NHSN Dialysis Event External Validation Toolkit

Version 3.1 – Updated February 2025. For review of 2023 data.

Table of Contents

Introduction

Purpose

The NHSN Dialysis Event External Validation Toolkit provides recommended approaches to investigate and enhance the accuracy and completeness of NHSN Dialysis Event data.

Organizations beginning validation activities are encouraged to use the methods and tools in this document, which are intended to promote a robust national standard for evaluation of dialysis event data. Those with existing validation programs are encouraged to review the toolkit and documents and consider incorporating any elements that may enhance their current approach.

Intended Audience

This document is designed for use by nurses, infection preventionists, or quality professionals at outpatient dialysis facilities that report to NHSN; state health department or end-stage renal disease (ESRD) network personnel who work with facilities to ensure high-quality, actionable surveillance data to enhance patient safety; and other groups seeking to enhance NHSN data quality for surveillance, reimbursement, quality improvement, research, or public reporting purposes.

Overview of Validation Activities

External validation of NHSN Dialysis Event Surveillance data is conducted by an agency outside the reporting facility, such as an ESRD Network or a state or local health department. This Toolkit recommends an evaluation process that is conducted by trained staff and uses the NHSN Dialysis Event Surveillance Protocol as the standard to make data evaluation determinations, with CDC input when necessary.

The data validation activities include a survey of the facility staff's surveillance knowledge and practices, and a review of medical records to assess concordance of facility reported data with validators' determinations of reportable NHSN data. These activities may be performed together or individually, depending on the scope and goals of your data quality validation project. All tools required to implement the evaluation project, as outlined in this document, are included in template form so they can be easily customized to your organization and specific project parameters.

Completeness and accuracy of dialysis events (numerator data) are assessed through either an on-site or remote review of patient and facility medical records and documents, and involves several key steps:

- Selection of facilities
- Selection of patient medical records within selected facilities

- Review and abstraction of data from patient and facility medical records
- Comparison of information reported to NHSN by the facility with information deemed reportable to NHSN during the medical record review

Upon completion of each facility's validation activities, the validating entity develops a summary report for the facility, which addresses recommendations for data correction, surveillance program improvements, and/or additional surveillance program support when appropriate.

Goals of NHSN Dialysis Event Validation

The goals are to:

Evaluate facility NHSN Dialysis Event surveillance practices:
- Assess staff understanding of the Dialysis Event Protocol
- Assess data collection and reporting methods
- Identify common barriers to complete and accurate data collection and reporting

Educate dialysis facility staff on NHSN Dialysis Event Surveillance:
- Improve staff understanding of the methods and definitions in the Dialysis Event Protocol
- Improve staff data collection and reporting practices
- Increase staff awareness of reporting resources

Assess and improve the quality of Dialysis Event data reported to NHSN:
- Identify under- and over-reported Dialysis Events and provide instructions for correcting those events in NHSN
- Identify systematic and recurrent errors that may require correction to data beyond the specific feedback provided
- Suggest strategies to improve facility data collection and reporting practices

Provide feedback to CDC to support continuous improvement of public resources in order to:
- Improve this Toolkit and the corresponding documents
- Develop optimal and standardized data evaluation methods
- Improve existing NHSN Dialysis Event surveillance and reporting resources, such as training materials, reporting instructions, and frequently asked questions (FAQs) to address common areas of confusion

Feedback to CDC

Widespread reporting of NHSN Dialysis Event data and validation of these data are both relatively new. This Toolkit is intended to serve as a starting point for ESRD Networks, state health departments, and other organizations planning to conduct data evaluation and data quality improvement projects with NHSN Dialysis Event data. This Toolkit provides a standardized method that can be widely used, and field-tested data collection instruments to implement the project. Feedback from persons conducting validation activities, both during and after the process, is essential to CDC's further development and optimization of this toolkit, the standardized methods, and data collection instruments. Your feedback and suggestions can be emailed directly to the NHSN Helpdesk at nhsn@cdc.gov, using the phrase "External Validation Dialysis Event" in the subject line to route to the Measure Development and Validation Unit (MDVU), or by signing into SAMS and submitting a ticket through the ServiceNow portal.

Appendix Documents and Descriptions

| Appendix	Name; brief description
1	a) **Facility Selection**: Instructions for generating a list of dialysis facilities reporting data to NHSN and a random sample selection. b) **Freeze Facility Data/Creating the Dialysis Event (DE) Line List**: Instructions for generating a facility's Dialysis Event Line List report from NHSN c) **Patient Medical Record Selection**: Instructions for selecting a targeted random sample, using the 5 patient lists from the facility and the DE Line List from NHSN d) **Random Number Assignment Methods**: Three methods for random number generation and assignment
2	**Letter Template – Introduction and Request to Participate:** Letter addressed to the facility manager to explain the NHSN Dialysis Event data validation project and solicit the facility's participation.
3	a) **Letter Template – Confirm On-Site Visit and Preparation**: Letter addressed to the facility manager confirming the date of the site visit, description of the site visit, and a request for specific lists of patient information that will be used to select patients' charts for review. b) **Letter Template – Confirm Remote Participation and Preparation**: Letter addressed to the facility manager confirming participation, method(s) of chart review, and a request for specific lists of patient information that will be used to select patients' charts for review.
4	**Letter Template – Post-Validation Activities Summary:** Letter addressed to the facility manager thanking him/her for participating, summary of data evaluation findings, instructions for data corrections (if necessary), and excerpts from the protocol to address issues identified (if necessary).
5	**Survey to Assess NHSN Dialysis Event Surveillance**: A multi-purpose survey of the facility's surveillance practices. This form collects information about the facility's surveillance methodology and understanding of the Dialysis Event Protocol and provides the interviewer with the information and opportunity to address questions and correct misunderstandings about NHSN Dialysis Event Surveillance requirements.
6	**Facility Validation Summary and Line Listings of NHSN Dialysis Event Reporting:** A summary report with line lists to provide to the facility during the debrief. Contains results of the validation efforts (including the number of charts reviewed per event type, the number of events correctly or incorrectly reported, etc.) as well as line lists of all events identified from the patients' charts with pertinent information for the facility to review.
7	**External Validation of Dialysis Event Summary Report:** A summary report to provide to CDC once validation activities are completed for your jurisdiction. Contains information related to number of facilities participating and total number of charts reviewed, refusal numbers and reasons, and methodology used.
8	**Medical Record Abstraction Template:** A standardized tool that structures the collection of Dialysis Event data from a patient's chart so it may be compared to NHSN Dialysis Event surveillance data that were reported.

Project Timeline and Flowchart

The duration of each step will depend upon the scope of your organization's validation project and the number of participating facilities. Refer to the table below for the suggested duration of these steps; several activities may occur concurrently. Consider your project's scope and available resources and use the right-hand column to create a timeline more specific to your project.

NHSN Dialysis Event Data Validation Project Timeline

Total estimated duration ~26 weeks	Project Duration
1) Preparation (estimated duration 4 weeks) ☐ Train project staff on NHSN Dialysis Event Surveillance ☐ Train project staff on use of the validation tools and resources ☐ Determine the validation time period (which months of NHSN data will be reviewed) ☐ Determine the number of facilities that will be included in the project, if different than the recommended facility sample size of 30 (Appendix 1a). ☐ Select facilities to be included in the validation ☐ Determine when chart reviews and other validation activities will occur	
2) Solicit Facility Participation (estimated duration 2 weeks) ☐ Download, or "freeze", reported dialysis event data as outlined in Appendix 1b for the validation time period selected. ☐ Send <u>Letter Template – Introduction and Request to Participate</u> (Appendix 2) to the Managers of the selected facilities ☐ Follow-up with Facility Managers to provide a brief description of the project ☐ Document facilities that decline to participate and reasons why; be able to provide this information to CDC upon project completion	
3) Schedule Site Visits/Validation Activities (estimated duration 4 weeks) ☐ If doing on-site chart reviews, schedule on-site visits and customize the letter template in Appendix 3a to Facility Managers to confirm the details of visit and request patient lists. ☐ If doing chart review remotely (not on-site at facility), plan and confirm method of chart access with Facility Managers, using the letter template in Appendix 3b. ☐ Use patient lists sent by the facility to determine which patient charts will be selected for review using the chart selection methodology in Appendix 1c ☐ Inform Facility Manager of patient charts to be reviewed, and ask for these patient charts to be available on the day of the site visit	
4) Prepare for Chart Reviews **a) On-Site Visit** (estimated duration 1 day) ☐ Maintain a secure list of the 40 sampled patient charts ☐ Maintain a secure list of the facility's "frozen" data (NHSN DE Line List) for reference	

☐ Have extra materials (e.g., calendar, pens, etc.) ready ☐ If abstracting directly into REDCap MRAT, have a laptop/device with internet access available to bring; bring device's charger; otherwise prepare multiple printed copies of MRAT (Appendix 8) for data collection ☐ Contact Facility Manager a few days before the site visit to confirm the date and time. Ensure that space and computer access is ready or the selected patient charts will be otherwise available, and staff will be available for survey administration and intermittent questions throughout day. **b) Remote Access** (estimated duration 1 week) ☐ Ensure pertinent staff have submitted any required paperwork to facility to gain electronic health record access, as applicable; or ensure staff have access to a secure fax or email to receive charts ☐ Maintain a secure list of the 40 sampled patient charts ☐ Maintain a secure list of the facility's "frozen" data (NHSN DE Line List) for reference	
5) Conduct Validation Activities (estimated 6-12 weeks) ☐ If on-site, conduct greetings and introductions and get settled into allotted space ☐ Administer Survey to Assess NHSN Dialysis Event Surveillance (Appendix 5) ☐ Conduct chart review/abstraction and enter data into REDCap medical record abstraction tool (MRAT) ☐ Conduct a facility debrief to discuss survey and chart review findings using the Dialysis Event Validation Summary in Appendix 6 or the corresponding SAS code located on the NHSN External Validation webpage under 'Statistical Tools'.	
6) Post Validation Activities: Facility follow-up and Data Summary and Dissemination (estimated duration 4 - 8 weeks) ☐ Customize the letter template in Appendix 4 to send to the facility manager to reiterate validation findings and items needing correction in NHSN ☐ Follow-up 4 weeks after validation activities completed to ensure identified errors were corrected in NHSN ☐ Export deidentified data and send to CDC, for instructions on sending data via REDCap, see the How to Guide located on the Validation webpage under "Training Materials". ☐ Complete the External Validation of Dialysis Event Summary Report (Appendix 7) to send to CDC ☐ Aggregate and summarize findings for all facilities that participated in the project ☐ Write a report, disseminate findings to key stakeholders	

Flowchart of Validation Activities

Read Dialysis Event EVT →	Ensure Validator expertise →	Select Facilities for Validation →	Download ("freeze") facility NHSN data

Select patient charts for review ←	Establish secure data transfer ←	Customize letter from Appendix 3 to confirm site visit and provide instructions on patient list preparation ←	Contact managers (Appendix 2) at each facility selected to introduce validation project and request participation

Inform facility manager of patient charts to be reviewed, and request their availability for site visit →	Conduct facility site visits (on site or remote) →	Abstract patient charts using MRATs and administer surveillance methods survey →	Conduct facility debrief using DE Validation Summary or CDC-provided SAS code

Write report and disseminate findings ←	Aggregate and summarize findings for all facilities that participated ←	Export de-identified data and complete External Validation of DE Summary Report and send to CDC ←	Follow up with facility by customizing post-visit letter in Appendix 4

Pre-Validation Activities

Ensure Project Staff Expertise

To effectively evaluate NHSN Dialysis Event Surveillance data, project staff should be very familiar with and understand the NHSN Dialysis Event Surveillance Protocol especially the event definitions and application of the 21-day rule, the Dialysis Event form, and the method for correctly completing the Denominators for Outpatient Dialysis form.

Data validation staff should complete the required NHSN Dialysis Event Protocol training, which includes reading the NHSN Dialysis Event Surveillance Protocol and completing the self-paced, computer-based NHSN Annual Dialysis Surveillance Training. Staff conducting data validation activities are also strongly encouraged to read the Frequently Asked Questions About Dialysis Event Reporting. Organizations may consider taking additional training on application of the protocol to challenging situations. Contact the NHSN Helpdesk at nhsn@cdc.gov to request additional case studies for review and other content designed to assist data evaluators, using subject line "External Validation Dialysis Event," or by signing into SAMS and submitting a ticket through the ServiceNow portal.

Data Review Time Period

Determine the data validation time period, which includes the months that NHSN Dialysis Event Surveillance data will be reviewed for this project. Note that some facilities do not report their data into NHSN until the CMS deadline, which is three months after the end of the quarter (e.g., October through December 2023 data are due by March 31, 2024). Therefore, it is necessary to ensure that the time period selected includes complete, up to date data with a sufficient number of dialysis events to be reviewed. It is also critical that the time period chosen be identical across all participating facilities. A period of no less than 6 consecutive months during the same calendar year is recommended. Note that because of the 21-day rule, access to patient information for the month preceding the review time period will be needed. For example, if the review period is July through December 2023, it will be necessary to review charts and records from June 2023. Sufficient time should be given at the end of the review period to ensure that facility data reported to NHSN is corrected and complete ahead of any reporting deadlines.

Selection of Facilities

Selection of dialysis facilities for participation can be done in various ways to meet different goals. It is typically not possible or necessary to visit every facility and review every patient record. This Toolkit primarily recommends the selection of 1) a random, representative sample of facilities or when a random sample is not feasible, 2) a convenience sample of facilities (e.g., a sample of volunteer facilities). To make the most of

available resources and project goals, organizations are encouraged to determine how many facilities can participate in the project and decide which of these two methods for facility selection is most appropriate for their specific jurisdiction.

Since all facilities should be accountable for accurate reporting of Dialysis Event data to NHSN, using a random sample to select facilities for participation is preferred and will provide representative data for the jurisdiction. See Appendix 1a for instructions on how to generate and select a random sample of facilities.

Once a facility has been selected and before requesting participation, follow the steps in Appendix 1b to generate the Dialysis Event Line List report and maintain a secure copy to "freeze" the facility's reported data for the validation timeframe. This list will also be used in the patient record selection process.

Solicit Facility Participation and Schedule Site Visits

Customize Letter Template – Introduction and Request to Participate (Appendix 2) to be specific to your organization and project parameters and send to Facility Managers of the facilities selected during sampling. A follow-up phone call to answer questions and address concerns is encouraged. As Facility Managers agree to participate in the data validation project, customize the letter templates in Appendix 3 to confirm on-site visits and preparation of patient lists (Appendix 3a) and/or to confirm the details of the remote participation and preparation of patient lists (Appendix 3b). Document facilities that decline participation and reasons why to include in the summary report for CDC (Appendix 7)

Selection of Patient Charts for Review

Establish a Mechanism for Secure Data Transfer between Facilities and Your Organization

To determine which patient charts will be reviewed, your organization will need to request specific patient lists from each participating facility, which will include protected health information (e.g., medical record numbers, patient names, etc.). Therefore, it is necessary for your organization to establish a mechanism for secure data transfer and determine how those data will be secured upon receipt.

Patient Chart Lists and Chart Selection

A sample size of 40 medical records per facility is recommended. The methodology provided for the selection of medical records in Appendix 1c produces a sampling frame designed to target records that may have events. This targeted sample includes randomly selecting 20 unique patient charts from the NHSN Dialysis Event Line List report (refer to Appendix 1b for steps on generating this report) and 20 unique patient charts

from five facility-provided patient lists. Each participating facility will need to provide these lists of patients. Appendix 3a (for on-site review) and Appendix 3b (for remote review) contain letter templates which can be customized as needed to request the five patient lists defined below.

1. All patients who had one or more in-center hemodialysis treatment(s) during the validation timeframe
2. All patients who received any intravenous antimicrobials in an outpatient setting during the validation timeframe
3. All patients who had any positive blood cultures during the validation timeframe, including those during hospitalizations.
4. All patients who had any pus, redness or swelling at the vascular access site during the validation timeframe.
5. All patients who were hospitalized for any reason during the validation timeframe

Confirmation of Site Visit

As applicable, a few days prior to an on-site visit, contact the Facility Manager to remind them of the upcoming site visit. Verify that the staff involved in NHSN data collection and reporting will be available to be interviewed, that requested patient charts will be available, and that any necessary arrangements for workspace and/or computer system access have been made.

Checklist for NHSN Dialysis Event Data Validation Site Visits

☐ Facility Manager's name and contact information
☐ Facility address and directions, if needed
☐ End Stage Renal Disease (ESRD) Network/state ID badge or other identification
☐ List of patient charts that will be reviewed
☐ Access to the NHSN Dialysis Event Protocol, either electronic or printed copies for each validator
☐ Survey to Assess NHSN Dialysis Event Surveillance (Appendix 5) for the interviewer and note-taker copies, if applicable/needed
☐ Internet access if planning on entering abstracted patient chart data directly into REDCap Medical Record Abstraction Tool (MRAT) or multiple copies of word-version MRAT (Appendix 8; at least one printed copy per patient chart to be reviewed)
☐ Other helpful supplies:
   • Calendar for each chart reviewer
   • Straight edge (e.g., a ruler) for reading data printouts
   • Stapler/binder clips
   • Pens/highlighters
   • Sticky notes/tape flags

Conducting Validation Activities

Chart Reviews and Site Visits

Upon arrival at the facility, following introductions, validators should reiterate the project goals, stressing the educational nature of the validation activities. Reporting staff may be worried that an unfavorable evaluation may lead to sanctions by their supervisors which may bias answers to survey questions. Every effort should be made to make participating staff feel comfortable providing honest feedback.

Validators can choose to begin by administering the Survey to Assess NHSN Dialysis Event Surveillance (Appendix 5) or by initiating the patient chart review process. If multiple evaluators are present, these activities can occur concurrently.

Administration of the Dialysis Event Surveillance Practices Survey

Identify staff involved in NHSN data collection/reporting and administer the Survey to Assess NHSN Dialysis Event Surveillance (Appendix 5). If conducting an on-site visit, schedule time to administer the survey prior to departure. If time is limited, on-site or virtually, consider having the facility complete the survey independently before meeting and then reviewing together during the visit. If doing chart reviews virtually, schedule a convenient time to meet with the facility staff virtually. The survey is dual purposed to assess understanding of the NHSN Dialysis Event Protocol and the facility's data collection and reporting methods, as well as provide education to improve data quality going forward. **This educational feedback is an essential component of the validation project** and is the most valuable element to the participating facility.

During survey administration, record staff answers to all questions. The recorded answers will be used for educational discussions with facility staff during the Facility Debrief at the end of the visit. These discussions will review incorrect survey answers and reporting errors discovered during chart reviews and serve as learning opportunities for facility staff and validators. The discussions will also provide insight into areas where additional training may be beneficial.

Patient Chart Review Process

The patient charts to be reviewed should be specified prior to any on-site visits to ensure all records are available for review on the date of the site visit. Coordinate with the facility to gain access to the requested patient charts, electronic medical records, and any other data sources needed (e.g. outside laboratory reports, hospitalization records, etc.).

Patient charts should be reviewed to identify Dialysis Events using the REDCap Medical Record Abstraction Tool (MRAT) instrument (for printable version, see Appendix 8) to collect the essential data. Look carefully for

systematic reporting errors or misconceptions that could impact reporting beyond the medical records that are reviewed. An example of a systematic error would be the consistent measurement of 21 days between resolution of first set of symptoms to onset of next set of symptoms rather than measuring between onsets of first and next set of symptoms. If systematic errors are made, the facility should be asked to review and correct all numerators or denominators, not just those reviewed by validators. These errors should be re-assessed during the next review to assess improvement. Document all reporting errors that were identified.

Concordance Check

A concordance check is built into the MRAT. At the end of each chart review, the reviewer will compare the validated chart data entered into the MRAT to the facility's frozen data (i.e. the DE Line List report generated from NHSN prior to contacting the facility for participation). If any findings are discordant, determine the reason for discordance. Use the NHSN Dialysis Event Protocol as the gold standard for making determinations of what is reportable. For difficult cases, seek additional input from CDC by nhsn@cdc.gov, using subject line "Dialysis Event Adjudication," or by signing into SAMS and submitting a ticket through the ServiceNow portal.

Once all selected patient charts have been reviewed, briefly summarize the findings, with a focus on any common or repetitive errors. See Appendix 6 for a report template summarizing the dialysis event data entered into the REDCap MRAT, or the corresponding SAS code located on the NHSN External Validation webpage under 'Statistical Tools'.

Facility Debrief

Debrief the Facility Manager and any staff involved in NHSN reporting of the findings from the chart review and survey administration, using the report template in Appendix 6 or the corresponding SAS code, located on the NHSN External Validation webpage under 'Statistical Tools'. This provides an opportunity to discuss your findings in general terms, address any outstanding questions, commend staff for excellent processes and/or progress, and suggest improvements. It may also be necessary to develop a process improvement plan if serious deficiencies are found. Leave a copy of expected changes to NHSN data with the Facility Manager and mutually agree upon a deadline for changes to be made. Thank the Facility Manager and staff for their participation.

Post-Validation Activities

Facility Follow-up

Compile your evaluation findings using Letter Template – Post-Validation Activities Summary (Appendix 4), and send the findings to the Facility Manager, thanking them and documenting results, necessary

corrections, and recommendations. When appropriate, identify systematic strengths as well as problems with surveillance, data collection, and reporting, and potential underlying reasons. Identify resource and support issues that should be addressed.

If you have instructed the facility to modify data in NHSN or re-review information due to systematic errors, follow-up with the facility in 2-4 weeks to ensure corrections were made by the agreed upon deadline.

Aggregate, Summarize and Disseminate Findings

Following the completion of all facility site visits, medical chart reviews, and entering of data into the REDCap MRAT instrument, deidentified data should be exported out of REDCap and sent to CDC. See the How To Guide for step-by-step instructions for exporting and sending deidentified data. Contact NHSN Helpdesk at nhsn@cdc.gov using subject line "External Validation Dialysis Event" if you would like to discuss how to aggregate and summarize your data or write up your findings, or by signing into SAMS and submitting a ticket through the ServiceNow portal. Identify opportunities to share your findings with key stakeholders; this should include CDC and all participating facilities.

Data collected through the course of the validation project will be used to inform future CDC data quality improvement efforts, including the development of:

- Trainings to address common reporting errors
- Frequently Asked Questions
- Updates to this document

Appendices for 2023 NHSN Dialysis Event External Validation Toolkit

Appendix 1: Selection of facilities, Freezing facility data, and selection of patient records for validation

1a: Facility Selection

1) Generate new datasets in NHSN to ensure any data updates are included for analysis. On the NHSN Landing Page, navigate to the Dialysis component, and the appropriate state/jurisdiction Users' Group. Select the Analysis tab and click Generate Data Sets. For Beginning, enter 01/2023 and for Ending, 12/2023 (or other dates corresponding to the timeframe being validated) for the data set time period. Click the Generate Reporting Data Sets button. Allow the dataset generation process to complete; you can leave NHSN during the generation process.

2) After successful dataset generation, navigate to Analysis → Reports to display the tree view list of all analysis reports available within NHSN's analysis tool.
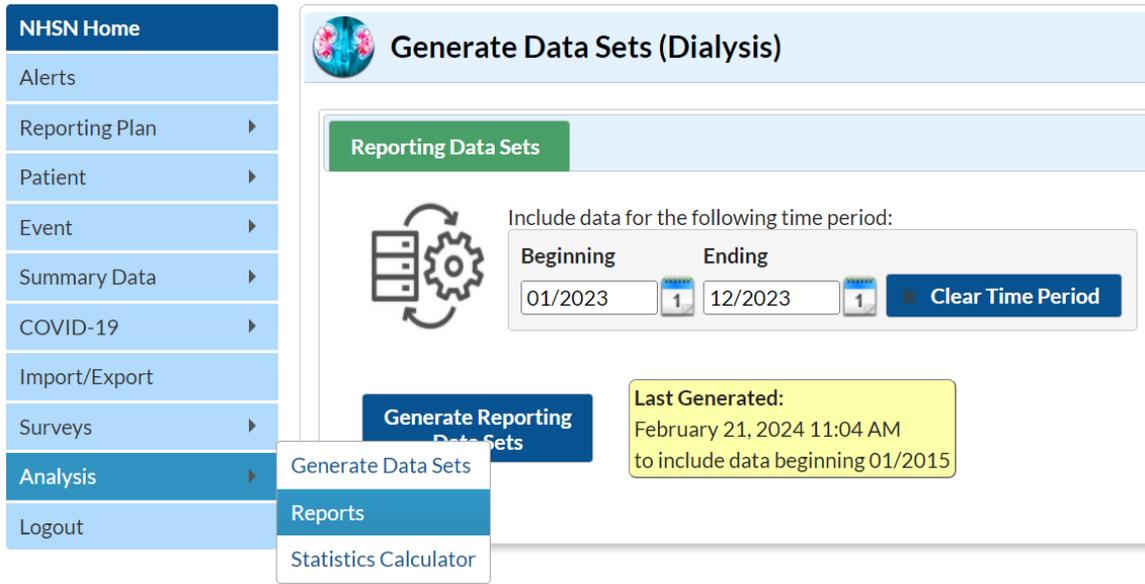
3) From Reports, select Dialysis Events → Advanced → Facility-level Data → Line Listing – Outpatient Dialysis Center Practices Survey for v.8.3 – 9.5 (for 2015-2023). Click the Modify Report button to proceed to the modification screen.
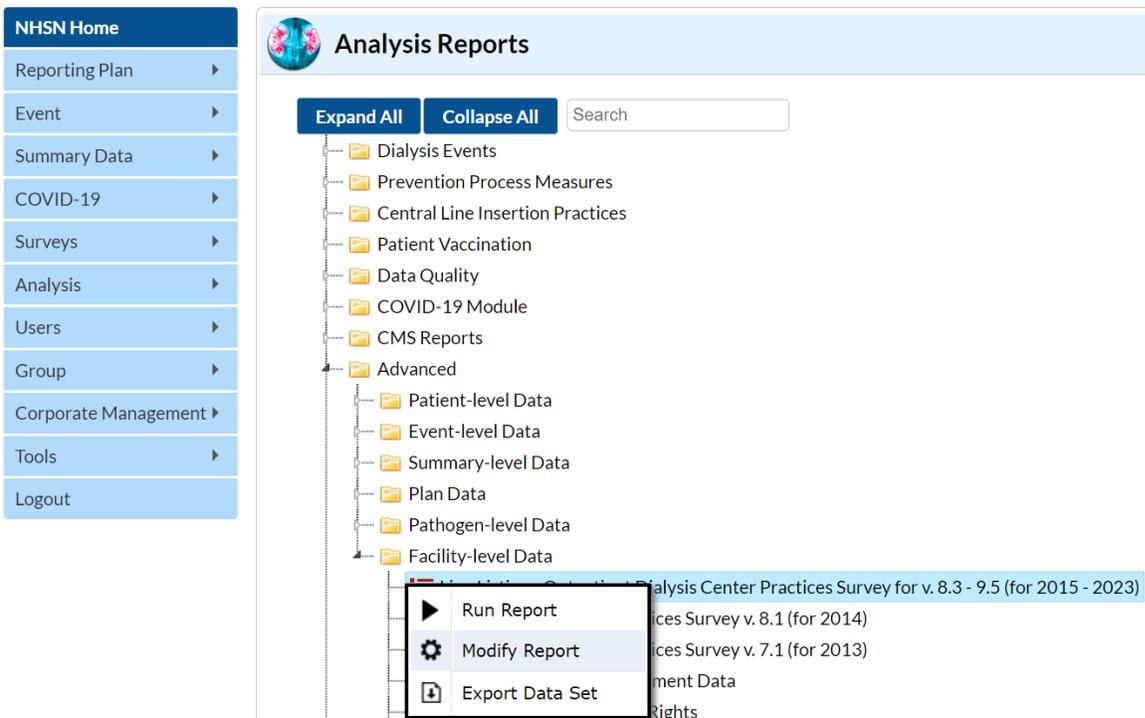
4) In the modification window, go to the Title/Format tab and select xls format. Then navigate to the Time Period tab and select the Date Variable "Facility Survey Year." Enter 2023 for the survey year of data being validated.
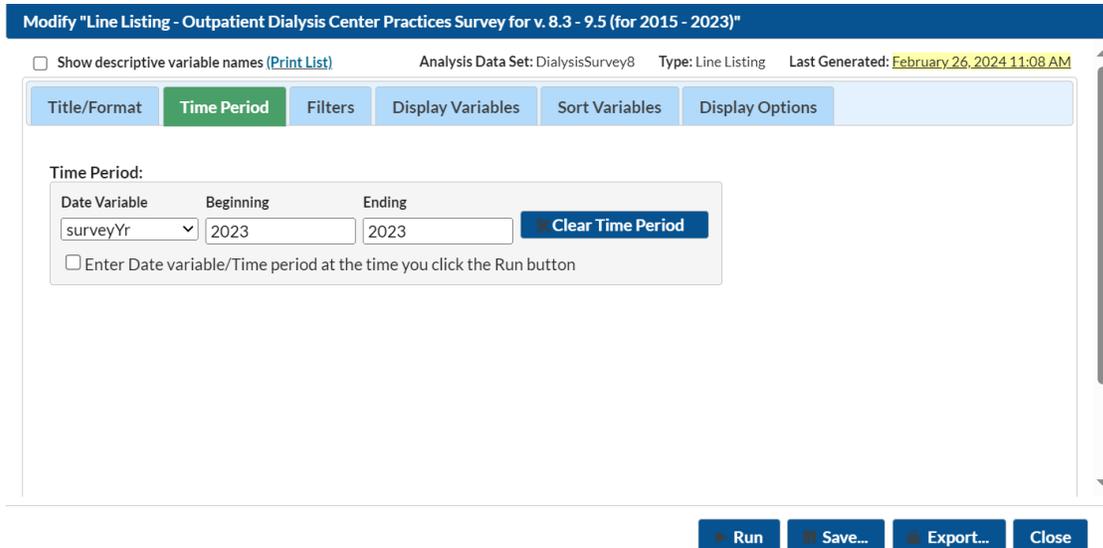
5) Scroll to the bottom of the modification window and click the Export button. When the Export Analysis Data Set window appears, use the default file format (.csv) and select the bullet "Export Analysis Data Set using Modifications." Click on the Export Button in the Export Analysis Data Set window to export the modified data.
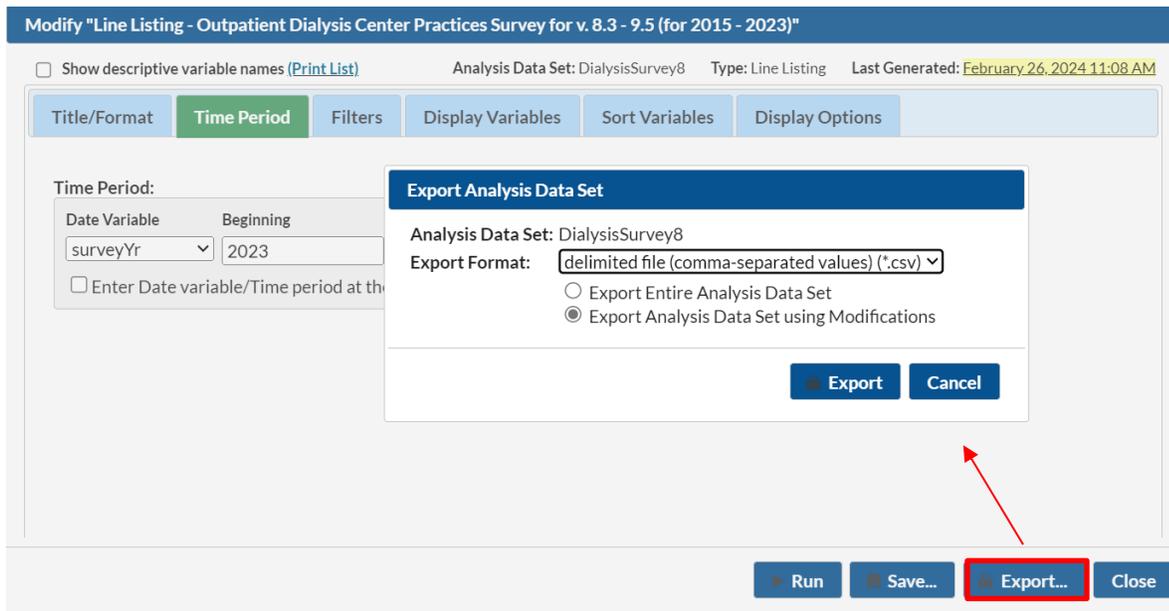
6) Assign each facility a random number using one of the methods outlined in the table in Appendix 1d.

7) Sort facilities in ascending order by the random number assigned and select the first 30 as your sample.

8) Before contacting the facility, be sure to download, or "freeze", the facilities' data (Appendix 1b). If the sampled facility did not report any data to NHSN during the validation timeframe, replace facility with the next lowest random number. Once the final list of 30 sampled facilities is complete, contact the selected facilities to request participation. If any facility declines to participate, select additional facilities from the list sorted by lowest random number.

Note: Maintain a record of the facilities that declined to participate and the reason(s) why. When asking the facility why they are declining, tell them the information is being collected for CDC to better understand the refusal rate and reasons for not participating. In the final report submitted to CDC, you will provide the number of declining facilities and a tally of their reasons for refusal ([Appendix 4](#)).

1b. Freeze Facility Data/Creating the Dialysis Events Line List

1) Follow steps 1 and 2 in Appendix 1a to generate new datasets
2) Once datasets have been generated, navigate to Analysis → Reports → Dialysis Events → Numerators → LineListing-Dialysis Events → Modify Report
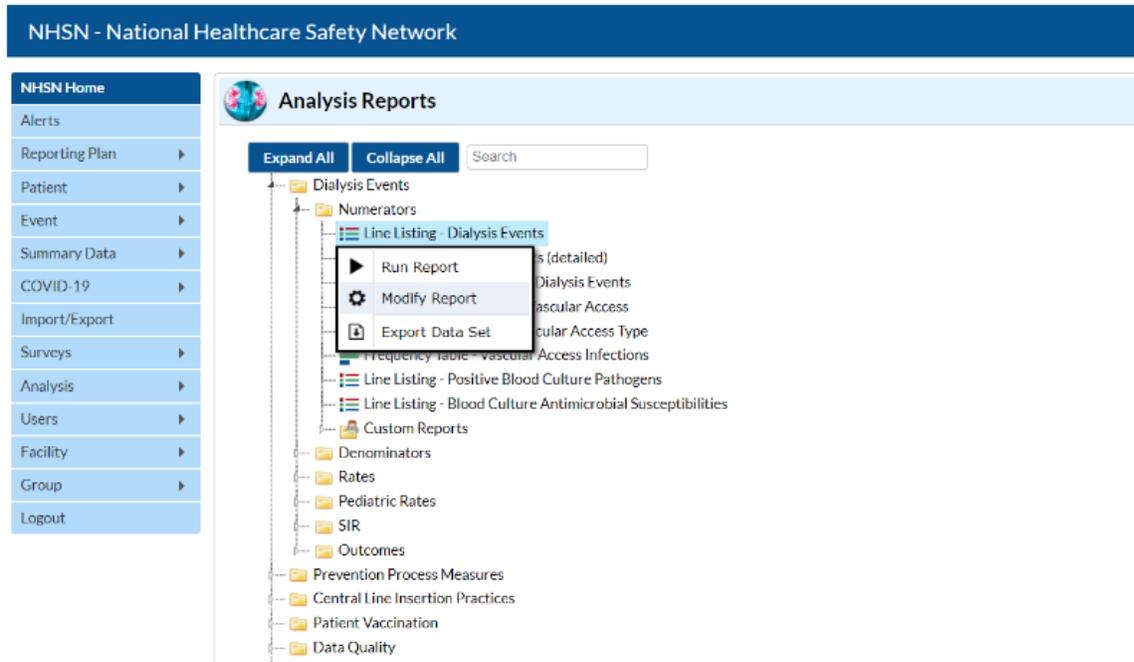
3) Once the Modification window appears, navigate to the Title/Format tab and select xls as the format. Then under the Time Period tab, go to the Date Variable drop-down and select "Event – Yr/Mon" and enter the first and last month/year of data to be validated. You may need to add an additional month of time for the "Beginning" range to account for the 21-day rule.
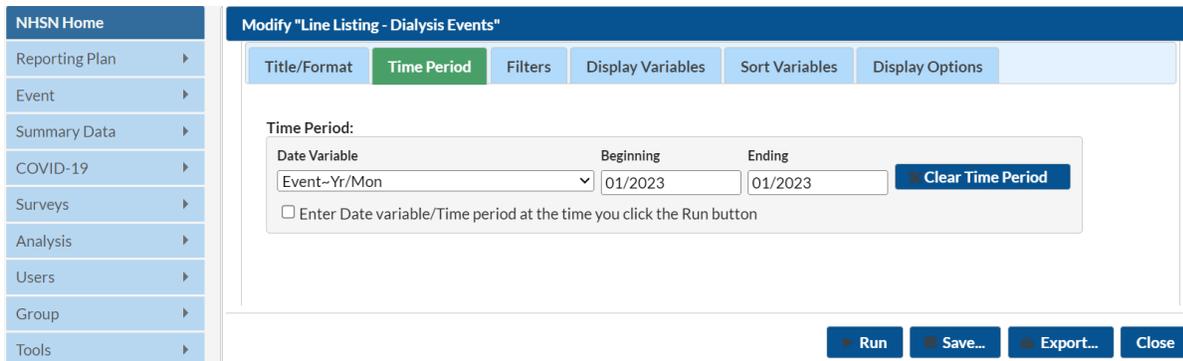
4) Click on the "Display Variables" tab and ensure that patient first and last name are included, as well as any other variables that may be helpful. You can select multiple variables at once by clicking on one and holding

the "ctrl" key while clicking on additional variables.
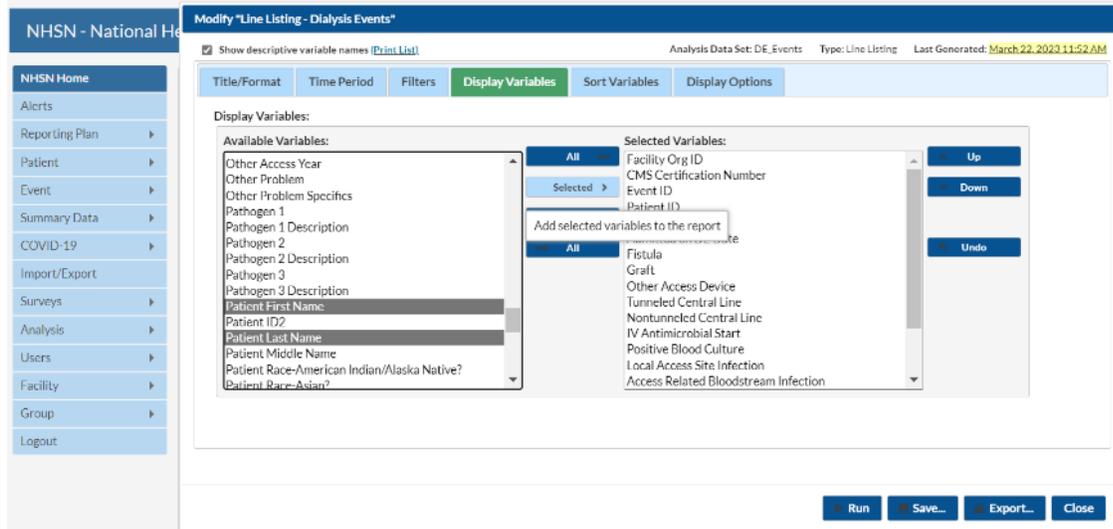
5) Scroll to the bottom of the modification window and click the Export button. When the Export Analysis Data Set window appears, use the default file format (.csv) and select the bullet "Export Analysis Data Set using Modifications." Click on the Export Button in the Export Analysis Data Set window to export the modified data.
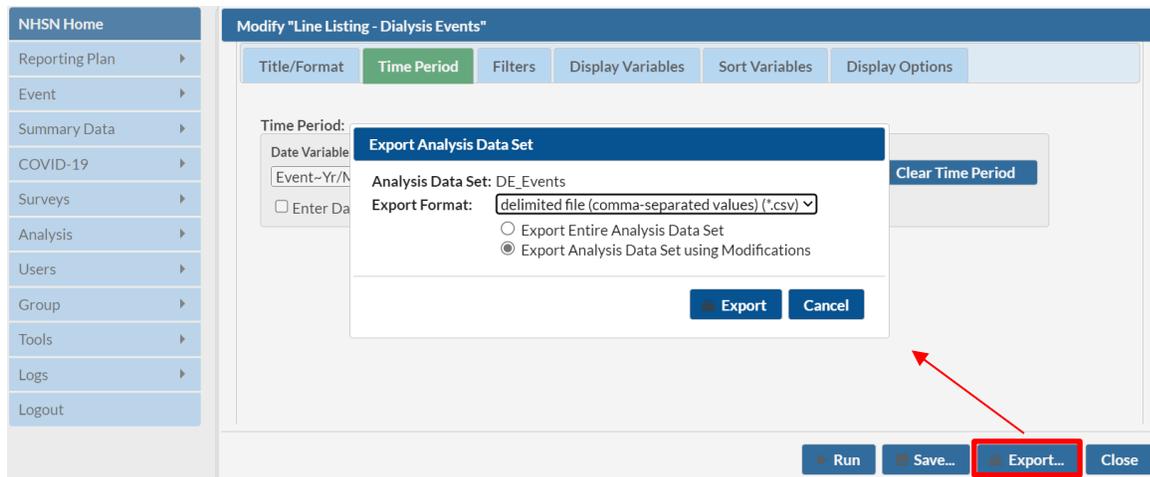
6) Save the output dataset in a secure location to reference later as needed

1c. Patient Medical Record Selection Methodology

Before requesting patient charts, generate the facility's Dialysis Event Line List report from NHSN (as outlined in Appendix 1b) for the validation time period. This is also considered "freezing" the facilities' data reported to NHSN during the validation period. Be sure to maintain these data in a secure location. Once the data have been frozen, request facilities to send the 5 patient lists for the validation timeframe, as described in the Patient Chart Selection criteria.

1) Starting with the Dialysis Event Line List report, assign a random number to each event using one of the 3 methods outlined in the table in Appendix 1d.
2) Sort by the random number and select the first 20 events. If any patients are duplicated, remove the duplicate and select the event with the next random number.
3) Obtain the 5 patient lists from the facility. Refer to the Patient Chart Selection for the specific patient criteria for each list. Combine patient lists 2-5 into a single patient list, removing any duplicate patients as needed.
a) If this combined, deduplicated list has 20 patients, review all.
b) If this combined, deduplicated list has over 20 patients, assign each patient a random number using a method from Appendix 1d. Sort by random number and select the first 20 unique patients.
c) If this combined, deduplicated list has less than 20 patients, use patient list 1 to supplement the difference to reach 20 patients:
   • Remove any duplicate patients from list 1 that are already included in the combined, deduplicated list created from lists 2-5.
   • Assign all remaining patients on list 1 a random number, using a method from the Appendix 1d. Sort by random number and select the first number of patients needed to reach 20 (i.e.- if you have 15 deduplicated patients from lists 2-5, select the first 5 patients from list 1 after sorting by random number to reach a total of 20 patients).
4) If the NHSN Dialysis Event Line List does not have 20 unique events, or if the facility-provided lists do not have a total of 20 unique patients, supplement the difference using the other group to reach a total of 40 records, as possible.

Note: If there is duplication between the NHSN Dialysis Event Line List and the facility-provided patient lists, the duplicate record(s) should be excluded from the sample and another record selected if possible. If there is not a total of 40 unique records between the two groups of charts, all unique records should be reviewed.

1d. Random Number Assignment Methods

Option 1: Excel	1. Using a facility or patient list created above, insert the command =ROUND(RAND()*1000000,0) into column B (or any empty column) and drag to paste this command for each row of the facility list. This will generate a random number for each orgID (or event).
	2. Select and copy the values from column B and use the Paste Special (Paste Values) feature to paste the number values into column C. Note: any edit made to the Excel sheet will cause the numbers in column B to recalculate. This is normal and can be ignored if you have an iteration copied.
	3. Delete column B so the columns shift left and column C becomes column B.
	4. Sort by column B, making sure column A is included in the sort (click on "Expand selection" if a dialog box appears). This is your final list that has been assigned and sorted by a random number.
Option 2: Random Number Generator Website + Excel	1. Identify the total number of facilities from the list created above, or the number of records on an HAI line list.
	2. Go to https://www.random.org/sequences/
	3. Input 1 as the smallest value, and the total number of facilities/records as the largest value, and click "Get Sequence"
	4. Copy the sequence created and paste it into column B (or any empty column) of your spreadsheet.
	5. Sort by column B, making sure column A is included in the sort (click on "Expand selection" if a dialog box appears). This is your final list that has been assigned and sorted by a random number.
Option 3: SAS Codes	1. Download the appropriate SAS code from the NHSN Validation website for the respective year being validated.
	2. Open the program and enter the file path where prompted in the code.
	3. For medical record random number generation, determine if you need/want the program to create an 'EoC' number. If yes, run code as written. If no, delete the lines of code as specified in the program, then run code.
	4. The final list, assigned and sorted by a random number, will be exported to the same folder specified in step 1.

Appendix 2: Letter Template – Introduction and Request to Participate

<<Insert Date >>

<<Facility Name>>

<<Facility Street Address>>

<<Facility City, State, Zip>>

Dear *<<Name of Facility Manager>>*:

I am writing to ask for your help and participation in a data quality and validation project on Dialysis Event data that are reported to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). This validation is being conducted by *<<agency/group conducting validation>>* to learn how NHSN Dialysis Event surveillance data collection procedures are understood and carried out in dialysis facilities, as well as identify and address barriers to reporting complete and accurate data.

We are contacting you because your facility is among a subset of dialysis facilities within *<<Network/state/area>>* that have been selected as part of a random sample. Please be assured that this validation is NOT related to any regulatory surveys. No observations of infection control practices or other aspects of patient care will be made during the site visit. Moreover, the identities of participating facilities will remain confidential, and all patient identifiable information will be maintained securely and remain confidential. All on-site visits will be scheduled – no unannounced visits will occur.

To conduct the validation activities, staff from *<<agency/group conducting validation>>* will be visiting several dialysis facilities in *<<geographic area>>* during *<<time period month(s)/year of visits>>*. If an on-site visit is not feasible for your facility, the activities may be done remotely. These activities include three main items:

1. A standardized interview with facility staff involved in NHSN Dialysis Event data collection or reporting to evaluate surveillance practices within your facility.
2. A review of preselected patient medical records to assess the completeness and accuracy of the data reported to NHSN.
3. Education for facility staff about Dialysis Event surveillance, use of the NHSN system, and common reporting omissions and errors and their causes.

It is anticipated that the on-site visit will be completed in *<<number of days>>* day(s), and the staff interview (in person or virtual) will take no longer than one hour. On the day of the on-site visit, *<<agency/group*

conducting validation>> staff will need a space to review patient charts and access the facility's electronic medical records systems. If the chart review is being done remotely, off-site, it may be conducted over a predetermined period of time and the method of patient chart access *<<agency/group conducting validation>>* staff will use is at the discretion of your facility. This includes methods such as securely emailing or faxing the complete patient records or by letting staff members access your electronic health record system directly.

Validation of the data is critical to ensure they are complete and accurate. The findings from this validation will be used to identify, correct, and prevent common reporting errors. Your participation is vital to these surveillance support and data quality improvement efforts. In return for your facility's participation, you will have opportunities to get confidential feedback about your facility's NHSN reporting, interact one-on-one with an NHSN Dialysis Event Surveillance expert who can address any questions you may have about reporting, and provide feedback about your experience with Dialysis Event data collection and reporting that will be used to help inform changes that will improve future reporting efforts.

Please confirm your interest in participation by contacting me at *<<phone number>>*. Once you confirm your participation, we will schedule a mutually agreed upon date for the site visit, if applicable, and ask you to prepare some information on the patients who received hemodialysis treatment during *<<validation period>>*. If you opt for a remote visit, we will discuss your preferred method for us to review patient charts and schedule time to meet with the pertinent staff from your facility.

I am happy to answer any questions you have or provide further information. I can be reached at *<<phone>>* or via email at *<<email address>>*.

Thank you for your assistance to evaluate and improve the quality of NHSN Dialysis Event surveillance data and reporting.

Sincerely,

<<Primary Contact's Name>>

<<Primary Contact's Title>>

<<Agency/Group's Contact Information>>

Appendix 3a: Letter Template—Confirm On-Site Visit and Preparation

<<Insert Date >>

<<Facility Name>>

<<Facility Street Address>>

<<Facility City, State, Zip>>

Dear *<<Name of Facility Manager>>*:

Thank you again for agreeing to participate in our validation of NHSN Dialysis Event data and reporting. Without your participation, this valuable project would not be possible.

As discussed, we will be visiting your facility on *<<date of visit>>*. *<<Names of persons who will be conducting validation>>* from *<<name of agency>>* will arrive at approximately *<<time of arrival>>*.

Preparation before the site visit

To prepare for the chart reviews, we need you to provide the five lists of patients outlined below. Each list should include a patient medical record number, date of birth, sex, patient first name, and patient last name. Please make sure the lists are clearly identified (1-5). Send these lists via secure/encrypted email to the attention of *<<Name>>* at *<<number>>* by *<<deadline date>>*.

1. All patients who had one or more <u>in-center hemodialysis treatment(s)</u> between *<<month year to month year – the validation timeframe>>*.
2. All patients who received <u>any intravenous antimicrobials</u> in an outpatient setting during *<<month year to month year – the validation timeframe>>*.
3. All patients who had <u>any positive blood cultures</u> between *<<month year to month year – the validation timeframe>>, including those during hospitalizations*.
4. All patients who had <u>any pus, redness or swelling at the vascular access site</u> during *<<month year to month year – the validation timeframe>>.*
5. All patients who were <u>hospitalized</u> for any reason during *<<month year to month year – the validation timeframe>>*.

These lists will be maintained securely by us to protect the release of any patient identifiers. Using the lists provided, we will preselect patient charts for us to review during the site visit. The list of patient charts for review will be provided to you in advance of the site visit.

What to expect during the site visit

When we arrive, we will need assistance to obtain the preselected patient charts. For the chart review, we will require a workspace and access to your electronic medical record system(s). You do not need to stay with us during our review, but we may need your assistance to answer intermittent questions throughout the day.

When it is most convenient for you, we will interview the facility staff involved in NHSN data collection or entry, which takes about 45 minutes. The group interview is interactive and provides on-the-spot feedback about NHSN surveillance practices and is a valuable learning opportunity for staff. Before we conclude, we will summarize our findings and review them with you, as well as address any outstanding questions from you or your staff.

Please confirm your receipt of this information and contact me if you have any questions about preparing the lists or the site visit itself.

Thank you,

<<Primary Contact's Name>>

<<Primary Contact's Title>>

<<Agency/Group's Contact Information>>

Appendix 3b: Letter Template — Confirm Remote Participation and Preparation

<<Insert Date >>
<<Facility Name>>
<<Facility Street Address>>
<<Facility City, State, Zip>>

Dear *<<Name of Facility Manager>>*:

Thank you again for agreeing to participate in our validation of NHSN Dialysis Event data and reporting. Without your participation, this valuable project would not be possible.

As discussed, we will be reviewing all sampled medical charts remotely via *<<method of chart access, such as secure faxing of complete charts, directly accessing facility's electronic health record system, etc.>>*. These records will be *<<select which option>>* sent to *<<fax number>>* by *<<date>>* or accessed by *<<Jurisdiction name>>* staff between *<<start date>> - <<end date>>*.

To prepare for the chart reviews, please provide the five lists of patients outlined below. Each list should include a patient medical record number, date of birth, sex, patient first name, and patient last name. Please make sure the lists are clearly identified (1-5). Send these lists to *<<Name>> at <<email>>* via encrypted/secured email or by secure fax at *<<number>>* by *<<deadline date>>*.

1. All patients who had one or more <u>in-center hemodialysis treatment(s)</u> between *<<month year to month year – the validation timeframe>>*.
2. All patients who received <u>any intravenous antimicrobials</u> in an outpatient setting during *<<month year to month year – the validation timeframe>>*.
3. All patients who had <u>any positive blood cultures</u> between *<<month year to month year – the validation timeframe>>, including those during hospitalizations*.
4. All patients who had <u>any pus, redness or swelling at the vascular access site</u> during *<<month year to month year – the validation timeframe>>.*
5. All patients who were <u>hospitalized</u> for any reason during *<<month year to month year – the validation timeframe>>*.

These lists will be maintained securely to protect the release of any patient identifiers. Using the lists provided, we will select patient charts to be validated. This selected list of patient charts for review will be provided to you.

After we complete the review of all patient charts, we will schedule time at your convenience to interview the facility staff involved in NHSN data collection or entry, which takes about 45 minutes. The group interview is interactive and provides on-the-spot feedback about NHSN surveillance practices and is a valuable learning opportunity for staff. Before we conclude, we will summarize our findings and review them with you, as well as address any outstanding questions from you or your staff.

Please confirm your receipt of this information and contact me if you have any questions about preparing the lists.

Thank you,

<<Primary Contact's Name>>

<<Primary Contact's Title>>

<<Agency/Group's Contact Information>>

Appendix 4: Letter Template – Post-Validation Activities Summary

<<Insert Date >>
<<Facility Name>>
<<Facility Street Address>>
<<Facility City, State, Zip>>
Date of site visit:_____/_____/_____

Dear *<<Name of Facility Manager>>*:

Thank you for participating in the validation of facility surveillance practices and the Dialysis Event data reported to the National Healthcare Safety Network (NHSN). We appreciate you taking time from your schedule to work with us. The valuable information you provided will enable us to improve the quality of the data reported to NHSN and identify focus areas for education and training of NHSN users.

During our validation efforts, *<<number>>* patient charts were reviewed. The documentation from these charts was used to identify Dialysis Events that should have been reported to NHSN. Here is a summary of our findings, by event type:

IV antimicrobial starts:

- *<<Number>>* of IV antimicrobial start events found in charts by our staff
  - o *<<Number>>* of these events found in charts that were reported to NHSN
  - o *<<Number>>* of these events found in charts that were not reported to NHSN
  - o *<<Number>>* of these events reported to NHSN, but were not found in charts

Positive blood cultures:

- *<<Number>>* of positive blood culture events found in charts by our staff
  - o *<<Number>>* of these events found in charts that were reported to NHSN
  - o *<<Number>>* of these events found in charts that were not reported to NHSN
  - o *<<Number>>* of these events reported to NHSN, but were not found in charts

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

- *<<Number>>* of pus, redness, or increased swelling events found in charts by our staff
  - o *<<Number>>* of these events found in charts that were reported to NHSN
  - o *<<Number>>* of these events found in charts that were not reported to NHSN
  - o *<<Number>>* of these events reported to NHSN, but were not found in charts

A summary of our findings can be found in the table below with additional details. **We would like you to perform the following steps to correct data discrepancies that were identified**:

1. Report to NHSN the events listed below as "under-reported". These are events that were not reported to NHSN by your facility staff, but should have been.

2. Delete or edit the NHSN records of the events listed below as "over-reported". These are events that were reported to NHSN by your facility staff, but should not have been.

Please make these corrections by <<*deadline*>>. Please contact us with any questions or concerns you have about making these changes.

Denominators for Outpatient Dialysis Form

From the information obtained during the interview, it appears the monthly denominator data/patient census data <<*is/is not*>> being reported correctly on the Denominators for Outpatient Dialysis form. Please

<<*begin/continue*>> to report using the NHSN Dialysis Event Protocol instructions: "Report Denominator Data Monthly".

In addition, it is recommended that you and any staff involved in reporting, review the NHSN Dialysis Event Protocol, noting the following common reporting issues found at your facility:

- *<<Highlight up to 3 main issues that were discovered during the validation process. Include excerpt(s) of the NHSN Dialysis Event Protocol that pertain to those issues.>>*
- *<<Issue 2>>*
- *<<Issue 3>>*

Thank you for your work to help improve the quality of NHSN Dialysis Event surveillance data. We recognize the time and effort you have invested and appreciate your willingness to participate in these important quality improvement activities. We hope the experience was helpful to you. Please don't hesitate to contact us with any remaining questions or concerns you may have.

Sincerely,

<<Primary Contact's Name>>

<<Primary Contact's Title>>

<<Agency/Group's Contact Information>>

Appendix 5: Survey to Assess NHSN Dialysis Event Surveillance

INTERVIEWER INSTRUCTIONS:

Prior to interview:

Identify the primary person who does NHSN Dialysis Event data collection at the facility to interview. If other staff perform NHSN activities such as data entry or analysis, it is ideal for them to also be included.

During Interview:

This interview is a tool to evaluate and improve NHSN Dialysis Event data collection and reporting. If data collection or reporting errors are identified through this assessment of practices, the interviewer should provide education and information to help correct errors and ensure that staff report data correctly to NHSN. Refer to the "*Note to Interviewer*" boxes for reference information. If there is a correct answer to a question, the correct answer is **bolded**.

> *Note to Interviewer* – Additional information that may be helpful for the Interviewer can be found in these boxes

---

SECTION A: FACILITY INFORMATION AND NHSN

Facility Name:_____ NHSN Org ID:_____ Number stations/chairs_____

Interviewer Name:_____ Interview Date: _____

1. Is any Dialysis Event data collected or reported by persons that do not work directly within this facility (for example, a regional or corporate employee)   No   Yes
   a. If yes, specify who and what data:_____
   _____

2. Please list all staff involved in NHSN Dialysis Event Surveillance and their involvement:

	Interviewee 1	Interviewee 2	Interviewee 3
Name(s)			
Job Title(s)			
Background/Degree(s)			

Collects NHSN dialysis event data?	Yes No	Yes No	Yes No
Collects NHSN dialysis denominator data?	Yes No	Yes No	Yes No
Has access to NHSN?	Yes No	Yes No	Yes No
Does NHSN data entry?	Yes No	Yes No	Yes No
Creates reports/uses NHSN analysis?	Yes No	Yes No	Yes No
Has read the NHSN Dialysis Event Protocol?	Yes No	Yes No	Yes No
Has completed NHSN Dialysis Event Surveillance reporting training?	Yes No	Yes No	Yes No

3. For staff that completed NHSN Dialysis Event Reporting Training, what kind of training did they do?

> *(Check all that apply)*

> ☐ Online NHSN Dialysis Event Surveillance Protocol training

> ☐ Webinar, presented by a CDC trainer

> ☐ In person, by a non-CDC trainer (e.g., ESRD Network, State Health Dept.)

> ☐ Webinar, by a non-CDC trainer (e.g., ESRD Network, State Health Dept.)

> ☐ Other, specify: _____

4. What do you (would you) do if you have a question about how or what to report to NHSN?

> *(Check all that apply)*

> ☐ Read the NHSN Dialysis Event Protocol

> ☐ Visit the NHSN Dialysis Event website (http://www.cdc.gov/nhsn/dialysis/dialysis-event.html)

> ☐ Send an e-mail to the NHSN Helpdesk (nhsn@cdc.gov) or submit a ticket via SAMs ServiceNow

> ☐ Contact the ESRD Network

> ☐ Contact Corporate

> ☐ Contact State Health Department

> ☐ Other, specify: _____

5. Once data are reported to NHSN, does anyone from your facility go back and review the reported data to make sure it is correct?   Yes   No
> a. If yes, specify who: _____

6. Within the NHSN application, have you ever generated any of the reports (also called "output options") using the analysis function?   Yes   No

    a.   If yes, which ones? _____

    b.   If yes, what are the reports used for?

      (Check all that apply)

          ☐ Check if reported data are correct

          ☐ Share at quality improvement meetings

          ☐ Communicate to leadership about event rates

          ☐ Communicate to frontline staff about event rates

          ☐ Root cause analysis of infections

          ☐ Inform prevention activities

          ☐ Other, specify: _____

SECTION B: DENOMINATOR DATA COLLECTION

7. In your facility, which days of the month are used to count patients to obtain the monthly denominator data/patient census data? Let interviewee provide answer. If they give correct answer (below), circle yes.

      The first 2 working days of the month   **Yes** No

      If no, specify which days are _____

8. Are patients ever counted twice in monthly denominator data?   Yes **No**

9. How is the monthly denominator/patient census data obtained for the "NHSN Denominators for Outpatient Dialysis " form? (*Check all that apply*)

    ☐ From a computer-generated report

        What data source is used for determining the number of patients present and their vascular access type(s) _____

        _____

    ☐ By performing patient chart reviews

    ☐ By observation and counting of patient's vascular access types

    ☐ Other method use, specify: _____

10. Has the method used at your facility for the monthly denominator/patient census data ever been checked to identify errors?   Yes   No

SECTION C: VASCULAR ACCESS

11. Please tell me how you would define the following:
    Correctly described?

a. Non-tunneled central line	Yes	No	N/A
b. Tunneled central line	Yes	No	N/A
c. Graft	Yes	No	N/A
d. Fistula	Yes	No	N/A
e. Other access device	Yes	No	N/A

Note to Interviewer – NHSN Surveillance Vascular Access Definitions:

Mark N/A only if the interviewee indicates they do not have or have not seen patients with that access type.

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

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

- Graft: a surgically created connection between an artery and a vein using implanted material (typically synthetic tubing) to provide a permanent vascular access for hemodialysis.

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

| HIGHER | Nontunneled Central Lines | Tunneled Central Lines | Other Access Devices | AV Grafts | AV Fistulas | LOWER |
| RISK | | | | | | RISK |
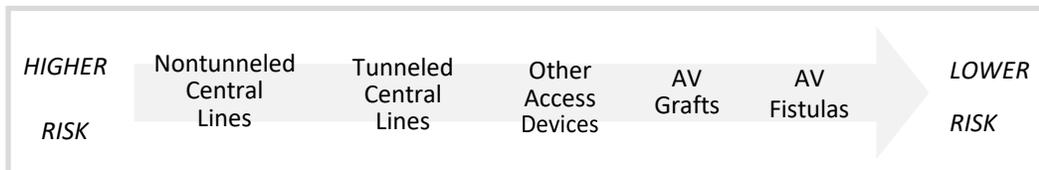
12. When determining in which vascular access category to count a patient for the monthly denominators:

a. Do you consider vascular accesses <u>not presently in use</u> (e.g., a tunneled central line that is retained as a back-up while a new fistula is tested for patency) to determine the appropriate category?	**Yes**	No
b. Do you consider vascular accesses that are <u>not used for dialysis</u> (e.g., chemotherapy ports) to determine the appropriate category?	**Yes**	No
c. Do you consider <u>abandoned vascular accesses</u> (e.g., clotted AV fistulas) to determine the appropriate category?	**Yes**	No

d. How are patients with <u>more than one access type categorized</u>?

Specify:

Correct answer: *According to their highest risk access, including those not presently in use, no longer in use and those not used for dialysis.*

13. When counting denominator data, which of the following patients are included?

a. Hospitalized patients	Yes	**No**
b. Patients who missed their scheduled treatment	Yes	**No**
c. Transient patients	**Yes**	No

<u>*Note to Interviewer*</u> – Protocol instructions for dialysis denominator data collection:

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

14. If not using NHSN denominator criteria, summarize below how denominator is determined at this facility:

_____

_____

_____

_____

_____

_____

_____

_____

SECTION D: DIALYSIS EVENTS

15. What are the three types of "dialysis events" monitored for NHSN Dialysis Event surveillance? Note to interviewer: Let interviewee answer without prompting.

	Identified	Not identified
IV antimicrobial starts in outpatient settings	☐	☐
Positive blood cultures	☐	☐
Pus, redness or increased swelling at the vascular access site	☐	☐

Note to Interviewer – Protocol definitions for dialysis events:

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

- Positive blood culture: Report **all** positive blood cultures collected as an outpatient or collected within 1 calendar day after a hospital admission, regardless of whether or not the patient received treatment.

- Pus, redness, or increased swelling at the vascular access site: Report **each** new outpatient episode where the patient has one or more symptoms of pus, greater than expected redness or greater than expected swelling at a vascular access site, regardless of whether the patient received treatment.

---

16. Do you check to see if the "21-day rule" applies, before reporting a new dialysis event?

☐ **Yes**, the 21-day rule is checked

☐ No, the 21-rule is not checked

☐ No, not aware of the 21-day rule

17. If <u>yes</u>, please describe how you apply the rule:

	Correctly described?	
a. For outpatient IV antimicrobial starts:	Yes	No
b. For Positive blood cultures:	Yes	No
c. For Pus, redness, or increased swelling at the vascular access site:	Yes	No
When applying the 21-day rule, do you look within the current month only or look back to the preceding month for events?	Yes	No

Note to Interviewer – 21 Day Rule applies only within the same dialysis event types:

If a patient has two dialysis events of the same type, the second occurrence is reported only if there are 21 or more days between the events. If the second event falls exactly on the 21st day, it is reported.

IV antimicrobial starts: There must be 21 or more days from the **end** of one IV antimicrobial course to the **beginning** of a second IV antimicrobial dose or course in an outpatient setting for two starts to be reported as separate dialysis events, even if different antimicrobials are used.

Positive blood cultures: 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.

Pus, redness, or increased swelling: Count days between onset to onset.

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.

Examples:

21-day rule for IV antimicrobial starts: A single dose of IV cefazolin is administered in the dialysis facility prophylactically prior to AV graft placement surgery. Within two weeks, patient shows signs of bloodstream infection and is started empirically on IV vancomycin. Report only one dialysis event for the IV cefazolin; the IV vancomycin was started within 21 days of the prophylactic dose and is therefore, not reported.

21-day rule for positive blood cultures: Patient has a positive blood culture on January 1, 22, and 24. Report two dialysis events: one for January 1 and one for January 22. The positive blood culture from January 24 is not reported because there are fewer than 21 days between January 22 and 24.

21-day rule for pus, redness, or increased swelling at the vascular access site: Patient's tunneled central line exit site is slightly red on January 1. Over the course of four days, the redness worsens, and the vascular access site becomes warm to the touch, and tender. Patient receives a 10-day course of oral antibiotics, and the symptoms resolve. On January 19, the redness returns. Report one dialysis event: the second onset of redness on January 19 is within 21 days of the first onset of redness on January 1 and is therefore not reported.

18. How are Dialysis Events identified and tracked for NHSN surveillance at your facility?

Note to interviewer: Ask about the different sources of data that are used to find each type of dialysis event, and the process that is used to ensure all information is captured and reported correctly. Prompt the interviewee with examples as necessary. Use the table below to summarize the responses by checking the box if the interviewee indicated they used that data source or process.

	Type of Dialysis Event		
	IV antimicrobial start	Positive blood culture	Pus, redness, or increased swelling
What data sources do you use to help you find Dialysis Events?			
Daily direct observation of patients	☐	☐	☐
Patient chart reviews	☐	☐	☐
Review computer generated reports	☐	☐	☐
If used computer reports, specify the type(s):			
Staff discussion	☐	☐	☐
Pharmacy records	☐	☐	☐
Positive laboratory reports	☐	☐	☐
Hospitalization records	☐	☐	☐
Patient temperature records	☐	☐	☐
Administrative (billing or discharge) codes	☐	☐	☐
Other data sources, specify:			
How frequently is case finding done (e.g., daily, weekly, monthly, quarterly)?			
Once you have identified a patient with a Dialysis Event, what process do you use to keep track of them before they are entered into NHSN?			
Keep a line listing (e.g., a log) of events			
Fill out a paper NHSN Dialysis Event form			
Flag events in Electronic Medical Record			
Other, specify:			

19. Does your facility keep track of all patient hospitalizations? **Yes** No

20. Are patients routinely asked the following at each treatment visit:

    a. Do you have any signs or symptoms of infection?   **Yes** No

    b. Have you had any ED visits or hospitalization since the last treatment?   **Yes** No

    c. If no to b, what process is used to find out if a patient had an ED visit or was hospitalized *between* treatments?

---

21. After patients return to your facility following a hospitalization, does your facility request a copy of the patients' medical records?   **Yes** No

    a. Are hospital records requested for <u>every</u> hospitalization?   **Yes** No

    b. Is there a standard process to request hospital records (e.g., a request form)?   **Yes** No

    c. Does your facility have a follow-up system in place to ensure all requested records are received?   **Yes** No

    d. Please specify the type of records requested for all patient hospitalizations:

        (Check all that apply)

            ☐ Admission history and physical

            ☐ Microbiology laboratory reports

            ☐ Pharmacy/drug administration records/logs

            ☐ Discharge summary

            ☐ The complete hospitalization record

            ☐ Other, specify: _____

22. Does your facility have a process in place to identify and report positive blood cultures collected during the first day of a dialysis patient's hospital admission?   **Yes** No

    a. If yes, please describe the process:

    _____

    _____

23. If new dialysis event information is identified after the event has already been reported, do you go back and revise the record?   **Yes** No

> *Note to Interviewer* – revising reported data:
>
> On occasion, data reported to NHSN may need to be updated with new information and/or corrected if errors are identified. It is expected that the information will be revised in these instances.
>
> *Example: A patient has a positive blood culture in January. This dialysis event is reported to NHSN in February. The patient dies in March as a result of the bloodstream infection. The record should be accessed in March and edited to modify "Outcome: Death" to "Yes".*

SECTION E: ADDITIONAL QUESTIONS TO IDENTIFY AREAS OF NHSN IMPROVEMENT

24. What 2 things would be most helpful to improve NHSN data collection and/or reporting?

    a. _____

    b. _____

25. What are the 2 main challenges to NHSN reporting?

    a. _____

    b. _____

26. Do you have any other questions or comments about NHSN?

    _____

    _____

    _____

Appendix 6: Facility Validation Summary and Line Listings of NHSN Dialysis Event Reporting

<<Facility Name>> Dialysis Event Validation Summary

Table 1. Overall Validation

Facility	Validator Yes	No	
Yes			0
No			0
	0	0	0
Overall Percent Agreement =			

Table 2. IVAM Event Validation

Facility	Validator Yes	No	
Yes			0
No			0
	0	0	0
IVAM Percent Agreement =			

Table 3. PBC Event Validation

Facility	Validator Yes	No	
Yes			0
No			0
	0	0	0
PBC Percent Agreement =			

Table 4. PRS Event Validation

Facility	Validator Yes	No	
Yes			0
No			0
	0	0	0
PRS Percent Agreement =			

<<Facility Name>> - IVAM Line List

OrgID	Patient ID	IVAM Drug Name	IVAM Start Date	Reportable to NHSN	Reported by Facility	Report Date	VA Present^	VA Reported^	Misclassification Reason(s)*

Add rows as needed

* I) Misinterpretation of antibiotic administration or reporting criteria
    a) A one-time or prophylactic dose was given
    b) Related blood culture results were negative
    c) IVAMS is for non-vascular access problem (e.g., pneumonia)
    d) First outpatient IVAM administration resulting from continuation of inpatient treatment
    e) Administered on outpatient basis, outside of dialysis facility (e.g., LTC or prison)
    f) Facility thought they were only supposed to report specific microbials (e.g., vanco)
    g) Misapplication of 21-day rule; event was within 21 days of previous IVAM event
    h) Reported for an oral antibiotic
    i) Not reported when drug not owned by clinic
    j) Not reported for deceased patients or patients transferred out of facility

* II) Missing data elements or incorrect information reported
    a) Did not report all event elements (e.g., reported PBC but not IVAM)
    b) Event Date incorrect
    c) Vascular Access type incorrect
    d) Other, specify

* III) Other, specify

^ Vascular Access (VA) types: F=Fistula, G=Graft, T=Tunneled central line, NT=Non-tunneled central line, O=Other access device, N/A=None or not applicable

<<Facility Name>> - PBC Line List

OrgID	Patient ID	Specimen Collection Date	Pathogen(s) Identified	Reportable to NHSN	Reported by Facility	Report Date	VA Present^	VA Reported^	Misclassification Reason(s)*

Add rows as needed

* I) Misinterpretation of PBC reporting criteria
    a) Source of infection reported as contamination or uncertain
    b) IV antimicrobials were not started
    c) Attributed to non-vascular access problems (e.g., wound, pneumonia)
    d) Obtained within first day after hospital admit
    e) Misapplication of 21-day rule; event was within 21 days of previous PBC event
    f) Not reported for deceased patients or patients transferred out of facility

* II) Missing data elements or incorrect information reported
    a) Did not report all event elements (e.g., reported IVAM but not PBC)
    b) Event Date incorrect
    c) Vascular Access type incorrect
    d) Other, specify

* III) Other, specify

^ Vascular Access (VA) types: F=Fistula, G=Graft, T=Tunneled central line, NT=Non-tunneled central line, O=Other access device, N/A=None or not applicable

<<Facility Name>> - PBC Line List

OrgID	Patient ID	Symptom Onset Date	VA Affected^	Reportable to NHSN	Reported by Facility	Report Date	VA Present^	VA Reported^	Misclassification Reason(s)*

Add rows as needed

* I) Misinterpretation of PRS identification or reporting criteria
    a) Not reported because antimicrobials were not started
    b) Infection suspected but not confirmed and/or doctor says PRS is cellulitis
    c) Facility lacks process to track PRS events
    d) Misapplication of 21-day rule; event was within 21 days of previous PRS event
    e) Not reported for deceased patients or patients transferred out of facility

* II) Missing data elements or incorrect information reported
    a) Did not report all event elements (e.g., reported IVAM but not PRS)
    b) Event Date incorrect   *** III) Other, specify**
    c) Vascular Access type incorrect
    d) Other, specify

^ Vascular Access (VA) types: F=Fistula, G=Graft, T=Tunneled central line, NT=Non-tunneled central line, O=Other access device, N/A=None or not applicable

Appendix 7: External Validation of Dialysis Event Summary Report

Jurisdiction name	
Point of Contact	
Year of Data Validated (or date range if less than 1 year)	
Total number of facilities and charts reviewed	
Number of facility refusals, and reasons provided for refusal	
Was the NHSN validation toolkit used? If partly, what was used?	
If NHSN guidance not implemented, please describe the facility and record selection process.	
Common errors identified across facilities	
Can you provide how many health department staff were involved in the project and approximate timeline?	
Please provide any feedback on the external validation process or toolkit.	
Once completed, email this form to: nhsn@cdc.gov, using the phrase "Dialysis External Validation Summary Report" in the subject line.	

Appendix 8: NHSN Dialysis Event Surveillance: Medical Record Abstraction Tool

Instructions: This instrument is a tool to review a hemodialysis outpatient chart and collect NHSN Dialysis Event Surveillance information to determine whether data were correctly reported. Chart reviewers must be familiar with the NHSN Dialysis Event Protocol instructions and definitions prior to chart review.

Table 1. Common Dialysis Event acronyms, problems, and rule definitions		
Dialysis Events	**IVAM**	IV antimicrobial
	IVAMS	IV antimicrobial start
	PBC	Positive Blood Culture
	PRS	Pus, redness, or increased swelling of the vascular access site
Suspected Sources	**VA**	Vascular access site
	O	Source other than the vascular access site
	C	Contamination
	U	Uncertain
Vascular Accesses	**F**	Fistula
	G	Graft
	T	Tunneled central line
	NT	Non-tunneled central line
	O	Other access device
Result	**Y**	Yes
	N	No
	U	Unknown
21 Day Rule Summary	**21 Day Rule**	There must be 21 or more days between two events of the <u>same type</u> for the second event to be reported.
	IVAMS	From the <u>end</u> of one course to <u>beginning</u> of the next (i.e., only IV antimicrobials restarted on or after 21st day after end of previous dose/course are reported)
	PBC	Between blood specimen collection dates (i.e., only positive blood cultures collected on or after the 21st day following the last collected positive blood culture are reported)
	PRS	Between onset to onset (i.e., only new onset on or after 21st day following the previous onset is reported)

Table 2. Misclassification reasons for Sections 2a-2c.		
2a. IV Antimicrobial Starts (IVAMS)	**2b. Positive Blood Cultures (PBC)**	**2c. Pus, Redness, Swelling (PRS)**
I) Misinterpretation of antibiotic administration or reporting criteria a) A one-time or prophylactic dose was given b) Related blood culture results were negative c) IVAMS is for non-vascular access problem (e.g., pneumonia) d) First outpatient IVAM administration resulting from continuation of inpatient treatment e) Administered on outpatient basis, outside of dialysis facility (e.g., LTC or prison) f) Facility thought they were only supposed to report specific microbials (e.g., vanco) g) Misapplication of 21-day rule; event was within 21 days of previous IVAM event h) Reported for an oral antibiotic i) Not reported when drug not owned by clinic j) Not reported for deceased patients or patients transferred out of facility **II) Missing data elements or incorrect information reported** a) Did not report all event elements (e.g., reported PBC but not IVAM) b) Event Date incorrect c) Vascular Access type incorrect d) Other, specify **III) Other, specify**	**I) Misinterpretation of PBC reporting criteria** a) Source of infection reported as contamination or uncertain b) IV antimicrobials were not started c) Attributed to non-vascular access problems (e.g., wound, pneumonia) d) Obtained within first day after hospital admit e) Misapplication of 21-day rule; event was within 21 days of previous PBC event f) Not reported for deceased patients or patients transferred out of facility **II) Missing data elements or incorrect information reported** a) Did not report all event elements (e.g., reported IVAM but not PBC) b) Event Date incorrect c) Vascular Access type incorrect d) Other, specify **III) Other, specify**	**I) Misinterpretation of PRS identification or reporting criteria** a) Not reported because antimicrobials were not started b) Infection suspected but not confirmed and/or doctor says PRS is cellulitis c) Facility lacks process to track PRS events d) Misapplication of 21-day rule; event was within 21 days of previous PRS event e) Not reported for deceased patients or patients transferred out of facility **II) Missing data elements or incorrect information reported** a) Did not report all event elements (e.g., reported IVAM but not PRS) b) Event Date incorrect c) Vascular Access type incorrect d) Other, specify **III) Other, specify**

Section 1: Facility and patient information			
Facility (NHSN) OrgID:	Date of Audit: ___ / ___ / ___	Review Start Time: am/pm	Review End Time: am/pm
Patient ID:	Patient DOB: ___ / ___ / ___	Transient Patient: Yes No	Reviewer Initials:

Section 2

Identify all instances of the following events, as defined by the NHSN Dialysis Event Protocol. Arrange events of the same type chronologically. Refer to a calendar to help you apply the 21-day rule to determine which events should have been reported during the validation time period.

- Section 2a: Note all IV antimicrobial starts (IVAM)
- Section 2b: Note all positive blood cultures (PBC)
- Section 2c: Note all instances of pus, redness or increased swelling (PRS) at the vascular access (VA) site

2a. IVAM – All IV Antimicrobial Courses

For each IVAM course, starting with the earliest, enter the start and end dates and drug name. Select all documented problems and VA types that were present. Determine and enter if the event should have been reported to NHSN, and then select if it was reported. If it was reported to NHSN, enter the reported event date, and select the type(s) of VA reported as being present. If no VA types were present or reported, select "n/a" for that column. If the event was not reported correctly, select the most applicable misclassification reason from Table 2.

☐ Chart review for this patient completed and no IVAM found during the validation time period

Drug Name; Start & End Date	Problems documented*	Type(s) of VA present (per chart)	Should event be reported to NHSN?	Was event reported to NHSN?	Type(s) of VA reported present (per NHSN)	Reported Event Date (per NHSN)	Reporting Misclassification Reason
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		
		F G T NT O n/a	Y N	Y N	G T NT O n/a		

*Problems include: Fever, chills/rigors, drop in blood pressure, wound infection, urinary tract infection, cellulitis, pneumonia, other, or none

2b: PBC - All positive blood cultures

For each PBC, starting with the earliest, enter the specimen collection date, pathogen(s) identified, and suspected source. Select all documented problems and VA types that were present, per patient's chart. Determine and enter if the event should have been reported to NHSN, and then select if it was reported. If it was reported to NHSN, enter the reported event date and select the type(s) of VA reported as being present. If no VA types were present or reported, select "n/a" for that column. If the event was not reported correctly, select the most applicable misclassification reason from Table 2.

☐Chart review for this patient completed and no PBC found during the validation time period

Collection Date	Pathogen(s) identified	Suspected Source	Problems documented*	Type(s) of VA present (per chart)	Should event be reported to NHSN?	Was event reported to NHSN?	Type(s) of VA reported present (per NHSN)	Reported Event Date (per NHSN)	Reporting Misclassification Reason
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
		VA O C U		F G T NT O n/a	Y N	Y N	F G T NT O n/a		

*Problems include: Fever, chills/rigors, drop in blood pressure, wound infection, urinary tract infection, cellulitis, pneumonia, other, or none

2c: PRS - All pus, redness, or increased swelling at the vascular access site

For each PRS event, starting with the earliest, enter the onset date, select which symptoms were present (pus, redness, and/or swelling). Select the VA type(s) affected and all documented problems, per patient's chart. Determine and enter if the event should have been reported to NHSN, and then select if it was reported. If it was reported to NHSN, enter the reported event date and select the type(s) of VA reported as being present. If no VA types were present or reported, select "n/a" for that column. If the event was not reported correctly, select the most applicable misclassification reason from Table 2.

Other terms that may be used to document PRS may include:

- For PUS: purulent, excretion, secretion, discharge, seepage, ooze, suppuration
- For REDNESS: cellulitis, inflamed, ruddy, rosy
- For SWELLING: distended, puffy, tumescent, tumid, edema

☐ Chart review for this patient completed and no PRS found during the validation time period

PRS Onset Date	Pus, Redness, Swelling	Vascular Access(es) Affected	Problems documented*	Type(s) of VA present (per chart)	Should event be reported to NHSN?	Was event reported to NHSN?	Type(s) of VA reported present (per NHSN)	Reported Event Date (per NHSN)	Reporting Misclassification Reason
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		
	P R S	F G T NT O		F G T NT O n/a	Y N	Y N	F G T NT O n/a		

*Problems include: Fever, chills/rigors, drop in blood pressure, wound infection, urinary tract infection, cellulitis, pneumonia, other, or none

Notes: