2023 CDI LabID External Validation Toolkit

The 2023 CDI LabID External Validation Toolkit is a HAI-specific supplement to be used in conjunction with the 2023 NHSN Patient Safety External Validation Toolkit (2023 PS EVT). It is intended to help guide the process of external validation specifically for CDI LabID events with step-by-step instructions and screenshots from NHSN.

Table of Contents

Section 1. Facility Selection

1.1 Steps applicable to all Facility Selection Methods

Generate Datasets and Modify Report

1. Generate new data sets in NHSN to ensure any data updates are included for analysis. On the NHSN Landing Page, navigate to Patient Safety Component → [YOUR Jurisdiction/State 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 New button. Allow the data set generation process to complete; you can leave NHSN during the generation process.

2. After successful data set generation, navigate to Analysis → Reports to display the tree view list of all analysis reports available within NHSN's analysis tool.
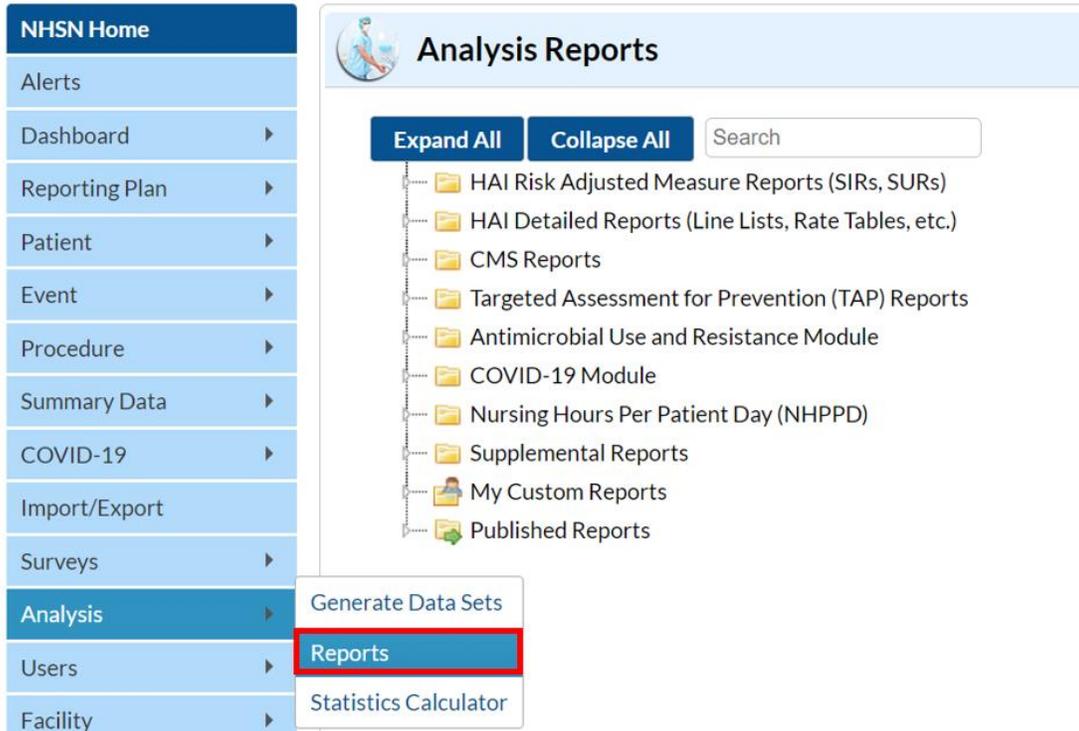
3. Expand the HAI Risk Adjusted Measure Reports (SIRs, SURs) folder, select 2015 Baseline (Baseline Set 2), CDI LabID, and then SIR – ACH CDI FacWideIN LabID Data (2015 Baseline). If you are validating Critical Access Hospitals (CAHs), Inpatient Rehab Facilities (IRFs), or Long-term Acute Care Hospitals (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 that 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 2023, or to the year of data being validated.

> 4b. Navigate to the "Filters" tab. In the row of drop-down boxes, select "cdifLabIDPlan," "equal," and enter "Y." Note: CDI SIR will only calculate at FACWIDEIN level.
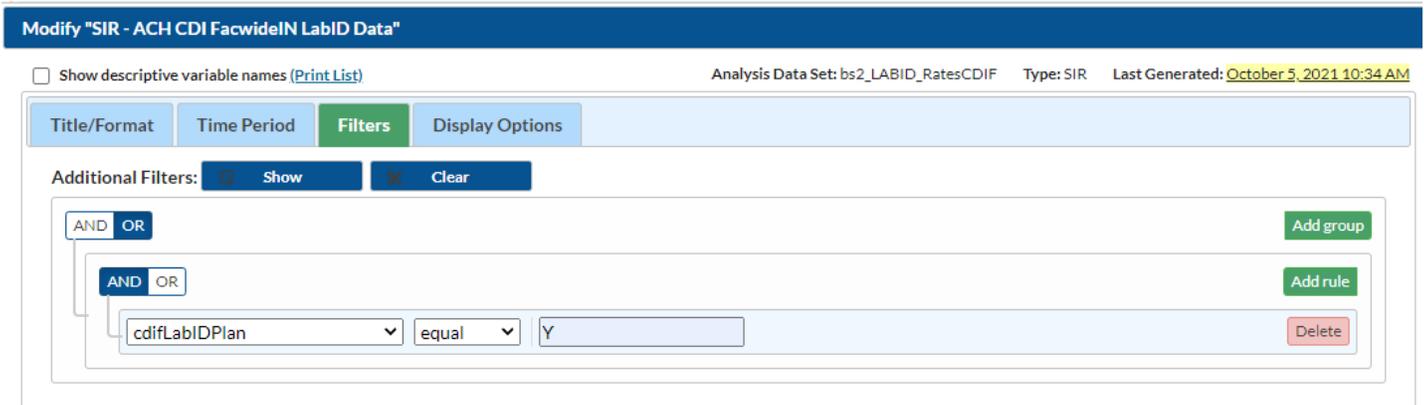
Note: CDI SIR will only calculate at FACWIDEIN level.

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."
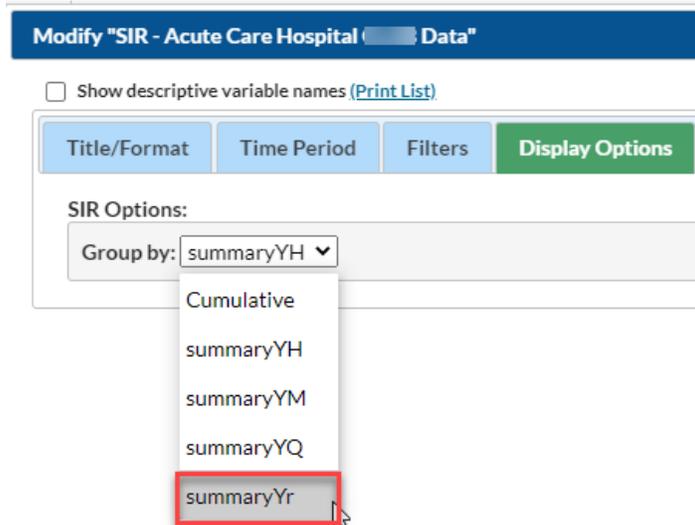
5. After making the above modifications, scroll to the bottom of the modification window. Click the Export button to export the data selected by your modifications. This will open the "Export Analysis Data Set" window.

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. Select the orgID level, as illustrated in the screenshot below, to get an unduplicated list of facilities in your jurisdiction.

summaryYr	_TYPE_	_FREQ_	CDIF_facIncHOCount	numPred	numpatdays	sir_l	sir_u	SIR_pval	SIR	spcOrgType	orgID	
2020	0	175	9941	8981.348	11944462	1.085	1.129		1.107	*SIR for all facilities in the Group*		
2020			322	235.998	254200	1.219	1.522	0	1.364	CDIF	100	
2020			8	57.016	68795	0.061	0.276	0	0.14	CDIF	101	
2020			135	95.419	158536	1.186	1.675	0.0001	1.415	CDIF	102	
2020			183	168.317	183307	0.935	1.257	0.1376	1.087	CDIF	103	
2020			61	129.912	186976	0.359	0.603	0	0.47	CDIF	104	
2020			59	67.143	83769	0.669	1.134	0.176	0.879	CDIF	105	
2020			61	104.33	151973	0.447	0.751	0	0.585	CDIF	106	
2020			39	65.961	99509	0.42	0.808	0.0002	0.591	CDIF	107	*THIS IS THE LEVEL TO INVESTIGATE*
2020			127	116.421	124068	0.909	1.298	0.1745	1.091	CDIF	108	SIR for each facility in the group
2020			140	156.752	229709	0.751	1.054	0.0954	0.893	CDIF	109	
2020			91	40.829	68914	1.794	2.737	0	2.229	CDIF	110	
2020			6	54.44	81964	0.04	0.24	0	0.11	CDIF	111	
2020			144	134.459	168483	0.903	1.261	0.2161	1.071	CDIF	112	
2020			38	63.655	95871	0.422	0.819	0.0004	0.597	CDIF	113	
2020			52	64.913	76570	0.598	1.051	0.0579	0.801	CDIF	114	
2020			13	30.273	49980	0.229	0.734	0.0003	0.429	CDIF	115	
2020			29	72.694	107924	0.267	0.573	0	0.399	CDIF	116	
2020			57	80.046	115823	0.539	0.923	0.0042	0.712	CDIF	117	

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 <u>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</u>). This will allow you to explore the level of exposure risk for CDI LabID Event and measured performance at each facility. 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.

2. 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 of CDI LabID events. This top tertile of facilities where CDI LabID events 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" (largest to smallest). 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 2023 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 <u>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)</u>. This will allow you to explore the level of exposure risk for CDI LabID Event and measured performance at each facility. 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.

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 for 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, 1.170			100008	HOSP-GEN
22	15.32671	9910	0.1034	1.435	0.922, 2.138			100030	HOSP-CHLD
10	9.736101	8387	0.8926	1.027	0.522, 1.831				
8	9.542312	7958	0.6509	0.838	0.389, 1.592				
1	9.064373	7682	0.0013	0.11	0.006, 0.544				
2	7.578169	6272	0.0235	0.264	0.044, 0.872				
7	5.689505	4581	0.5585	1.23	0.538, 2.434				
4	5.504663	4879	0.558	0.727	0.231, 1.755				
2	3.159258	2784	0.5651	0.633	0.106, 2.092				
2	2.437844	2304	0.8601	0.82	0.138, 2.710				
0	1.945079	1724	0.143	0	, 1.540				
3	1.572374	1812	0.2846	1.908	0.485, 5.193				
1	1.527251	1760	0.7659	0.655	0.033, 3.229			100010	HOSP-GEN
2	1.329405	1357	0.5333	1.504	0.252, 4.970			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, 6.077			100005	HOSP-GEN
1	1.052644	933	1	0.95	0.048, 4.685			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

> **Sort the facilities in descending order of number of predicted infections (numPred) and compute the 75th percentile value of the variable numPred**

4. Identify the 75th 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 75th percentile value.

Function Arguments   ?   ✕

PERCENTILE.INC

Array   C2:C50 ⬆ =

K   0.75 ⬆ = 0.75

         = PERCENTILE.INC(C2:C50,0.75)

Returns the k-th percentile of values in a range, where k is in the range 0..1, inclusive.

         Array   is the array or range of data that defines relative standing.

Formula result =   PERCENTILE.INC(C2:C50,0.75)

Help on this function   OK   Cancel

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

infCount	numPred	numclday	SIR_pval	SIR	sir95ci	locationTy	locCDC	orgID	facType
13	18.51959	15267	0.1921	0.702	0.390, 1.170			100008	HOSP-GE
22	15.32671	9910	0.1034	1.435	0.922, 2.138			100030	HOSP-CH
10	9.736101	8387	0.8926	1.027	0.522, 1.831			100014	HOSP-GE
8	9.542312	7958	0.6509	0.838	0.389, 1.592			100046	HOSP-GE
1	9.064373	7682	0.0013	0.11	0.006, 0.544			100001	HOSP-GE
2	7.578169	6272	0.0235	0.264	0.044, 0.872			100002	HOSP-GE
7	5.689505	4581	0.5585	1.23	0.538, 2.434			100022	HOSP-GE
4	5.504663	4879	0.558	0.727	0.231, 1.753			100027	HOSP-GE
2	3.159258	2784	0.5651	0.633					
2	2.437844	2304	0.8601	0.82					
0	1.945079	1724	0.143	0					
3	1.572374	1812	0.2846	1.908					
1	1.527251	1760	0.7659	0.655					
2	1.329405	1357	0.5333	1.504					
0	1.242188	1101	0.2888	0					
2	1.087298	1253	0.3934	1.839	0.308, 6.077			100005	HOSP-GEN

75th percentile value of numPred= 5.5. Select facilities with numPred >5.5. Only facilities in the red box (where numPred >5.5) are included in the sampling frame for targeted validation.

6. Create a subset of facilities that includes facilities with predicted number of CDI LabID 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 75th 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 75th 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 CDI LabID events and actual observed CDI LabID events (reported). The infCount is an aggregated count of observed CDI LabID events.
   - 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.
   o 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 pooled aggregate estimate of 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 pooled aggregate 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	
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								HOSP-GEN	
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		0.11	0.0				CEN
2	7.578169	-5.57817	6272	0.0235		0.264	0.				N
13	18.51959	-5.51959	15267	0.1921		0.702	0.				N
8	9.542312	-1.54231	7958	0.6509		0.838	0.				N
4	5.504663	-1.50466	4879	0.558		0.727	0.				N
10	9.736101	0.263899	8387	0.8926		1.027	0.				N
7	5.689505	1.310495	4581	0.5585		1.23	0.				N
22	15.32671	6.673286	9910	0.1034		1.435	0.9				HLD

Compute the CAD values for all facilities in the sampling frame. Filter for stratum 2 facilities, where infCount > 0. Sort by ascending CAD value (lowest values on the top). If the sampling frame has greater than 15 facilities, select the top 15 facilities.

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 75th 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). This will allow you to explore the level of exposure risk for CDI LabID Event and measured performance at each facility. 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.

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 CDI LabID events 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.
   b. Use the tree view structure to select Supplemental Reports, Facility-Level Data, and Line Listing – Hospital Survey (2021 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 01/01/2023 for Beginning and 12/31/2023 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 the 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 number assignment methods	
Option 1: Excel	1. 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. 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 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 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. Enter the appropriate file path where prompted in the code 2. 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. 3. The final list, assigned and sorted by a random number, will be exported to the same folder specified in step 1.

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 CDI LabID 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 the HAI Detailed Reports (Line Lists, Rate Tables, etc.), MDRO/CDI Module – LabID Events, C. Difficile LabID Events, and then "Line Listing for All CDI LabID 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 CDIF LabID Events Line List)).
- Under the Time Period tab, go to the Date Variable and select "specDateYr." For both Beginning and Ending, enter 2023, or the year of data to be validated.
- Under the Filters tab, verify the drop-down boxes read "spcOrgType," "equal," and "CDIF – C. difficile."
- Click on the Add rule button to add another line, and 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 "specimenDate."
- 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.

To find a facility's NHSN Annual Survey, log into NHSN and select Surveys in the Navigation bar, then click 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 survey year for which 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: http://www.cdc.gov/nhsn/PS-Analysis-resources/reference-guides.html.

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 2023 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

CDI LabID Event, facility-wide inpatient (FacWideIN)

For CDI LabID Event, the sampling frame is derived from positive laboratory (CD-positive stool specimen) line listings. From each selected facility, obtain a complete list of final *C. difficile* PCR-positive laboratory results collected in 2023 for inpatients facility-wide (excluding neonatal intensive care units [NICU], skilled care nursery, babies in labor/delivery/recovery/post-partum [LDRP] locations, and well-baby nurseries), plus ED/24-hour observation units. Laboratories may conduct one-, two-, or three-step testing for toxigenic *C. difficile* on unformed stool specimens; regardless of the testing approach, only final positive results indicating the presence of *C. difficile* should be included. 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.

For positive CDI LabID Event (FacWideIN), the MRN, facility admission date, stool specimen number, specimen collection date, result of final CDI test, specific inpatient (or ED/24-hour observation) location at time of specimen collection, patient sex, and patient date of birth are required. Additional patient identifiers such as patient name may be helpful. See example of line list template in Appendix 1.2 of the 2023 PS EVT.

Section 5. Medical Record Selection

Use the securely transmitted line listing of *Clostridioides difficile* (C. diff) stool specimens obtained from each selected facility in the following medical record selection process.

1. For each facility, assign a random number to every positive C. diff result, following steps outlined in Table 1.
2. Sort the list by MRN, admission date, and specimen date to generate clusters of specimens with the same MRN and admission date, called unique "Episodes of Care" (EoC). Create an EoC column where the first EoC = 1. All positive C. diff results in an episode should have the same EoC number.
3. Identify the first positive C. diff specimen for each EoC and randomly select 20:
   a. Create a new column, "stratum," and assign the first positive specimen from each EoC to stratum 1.
   b. Filter to where stratum = 1.
   c. Sort by random number and select the first 20 specimens with a unique EoC.
4. Identify and randomly select 20 non-first positive specimens:
   a. Filter to where stratum does not equal 1.
   b. Sort by random number and select the first 20 specimens with a unique EoC number.
5. If there are any duplicate EoC numbers, keep the record with the smallest random number and substitute out the others with the next C. diff specimen on the list with a unique EoC number.
6. The final screening sample should contain 40 positive C. diff specimens. If the total number of sampled specimens does not equal 40, supplement the difference with the remaining specimens, as possible.
7. Request the selected medical records prior to the facility site visit using the template letter found in Appendix 1.3 in the 2023 PS EVT.

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 2023 Medical Records Abstraction Tool (MRAT), which can be found at 2023 PSC Data Validation Resources | NHSN | CDC, Resources by HAI, CDI LabID Event. 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.

6.2 Review risk adjustment variables:

Have a copy of the facility NHSN Annual Survey available and review location mapping facility-wide if this has not been done to the jurisdiction's satisfaction in the past 3 years. Otherwise, review changes since the last facility-wide review.

Review location mapping and bed size information with the IP. A list of CDC locations and descriptions can be found in the NHSN Patient Safety Manual Chapter 15. If there is insufficient time to complete this onsite, consider arranging a conference call to review location mapping when data are readily accessible.

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 CDI facility-wide inpatient (FacWideIN) denominators

"FacWideIN" surveillance data includes all patient days counted at the same time each day for all inpatient locations, including any patients housed for the day in inpatient locations, whether the facility considers them "admitted patients" or "observation" patients, but excluding any patients housed for the day in outpatient "observation" locations. This information is often collected electronically. Because the task of validating "FacWideIN" patient days and admissions is daunting, denominator data validation can be accomplished using manual counting of patient days and admissions in three specified location types for one month each: one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location (if available), and one or more wards where "observation" patients are frequently located. Manual counts should be within 5% of the referent (usual) electronic counts, or an evaluation of why they differ should be conducted. This can be documented using the template in Section 6.6. One consideration is the facility's ability to capture "observation" patients within inpatient locations electronically. Electronic admissions, discharge, and transfer (ADT) data often are found to be more accurate than electronic billing data in this regard. This internal validation process can be conducted by facilities when requested or required.

6.4 (Optional) Template for *Clostridioides difficile* Infection (CDI) LabID Event 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 CDI LabID Event with 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 specimen, confusion regarding common commensals, did not meet alternative primary definition, not a uropathogen, 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. F=facility; V=validator

Pt. ID		Admission Date	Date of first reportable LabID Event during this encounter	NHSN location of LabID Event	CDI -positive result from date of admission specimen? Y/N	Prior CDI -positive result from same location within prior 14 days? Y/N	Other reason for error
	F						
	V						
Comment:							
	F						
	V						
Comment:							
	F						
	V						
Comment:							
	F						
	V						
Comment:							
	F						
	V						
Comment:							
	F						
	V						
Comment:							

6.5 CDI LabID Event Surveillance Methods Survey (with Key)

OrgID / Name of Hospital _____ Date:_____

LabID Event Surveillance Methods Survey				
Instructions: Administer this survey to the person who oversees NHSN LabID Event reporting				
Denominator Data Collection Questions				
Name of individual interviewed:	Position:	☐ FacWideIN CDI	Interviewer initials:	Date of survey:
1) For FacWideIN reporting, denominator data are entered into NHSN once a month at the facility-wide level		☐ True ☐ False		T
2) For CDI reporting, the denominator should include all completed CDI tests		☐ True ☐ False		F (denominator = admissions and patient days)
3) Patient days include only admitted patients on inpatient wards; observation patients located on inpatient wards are excluded		☐ True ☐ False		F (all patients housed in inpatient locations)
4) For CDI reporting pediatric locations should be excluded from FacWideIN reporting		☐ True ☐ False		F (NICU and well-baby locations and babies on LDRP are excluded for CDI)
LabID Event (Numerator) Data Collection Questions				
Name of individual interviewed:	Position:	☐ FacWideIN CDI	Interviewer initials:	Date of survey:
5) For FacWideIN reporting, one monthly numerator for Events is reported at the facility-wide level		☐ True ☐ False		F (events are reported by location)
6) For CDI reporting, the numerator should include –toxin positive CDI results conducted on formed stool specimens		☐ True ☐ False		F (laboratories should only process and report results for unformed stools)
7) A second event is always reported if >14 days have passed from the most recent positive CDI test result		☐ True ☐ False		T
8) A second event is only reported if >14 days have passed from the most recently reported CDI LabID event		☐ True ☐ False		F (If the patient changes location, a second event is reported even within 14 days of prior event)
9) A second event is only reported if the patient changes location OR >14 days have passed since the most recent positive CDI test in the same location		☐ True ☐ False		T

10)	Only reportable CDI LabID Events should be entered into NHSN	☐ True ☐ False	T
Policy Question			
11)	Does your facility laboratory limit CDI testing and reporting to unformed stool specimens only, or does the laboratory process all stool specimens for CDI if ordered?	☐ Unformed stool specimens only ☐ All stool specimens	Recommended policy is to only process unformed stool specimens for CDI

6.6 LabID Event Facility-Wide Inpatient (FacWideIN) Denominator Validation Template

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

Electronically CDI FacWideIN denominators

"FacWideIN" includes all patient days counted at the same time each day for all inpatient locations, including any patients located for the day in inpatient locations, whether or not the facility considers them admitted patients or observation patients, but excluding any patients located for the day in outpatient observation locations. This information is typically collected electronically.

Because the task of validating electronic patient days and admissions facility-wide is daunting, denominator validation can be accomplished using manual counting of patient days and admissions in three specified location types for three months each: one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location (if available), and one or more inpatient wards where observation patients are frequently located. Facilities with inpatient rehabilitation facility (IRF) and/or inpatient psychiatric facility (IPF) locations with separate CCNs and facilities with baby-based locations (for example, NICU, well baby nursery, etc.) should also validate these locations.

Electronic counts should be within 5% of manual counts or an evaluation of why they differ should be conducted.

CDI LabID Event Denominator Validation							
Location of Validation*	Month of Validation *(specify)*	Admissions			Patient Days		
		Usual Count	5% Tolerance interval†	Manual Count	Usual Count	5% Tolerance interval†	Manual Count
	1						
	2						
	3						
	1						
	2						
	3						
	1						

	2						
	3						

*Select one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location if available, and one or more inpatient ward location where observation patients are frequently located and conduct manual (patient level) validation of admissions and patients days for three consecutive months, according to NHSN definitions. (https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual_current.pdf, and http://www.cdc.gov/nhsn/forms/instr/57_127.pdf).

Remember that for CDI, **only mothers (and not babies)** are counted in LDRP locations.

†Equation for 5% tolerance interval: Usual Count ± (Usual Count * 0.05).

Example calculations where Usual Count = 164 and Manual Count = 178:

Eligible 5% tolerance interval = [164±(164*0.05)]=155.8 to 172.2

Manual Count 178 falls outside the tolerance interval, suggesting that Usual Count is inaccurate and should be investigated.

6.7 (Optional) 2023 CDI LabID Validation Summary
*required   **conditionally required

Facility Validation Overview	
*Facility ID:	
*Facility Type:	☐ Acute care hospital ☐ Long term acute care hospital (LTAC/LTACH) ☐ Oncology hospital ☐ Inpatient rehabilitation facility (IRF)
*Facility sampling method:	☐ CDC Method 1 (Targeted Sampling) ☐ CDC Method 2 (Cumulative attributable difference) ☐ CDC Method 3 (Stratified Random Sampling)
Reason facility was sampled:	☐ All facilities were validated ☐ Targeted facility (Methods 1 or 2) ☐ Randomly selected facility

Numerator Validation			
*Sampling information for numerator validation at this facility:			
Event	Sampling Frame Elements	Sampling Frame (# episodes or procedures eligible for review for timeframe)	Total # events from facility reported to NHSN for timeframe (before validation)
CDI LabID event	Inpatient^ stools positive for C. difficile, excluding those from "baby locations"	_____	_____

* CDI LabID Event Validation Results:

Event Determination	Validation: Yes - CDI reportable LabID event	Validation: No – Not CDI reportable LabID event
Facility: Yes - Date-matched CDI test reported as LabID event	a. _____	b. _____
Facility: No - Date-matched CDI test NOT reported as LabID event	c. _____	d. _____

^Inpatient includes specimens, outpatient emergency department (adult and pediatric) and 24-hr Observation location(s).

Denominator Validation

**Has this facility completed any internal validation of LabID event denominator data counting?	☐ Yes ☐ No

Note: Validation of denominator data counting requires concurrent patient level denominator counting (reference) vs. standard electronic data for three specified location types [one ICU, one LDRP if available, and one or more wards where observation patients are frequently housed] for ≥1 month; validated data should fall within 5% of the reference standard.

**If yes, provide the following information for all months validated:

Location^ of validation	Month of validation	Admissions		Patient Days	
		Usual count	Manual count	Usual count	Manual count

^Excludes "baby locations"

NHSN Inpatient Location Validation: MAPPING

**Do any inpatient locations require mapping or re-mapping within NHSN?	☐ Yes ☐ No

**If yes, indicate which locations need to be mapped/re-mapped and recommendations:

Location	Current CDC location code designation	Current bed count	Recommended CDC location code designation	Recommended bed count

Add rows as needed.

**How does this facility obtain inpatient admissions data?	☐ Electronic from billing ☐ Electronic from vendor system ☐ Electronic from ADT ☐ 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	
*Teaching hospital affiliation	
Facility teaching hospital affiliation reported on 2023 NHSN annual facility survey:	☐ Non-teaching ☐ Major ☐ Graduate ☐ Undergraduate ☐ N/A (IRF & LTACH)
Is facility teaching hospital affiliation correct?	☐ Yes ☐ No
*Facility bed size (all inpatient locations, excluding 'baby locations')	
Facility bed size reported on 2023 NHSN Annual Facility Survey:	
Validated bed size:	

Comments