2023 COLO SSI External Validation Toolkit

The 2023 COLO SSI 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 COLO SSI with step-by-step instructions and screenshots from NHSN.

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Section 1. Facility Selection Methods

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 01/2023 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 dataset generation process to complete; you can leave NHSN during the generation process.
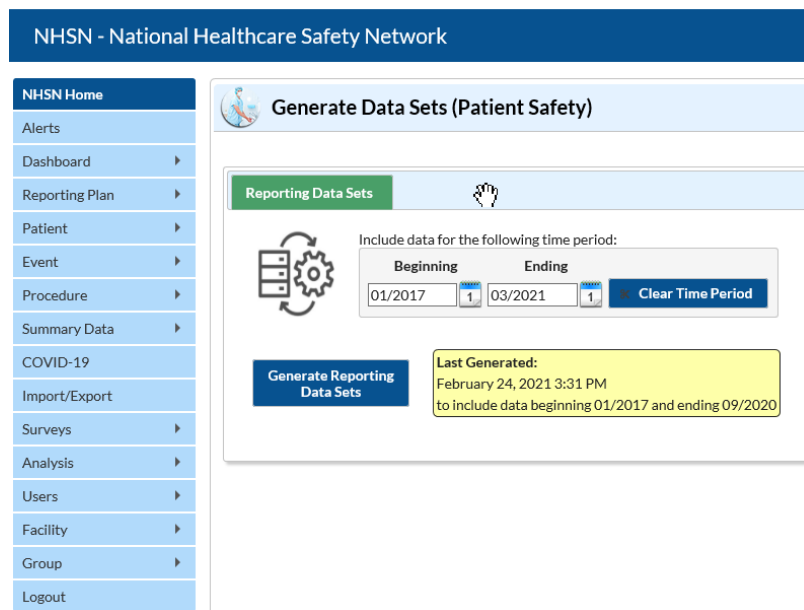
2. After successful data set generation, navigate to Analysis → Reports to display the tree view list of all analysis reports available within NHSN's analysis tool.
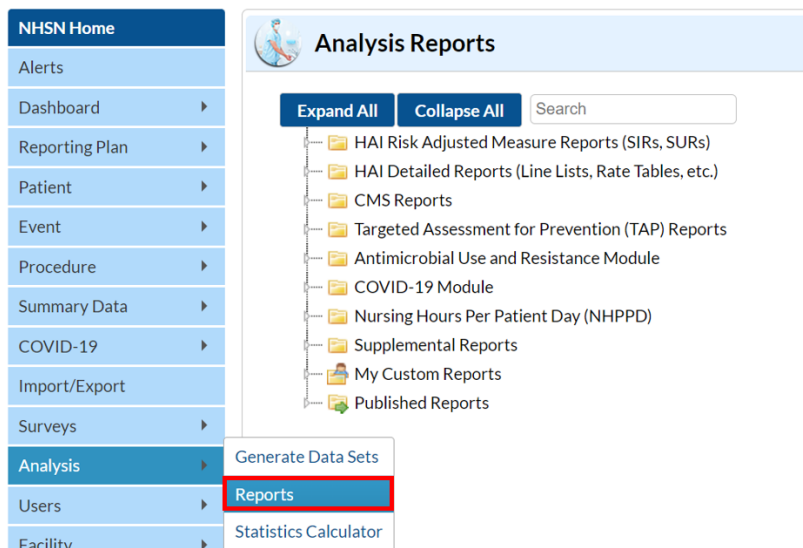
3. Use the tree view structure to select the HAI Risk Adjusted Measure Reports (SIRs, SURs), 2015 Baseline (Baseline Set 2), SSI, SIR – Adult All SSI Data (2015 Baseline). Select the Modify Report button to proceed to the modification window.
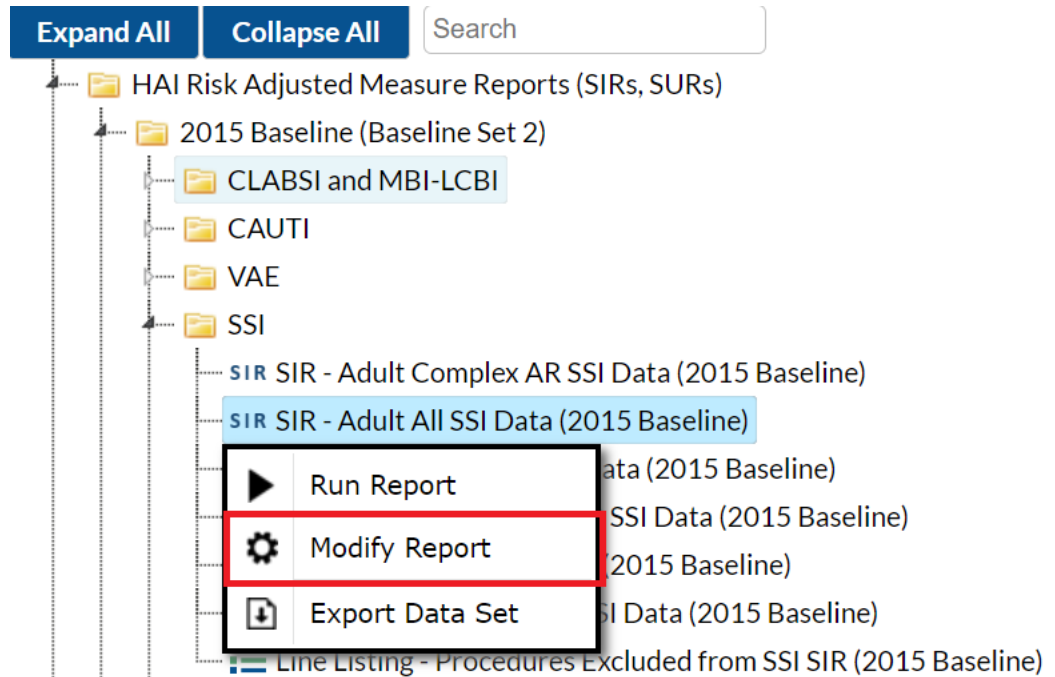
4. In the modification window, there are two key areas to modify, one that controls the time interval of data that are analyzed and displayed and one that controls the level of aggregation of that data.

    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 first row of drop-down boxes, select "ssiPlan," "equal," "Y - Yes." Click the green Add Rule button to add a new row. In the second row of drop-down boxes, select "procCode," "equals," and then "COLO - Colon Surgery."
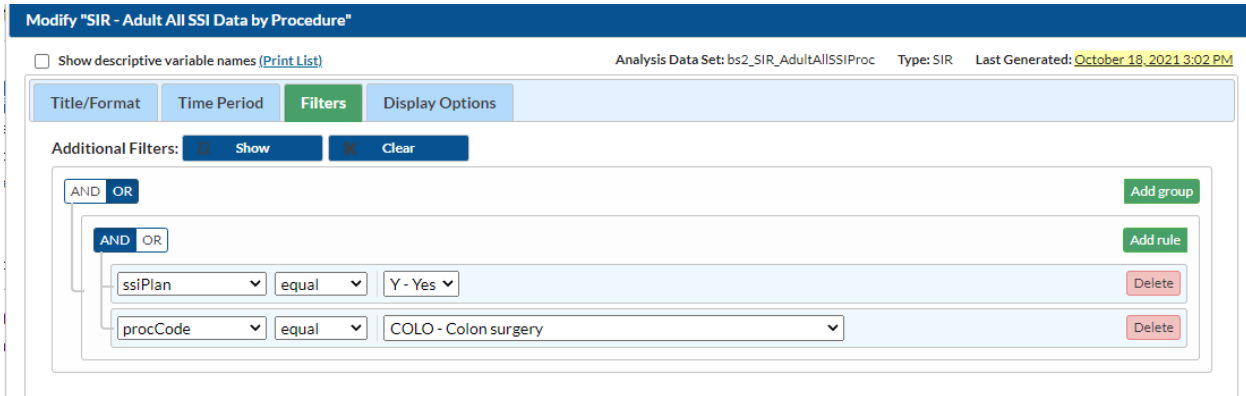
4c. Under the Display Options tab, use the Group by option to view the data at a particular level of aggregation. Change the Group by option to "summaryYr."
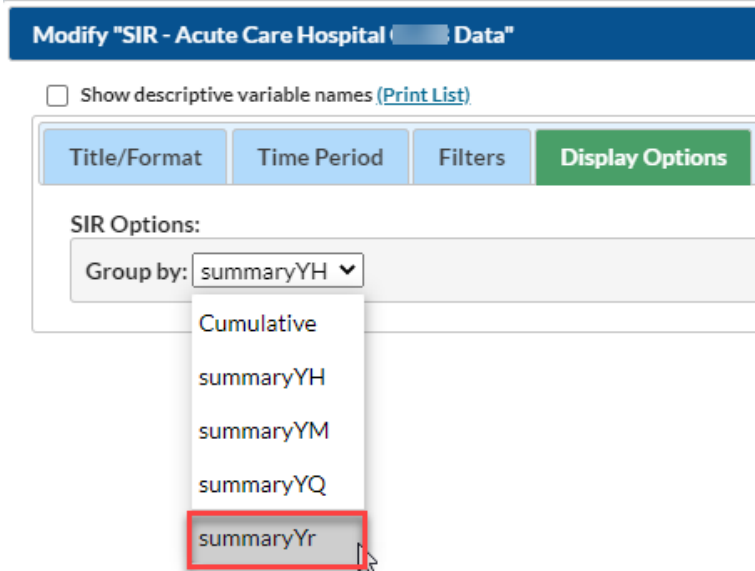
5. After making the above modifications, scroll to the bottom of the modification window. Click the Export button to export the data selected by your modifications. This will open the "Export Analysis Data Set" window.

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.

Export Analysis Data Set

Analysis Data Set: bs2_SIR_AdultAllSSIProc

Export Format: delimited file (comma-separated values) (*.csv) ⌄

    ○ Export Entire Analysis Data Set

    ◉ Export Analysis Data Set using Modifications

🔒 **Export**   **Cancel**

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.

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	summaryYH	procCount	infCountAdultAll	numPredAdultAll	SIRAll	SIRAll_pval	SIRAll95CI	proccode	orgid	months			
2	10/1/2021	39	3	4.912	0.611	0.4099	0.155, 1.662			*SIR for all facilities, all procedures*			
3	10/1/2021	39	3	4.819	0.623	0.4321	0.158, 1.694	COLO		*SIR for all facilities, specific procedures*			
4	10/1/2021	37	2	4.802	0.416	0.1900	0.070, 1.376		10000				
5	10/1/2021	2	0	0.051	.	.	.		15164	*SIR for each facility, all procedures*			
6	10/1/2021	37	2	5.010	0.399	0.1639	0.067, 1.319	COLO	10000	*THIS IS THE LEVEL TO EVALUATE*			
7	10/1/2021	2	0	0.177	.	.	.	COLO	15164	*SIR for each facility, specific procedures*			
8	10/1/2021	37	2	4.899	0.408	0.1774	0.068, 1.349	COLO	10000		6		
9	10/1/2021	2	0	0.113	.	.	.	COLO	15164		2		
10													
11													

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>) so you have an unduplicated list of all facilities reporting data for COLO SSI during the validation timeframe. This level of aggregation will allow you to explore the exposure risk for COLO SSI 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 COLO SSIs. This top tertile of facilities where COLO SSIs 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 within each stratum 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 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 next facility with the 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 the 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) so you have an unduplicated list of all facilities reporting data for COLO SSI during the validation timeframe. This will allow you to explore the exposure risk for COLO SSI 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, stop here 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	0.251, 1.733				
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
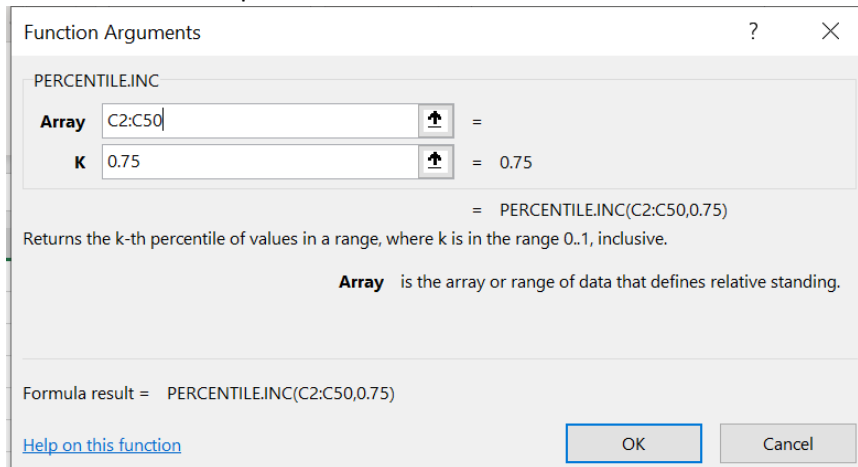
5. Use the numPred value corresponding to the 75th percentile as the minimum threshold value for selection of facilities eligible for validation. If this value is greater than 1, use the 75th percentile numPred value, otherwise use numPred=1 as the minimum threshold value.

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 COLO SSI 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 COLO SSIs and actual observed COLO SSIs(reported). The infCount is an aggregated count of observed COLO SSIs.
- 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

Compute the CAD values for all facilities in the sampling frame. Filter for stratum 1 facilities, where infCount=0. Sort by ascending CAD values (lowest on the top). If the sampling frame has greater than 15 facilities, select the top 15 facilities.

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						HOSP-GEN
2	7.578169	-5.57817	6272	0.0235						HOSP-GEN
13	18.51959	-5.51959	15267	0.1921						HOSP-GEN
8	9.542312	-1.54231	7958	0.6509						HOSP-GEN
4	5.504663	-1.50466	4879	0.558						HOSP-GEN
10	9.736101	0.263899	8387	0.8926						HOSP-GEN
7	5.689505	1.310495	4581	0.5585						HOSP-GEN
22	15.32671	6.673286	9910	0.1034	1.4..	0.922, 2.1..			1.0..30	HOSP-CHLD

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) so you have an unduplicated list of all facilities reporting data for COLO SSI during the validation timeframe. This level of aggregation will allow you to explore the exposure risk for COLO SSI 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 COLO SSI 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.

Modify "Line Listing - Hospital Survey (2021 and later)"

☐ Show descriptive variable names (Print List)   Analysis Data Set: HospSurveyV7

| Title/Format | **Time Period** | Filters | Display Variables | Sort Variables | Display Options |

Time Period:

Date Variable	Beginning	Ending	
completeddate ⌄	01/01/2023	12/31/2023	✕ Clear Time Period

☐ Enter Date variable/Time period at the time you click the Run button

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      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.
    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 COLO SSI events. Freeze the data for each facility selected for validation.

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.), Procedure-Associated (PA) Module, SSIs, and then "Line Listing – All SSI 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 COLO SSI Events Line List).
- Under the Time Period tab, go to the Date Variable and select "procDateYr." 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 "procCode," "equal," "COLO – Colon Surgery."
- Click on the Add rule button on the right to add another line, and select "outpatient" in the first box, then "equal," and then "N-No."
- Click on the Add rule button to add another line, and select "ageAtProc" in the first box, then "greater or equal," and enter "18" in the last box.
- 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.
- Under the Display Variables tab, keep the default Selected Variables: orgID, patID, spcEvent, DOB, gender, and procDate, and add linkedproc by double clicking in the left-hand list. There are additional display variables pre-selected but are optional to include in this line list.
- Under the Sort Variables tab, double click on linkedproc from the left-hand list to add it as the sorting variable.
- Click on the "Export" button. Keep the export format as-is (.csv) and select the "Export Analysis Data Set using Modifications" radio button. This will generate a line listing in Excel sorted by linkedproc.
- Save the line list in a secure location. This list will also be used in the medical record selection process in Section 5.

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

Request a monthly breakdown of how many COLO procedures were performed using ICD-10-PCS coded data. Additional 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

For SSI, sampling frames are derived from procedures reported in NHSN. However, to ensure the NHSN procedure sampling frame is complete, validators should use a monthly tally from the facility for COLO procedures performed in 2023, based on ICD-10 procedure/CPT codes in discharge data. Compare the facility-generated list of COLO procedures based on discharge data to the NHSN COLO Procedures Line List (instructions on how to run report below in Section 5, step 1). If the numbers in the facility-generated list are reasonably close to the number of procedures listed in NHSN, validators can assume the procedure denominator data is relatively complete. If the numbers between lists significantly vary, investigate the issue with the IP to rectify.

Section 5. Medical Record Selection

1. Using NHSN, download a line listing of all COLO procedures ("COLO Procedures line list") for the validation year to serve as your primary COLO sampling list:
    a. Log in to NHSN for the facility being validated and the Patient Safety Module. From the left-hand navigation bar, select Analysis, and generate new datasets. Once datasets are created, go to Analysis, Reports, Supplemental Reports, Procedure-level Data, and select the "Line Listing – All Procedures" report, and then select "Modify Report."
    b. Under the Title/Format tab, select xls format.
    c. Under the Time Period tab, go to Date Variable and select ProcDateYr. For both Beginning and Ending, enter 2023, or the year of data to be validated.
    d. Under the Filters tab, navigate to the first row of drop-down boxes, select "procCode" in the first box, "equal" in the middle box, and "COLO-Colon surgery" in the last box.
    e. Click on the Add rule button on the right to add another line, and select "outpatient" in the first box, then "equal," and then "N-No."
    f. Click on the Add rule button to add another line, and select "ageAtProc" in the first box, then "greater or equal," and enter "18" in the last box.
    g. Under the Display Variables tab, keep the default Selected Variables: orgID, patID, DOB, gender, procID, and procDate, and add bs2_modelRiskAdultAll by double clicking on it in the left-hand list. There may be additional display variables pre-selected but are optional to include in this list.

      h. Under the Sort Variables tab, remove the default sorting variable, procCode, from the right-hand list by double clicking on it. Then, double click on procID from the left-hand list to add it as the sorting variable.

      i. Optional: save the report for future use by clicking on the "Save" button at the bottom right.

      j. Click on the "Export" button. Keep the export format as-is (.csv) and select the "Export Analysis Data Set using Modifications" radio button. This will generate a line listing in Excel sorted by procID. Click the Export button and save the line list in a secure folder.

2. On the COLO Procedures line list from step 1, assign a random number to each procedure, following steps outlined in Table 1.

3. Identify reported COLO SSIs on the COLO Procedures line list and create Stratum 1:
   a. Reference the COLO SSI Events line list created in Section 2 to identify any COLO procedure reported with an SSI. Create a new column, "stratum," and assign the procedures reported to NHSN with SSIs as Stratum 1.
   b. NOTE: The "procID" variable in the COLO Procedures line list is the same as the "linkedproc" variable in the COLO SSI Events line list.
   c. If there is not a linked procedure for an event in the COLO SSI Events Line List, this SSI may have been entered off-plan.

4. Randomly select 20 reported COLO SSIs:
   a. Filter to where stratum = 1.
   b. Sort by random number and select the first 20 random numbers.
   c. If fewer than 20 COLO SSIs reported, review all and supplement the difference using non-stratum 1 procedures.

5. Select 20 unreported candidate COLO SSI procedures with highest SSI risk:
   a. Filter to where stratum does not equal 1.
   b. Sort by "bs2_modelRiskAdultAll," largest to smallest.
   c. Select the first 20 candidate COLO procedures with the highest SSI risk.

6. The final sample should contain 20 reported COLO SSIs and 20 unreported candidate COLO SSI procedures. If final sample does not contain a total of 40 COLO procedures, supplement as possible to reach 40.

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

Medical records should be reviewed in a blinded manner using 2023 Medical Records Abstraction Tool (MRAT), which can be found at 2023 PSC Data Validation Resources | NHSN | CDC, Resources by HAI, SSI-COLO. 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.

The use of an appropriate NHSN checklist (available at https://www.cdc.gov/nhsn/hai-checklists/index.html) is highly recommended. They provide a structure to record required elements from the NHSN Patient Safety Component Manual's Chapter 17 criteria. The NHSN checklists are useful for surgical site infection (SSI) validation when documenting organ/space SSIs. Be sure the selected version is for 2023 definitions.

6.2 Review risk adjustment variables

Risk adjustment variables can be validated as part of the medical record review process. The MRAT for COLO SSI includes fields for ASA score, patient age, and other risk adjustment variables, as well as SSI outcome. Validation of risk adjustment variables is recommended to ensure that sampling has appropriately targeted high-risk procedures.

6.3 Review denominator collection methods and documentation

Completeness and accuracy of COLO SSI denominators

Compare the facility-generated list of procedures based on ICD-10 procedure/CPT codes in discharge data to the NHSN COLO Procedures Line List. If there were large differences between the two lists, discuss this with the IP. Consider matching a subset of records between the two lists and examining un-matched records to explore potential reasons for this discrepancy. In particular, all COLO procedures meeting the NHSN procedure definition should be entered, regardless of pre-existing infection / wound class or incision closure method. If the two lists generate roughly similar data, the NHSN procedure denominator should be considered complete.

6.4 (Optional) Template for Surgical Site Infection (SSI) Following Colon Procedure (COLO) 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 COLO SSI 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 culture; 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		Procedure Date:	Surveillance window closed Date:	Select One:			Event date (if SSI)	Attributable to COLO? Y/N	Optional Validation of SSI Risk Factors					
				NHSN procedure Y/N	No SSI	SI SSI DI SSI O/S SSI* (specify)			ASA†	Age	SW class‡	Duration of procedure	Diabetes	Closure type
	F													
	V													
Comment:														
	F													
	V													
Comment:														
	F													
	V													
Comment:														
	F													
	V													
Comment:														
SI, DI, O/S SSI (NHSN): depth (superficial incisional, deep incisional, organ/space) of surgical site infections. ***†ASA score: American Society of Anesthesiologists Score*** ***‡ SW class: Surgical wound class. See definitions NHSN PSC Manual Chapter 9.***														

Instructions: *Administer this survey to the person who oversees NHSN SSI surveillance and reporting of surgical denominator (surgical procedure) data*				
Facility org ID:	Name / ID of individual interviewed:	Position: ☐ IP ☐ Other (explain):	Interviewer initials:	Date of survey:

Procedure (Denominator) Data	*Answer Key/Rationale*	
1) Does your facility normally upload surgical procedure data electronically to NHSN (via CSV or CDA), or is procedure data entered manually? *(choose one):*	☐ Electronic (skip to Q3) ☐ Manual ☐ Other (comment): _____	
2) If manual, who has primary responsibility for surgical procedure data entry to NHSN? *(choose one):*	☐ IP ☐ Clerical/support staff ☐ Clerical/support staff with IP oversight ☐ Other _____	*If IP is responsible for entering denominator data and unable to fully meet other responsibilities, please recommend clerical support for this task. The IP should explore all resources for timely and accurate data.*
3) What source(s) of information does your facility NORMALLY use to identify COLO procedures? *(choose all that apply):*	☐ The complete OR records/reports system ☐ Selected flagged/filtered OR records/reports based on key words ☐ CPT codes assigned by surgeons ☐ ICD-10-PCS/CPT operative procedure codes assigned by coders after discharge ☐ Vendor system using OR records (specify) _____ ☐ Vendor system using ICD-10-PCS operative procedure codes assigned after discharge (specify) _____ ☐ Vendor system using both OR records and ICD-10—PCS/CPT operative procedure codes assigned after discharge (specify) _____ ☐ Other _____	*ICD-10-PCS/CPT operative procedure codes are required to determine the correct NHSN operative procedure category to be reported.* *ICD-10-PCS/CPT operative procedure codes should be assigned by a professional medical coder.* *If there are questions regarding the accuracy of an assigned operative procedure code, these questions should be reviewed with your professional medical coder.*
4) How are you ensuring that all qualifying inpatient COLO procedures are included in your denominator data?	☐ No systematic way ☐ Review **only** CPT operative procedure codes ☐ Review **only** ICD-10-PCS operative procedure codes ☐ Review **both** CPT and ICD-10-PCS operative procedure codes☐ Cross-reference*(multiple) data sources (explain): _____ ☐ Other _____	*NHSN does not require a facility use one coding system over another (ICD-10 codes or CPT codes). From a reporting standpoint, it is important to have a standard method of identifying procedures so that ALL appropriate procedures are included in the denominator for procedure data.*

<table>
<tr>
<td colspan="2"></td>
<td><i>Instances such as a facility using CPT codes for what they consider is an 'outpatient' procedure but the procedure actually meets the NHSN inpatient procedure definition, the facility must include CPT codes in addition to ICD-10 codes in their surveillance in order to capture all of the 'outpatient' procedures that meet the NHSN inpatient definition.

A facility should set up a process to identify procedures for reporting using both ICD-10 and CPT codes if both are being assigned by the facility's coders. This prevents the possibility of procedures from being missed; however, a process must also be in place to prevent reporting duplicate procedures.

*Cross-referencing of sources (for example, OR records plus ICD-10-PCS/CPT operative procedure codes assigned after discharge) is the best way to assure complete denominator count.</i></td>
</tr>
<tr>
<td>5) If you are following inpatient procedures, under what circumstances do you remove COLO procedures from NHSN? <i>(choose all that apply)</i>:</td>
<td>☐ a. COLO ICD-10-PCS/CPT operative procedure code was not assigned to the operative procedure
☐ b. COLO ICD-10-PCS/CPT operative procedure code was assigned, but IP believes coder assigned COLO code in error
☐ c. Incision not primarily closed in OR
☐ d. The admission and discharge date were the same calendar date (NHSN outpatient operative procedure)
☐ e. Infection was present at the time of surgery (PATOS)
☐ f. COLO wound class = Clean (C)
☐ g. ASA score = 6
☐ h. Other _____</td>
<td><i>Correct Answers: a, d, f, g

Although questioning of ICD-10-PCS/CPT operative procedure codes is acceptable, removal of procedures with designated ICD-10-PCS/CPT operative procedure code is only acceptable if operative procedure does not meet other aspects of NHSN operative procedure definition. Therefore, it would be appropriate to remove a procedure if there is

a) no appropriate ICD-10-PCS/CPT procedure code assigned,

d) not an inpatient operative procedure) (<u>if</u> facility is <u>only</u> following inpatient procedures on monthly reporting plan),

f) COLO wound class = C. Based on feedback from external experts in the field of surgery, there are a group of NHSN procedures that can never be recorded as clean. These</i></td>
</tr>
</table>

			*operative procedure categories are APPY, BILI, CHOL, **COLO**, REC, SB, and VHYS. Therefore, for these procedures in the application clean is not an option on the drop-down menu.* ***g**) ASA score = 6* ……………………………………………………………… ***Note**:* *Facilities should keep clear and accurate documentation when procedures are excluded from NHSN reporting.*
6)	If the operative procedure report details do not match the listed ICD-10-PCS/CPT procedure codes, what should you do?	☐ a. Review coding assignment with the facility medical coder ☐ b. Query NHSN ☐ c. Other	*For validation purposes, NHSN recommends that IPs should bring coding mismatches to coders for review and should not over-ride coders' decisions.* *On a rare occasion the procedure performed was accurately coded but does not match the assigned the category description. In these cases, based on knowledge and review of the actual procedure performed, if the procedure clearly does not meet the procedure category description then for that specific instance the procedure should not be reported to NHSN for that procedure category. This determination must be made on a case by case basis and the facility may query NHSN. Clear and accurate documentation should be maintained in these instances.*
7)	Which of the following are consistent with the definition of primary wound closure? *(check ALL that apply)*	☐ a. Complete closure of skin with suture ☐ b. Partial closure of skin with staples ☐ c. Closure of skin except for wick/drain through incision ☐ d. Closed fascia with incision loosely closed at the skin level ☐ e. Closed fascia, with skin layer left open	***Correct answers: a, b, c, d*** *If any portion of the incision is closed at the skin level, by any manner, a designation of primary closure should be assigned to the surgery.* *The closure of the surgical wound in a way which leaves the skin level completely open following surgery is a non-primary closure (e).* *All procedures, regardless of closure method, must be reported to NHSN.*

8) Does your facility conduct NHSN analysis to look at longitudinal trends for COLO SSIs and procedures?	☐ Yes ☐ No	*This is recommended practice for facility use of NHSN data*
9) What would you do if your procedure denominator this month was dramatically higher from one month to the next?	_____	*Recommended: investigate this aggregate data by exploring the data at a patient/procedure level to identify the reason.*

Surgical site Infection (Numerator) Data Collection Questions

Instructions: Interview individual(s) directly responsible for identifying and reporting SSI data	Date of survey:
Name/ID of individual interviewed:	Position:

Numerator (SSI Event) Data:	*Answer Key/Rationale*	
10) If a patient with an SSI is admitted to your facility but the surgical procedure was performed in another hospital ("hospital A"), what do you do? *(choose all that apply)*	☐ Report the SSI to NHSN ☐ Report the SSI to "hospital A" ☐ Report the SSI to the health department ☐ No external reporting Comment: _____	*Best practice is to report to "hospital A" and (if required by the state) to health department. Hospital A should report to NHSN. The SSI event must be reported by the facility in which the procedure was performed and linked to the operative procedure (denominator details) associated to the SSI event.*
11) If you do not report the SSI to "hospital A", why not? *(choose all that apply)*	☐ HIPAA concerns ☐ Not a priority for IP program ☐ Logistically difficult (which hospital, who to contact) ☐ Not required Comments: _____	*Best practice is to report to "hospital A"* *If facility cites HIPAA concerns, consider sharing Appendix 2, or CSTE position statement 13-ID-09, which contains information from the Office of Civil Rights assuring that sharing SSI information with the originating facility does not violate HIPAA.*
12) If you are contacted by the IP from another hospital regarding a patient with an SSI who underwent a procedure in your facility, what do you do? *(choose all that apply)*	☐ Ask the IP for help completing the NHSN report ☐ Document in your tracking records ☐ Report the SSI to NHSN ☐ Ask the IP to report the SSI to NHSN ☐ No internal reporting or documentation	*The other IP can provide details regarding the infection but cannot report the event to NHSN (the SSI event must be reported by the facility in which the procedure was performed and linked to the operative procedure [denominator details] associated to the SSI event). Request pertinent details regarding the SSI event to assist with completion of the SSI event form (such as date of event 'DOE', signs/symptoms, etc.)*

	Comment:	*Include relevant details in the patient medical record.*
13) What methods are routinely and systematically used to identify possible SSI? (*Check all that apply*)	**Reports/Rounds:** ☐ Emergency department line lists with diagnoses ☐ Admissions line lists with diagnoses ☐ Patient chart review for signs and symptoms of SSI ☐ Surgical ward rounds – talk to primary care staff ☐ Clinician/healthcare professional notes ☐ Positive laboratory cultures from inpatients ☐ Positive laboratory cultures from ED ☐ Positive laboratory cultures from outpatient clinics ☐ Pharmacy reports (antibiotic starts or continuations) ☐ Other _____ **Surgical service information:** ☐ Inpatient returns to surgery ☐ Surgical service readmissions **ADT/Medical Records Data Mining:** ☐ Readmissions within one month of discharge ☐ Extended LOS	*Any combination of these methods (or other methods identified by the facility) with the capacity to identify all SSIs is acceptable for use; however, NHSN criteria for SSI must be used*

	□ Discharge diagnostic coding (for example, ICD-10-CM Infection Diagnosis Codes to prompt further review) □ Other/Comment: _____	
14) How does your facility conduct post-discharge surveillance for SSIs? *(check all that apply)*	□ IP does not have a formal post-discharge surveillance plan □ IP conducts patient survey by mail □ IP conducts patient survey by telephone □ IP provides line list of patients to surgeon for response □ Surgeon indicates SSIs identified at surgical follow-up □ Surgeon surveys patient by mail □ Surgeon surveys patient by telephone □ IP reviews surgical clinic / wound clinic information □ IP reviews surgical patient records within a time period that aligns with the operative procedure category surveillance period. □ Other/ Comment: _____	*It is important to perform post-discharge surveillance as the majority of SSI's may be detected this way.*
15) During one trip to the operating room, both a COLO procedure and a HYST procedure is performed. The patient meets criteria for a deep incisional SSI event following the COLO and HYST procedure. SSI attribution is not clear. To which procedure should you attribute the SSI?	□ COLO □ HYST □ Both □ Neither	*Correct answer: a* *Refer to SSI Event Reporting Instruction #9. Since SSI attribution is not clear, the procedure which is higher on the 2023 procedure hierarchy (Table 4 found within the SSI Protocol) gets the SSI attribution (**COLO**).*
16) At the conclusion of a COLO procedure, the skin around the stoma is closed, but the midline abdominal incision is left open. Is this a primary or non-primary closure?	a) Primary closure b) Non-primary closure	*Correct answer: a* *The stoma is a primary incision site. If a procedure has multiple incision/laparoscopic trocar sites and any of the incisions are closed primarily then the procedure technique is recorded as primary closed.*
17) SSI events where PATOS = Yes do not get reported to NHSN.	a) True b) False	*Correct answer: b* *SSI events where PATOS = YES are still SSI events and must be reported to NHSN.*
18) COLO is assigned a wound class of Clean (C). The IP should change the wound class to Clean Contaminated (CC) to submit the COLO into NHSN.	a) True b) False	*Correct answer: b* *A COLO with a wound class designation of C cannot be entered into NHSN. There are situations where a clean wound class can be appropriately assigned to a COLO and*

		therefore, the procedure would not be included in the denominator for procedure data.
		Excluding a procedure from the denominator for procedure data should be made on a case by case basis with knowledge of the procedure and after review of the operative report. We recommend that you document the rationale for excluding a procedure in your facility's surveillance records in the event an explanation is needed in the future.

6.6 (Optional) 2023 COLO SSI Validation Summary

*required   **conditionally required

Facility Validation Overview	
*Facility ID:	
*Facility Type:	☐ Acute care hospital ☐ Oncology hospital
*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)
DI/OS^ COLO SSI	COLO procedures	_____	_____

*DI/OS^ COLO SSI in surveillance locations (including NICU) Validation Results:

Event Determination	Validation: Yes - DI/OS COLO SSI	Validation: No – Not DI/OS COLO SSI
Facility: Yes - Date-matched DI/OS COLO SSI reported	a. _____	b. _____
Facility: No - Date-matched DI/OS COLO SSI NOT reported	c. _____	d. _____

^DI/OS - deep incisional or organ/space SSI

Denominator Validation: COLO

**Document number of COLO procedures from two lists by month:

Month	Number of COLO procedures entered into NHSN by facility before validation	Number of ICD-10-PCS/CPT procedure codes for COLO identified from hospital discharge billing

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
**ASA score
Number (% of validated) correct for COLO: _____
**Patient age
Number (% of validated) correct for COLO: _____

Comments