# 2024 CLABSI External Validation Toolkit

The 2024 CLABSI External Validation Toolkit is a HAI-specific supplement to be used in conjunction with the 2024 NHSN Patient Safety External Validation Toolkit (2024 PS EVT). It is intended to help guide the external validation process specifically for CLABSI with step-by-step instructions and screenshots from NHSN.

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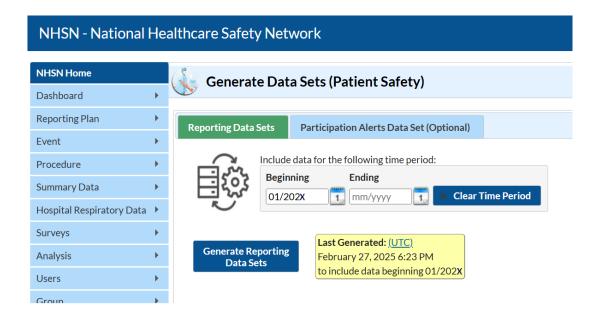
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# Section 1. Facility Selection

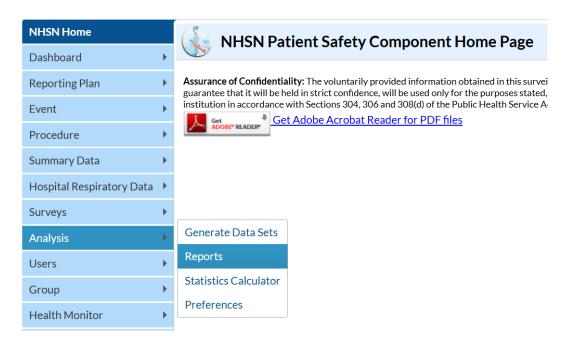
#### 1.1 Steps Applicable to all Facility Selection Methods

#### Generate Datasets and Modify Report

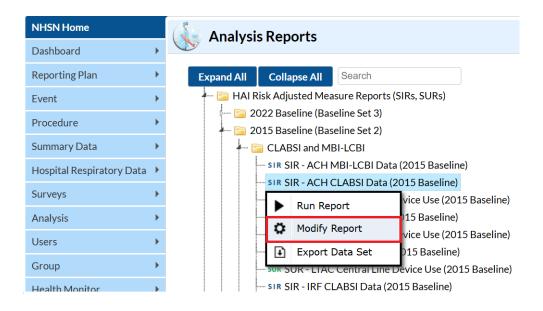
1. Generate new datasets in NHSN to ensure any data updates are included for analysis. On the NHSN Landing Page, navigate to Patient Safety Component → [YOUR State/Jurisdiction Users' Group]. Select the Analysis tab and click Generate Data Sets. For Beginning, enter 01/2024 and for Ending, 12/2024 (or other dates corresponding to the timeframe being validated) for the data set time period. Click the Generate New 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.

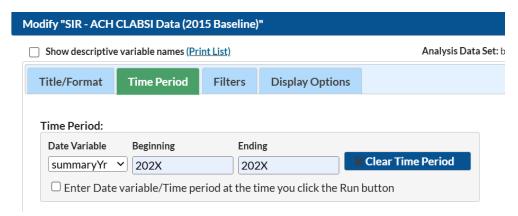


3. Use the tree view structure to select HAI Risk Adjusted Measure Reports, 2015 Baseline (Baseline Set 2), CLABSI and MBI-LCBI, SIR – ACH CLABSI Data (2015 Baseline). If you are validating Critical Access Hospitals (CAHs), Inpatient Rehab Facilities (IRFs), or Long-term Acute Care Hospitals (LTACHs), select the SIR report that corresponds with that facility type. Click the Modify Report button to proceed to the modification window.



- 4. In the modification window, there are two key areas to modify, one that controls the time interval of data that are analyzed and displayed and one that controls the level of aggregation of those data.
  - 4a. Under Title/Format tab, select xls format. Then navigate to the Time Period tab to define the time period of data that is included in the report to be exported. Set Date

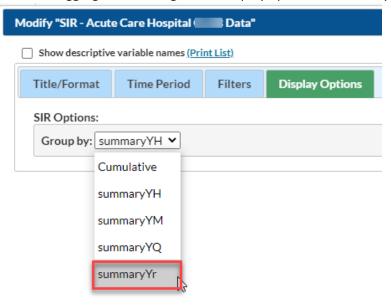
Variable to "summaryYr," Beginning and Ending to 2024, or to the year of data being validated.



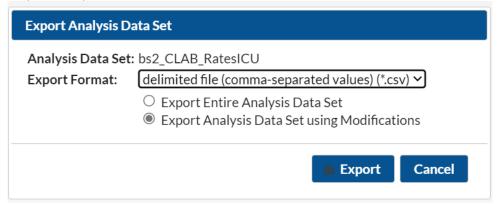
4b. Navigate to the "Filters" tab. In the row of drop-down boxes, select "bsiPlan," "equal," and enter "Y."



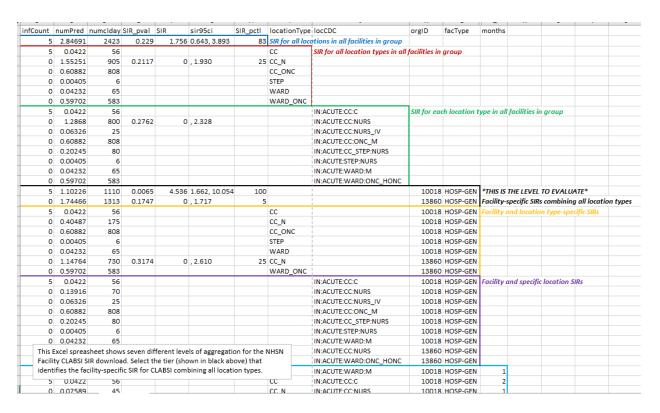
4c. Under the Display Options section, use the Group by option to view the data at a particular level of aggregation. Change the Group by option to "summaryYr."



- 5. After making the above modifications, scroll to the bottom of the modification window. Click the Export button to export the data selected by your modifications. This will open the "Export Analysis Data Set" window.
- 6. Use the default file format (.csv) and select the bullet "Export Analysis Data Set using Modifications" to export the data. Click the Export button to begin the export process. NHSN will create a .zip file with your SIR data report in it and prompt you to specify a location to save the file on your computer.



7. The exported SIR report will be displayed at several levels of aggregation. Select the orgID level, as illustrated in the screenshot below, to get an unduplicated list of facilities in your jurisdiction.



# 1.2 Calculate Ranking and Selection:

#### Method 1: Prioritizing Facilities with Highest Likelihood of Event Occurrence

- 1. Open the exported SIR report in Excel and select the aggregation level that provides a facility-specific SIR at the orgID level (shown in black in the screenshot seen in Section 1.1 step 7). This will allow you to explore the level of exposure risk for CLABSIs and measured performance for each facility. An easy way to find this level of aggregation is to look at the "loccdc" column and scroll until it is blank. The unique orgIDs will then begin to list in ascending order. Once you see the list go through the highest orgID and start over at the smallest orgID, that is where the unduplicated facility list ends. You will also notice that once the list of orgIDs starts over, the column "locationtype" will begin to have data as well. Tip: the columns "loccdc" and "locationtype" are blank for the rows you want.
- Copy this information to a new spreadsheet. Arrange the facilities in descending rank order according to SIR, and create three new columns titled "Delta," "Stratum," and "Targeted Selection Number."
- 3. Calculate Delta for each facility/row using the formula =ABS[row cell under InfCount]-[row cell under numPred]. Delta will be used only where an SIR is not calculated by NHSN.
- 4. Select the top tertile (33%) of facilities by predicted number (numPred) of CLABSIs in surveillance locations. This top tertile of facilities where CLABSIs in surveillance locations are most expected and may have the greatest potential for surveillance and prevention impact.
- 5. Within the top tertile, sort by SIR in descending order, and identify the current median SIR for the top tertile. To sort just the top tertile, highlight the entire row for each facility in the top tertile, and click "Data," "Sort"; Sort by "Column" (select SIR), "Sort On" (cell values), and "Order" (largest to smallest).
- 6. Within the top tertile, assign stratum A to facilities with SIR above the current median SIR, stratum B for remaining facilities with SIR less than or equal to the median and above zero, and stratum C for facilities with SIR = zero (but not missing). Note that some facilities will not have a calculated SIR; do not include these in the strata (see step 9 below).
- 7. Re-sort <u>within each stratum</u> A, B, and C, by numPred from highest to lowest. To sort just one stratum at a time, highlight the entire row for each facility in the first stratum, and click "Data," "Sort"; Sort by "Column" (select numPred), "Sort On" (cell values), and "Order" (highest to lowest). Repeat this process for the next two strata, one-by-one.
- 8. Assign sequential Targeted Selection Numbers to facilities by selecting the highest available numPred from each stratum, alternating through stratums A, B, and C. For example, the facility with the highest numPred from stratum A would be Targeted Selection Number=1, the facility with the highest numPred from stratum B would be Targeted Selection Number=2, and the facility with the highest numPred from stratum C would be Targeted Selection Number=3. Return to stratum A and assign the facility with the next highest numPred as Targeted Selection Number=4. Continue alternating strata until no facilities remain or the target number of facilities is reached (typically 18 or 21; refer to the 2024 PS EVT for facility sample size recommendations). If additional facilities are needed, repeat steps 4-8 using the second and then third tertile based on risk level.

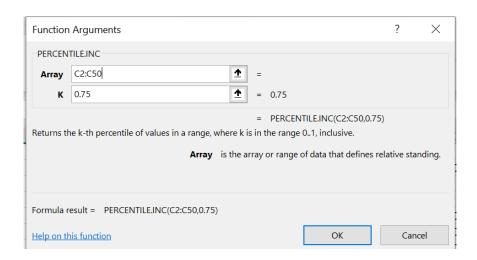
- 9. If additional facilities are needed to reach the targeted number after step 8 is complete, sort the remaining facilities without a calculated SIR by Delta in descending order, starting with the highest, and select facilities from the top of the list until targeted number is reached.
- 10. After the targeted selection is complete, randomly select additional 5% of remaining facilities from ALL tertiles. The targeted facilities along with the 5% randomly selected make up the total sample.

#### Method 2: Cumulative Attributable Difference (CAD) Approach

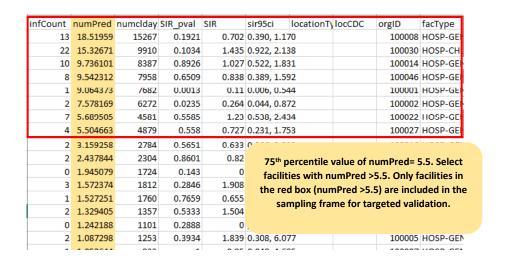
- 1. Open the exported SIR report in Excel and select the aggregation level that provides a facility-specific SIR at the orgID level (shown in black in the screenshot seen in Section 1.1 step 7). This will allow you to explore the level of exposure risk for CLABSIs and measured performance for each facility. An easy way to find this level of aggregation is to look at the "loccdc" column and scroll until it is blank. The unique orgIDs will then begin to list in ascending order. Once you see the list go through the highest orgID and start over at the smallest orgID, that is where the unduplicated facility list ends. You will also notice that once the list of orgIDs starts over, the column "locationtype" will begin to have data as well. Tip: the columns "loccdc" and "locationtype" are blank for the rows you want.
- 2. If there are 30 or fewer facilities in your jurisdiction, <u>stop here</u> and validate them all. If there are more than 30 facilities, proceed through the following steps to create facility sampling frame.
- 3. Select the rows from the aggregation level being evaluated and copy this information to a new spreadsheet. Insert a row above your data and copy the header row so you can identify the variables on the new spreadsheet. Next, sort the facilities by numPred (number of predicted events) in descending order (high to low).

infCount	numPred	numclday	SIR_pval	SIR	sir95ci	locationTy	locCDC	orgID	facType	
13	18.51959	15267	0.1921	0.702	0.390, 1.3	170		100008	HOSP-GEN	
22	15.32671	9910	0.1034	1.435	0.922, 2.3	138		100030	HOSP-CHLD	
10	9.736101	8387	0.8926	1.027	0.522, 1.8	331		*****		
8	9.542312	7958	0.6509	0.838	0.389, 1.5	592				
1	9.064373	7682	0.0013	0.11	0.006, 0.5	544		Sort the	e facilities in	n descending order of
2	7.578169	6272	0.0235	0.264	0.044, 0.8	372		nur	mher of nre	dicted infections
7	5.689505	4581	0.5585	1.23	0.538, 2.4	434			•	
4	5.504663	4879	0.558	0.727	0.231, 1.	/33		(nur	nPred) and	compute the 75 <sup>th</sup>
2	3.159258	2784	0.5651	0.633	0.106, 2.0	092		percenti	ile value of	the variable numPred
2	2.437844	2304	0.8601	0.82	0.138, 2.7	710			ic value of	the variable mannifed
0	1.945079	1724	0.143	0	, 1.540					
3	1.572374	1812	0.2846	1.908	0.485, 5.3	193				
1	1.527251	1760	0.7659	0.655	0.033, 3.2	229		100010	HOSP-GEN	
2	1.329405	1357	0.5333	1.504	0.252, 4.9	970		100032	HOSP-GEN	
0	1.242188	1101	0.2888	0	, 2.412			100049	HOSP-GEN	
2	1.087298	1253	0.3934	1.839	0.308, 6.0	077		100005	HOSP-GEN	
1	1.052644	933	1	0.95	0.048, 4.6	585		100007	HOSP-GEN	
1	0.915007	934						100040	HOSP-GEN	
0	0.745198	989						100026	HOSP-GEN	
0	0.719899	823						100004	HOSP-GEN	
2	0.669096	888						100023	HOSP-GEN	

4. Identify the 75<sup>th</sup> percentile of numPred for the validation period (minimum of two quarters of data) using the Percentile.inc function in Excel by clicking on the function button (fx) to the left of the white text box and selecting "Percentile.inc." A Function Arguments window will open and require an array and K values. For the "array" argument, select the column of your spreadsheet containing numPred values. For the "K" argument, enter the percentile value to be generated (0.75), making sure to use a decimal. Click OK and the cell where the function was entered will now show the 75<sup>th</sup> percentile value.



5. Use the numPred value corresponding to the 75<sup>th</sup> percentile as the minimum threshold value for selection of facilities eligible for validation. If this value is greater than 1, use the 75<sup>th</sup> percentile numPred value, otherwise use numPred=1 as the minimum threshold value.



- 6. Create a subset of facilities that includes facilities with predicted number of CLABSI events greater than the threshold. In the example above, the 75% percentile value of the numPred variable was 5.5. All facilities with numPred value above 5.5 are selected for inclusion in the validation sampling frame.
- 7. If the sampling frame derived from the 75<sup>th</sup> percentile of numPred consists of 30 or fewer facilities, select all facilities for validation, plus an additional random sample of 5% of facilities where numPred was less than the 75<sup>th</sup> percentile value. Refer to Table 1 below for 3 random number generation methods. In the example above, the number of facilities with numPred value >5.5 is fewer than 30 so all facilities with numPred value >5.5 are selected for validation and a 5% random sample is selected from the facilities with numPred value ≤5.5.
- 8. If sampling frame consists of greater than 30 facilities, select 30 facilities based on the criteria described in section B below.

#### A. Observed Events

- The Cumulative Attributable Difference (CAD) approach focuses on the difference between the predicted number of CLABSIs and actual observed CLABSIs (reported). The infCount is an aggregated count of observed CLABSIs for individual surveillance locations.
- Create a column titled CAD next to numPred and compute the CAD values for each line by subtracting numPred from infCount (observed – predicted).

#### B. Facility Selection: use this step if the sampling frame consists of greater than 30 facilities

- 1) Divide the total facilities in the sampling frame into two strata.
  - Create a new column, "stratum," and assign each facility to either Stratum 1 or Stratum
     2:
    - Stratum 1: Includes all facilities in the sampling frame that had zero infCount value, that is, zero reported observed events for the validation time frame.
    - Stratum 2: Includes all facilities in the sampling frame with non-zero infCount value, that is, non-zero reported observed events for the validation time frame.
- 2) Stratum 1 (where facility reported zero events): Filter for Stratum 1 facilities (where infCount=0) and sort by ascending CAD value so stratum 1 facilities with the lowest CAD value are at the top, shown in the green column below. Select the first 15 facilities from Stratum 1.

infCount	numpred	CAD	numclday	SIR_pval	SIR	sir95ci	SIR_pctl	locationTy	locCDC	orgID	facType ı
0	15.11302	-15.1130	150								HOSP-GEN
0	12.12433	-12.1243	165								HOSP-GEN
0	11.03699	-11.0370	68								HOSP-GEN
0	10.03699	-10.0370	68								HOSP-GEN
0	9.113023	-9.1130	150								HOSP-GEN
0	8.124325	-8.1243	165								HOSP-GEN
0	8.113023	-8.1130	150								HOSP-GEN
0	8.011302	-8.0113	15								HOSP-GEN
0	5.011302	-5.0113	15								HOSP-GEN
0	4.036994	-4.0370	68								HOSP-GEN
0	3.036994	-3.0370	68								HOSP-GEN
0	3.011302	-3.0113	15								<b>HOSP-GEN</b>
0	2.036994	-2.0370	68								HOSP-GEN
0	1.011302	-1.0113	15								HOSP-GEN

3) Stratum 2 (facilities with non-zero events): Filter for Stratum 2 facilities (where infCount > 0). Sort the facilities by ascending CAD value so the facilities with the lowest CAD value are at the top, shown in the green column below. Select the first 15 facilities from Stratum 2.

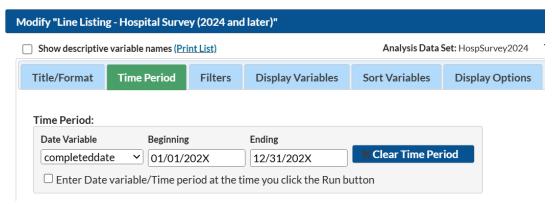
	-	-	_	_		•	_			-	
infCount	numPred	CAD	numclday	SIR_pval	SIR		sir95ci	locationTy	locCDC	orgID	facType
1	9.064373	-8.06437	7682	0.0013						`1	HOSP-GEN
2	7.578169	-5.57817	6272	0.0235			-	AD values fo			HOSP-GEN
13	18.51959	-5.51959	15267	0.1921				ame. Filter		2	HOSP-GEN
8	9.542312	-1.54231	7958	0.6509			•	infCount >	•		HOSP-GEN
4	5.504663	-1.50466	4879	0.558			Ū	value (lowe			HOSP-GEN
10	9.736101	0.263899	8387	0.8926				pling frame	_		HOSP-GEN
7	5.689505	1.310495	4581	0.5585		15 Ta	cilities, sei	ect the top	15 lacilities	·.	HOSP-GEN
22	15.32671	6.673286	9910	0.1034						0د	HOSP-CHLD

4) If there are insufficient facilities in either of the strata, supplement the sample from other strata to reach the required number of facilities for the validation sample.

Note: Remember to randomly select 5% of remaining facilities with a numPred less than the 75<sup>th</sup> percentile value.

#### Method 3: Stratified Random Sampling

- 1. Open the exported SIR report in Excel and select the aggregation level that provides a facility-specific SIR at the orgID level (shown in black in the screenshot seen in Section 1.1 step 7) so you have an unduplicated list of all facilities reporting data for CLABSI during the validation timeframe. An easy way to find this level of aggregation is to look at the "loccdc" column and scroll until it is blank. The unique orgIDs will then begin to list in ascending order. Once you see the list go through the highest orgID and start over at the smallest orgID, that is where the unduplicated facility list ends. You will also notice that once the list of orgIDs starts over, the column "locationtype" will begin to have data as well. Tip: the columns "loccdc" and "locationtype" are blank for the rows you want.
- 2. Once you identify where the aggregation at orgID starts, click on the first orgID cell and drag until you reach the highest value (before it starts to repeat). Copy the selected cells and paste into a new Excel worksheet or a new sheet within the same worksheet. This is your final list of all unduplicated facilities reporting CLABSI during the timeframe you specified. You will use this list as your facility sampling frame.
- 3. Generate list of facilities that completed Annual Survey from NHSN:
  - a. On the NHSN landing page, use the Analysis button in the navigation bar and select Reports.
  - Use the tree view structure to select Supplemental Reports, Facility-Level Data, and Line Listing – Hospital Survey (2024 and later). If validating a type of facility other than Acute Care Hospitals, select the appropriate corresponding report.
  - c. Select Modify Report and make the following modifications:
    - i. Under the Title/Format tab, select the xls format.
    - ii. Under the Time Period tab, select "completeddate" from the dropdown box, and enter 01/01/2024 for Beginning and 12/31/2024 for Ending. Modify dates as needed for the timeframe being validated.



NOTE: If a facility did not complete the Annual Survey during specified time period, they will not appear in this report.

- iii. Under the Sort Variables tab, double click "surveyYear" in the right-hand box to remove. Find "orgID" in the left-hand box, and double click to move it to the right-hand box.
- iv. Click the Export button. In the Export Analysis Data Set window, keep the default file type (.csv) and click Export. This will generate a .zip file with a spreadsheet of all facilities that completed the NHSN Annual Survey in the time period designated above.
- 4. In the facility sampling frame spreadsheet, create a new column for variable "bed size."
  - a. Ensure that facilities are sorted by orgID, in ascending order, in both the facility sampling frame and the Annual Survey line list. Confirm the orgIDs match up before proceeding.
  - b. Copy the numBeds column from the Annual Survey line list and paste into the bed size column in the facility sampling frame spreadsheet. Ensure that the pasted bed size variable is matched to the correct facility.
- 5. Divide the total facilities in the sampling frame into two strata. Create a new column, "stratum," and assign each facility to either Stratum 1 or Stratum 2:
  - a. Stratum 1: Includes all facilities in the sampling frame that have a bed size of <400.
  - b. Stratum 2: Includes all facilities in the sampling frame that have a bed size of ≥400.

#### 6. Stratum 1:

- a. If there are 25 or fewer facilities within Stratum 1, select all facilities within Stratum 1 and proceed to Stratum 2.
- b. If there are more than 25 facilities within Stratum 1, assign a random number to each facility. Sort facilities by random number and select the first 25 facilities.
  - i. Refer to Table 1 below for three methods for random number assignment.

#### 7. Stratum 2:

- a. If there are 5 or fewer facilities within Stratum 2, select all facilities within Stratum 2 then return to Stratum 1. Select additional facilities from Stratum 1 in descending order, starting with the first facility on the list that was not sampled during step 6, to reach a total of 30 facilities selected.
- b. If there are more than 5 facilities within Stratum 2, assign a random number to each facility. Sort facilities by random number and select the first 5 facilities.
  - i. Refer to Table 1 below for three methods for random number assignment.

- c. If Stratum 1 has fewer than 25 facilities, return to Stratum 2.
- 8. Select additional facilities from Stratum 2 in descending order, starting with the first facility on the list not previously sampled, to reach a total of 30 facilities selected.

Table 1. Random ni	umber assignment methods
Option 1: Excel	<ol> <li>Using the facility list created above, or an HAI line list, insert the command =ROUND(RAND()*1000000,0) into column B and drag to paste this command for each row of the facility list. This will generate a random number for each orgID.</li> <li>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.</li> <li>Delete column B so the columns shift left and column C becomes column B.</li> <li>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</li> </ol>
Option 2: Random Number Generator Website + Excel	<ol> <li>Identify the total number of facilities from the list created above, or the number of records on HAI line list,</li> <li>Go to <a href="https://www.random.org/sequences/">https://www.random.org/sequences/</a></li> <li>Input 1 as the smallest value, and the total number of facilities/records as the largest value, and click "Get Sequence"</li> <li>Copy the sequence created and paste it into column B of your spreadsheet.</li> <li>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.</li> </ol>
Option 3: SAS Codes	<ol> <li>Enter the appropriate file path where prompted in the code</li> <li>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.</li> <li>The final list, assigned and sorted by a random number, will be exported to the same folder specified in step 1.</li> </ol>

# Section 2. Download ("freeze") the facility's reported data from NHSN

Prior to selecting the medical records sample, use NHSN Analysis Reports and the modifications described below to "freeze" (take a snapshot of) the data and export the facility's reported CLABSI events. Freeze the data for each facility selected for validation. While in the NHSN application, this would be an opportune time to download each facility's NHSN Annual Survey, which will be needed during the on-site, or virtual, visit. The Annual Survey will be used to review risk adjustment variables (teaching hospital affiliation, bed count, number of patient days, and number of admissions).

To "freeze" data, select the Analysis tab in the left-hand navigation bar, and then Reports. Select HAI Detailed Reports (Line Lists, Rate Tables, etc.), Device-Associated (DA) Module, CLABSI, and then "Line Listing – All CLABSI Events," and then click Modify Report.

#### **Suggested Modifications:**

- Under the Title/Format tab, select xls as the format. You may also change the title of the report (i.e. <Facility ID> <Freeze Date> NHSN CLABSI Events Line List).
- Under the Time Period tab, go to the Date Variable drop-down and select "eventDateYr." For both Beginning and Ending, enter 2024, or the year of data to be validated.
- Under the Filters tab, in the row of drop-down boxes, select "orgID," "equal," and enter the facility's orgID number.
  - Optional: Export single report with all facilities, sort by "orgID," and copy/paste each facility's data into its own spreadsheet. Save each line list in a secure location.
- Optional: Under the Sort Variables tab, select "eventDate."
- Click on the "Export" button. Keep the format as-is (.csv) and select the "Export Analysis Data Set using Modifications" radio button. This will generate the line listing in Excel.
- Save the line listing to a secure location. It will be needed again for the medical record selection process in Section 5.

To find a facility's NHSN Annual Survey, log into NHSN and select Surveys in the Navigation bar, then Find. In the Survey Type drop down menu, select the survey for the type of facility you are validating (for example, FACSRV-PS – Hospital Survey Data, for validation of Acute Care Hospitals). Then, select the appropriate survey year you are validating. Finally, click on the Find button, and a list of facilities and their annual surveys will be generated.

NOTE: Use the **Analysis** button on the Navigation bar and select Reports to export the data. For more information about how to make modifications to these output options, read "How to Modify a Report" found in the Analysis Quick Reference Guide library at: <a href="http://www.cdc.gov/nhsn/PS-Analysis-resources/reference-guides.html">http://www.cdc.gov/nhsn/PS-Analysis-resources/reference-guides.html</a>.

# Section 3. Notify facilities of the planned validation and request the required laboratory line listings

Suggestions on what information should be included in any outreach to facilities notifying them of their selection can be found in section 2.4 of the 2024 PS EVT. Template letters with suggested format of line listings are located in Appendix 1.

# Section 4. Develop the medical record sampling frame for each selected facility

#### CLABSI in surveillance locations

For CLABSI, the sampling frame is derived from positive laboratory (blood culture) line listings in surveillance locations (SLs). From each selected facility, obtain a complete list of positive blood cultures (PBCs) collected from SLs in 2024 (includes all PBCs taken during SL stay, the day of transfer from the SL, and the day following transfer or discharge) to select the medical record sample before the site visit. NHSN encourages facilities to develop capacity to generate these lists electronically as recurring need for this task is expected, and the creation of manual line listings present an excessive burden.

**Note:** The term "surveillance locations," abbreviated SL, is used in the toolkit to indicate that in plan NHSN-reporting locations will be targeted for the validation efforts for CLABSI.

 Validation of CLABSI in NHSN-reporting surveillance locations includes neonatal intensive care unit (NICU) locations

For SL PBCs, identifying organism(s), the MRN, admission date, laboratory specimen number, date of specimen collection (not date of report), resulting first organism genus and species, surveillance location, and patient date of birth are required. Additional patient identifiers such as patient name may be helpful. If needed, ask the IP to translate specific patient location information on the laboratory line listings to mapped NHSN-reporting SLs, and ensure that results for all SLs are included. Be sure it is possible to distinguish NICU from adult/pediatric SLs on this line listing to stratify the CLABSI sample. Information about central line use should <u>not</u> be requested; validators will screen for this information while reviewing records. See example of line list template in Appendix 1.2 of the 2024 PS EVT.

### Section 5. Medical Record Selection

Use the securely transmitted line listing of PBCs obtained from each selected facility in the following medical record selection process:

- 1. For each facility, assign a random number to every PBC following steps outlined in Table 1.
- 2. Sort the list of PBCs by MRN and admission date to generate clusters of PBCs with the same MRN and admission date, also called unique episodes of care (EoC). Create an EoC column where the first EoC = 1. All PBCs in an episode should have the same EoC number.
- 3. Identify NHSN-reported CLABSIs on the facility-provided PBC line listing and assign strata:
  - a. Reference the NHSN CLABSI Events line list created in <a href="Section 2">Section 2</a> to identify any PBCs reported to NHSN as a CLABSI. Create a new column, "stratum," and assign any PBCs reported to NHSN as a CLABSI to stratum 1. Additional PBCs in the same EoC as a reported CLABSI should be assigned to stratum 2.
  - b. If any reported CLABSIs, identified from the NHSN CLABSI Events line listing, are missing from the facility-provided PBC line listing, the facility list may be incomplete. Work with the facility to address the missing CLABSIs. Update the facility-provided PBC line list with the missing CLABSI events once the issue has been rectified.
- 4. Select a simple random sample of 20 reported CLABSIs in NHSN-reporting surveillance locations for review:
  - a. Filter to where stratum = 1.
  - b. Sort by random number.
  - c. Select the first 20 random numbers with a unique EoC number.
  - d. If there are less than 20 reported events, review all stratum 1 and supplement the difference from stratums 3 or 4.
- 5. Identify unreported candidate CLABSI events and stratify by targeted pathogens:
  - a. Filter to where stratum does not equal 1 or 2 and review each PBC to determine if the identified organism is on targeted pathogens list (listed below).
  - b. Sort the unassigned PBCs by identified organism. If more than one organism was identified in an EoC, use the first organism listed.
  - c. If the first listed organism is a targeted pathogen, assign the PBC to stratum 3. If the organism is not a targeted pathogen, assign the PBC to stratum 4.
    - i. Targeted Pathogens\*\*:
      - 1. Candida spp. (yeast)
      - 2. Enterococcus spp.
      - 3. Staphylococcus aureus (includes MRSA, MSSA)
      - 4. Coagulase-negative *Staphylococcus* (includes most *Staphylococcus* spp. Other than *S. aureus*, MRSA, MSSA)
      - 5. Klebsiella spp., E. coli, or Pseudomonas spp. (common gram negatives)
- 6. Among stratums 3 and 4, use location information to identify NICU vs other SL PBCs. Create a new variable, "NICU," and assign a NICU status (yes/no) to PBC as appropriate. Note: If facility has no NICU, skip to step 8 below and select 5 additional medical records from other SLs for screening sample.
- 7. Select a targeted NICU screening sample:
  - a. Filter to where NICU = yes and stratum = 3 (targeted pathogens).
  - b. Sort by random number.
  - c. Select the first 5 random numbers with unique EoC numbers.

- d. If 5 PBCs where NICU = yes and stratum = 3 are not available, supplement the difference to reach 5 by using PBCs where NICU = yes and stratum = 4, taking the lowest random number(s) with unique EoCs.
- 8. Select a targeted non-NICU screening sample:
  - a. Filter to where NICU = no and stratum = 3 (targeted pathogens).
  - b. Sort by random number.
  - c. Select the first 15 random numbers with unique EoC numbers.
  - d. If 15 PBCs where NICU = no and stratum = 3 are not available, supplement to reach 15 by using PBCs NICU = no and stratum = 4, taking the lowest random number(s) with unique EoCs.
- Review selected PBCs to ensure no EoC are repeated/duplicated. If any EoCs are duplicated, keep the first sampled PBC, and replace the subsequent samples from the pertinent screening sample lists.
- 10. The final screening sample should contain 20 PBCs with reported CLABSIs and 20 candidate PBCs divided among NICU, if available, and non-NICU SLs. If final sample contains less than 40 records, randomly select additional records to reach 40, as possible.
- 11. If medical records are not well balanced among different targeted pathogens, consider post-selection adjustment to include a variety of these organisms to evaluate a variety of surveillance skills, as noted below.
- 12. Request the selected medical records in advance of the facility site visit using the template letter found in Appendix 1.3 in the 2024 PS EVT.

#### Why Target CLABSI Pathogens?\*\*

The targeted pathogens provide an opportunity to assess a facility's competency in correctly using different components of the NHSN CLABSI definition. For example:

- Candida BSI is common in ICU patients receiving parenteral nutrition. Reviewing medical records with Candida BSI may provide an opportunity to look for misclassification. Candida species and yeast spp. are commonly seen in sputum samples, but infrequently cause true healthcare-associated pneumonia, therefore are considered excluded organisms for PNU criteria, with some exceptions. NHSN cautions against reporting Candida pneumonia in immunocompetent patients unless there is evidence of invasive infection on lung biopsy or in pleural fluid under the definitions for PNU. These restrictions are further codified (as prohibitions) under ventilator-associated event (VAE).
- Some facilities that do MRSA active surveillance testing on admission incorrectly assume that MRSA colonization on admission means that a MRSA bloodstream infection would not need to be reviewed for CLABSI.
- Including enteric organisms such as Enterococcus and gram-negative rods can demonstrate a
  facility's ability to distinguish primary bloodstream infection vs. an alternative primary
  infection like UTI, GIT, or IAB with secondary bloodstream infection. Interested states can also
  assess use of the mucosal barrier injury reporting definitions, although these are not included
  in the Toolkit.
- Facilities need to know how to correctly report single and confirmed isolates of common commensal organisms like coagulase-negative *Staphylococcus* and should be able to recognize synonyms (for example *Staphylococcus epidermidis*), used by the microbiology laboratory.

### Section 6. Site Visit Activities

#### 6.1 Structured Medical Records Review

#### Validator blinding and consultation at the facility site-visit

Validator blinding as to HAI status is recommended, when feasible. This can be accomplished by mixing and reviewing the selected medical records before determining which have been reported to NHSN with HAIs.

Medical records should be reviewed in a blinded manner using the 2024 Medical Records Abstraction Tool (MRAT), which can be found at 2024 PSC Data Validation Resources | NHSN | CDC, Resources by HAI, CLABSI. This tool includes algorithms and logic designed to establish presence or absence of required criteria for case definitions and provide support to avoid common errors.

For CLABSI validation, when consideration is given to an alternative primary site infection leading to secondary bloodstream infection, use of an appropriate NHSN checklist (available at <a href="https://www.cdc.gov/nhsn/hai-checklists/index.html">https://www.cdc.gov/nhsn/hai-checklists/index.html</a>) is recommended. These checklists provide a structure to record required elements from the NHSN Patient Safety Component Manual's Chapter 17 criteria. Be sure the selected version is for 2024 definitions.

#### 6.2 Review risk adjustment variables

Have a copy of the facility NHSN Annual Survey available and review surveillance location mapping, location bed size, and teaching hospital status with the IP. A list of CDC locations and descriptions can be found in NHSN Patient Safety Manual Chapter 15.

Review NHSN definitions for teaching hospital types (under Key Terms, Patient Safety Manual Chapter 16), and ensure that facility teaching hospital status is accurate in the NHSN Annual Survey.

#### 6.3 Review denominator collection methods and documentation

#### Electronically collected CLABSI denominators

If the facility uses electronic denominator data collection, obtain documentation of their denominator validation process and any periodic spot checks. NHSN specifies that electronic denominator counts should fall within 5% of manual counts for three consecutive months before electronic counts can be used. This may be examined pre- or post-visit.

If documentation of electronic denominator validation is not available, the facility should resume manual counting (and ensure staff training) to re-validate electronic counts, and to retain evidence of valid electronic counting (within 5% for 3 months). Facilities should conduct periodic spot checks even after formal validation to prevent lost information due to changing medical records systems or other disruptions.

#### Manual CLABSI denominator counting methods

Denominator data collection surveys found in sections 6.5 through 6.7 may be administered to the IP contact before or during the site visit. If the facility is manually collecting denominator data, it may be impractical to interview multiple denominator data collectors during the site visit. In this case, collecting contact information during the site visit may be advisable for subsequent administration of surveys by telephone or virtual means. This allows time with the facility to be used efficiently and accommodates interviews with individuals who may work at other times (for example the night shift).

Knowledge of definitions and counting methods is important even in facilities where denominators are reported electronically in order that spot-checks can be conducted periodically. A form for facilities to document required internal validation of electronic denominator counting is provided in Section 6.5.

Facilities may have already administered denominator counting surveys for internal validation purposes. If this is the case, validators may choose to accept their evidence or conduct this survey among a more limited sample of denominator counters.

#### CLABSI denominator record documentation

While visiting, request original records of denominator data collection paperwork, which can provide insight into the frequency, reliability, and consistency of this task and how omissions are handled. NHSN provides guidance for missing device-associated denominator data that can be found at <a href="https://www.cdc.gov/nhsn/pdfs/gen-support/MissingDenomData-508.pdf">https://www.cdc.gov/nhsn/pdfs/gen-support/MissingDenomData-508.pdf</a>.

Consider whether patient days and central-line days data appear as anticipated when manually counted each day: different ink, different but similar numbers. Determine for what percent of day's data are missing and what was done for reporting on those days. This data is best assessed on site, if possible.

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6.4 (Optional) Template for Central Line-Associated Bloodstream Infection (CLABSI) Validation Discrepancies Discussion with Facilities

#### Please feel free to adapt these templates to meet your jurisdiction's needs to discuss discordant outcomes and request changes

Instructions: For each CLABSI Event with a discordant outcome between facility reporters and validators, record the following (first row: enter facility report; second row: enter validator's recommended changes). Use the Comment area to document reasons for discrepancy, for example: overlooked candidate culture, confusion regarding common commensals, did not meet alternative primary definition, etc. Many states have examined this type of data to identify common errors and direct future education and training. Keep a copy for your records and leave a copy with the facility; V=validator

Pt. ID		Positive blood culture event:	Select One:			Event date (if	If LCBI, MBI* LCBI?				
		first culture date	Not candidate CLABSI	Alternative primary (specify)	LCBI1, LCBI2, LCBI3*	LCBI)	MBI Yes or MBI No	POA, HAI or neither	Central line >2d (y/n)	Location of attribution	CLABSI in Surveillance Locations (y/n)
	F										
	V										
Comm	ent:									_	
	F										
	V										
Comm	ent:										
	F										
	V										
Comm	ent:		•					•			
	F										
	V										
Comm	ent:		•			•	•	•			•

\*LCBI 1, 2, 3 (NHSN): types of laboratory-confirmed bloodstream infection. MBI-LCBI (NHSN) mucosal barrier injury LCBI. See definitions in NHSN Patient Safety Manual Chapter 4.

OrgID/Name of Hos	spital:		Date of Survey	:				
Instructions: NHSN	N requires that the mo	nthly electronic deno	minator count falls withi	n a 5% tolerance interval				
of the monthly manual denominator count for 3 consecutive months before reporting electronic denominator								
-	counts for CLABSI. This validation is not conducted during the external survey. The facility is expected to have							
a copy of this inte	rnal validation compar	ing manual counts to	electronic counts availab	ble for the validator to				
		=	facility, skip this survey.					
If electronic device	e denominator countin	g is used for reporting	g at this facility, documen	nt the NHSN-required				
validation results i	below:							
Initial electronic deno	ominator validation (when	electronic denominator re	eporting began):					
Location name:		Manual count	*Calculated 5%	Electronic count				
			tolerance interval					
Month/year:	Patient days							
	Central line days							
Location name:				<u> </u>				
	Patient days							
Month/year:	Central line days							
Location name:				•				
	Patient days							
Month/year:	Central line days							
If available, please do	ocument additional informa	ation for any more recent	electronic denominator valido	ntion:				
Location name:		Manual count	*Calculated 5%	Electronic count				
			tolerance interval					
Month/year	Patient days							
	Central line days							
Location name:								
	Patient days							
Month/year	Central line days							
Location name:								
	Patient days							
Month/year:	Central line days							
•			± (manual count * 0.05).					
Example calculations where manual count = 164 and electronic count = 178:								
•	Eligible 5% tolerance interval = [164±(164*0.05)]=155.8 to 172.2							
Electronic count 178 falls outside the tolerance interval.								



## 6.6 Contact Information for Manual CLABSI Denominator Validation

# Please feel free to adapt this template to meet your jurisdiction's needs

NOTE: If facility ensures annual training updates for denominator counters, and three or more denominator counters show proficiency on the survey, or if facility has already internally surveyed denominator counter proficiency, this can serve as evidence of proficiency.

OrgID	/ Name of Hospi	ital	Date of Survey					
ID	Name of data collection professional	Surveillance locations covered	Work hours/ Preferred time for telephone survey	Phone number(s)	Supervisor			
1	,		, , , , , , , , , , , , , , , , , , , ,					
2								
3								
4								
5								
6								
7								
8								
9								
10								
Addı	rows as needed		_	_	_			





# 6.7 CLABSI Denominator Counting Survey (with Key)

where the	ese tasks are performed by	different persons	-	questions applicable to collecting <b>PA</b>	form is divided into 2 sections for facilities  TIENT DAYS (questions 1-9). The second	
		Positio	n:			
Facility OrgID:	Name/ID of individual	□ IP □ Cleri		Interviewer initials:	Date of survey:	
	interviewed:		er (explain)			
CLABSI De	enominators	NHSN location(s	s) covered:			
PATIENT I	DAYS (for CLABSI denomin	nator counters)		Answer Key:		
How are patient days usually collected? (choose one)  Electronically (document the software system utilized and skip to Q8):  Manually (daily/weekly)  Some units electronic and some units manual				estimated central line day collection in non-oncology SCA/ONC locations or NIC in the location (patient-do one central line of any type designated day each week same time each day.	kly sampling of denominator data to generate vs, may be used as an alternative to daily vs ICUs and wards. Sampling may not be used in CUs. During the month, the number of patients ays) and the number of patients with at least be (central line days) is collected on a k (for example, every Tuesday), and at the	
Со	mment:				device days per month must be greater ice days if using weekly denominator	
2. Is there a specified time when the denominator count is taken? ☐ Yes ☐ No				The answer should be Yes		
3. When is it done?				Counts should be done at a specific time daily, preferably at nearly the same time throughout the facility to avoid errors when patients transfer		



1	Describe the method used to count <b>patient days</b> :		From NHSN: Denominator data (patient days and central line			
	Count the number of <u>patients</u> assigned to a unit bed <u>at the same time central counts are conducted</u>	<u>Il line</u>	days) should be collected at the same time, every day, for each location performing surveillance to ensure that differing collection methods don't inadvertently result in central line days being > patient days.			
	Other (specify):					
5.	When reporting monthly patient day total, what is done if there are missing patient day data? (choose one)	denomin	NHSN issued specific guidance on imputing values for missing device-associated denominator data <a href="https://www.cdc.gov/nhsn/pdfs/qen-">https://www.cdc.gov/nhsn/pdfs/qen-</a>			
	Report the sum of available daily counts with no adjustment for missing data	support/	/MissingDenomData-508.pdf)			
	Estimate or re-create missing data from existing information using our own methods					
	Impute missing values using recent CDC/NHSN guidance					
	Other (specify):					
6.	Which best describes your training for denominator (patient days and central lin	ne days) d	counting? (select all that apply)			
	No specific training was provided		training by NHSN or NHSN-trained IP is recommended due to al aspects of definitions (for example, central line, permanent line,			
	Peer training (person who previously counted explained their approach to new staff)	temporary line) and methods (for example, when to count lines, how many to count).				
	Formal training by IP					
	Formal training by NHSN (for example, online training)					
	Annual training updates					
	Other (describe):					
7.	Which staff member counts patient days and central line days when the "regular" data collector(s) is/are not working?		P ☐ Another trained counter ☐ Nobody ☐ Other (specify)			
8.	Does your facility have a mechanism in place for quality control of denominator	data? (So	elect one):			
	(Electronic data) Yes, data submitted electronically is periodically checked using manual methods					



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	(Manual data) Yes, manually collected data are periodically counted by more than one staff member	
	Yes, other (explain)	
	No formal quality control process	
9.	Which staff member(s) is/are responsible for entering surveillance locations patient days and central line day data into NHSN?	☐ IP ☐ Counter ☐ Clerical ☐ Other (specify)
CEI	NTRAL LINE DAYS (for CLABSI denominator counters only)	Answer Key/Rational
10	How are <b>central line days</b> collected for the unit(s) you oversee? (choose one)	

CENTRAL LINE DAYS (for CLABSI denominator counters only)	Answer Key/Rational
10. How are central line days collected for the unit(s) you oversee? (choose one)	
Electronically (specify software system utilized and skip to Q13):	
Manually (daily/weekly)	
Some units electronic and some units manual	
Comment:	



11. Identify the method used to count central line days: (choose one)	A daily count of the number of patients with a central line in the		
Count the number of patients with at least one central line at the time surveillance rounds are conducted	patient care location during a time period, which is summed for the monthly total		
Count the number of central lines that are in place at the time surveillance rounds are conducted			
Count the number of central lines that are in use at the time surveillance rounds are conducted			
Other (specify):			
12. When reporting monthly central line day total, what is done if there are missing central line day data? (choose one)	NHSN issued specific guidance on imputing values for missing device- associated denominator data <a href="https://www.cdc.gov/nhsn/pdfs/gen-">https://www.cdc.gov/nhsn/pdfs/gen-</a>		
Report the sum of available daily counts with no adjustment for missing data	support/MissingDenomData-508.pdf)		
Estimate or re-create missing data using existing information (for example, medical records), then sum			
Impute missing values using recent CDC/NHSN guidance for missing denominator data			
13. A patient has a radial arterial line and a peripheral IV. How many central line days are counted for this patient on this day?	Zero. The radial arterial line and peripheral IV are not central lines.		
14. A patient has a temporary central line and a permanent central line that have both been used during this hospitalization. How many denominator device line days are counted for this patient on this day?	One. Although the patient has two central lines, a device day is defined as the number of patients who have the device, not the number of devices.		
15. The patient above with the temporary central line and the permanent central line is on an oncology ward. Should you report one temporary line day, one permanent line day, or both a temporary and a permanent line day?	When a patient in an oncology location has both temporary and permanent lines, the line day is reported as a temporary line day. (This information is detailed in the NHSN PSC Manual, Instructions for Form 57.117I)		
16. A patient has a port-a-cath that has not been accessed during this hospital stay, and a peripheral IV that is in use. How many denominator device days are counted for this patient on this day?	One. Beginning in January 2024, central lines that are present on admission should be included in denominator device day counts beginning on the day of admission to an inpatient location. This is regardless of access of the central line. The peripheral IV is not a central line.		



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17. A port-a-cath was inserted during this admission f not in use. How many denominator device days and day?	One. If a central line was accessed via placement in an inpatient location during the current admission, it is counted in the denominator device day count each day that it remains in place, whether in use or not.	
18. A patient has a central line that was accessed for a but is not currently in use, and a peripheral IV that days are counted for this patient on this day?	One. The central line was accessed in an inpatient location during this stay. All central lines should be included in denominator device day counts once the patient locates to an inpatient location. This is regardless of access of the central line.	
19. A patient has a central line that was accessed onc during evaluation leading to admission. The patien location, but the line is not currently in use. How have counted for this patient on this day?	One. All central lines should be included in denominator device day counts once the patient locates to an inpatient location. This is regardless of access of the central line.	
20. If a central line is removed at 2PM and replaced at 8PM. The central line day count is done at 5PM, should the line be counted?	Yes No Unknown	No. Central line must be in place at time of count.
NICU-Specific Central Line Questions ( <i>Optional: Check</i> 21. When reporting central line (CL) days, in neonates, which neonatal weight is used for	k here and skip section if NICU quest  Birth weight  Current weight	ions do not apply to your job) [])  Birth weight
reporting? (select one)  22. Neonates with both a CL and an umbilical catheter (UC) are included in the daily count as: (select one)	UC only  CL only  2 separate lines	CL only. No separate reporting of UCs; UCs are considered CLs. Although the patient has two central lines, a device day is defined as the number of patients who have the device, not the number of devices. When reporting the central line, it should be stratified by birth weight.



# 6.8 (Optional) 2024 CLABSI Validation Summary

*required **conditionally required	
------------------------------------	--

Facility Validation Overview					
*Facility ID:					
*Facility Type:	<ul> <li>□ Acute care hospital</li> <li>□ Long term acute care hospital (LTAC/LTACH)</li> <li>□ Oncology hospital</li> </ul>				
*Facility sampling method:	☐ CDC Method 1 (Ta☐ CDC Method 2 (Cu☐ CDC Method 3 (St	ımulative attributa	•		
Reason Facility was Sampled:	☐ All facilities were validated ☐ Targeted facility (Methods 1 or 2) ☐ Randomly selected				
Numerator Validation					
*Sampling information for nume	erator validation at thi	s facility:			
Event Sa	Sampling Frame Elements  Sampling Frame (# episodes/procedures eligible Total # events facility reported to NHSN for for review during timeframe)  timeframe (before validation)				• •
CLABSI (including NICU)	Medical records with PBC(s)				
*CLABSI in surveillance locations	(including NICU) Vali	dation Results:			
Event Determination		Validation: Yes - Cl	LABSI	Validation: No – Not CLABSI	
Facility: Yes - Date-matched C	d CLABSI reported a		b		
Facility: No - Date-matched Cl	cility: No - Date-matched CLABSI NOT reported c d				
<b>Denominator Validation: Central</b>	Line and Patient days	for CLABSI			
**Which method was used by this locations denominator (patient dath) this timeframe?	ays and central line da	ys) counting for	□ Manual counting:     □ Daily □ Weekly sa     □ Electronic counting     □ Both manual and electronic	counting	
++ Only ICU and ward location types	with an average of 75 or	more central line-da	ays per month are eligible to use t	his method.	



In	ne	2	กว	0

, '		□ Yes □ No				
**If yes, provide the following information for all locations and months valid						
Validation method						
Location of validation Month	of validation	(enter A, B, or C)		Count 1		Count 2
Notes: If Method A is chosen, Count 1	should be "Usual Co		d he "Exnert (Re	ferent) Cou	ınt "	
If Method B is chosen, Count 1						
If Method C is chosen, Count 1					,	
Validation of manual denominator data	a counting requires e	either:				
<ul> <li>Method A – Concurrent dual c</li> </ul>			reference) for ≥	three mor	iths OR	
<ul> <li>Method B – Concurrent patier</li> </ul>	nt days data (ADT-Ad	mission/Discharge/Trar	nsfer or other ref	erence) ar	nd manual counting for ≥	three consecutive months
Validation of electronic denominator d	ata counting require	s:				
<ul> <li>Method C – Concurrent manus</li> </ul>	al denominator cour	nting (reference) vs. elec	ctronic data for ≥	three mo	nths	
NHSN Inpatient Location Validation	n: MAPPING					
			☐ Yes			
**Do any inpatient locations require mapping or re-mapping within NHSN?		D No				
**If yes indicate which locations no	ed to be manned.	re-manned and recor				
**If yes, indicate which locations need to be mapped/re-mapped and recommendations:						
Current CDC	Dood Dood	ommended CDC	D = == == == = = = = = = = = = = = = =	المما لمما		
			Recommend	ea bea		
Location designation co	ount loca	tion code designation	count			
Add rows as needed.						
Add rows as needed.						



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Jun	ıe		UΖ	٦

Vas = 0 = 0	
**How does this facility obtain inpatient admissions data?	☐ Electronic from billing ☐ Electronic from vendor system ☐ Electronic from ADT ☐ Other (specify): ☐ Other (specify): ☐ Other (specify): ☐ Other (specify):
**How does this facility obtain inpatient patient days data?	□ Electronic from billing □ Electronic from vendor system □ Electronic from ADT □ Other (specify):
Risk Adjustment Variable Validation	
**CLABSI Surveillance location (SL) mapping (including NICUs)	
Number of SLs correctly mapped in NHSN (including NICUs):	
Number of SLs incorrectly mapped (including NICUs):	
Number of SLs (including NICUs) omitted from mapping:	
Number of SLs mapping errors:	
**Teaching hospital affiliation (CLABSI in surveillance locations)	
Facility teaching hospital affiliation reported on 2024 NHSN annual facility survey:	<ul> <li>□ Non-teaching</li> <li>□ Major</li> <li>□ Graduate</li> <li>□ Undergraduate</li> <li>□ N/A (LTACH)</li> </ul>
Is facility teaching hospital affiliation correct?	□ Yes □ No
Comments	
Comments	

