these data.	

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## **Custom Data Collection Forms and Fields**

Some NHSN participating facilities may be interested in expanding their data collection to support their quality improvement activities. These facilities have the option to create custom data collection forms or add custom data collection fields to existing NHSN forms. Users must have administrator rights to create custom forms or add custom fields.

Customized data collection forms and fields can be useful tools for prevention initiatives. If more than one facility is collecting the same information for group analysis, consider collecting and reporting custom data in the same manner to facilitate data analysis. If you are leading a prevention initiative and have questions about custom forms or fields, contact the NHSN Helpdesk.

## Custom Patient Safety Event Form Create a New Data Collection Form in the Patient Safety (PS) Component

To create a custom event form:

- 1. From the NHSN navigation bar, select "Facility" and then "Customize Forms"
- 2. Select Form Type "Custom PS Event"
- 3. Follow on-screen instructions

By default a custom patient safety event form includes the following optional fields:

o Date of Event

o Post-procedure (yes/no)

o Location

Date Admitted to Facility (mm/dd/yyyy)

Secondary Bloodstream Infection (yes/no)

Died (yes/no)

- o Discharge Date (mm/dd/yyyy)
- o Pathogens identified (yes/no)
- o Pathogens (up to three pathogens, includes antimicrobial resistance information)

#### **Custom Fields**

#### **Create New Data Collection Fields on Existing Dialysis Event Forms**

Up to 50 custom fields can be added to each customizable form. There are three types of fields:

- o Alphanumeric (maximum 15 characters)
- o Numeric (maximum 11 digits)
- Date (mm/dd/yyyy)

To add custom fields to dialysis forms:

- 1. From the NHSN navigation bar, select "Facility" and then "Customize Forms"
- 2. Follow on-screen instructions

Form	Dialysis Event	Denominators for Outpatient Dialysis
Form Type	CDC-Defined - PS - Event	CDC-defined – PS – Summary Data
Form	DE – Dialysis Event	DIAL – Outpatient Dialysis Census Form

#### **Deleting/Inactivating Custom Fields**

Once created, custom fields may be deleted only if data have never been entered. Otherwise, the field status can be set to "Inactive": the field will continue to be visible on the form, but will no longer be available for use.

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#### **Creating Reports with Custom Fields**

To run a report with custom fields, open the "Advanced" output options folder and select "Create New Custom Option" (shown below). On the "Create Custom Output" screen, select the desired data set (e.g., "Events" or "Noninfections") from the dropdown menu (shown below). For output type, select "Line Listing". For a reference list of the labels given to custom fields, run a line listing for the "PSCustomLabels" data set.

Many data sets include variables that are not applicable to Dialysis Event surveillance, but they can be excluded from the report using the "Modify Variables To Display" option at the bottom of the modify screen. See the Analysis & Reports section, page 46 of this manual, for more details on running reports.



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# **Reporting Methods**

All data are collected according to the NHSN Dialysis Event Protocol; therefore, the meaning of the data should be the same, regardless of which reporting method is employed.

There are three modes for reporting numerator and denominator data to NHSN:

- Manual data entry: an NHSN user accesses <a href="https://sdn.cdc.gov">https://sdn.cdc.gov</a> and logs into the Secure Data Network (SDN) and selects "NHSN Reporting" to select the facility of interest. Data are then manually typed into the NHSN web interface for that individual facility.
- Manual CDA import: an NHSN user accesses <a href="https://sdn.cdc.gov">https://sdn.cdc.gov</a> and logs into the Secure Data Network (SDN) and selects "NHSN Reporting" to select the facility of interest. The NHSN Import/Export option is used to import a zip file containing one or more NHSN reports in CDA file format for that individual facility.
- **Batch CDA submission** using NwHIN Direct (a.k.a. automated send): an NHSN user accesses NwHIN Direct (an intermediate transmission mechanism) to send a zip file containing one or more NHSN reports in CDA file format for one or more facilities. *This option is currently under development and is anticipated to be available in August 2013.*

NHSN enrollment, set-up (e.g., adding a reporting location and monthly reporting plans), and the Outpatient Dialysis Center Practices Surveys are completed manually for all modes of reporting.

#### Clinical Document Architecture (CDA)

CDA is a document markup standard that specifies the structure and semantics of a clinical document (such as a discharge summary or progress note) for the purpose of information exchange. For the purposes of NHSN specifically, CDA is a file format that allows a facility's data to be imported electronically into NHSN. The data in the file must include all NHSN required elements for the particular report forms.

To create valid CDA files, facilities work with a CDA implementer to develop software that extracts NHSN data from the facility's available electronic sources of medical information (e.g., electronic medical record software, laboratory information, and admission, discharge, and transfer data) and organizes the data into a valid CDA file. To report, the CDA files are created, zipped, and then imported into NHSN.

A facility-based NHSN user is expected to review the data in NHSN on an ongoing basis to verify that data reported via CDA are complete, accurate, and representative of what should be reported if data were entered manually.

#### **CDA Data Validation**

CDC expects facilities using CDA file submission to collect dialysis event data manually and compare it to CDA data for a minimum of three months to verify the data. This recommended timeframe should be extended in facilities that experience a low frequency of dialysis events. If discrepancies

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are identified, work with the CDA implementer to ensure all data are being correctly captured as described by the CDA Implementation Guide (IG) and the Dialysis Event Protocol. If it is determined that incorrect data have been reported to NHSN, add, edit, and delete records in NHSN as necessary to make corrections.

#### Reporting for the CMS ESRD QIP NHSN Dialysis Event Reporting Measure

The Centers for Medicare and Medicaid Services (CMS) End Stage Renal Disease (ESRD) Quality Incentive Program (QIP) NHSN Dialysis Event reporting measure requirements can be met with any of the methods of reporting, including submitting data to NHSN via CDA. However, CDC recommends at least one staff member at the facility be trained in and knowledgeable of how to report dialysis event data to the NHSN, and have access to NHSN, regardless of the method of data submission used. A complete understanding of the NHSN Dialysis Event Protocol is a prerequisite for the facilities participating in NHSN and this prerequisite must be met by at least one facility staff member.

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# **Analysis & Reports**

Monthly review of NHSN data is recommended to ensure all data have been reported and are accurate. Review of quarterly data is recommended to help detect problems in your facility, provide feedback to your staff, and engage staff in quality improvement.

With NHSN analysis, dialysis facilities can:

- Calculate risk-stratified dialysis event rates (e.g., vascular access infections)
- Benchmark against all NHSN facilities reporting dialysis events
- Use a variety of reports to inform quality improvement decisions

#### **Components of a Rate**

Stratified by access type, rates are calculated by dividing the number of dialysis events by the estimated number of patients who were at risk for a dialysis event during each month, multiplied by 100 to determine the rate of infection per 100 patient-months. Typically rates are stratified by vascular access type so that differences can be easily identified.

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

To calculate rates for a period of time that exceeds one month, the monthly numerators are pooled (summed) and divided by the pooled monthly denominators, and multiplied by 100.

#### **Comparison statistics**

NHSN rate tables and run charts provide aggregate rates combined from all facilities reporting according to the Dialysis Event Protocol. These aggregate rates can be used as a comparison for facilities. In addition to the aggregate rate, comparison statistics are provided (when possible) to indicate the statistical significance of any potential difference between facility and aggregate data.

These comparison statistics include:

- **p-value**: a p-value is a measure of statistical significance that indicates the probability that any difference between the facility's rates and NHSN aggregated rates is due only to chance.
  - Typically, a p-value of <0.05 is considered a statistically significant difference. A p-value of <0.05 means that there is a greater than a 95% chance that the two rates being compared are truly different from each other.</li>
- **Percentile**: is a value that indicates where the facility's rate ranks within the distribution of all NHSN facility-specific rates.
  - o The 50<sup>th</sup> percentile, also known as the median, indicates average performance: half of facilities have lower rates and half of facilities have higher rates.
  - o The lower the percentile, the better the facility is performing relative to others in NHSN. For example, a rate in the  $10^{th}$  percentile indicates that the facility's rate is lower than (= better than) 90% of other facilities that reported data to NHSN.

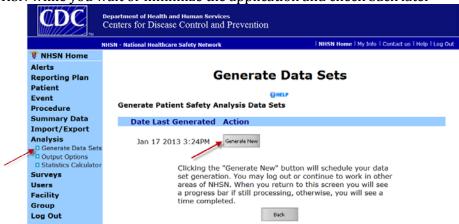
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### **How to Create an NHSN Report ("Output Option")**

From the NHSN navigation bar, select "Analysis"

- 1. Generate new data sets
  - Generating data sets captures all of your facility's NHSN data so that reports will be created using complete, <u>up-to-date</u> information
  - Each user has their own analysis data sets
  - Data sets may take several minutes to generate, but you can work elsewhere in NHSN while you wait or minimize the application and check back later



- 2. Select the report ("output option") from the list of templates
  - Most dialysis reports are located in the 'Device-Associated Module' folder > 'Dialysis Events' folder > 'CDC Defined Output' folder
  - Some dialysis reports are located in the 'Advanced' folder
  - Modify the report, if desired
- 3. Press "Run" button across from the report to create that report
  - Report will open in a new window, so allow pop-ups from \*.cdc.gov



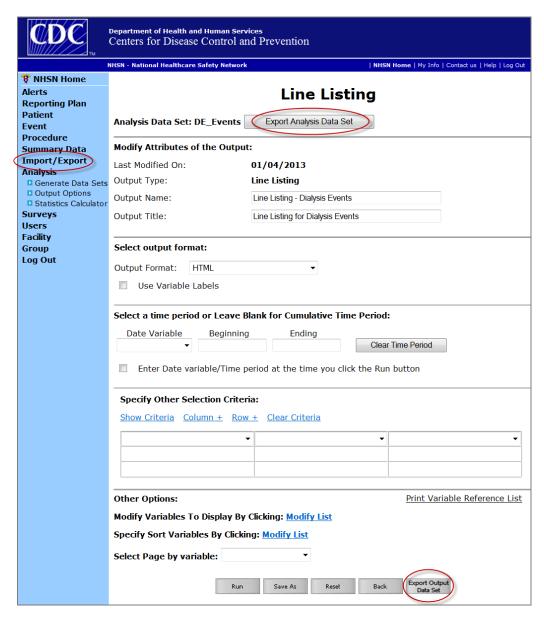
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Users are encouraged to experiment with the analysis function. NHSN data are not affected by creating reports, so users can explore the analysis function without risk to reported data.

#### Other Report Options (Data Export)

Data can also be exported from NHSN into preferred software (e.g., Excel, SAS). A facility's data can be exported using the "Import/Export" option on the navigation bar. Both groups and facilities can export specific data sets from a modify screen in analysis. The "Export Analysis Data Set" button at the top of the screen exports the data set as defined by NHSN, whereas the "Export Output Data Set" at the bottom of the screen includes any modifications.



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Template Reports ("Output Options")
Location: Device Associated Module, under Dialysis Events > CDC Defined Output

Report Type	Report Name	Report Description
Line Listing	Dialysis Events	Each row indicates by event characteristics including patient's vascular access type(s), dialysis event type(s), and outcomes.
Line Listing	Dialysis Events (detailed)	In addition to the above, each row indicates by event characteristics including if patient is transient; the location of pus, redness, or swelling; and problems associated with the event.
Frequency Table	Dialysis Events	Indicates the count and percent of access- related bloodstream infection (ARB) and local access site infection (LASI), per calendar quarter.
Bar Chart	Death as Outcome by Event	Indicates the count and percent of death reported as the outcome of a dialysis event by access-related bloodstream infection or local access site infection.
Bar Chart	Death as Outcome by Access	Indicates the counts and percent of death reported as the outcome of a dialysis event by type of vascular access.
Bar Chart	% Hospitalized by Event	Indicates the count and percent of hospitalizations reported as the outcome of a dialysis event by access-related bloodstream infection or local access site infection.
Bar Chart	% Hospitalized by Access	Indicates the counts and percent of hospitalizations reported as the outcome of a dialysis event by type of vascular access.
Pie Chart	LASI Affected Vascular Access	Indicates the count and percent of local access site infections that are attributed to each type of vascular access among reported local access site infections.
Frequency Table	LASI Vascular Access	Indicates the count and percent of local access site infection (LASI) by access type, per calendar quarter.
Line Listing	Dialysis Blood Culture Pathogens	Each row indicates for each positive blood culture, the suspected source, the microorganism(s) identified, and the outcomes.
Line Listing	Dialysis Blood Culture Antibiogram	Each row indicates for each positive blood culture, the patient's vascular access type, the organism(s) identified, and antimicrobial susceptibility information.

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(Continued)
Location: Device Associated Module, under Dialysis Events > CDC Defined Output

Report Type	Report Name	Report Description
Line Listing	All DE Denominators	Each row summarizes the month's number of maintenance hemodialysis outpatients by vascular access type.
Line Listing	All DE Numerators	Each row summarizes the month's number of dialysis events by type.
Rate Table	IV Antimicrobial Start Data	Each row provides the facility rate of IV antimicrobial starts by vascular access type per calendar quarter. Includes NHSN aggregate data (in yellow) for comparison.
Run Chart	IV Antimicrobial Start Data	Each graph charts the facility rate of IV antimicrobial starts per calendar quarter, separated by vascular access type.
Rate Table	IV Vancomycin Start Data	Each row provides the facility rate of IV vancomycin starts by vascular access type per calendar quarter. Includes NHSN aggregated data (in yellow) for comparison.
Run Chart	IV Vancomycin Start Data	Each graph charts the facility rate of IV vancomycin starts per calendar quarter, separated by vascular access type.
Rate Table	Local Access Site Infection	Each row provides the facility rate of local access site infection (LASI) by vascular access type per calendar quarter. NHSN aggregate data are not yet available for this dialysis event.
Run Chart	Local Access Site Infection	Each graph charts the facility rate of local access site infection (LASI) per calendar quarter, separated by vascular access type.
Rate Table	Positive Blood Culture Data	Each row provides the facility rate of positive blood culture (bloodstream infection) by vascular access type per calendar quarter. Includes NHSN aggregate data (in yellow) for comparison.
Run Chart	Positive Blood Culture Data	Each graph charts the facility rate of positive blood cultures per calendar quarter, separated by vascular access type.

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(Continued)
Location: Device Associated Module, under Dialysis Events > CDC Defined Output

	Location: Device Associated Module, under Dialysis Events > CDC Defined Output				
Report Type	Report Name	Report Description			
Rate Table	Access Related Bloodstream Infection	Each row provides the facility rate of access related bloodstream infection (ARB) by vascular access type per calendar quarter. Includes NHSN aggregate data (in yellow) for comparison.			
Run Chart	Access Related Bloodstream Infection	Each graph charts the facility rate of access related bloodstream infection (ARB) per calendar quarter, separated by vascular access type.			
Rate Table	Vascular Access Infection	Each row provides the facility rate of vascular access infection (VAI) by vascular access type per calendar quarter. NHSN aggregate data are not yet available for this dialysis event.			
Run Chart	Vascular Access Infection	Each graph charts the facility rate of vascular access infection (VAI) per calendar quarter, separated by vascular access type.			
Rate Table	Hosp Incident Data (old)	Applicable only to data reported prior to June 2011. Each row provides the facility rate of hospitalization dialysis events by vascular access type per calendar quarter. Includes old NHSN aggregate data (in yellow) for comparison.			
Run Chart	Hosp Incident Data (old)	Applicable only to data reported prior to June 2011. Each graph charts the facility rate of hospitalization dialysis events per calendar quarter, separated by vascular access type.			
Rate Table	Local Access infection (old)	Applicable only to data reported prior to June 2011. Each row provides the facility rate of local access infection per calendar quarter, separated by vascular access type. Includes old NHSN aggregate data (in yellow) for comparison.			
Run Chart	Local Access infection (old)	Applicable only to data reported prior to June 2011. Each graph charts the facility rate of local access infection per calendar quarter, separated by vascular access type.			

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## (Continued)

Location: Device Associated Module, under Dialysis Events > CDC Defined Output

Location: Device hissociated module, ander Dialysis Livents - CDC Defined output		
Report Type	Report Name	Report Description
Rate Table	Vascular Access Infection (old)	Applicable only to data reported prior to June 2011. Each row provides the facility rate of vascular access infection by vascular access type per calendar quarter. Includes old NHSN aggregate data (in yellow) for comparison.
Run Chart	Vascular Access Infection (old)	Applicable only to data reported prior to June 2011. Each graph charts the facility rate of vascular access infection per calendar quarter, separated by vascular access type.

Location: Advanced, under CMS Reports > CDC Defined Output

Report Type	Report Name	Report Description	
Line Listing	CMS ESRD QIP Rule	Each row indicates (yes/no) whether	
		minimum monthly Dialysis Event reporting	
		requirements have been met for the	
		Centers for Medicare and Medicaid	
		Services (CMS) End Stage Renal Disease	
		(ESRD) Quality Incentive Program (QIP)	
		NHSN Dialysis Event reporting measure.	

Location: Advanced, under Facility Level Data > CDC Defined Output

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Report Type	Report Name	Report Description
Line Listing	Dialysis Survey	Each row provides the responses to all
		questions on the Outpatient Dialysis Center
		Practices Survey. Each row summarizes a
		separate survey year.

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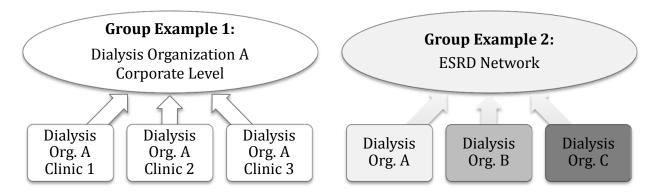


# **Groups for Data Sharing**

NHSN data can be shared through the Group function. Any entity can maintain a group in NHSN, such as state health departments, corporate dialysis chains, and ESRD Networks.

A facility will be invited to join the group, at which time the facility chooses whether or not to join the group and share pre-specified data. Facilities within a group do not have access to each others' data; only the group-level users can access the data as described in the data sharing agreement.

Facilities can join multiple groups and can have different data sharing agreements for each group. In dialysis, two common group types include:



Affiliated facilities (e.g., satellite clinics) share data with their overarching organization

Unaffiliated facilities share data for a specific purpose, such as quality improvement or mandated reporting

#### **Defining/Conferring Rights**

Each group sets-up a "Define Rights" template to specify which data they are requesting facilities to share. Upon joining a group, the facility reviews the data sharing template and then either "Confers Rights" to share those data or leaves the group. The decision to confer rights to a group is a decision made by a NHSN Facility Administrator. Existence of a group in NHSN should not be construed as a recommendation from CDC to join the group. Groups requesting facility data have the ability to export the data and therefore should have appropriate means of securing the data. CDC cannot be held accountable for how group users use data granted to the group by a facility once it is exported out of NHSN.

If a group changes which data they want the facility to share, the group will modify their data sharing template and facilities are notified upon logging into NHSN. The group cannot access data that the facility has not actively shared: the facility must actively agree to any change to the data sharing agreement by selecting the "Accept" button on the Confer Rights screen. If the facility does not agree to share the data requested by the group, they should not "Accept." They can instead contact the group to discuss their concerns or refuse to share the data and leave the group.

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# **Key Terms**

#### General NHSN Terms

- **21 day rule:** A rule used in dialysis event reporting to determine if an IV antimicrobial start; positive blood culture; or pus, redness and increased swelling at a vascular access site should be reported. There must be 21 or more days between dialysis events of the same type to report a second event. Refer to the Dialysis Event Protocol for details of how the rule is applied.
- **Buttonhole cannulation:** A technique for accessing a patient's fistula in which a blunt needle (cannula) is inserted into the fistula at the same location each time using an established track.
- **Challenge phrase:** A password for the Secure Data Network (SDN), which is used in combination with a digital certificate installed on the user's computer to access NHSN.
- **Denominator**: The estimated number of patients at risk of a dialysis event in a defined amount of time.
- **Device-Associated Module:** NHSN is divided into Components, and each Component is divided into Modules of similar types of surveillance. Dialysis Event surveillance is categorized in the Patient Safety Component and under the Device-Associated Module, which also includes surveillance for central-line associated bloodstream infection (CLABSI), ventilator-associated pneumonia (VAP), catheter-associated urinary tract infections (CAUTI), and central line insertion practices (CLIP) (refer to their corresponding Protocols for additional information).
- **Dialysis event date:** The date the dialysis event occurred is determined based upon what is being reported. For IV antimicrobial starts, it is the date the first outpatient administration was started. For positive blood cultures, it is the date the blood specimen was collected. For pus, redness or increased swelling, it is the sign/symptom onset date. If more than one of these event types is reported on a single form, it is the earliest date among the event types reported.
- **Digital certificate:** A digital certificate is an electronic document that is installed on a user's computer to certify the user's identity and authorization to exchange information on the Secure Data Network, through which NHSN is accessed.
- **Group**: An organization that is not a healthcare facility (such as an ESRD Network, state health department, or a corporate dialysis chain) with access to NHSN for the purpose of accessing data from facilities. Within NHSN, the Group specifies which data they want facilities to share and then provides facilities with joining information. Upon joining the Group, facilities review and then choose whether to share those data. A facility that joins a Group does not have access to any data from other facilities in the Group.

**Numerator:** The total number of dialysis events in a defined amount of time.

**Patient-months**: The unit of measure for the dialysis denominator (patient census information), where one patient-month means one patient was at risk of a dialysis event for the duration of one month. Each patient counted on the Denominators for Outpatient Dialysis form corresponds to one patient-month. Dialysis event rates are expressed per 100 patient-months.

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- **Patient Safety Component:** NHSN surveillance is divided into four Components: Patient Safety, Healthcare Personnel Safety, Biovigilance, and Long Term Care. Dialysis Event surveillance is part of the Patient Safety Component.
- **Surveillance:** Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding health-related events for use in public health action to reduce morbidity and mortality and improve health.
- **Transient patient:** Patients who are temporarily admitted for treatment at a facility for a short time (fewer than 30 days or 13 treatments) due to vacation, emergency, or other short-term displacement.

### **Dialysis Event Infections**

**Access related bloodstream infection (ARB):** A positive blood culture with the suspected source reported as either the vascular access or uncertain.

**Bloodstream Infection (BSI):** Any positive blood culture.

**Local access site infection (LASI):** Pus, or greater than expected redness, or greater than expected swelling of a vascular access site and access-related bloodstream infection was not present.

**Vascular access infection (VAI):** Either local access site infection or access-related bloodstream infection.

#### Vascular Access Types

**Graft:** A surgically created connection between an artery and a vein created with implanted material (often synthetic tubing) for hemodialysis.

Fistula: A surgically created connection between an artery and a vein for hemodialysis.

- **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.
- **Other Access Device** Includes hybrid access devices (e.g., HeRO®<sup>17</sup>), ports, and any other vascular access devices not meeting definitions for fistula, graft, tunneled central lines or nontunneled central lines.

**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.

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<sup>&</sup>lt;sup>17</sup> Use of trade names and commercial sources is for identification only and does not imply endorsement.