

NHSN Toolkit and Guidance for External Validation

Table of Contents

About the 2021 NHSN External Validation Guidance and Toolkit	3
Chapter 1: Overview and 2021 Validation Standards	7
Why Validate?	7
External Validation	8
2021 Validation Guidance	8
For 2021 data validation, algorithms specify using targeted sampling that allows	8
Chapter 2: Guidance for Conducting 2021 NHSN Validation	9
2.1 Assure or Update Validator Expertise in 2021 NHSN Validation	11
2.2 Method of Facility Section	13
2.3 Establish a mechanism for secure data transfer between facilities and the external validation agency.....	14
2.4 Develop and characterize the medical record sampling frame for each selected facility and each HAI to be validated, and for SSI assure a complete denominator.....	14
<i>CLABSI in validation locations</i>	15
<i>CAUTI in validation locations</i>	15
<i>COLO Procedures</i>	16
<i>HYST Procedures</i>	16
<i>MRSA bacteremia LabID Event, facility-wide inpatient (FacWideIN)</i>	16
<i>CDI LabID Event, FacWideIN</i>	16
2.5. Notify facilities of the planned audit and request the required laboratory line listings	16
2.6 Select medical records (to be discussed in Chapters 3 and 4).....	17
2.7 Download (“freeze”) the facility’s reported data from NHSN before disclosing which medical records were selected for the audit	17
CLABSI	17
CAUTI.....	18
COLO	18
HYST	20
MRSA.....	20
CDI.....	20
2.8 Request selected medical records in advance of the facility site-visit	20
Chapter: 3 Method 1 - Facilities and Medical Records Sampling: Prioritizing Facilities with Highest Likelihood of Event Occurrence	21
3.1 Determine the Minimum Facility Sample Size	21
3.2 Apply the Facility Ranking Algorithm	21
3.3 Step by step Targeted Facility Ranking and Selection	24
A. CLABSI IN VALIDATION LOCATIONS	24
B. CAUTI IN VALIDATION LOCATIONS.....	30
D. TARGETED FACILITY RANKING FOR HYST:	32
A. TARGETED FACILITY RANKING FOR MRSA BACTEREMIA LABID EVENT:	33
B. TARGETED FACILITY RANKING FOR CDI LABID EVENT:	34
3.4 Targeted Medical Record Sampling Overview	36
3.5 Step-by-Step Targeted Medical Record Selection	38
A. CLABSI in validation locations Targeted Medical Record Selection Process	38
B. CAUTI IN VALIDATION LOCATIONS Medical Record Selection Process	40
C. COLO Procedure Targeted Medical Record Selection Process	40

D. HYST Procedure Targeted Medical Record Selection Process.....	42
E. Strategy for Selection of MRSA Bacteremia LabID Events for Validation	43
F. Strategy for Selection of <i>C. difficile</i> Infection (CDI) LabID Events for Validation	43
Chapter 4: Method 2 - Targeted Sampling of Facilities and Medical Records using Cumulative Attributable Difference (CAD) Approach	45
4.1 Ranking Algorithm for facility selection.....	45
4.2 Medical Records Selection Overview.....	49
Chapter 5: Activities During and After the Facility Site Visit	50
Suggested Tools to bring along for validation site-visits	50
Request documentation of current NHSN reporter training.....	50
Review risk adjustment variables:	50
Review denominator methods and documentation.....	51
CLABSI and CAUTI denominator records	51
Electronically collected CLABSI and CAUTI denominators.....	51
Structured Medical Records Review	52
Discussion of audit results with IP	52
Post-visit.....	53
References.....	54
Appendix 1: Letter Templates.....	56
Appendix 1.1: Sample Letter Requesting Site Visit and Line Listings for External Validation	56
Appendix 1.2: Sample Letter Requesting Availability of Medical Records for Audit.....	59
Appendix 1.3: Example Validation Follow-up Letters, With and Without Identified Problems	60
Version One: Problems identified. Letter should be adapted to circumstances.....	60
Version Two: No problems identified. Letter should be adapted to circumstances.....	61
APPENDIX 2: Surveillance Surveys	62
Appendix 2.1: External Validation Data Form.....	62
Appendix 2.2: (Optional) Templates for Audit Discrepancies Discussion with Facilities.....	70
Central line-associated Bloodstream Infection (CLABSI) Discrepancies	70
Catheter-associated Urinary Tract Infection (CAUTI) Discrepancies	72
Surgical Site Infection (SSI) Following Colon Procedure (COLO) Discrepancies.....	74
Surgical Site Infection (SSI) Following Abdominal Hysterectomy Procedure (HYST) Discrepancies.....	76
Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) Bacteremia LabID Event Discrepancies.....	78
<i>Clostridium difficile</i> Infection (CDI) LabID Event Discrepancies	79
Appendix 3: Surveillance Surveys	81
Appendix 3.1: Documentation of Electronic CLABSI/CAUTI Denominator Validation.....	81
Appendix 3.2: Contact Information for Manual CLABSI/CAUTI Denominator Validation	82
Appendix 3.3: CLABSI and CAUTI Denominator Counting Survey (with Key)	83
Appendix 3.4: Surgical Procedure and SSI Surveillance Methods Survey (with Key)	89
Appendix 3.5: LabID Event Surveillance Methods Survey (with Key)	96
Appendix 3.6: LabID Event Facility-Wide Inpatient (FacWideIN).....	98
Denominator Validation Template	98
Appendix 4: Facility/Provider to Facility/Provider Communications under HIPAA: Questions and Answers	101

About the 2021 NHSN External Validation Guidance and Toolkit

The 2021 NHSN External Validation Guidance and Toolkit provides guidance for NHSN data validation. Like 2020, CDC provides 2021 validation guidance and tools for six healthcare-associated infection (HAI) metrics: Central-Line Associated Blood Stream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), selected Surgical Site Infections (following colon [COLO] and abdominal hysterectomy [HYST] procedures), Methicillin-Resistant Staphylococcus aureus (MRSA) Bacteremia LabID Event, and Clostridioides difficile infection (CDI) LabID Event. NHSN designed the guidance and tools for CLABSI and CAUTI to work in settings including and beyond acute care hospitals. CLABSI validation is applicable for long-term acute care hospitals (LTACHs) and CAUTI validation is applicable for LTACHs and inpatient rehabilitation facilities (IRFs).

The purpose of validation is to assure high-quality surveillance data through accountability and by identifying, understanding, and correcting reporting problems. This document focuses on external validation of facility reported NHSN surveillance data conducted by state health departments or other oversight agencies. Facilities that seek to conduct internal validation (data quality check) of their own NHSN data can find a separate guidance document available at <http://www.cdc.gov/nhsn/validation/index.html>.

Developing a standard approach to HAI data validation is important to assure nationwide data quality and to enhance fairness under current and planned reimbursement programs that use NHSN data. States may vary in their regulatory authorities and capacities for NHSN data validation but can best assure data quality by following these standards. NHSN-specified external validation standards are intended to ensure reported surveillance outcomes meet NHSN surveillance definitions and methods, as determined and documented by trained auditors. Recommended sample sizes attempt to balance feasibility with adequate precision for HAI metrics at the facility level. Survey tools assess reporter knowledge and facility practices required to conduct adequate surveillance.

For 2021 data audits, NHSN specified two methods for targeted sampling of facility and medical records. State health departments and other external validators are encouraged to select the method based on their validation priority. Targeted validation provides an efficient approach to identify and correct likely reporting errors in facilities with high patient volumes, and thus use limited validation resources as effectively as possible. There are two important limitations to keep in mind with targeted sampling. Accuracy measures (e.g., sensitivity and specificity) derived from a targeted sample are likely to be lower than those taken from a more representative, random sample. Although it may be a simpler and more efficient approach to begin the external validation process, targeted sampling does not generate representative information.

Comments and Feedback Welcome: NHSN validation approaches are a work-in-progress and will improve more quickly with generous input and feedback from those implementing the methods. Please direct any comments or suggestions for improvement to the NHSN Helpdesk: NHSN@cdc.gov.

Acknowledgements and Thanks

[NHSN adapted many aspects of this document from states conducting validation. However, the Guidance and Toolkit recommendations are the sole responsibility of the Centers for Disease Control and Prevention \(CDC\) and are not endorsed by any individuals or organizations outside of CDC.](#)

Abbreviations, Terms, and Acronyms Used in this Document

ABUTI*	(NHSN) Asymptomatic bacteremic urinary tract infection. This type of UTI may or may not be catheter-associated (CAUTI).
ADT	A core facility data system for capturing admissions, discharges, and transfers.
BABY LOCATIONS*	(NHSN) Patient care locations housing a high proportion of infants aged <1 year, i.e. newborn nurseries, NICUs, and LDRP locations.
BSI	Bloodstream infection.
CAUTI*	(NHSN) A UTI where an indwelling urinary catheter (IUC) was in place for >2 calendar days on the DOE, with day of device placement being Day 1, AND an indwelling urinary catheter was in place on the DOE or the day before. If an indwelling urinary catheter was in place for > 2 calendar days and then removed, the date of event for the UTI must be the day of discontinuation or the next day for the UTI to be catheter-associated.
CCN	CMS Certification Number, i.e., a facility identifier.
CDC	Centers for Disease Control and Prevention.
CDI	<i>Clostridioides difficile</i> infection.
CEO	Chief executive officer.
CL	Central line.
CLABSI*	(NHSN) Central line-associated bloodstream infection. A laboratory confirmed bloodstream infection where an eligible BSI organism is identified, and an eligible central line is present on the LCBI DOE or the day before.
CMS	Centers for Medicare & Medicaid Services.
C-SUITE	Office for senior executives such as Chief Executive Officer (CEO) or Chief Medical Officer (CMO) of a healthcare facility.
DELTA COUNT*	(NHSN, as used in this guidance) The absolute difference between the number of predicted events and observed events.
DI SSI*	(NHSN) Deep incisional surgical site infection.
DOB	Date of birth.
DOE *	(NHSN) Date of event. The first element used to meet an NHSN site-specific infection criterion occurs for the first time within the seven-day infection window period.
DOH	Department of health.
ED	Emergency department.
EMR	Electronic medical record.
EPISODE OF CARE	All medical services provided to a patient within a specific time period within a facility. For surveillance of HAIs, this term is used to indicate a single inpatient admission and includes the ED visit leading to admission.
EXTERNAL VALIDATION	Survey and record review process performed by an external agency to assure quality of NHSN surveillance and reporting.
FacWideIN*	(NHSN) Facility-Wide Inpatient. A type of surveillance used for LabID Event reporting, includes ED and observation units.
FOLEY CATHETER	Indwelling urethral (urinary) catheter.
GI*	(NHSN) Gastrointestinal system healthcare-associated infection.
HAI*	(NHSN) Healthcare-associated infection. An infection is considered an HAI if the DOE occurs on or after the 3rd calendar day of admission to the facility (the day of admission to an inpatient location is calendar day 1). All elements used to meet site-specific infection criteria must occur during the Infection Window Period.

IAB*	(NHSN) Intra-abdominal healthcare-associated infection; a subset of GI.
ICU	Intensive care unit.
INDWELLING URINARY CATHETER*	(NHSN) Drainage tube inserted through the urethra to the urinary bladder, left in place, and connected to a drainage bag. Also called a Foley catheter. May be used for drainage and/or irrigation. Excludes condom catheters, straight in-and-out catheters, nephrostomy tubes, and suprapubic catheters.
INFECTION WINDOW PERIOD*	(NHSN) Seven days during which all site-specific infection criteria must be met. It includes the collection date of the first positive diagnostic test that is used as an element of the site-specific infection criterion, the 3 calendar days before and the 3 calendar days after
INPATIENT SURGERY*	(NHSN) Surgery on a patient whose date of admission is different from date of discharge.
INTERNAL VALIDATION	Active efforts by a facility to assure completeness and accuracy of NHSN data.
IP	Infection preventionist or infection prevention department.
IT	Information technology.
LabID Event*	(NHSN) A measure developed for easy electronic infection surveillance using laboratory results without the requirement for extensive clinical documentation.
LCBI 1,2,3*	(NHSN) laboratory-confirmed bloodstream infection criteria.
LDRP	Labor, Delivery, Recovery, and Post-partum. A type of NHSN location in an acute care
LOS	Length of stay (days).
MEDICAL RECORD	A record systematically documenting a single patient's medical history and care across time within a healthcare provider's jurisdiction. For sampling, a medical record (which over time could include many healthcare encounters) refers to a single facility inpatient admission.
MRN	Medical record number.
MRSA	Methicillin-resistant <i>Staphylococcus aureus</i> .
MSSA	Methicillin-susceptible <i>Staphylococcus aureus</i> .
NICU	Neonatal intensive care unit.
NP	Nasopharyngeal.
NHSN	National Healthcare Safety Network.
OBSERVATION LOCATION	A bedded patient care location designated for patients under observation, a form of outpatient status. The purpose of observation is to allow the physician time to decide whether the patient should be admitted and then rapidly move the patient to the most appropriate setting, i.e., admit to inpatient status or to send home.
OBSERVATION PATIENT	Status for patients who are undergoing short-term treatment, assessment, and reassessment while a decision is made regarding the need for admission to the hospital. Observation patients may occupy beds in outpatient or inpatient locations. If housed in an inpatient location, observation patients are included in all inpatient surveillance
OrgID*	(NHSN) Organization ID. NHSN facility identifier.
O/S SSI*	(NHSN) Organ/space surgical site infection.
PATIENT DAYS*	(NHSN) The number of patients (inpatients and observation patients) housed in a facility inpatient location during the designated counting time each day and summed for a monthly denominator report for device-associated infections (CI ARSI, CAUTI, VAE) and Post-discharge surveillance.
PDS	
POA*	(NHSN) Present on admission. An infection is POA if the DOE occurs on the day of admission, during the two days before, or on the day after admission. POA infections should not be reported as HAIs. POA is not used for SSI, VAE, or LabID Events.

PRIMARY INFECTION*	(NHSN) Originating source of infection (see secondary BSI).
PROBABILITY SAMPLE	Sample based on randomization or chance that allows calculation of confidence intervals and estimates of how well the overall population is represented.
PURPOSIVE SAMPLE	Sample taken with a purpose in mind (see targeted sample).
QIO	Quality Improvement Organization.
SECONDARY BSI*	(NHSN) A BSI that is thought to be seeded from a site-specific infection at another body site (see NHSN PSC Manual: Bloodstream Infection Appendix B. Secondary BSI Guide (Ch-4), CDC/NHSN Surveillance Definitions for Specific Types of Infection [Ch-17], UTI [Ch-7], Pneumonia (Ch-6), and SSI (Ch-9).
SIR*	(NHSN) Standardized infection ratio.
SI SSI*	(NHSN) Superficial incisional surgical site infection.
SSI*	(NHSN) Surgical site infection.
SUTI*	(NHSN) Symptomatic UTI.
TARGETED SAMPLE	In this document, a targeted sample is a purposive sample taken to target facilities at higher risk for HAI or medical records at higher risk for HAI status misclassification (see
URINARY CATHETER*	(NHSN) See indwelling urinary catheter.
USI*	(NHSN) Urinary System Infection.
UTI	Urinary tract infection.
TERTILE	Lowest, middle, or highest one-third of a group.
VAE*	(NHSN) Ventilator-associated event. An objective surveillance algorithm that can identify a broad range of conditions and complications (including but not limited to pneumonia) occurring in mechanically ventilated adult patients, detailed in NHSN Patient Safety Component Manual Chapter 10.
VALIDATION	Assurance that reported NHSN surveillance data meet pre-determined specifications and quality standards.

*(NHSN) indicates a term used and defined by NHSN.

Chapter 1: Overview and 2021 Validation Standards

Validation can be defined as confirming or assuring that data meet pre-determined specifications and quality standards. NHSN validation assures high quality data across three healthcare-associated infection (HAI) reporting domains: denominators, numerators, and risk adjustment variables.

Why Validate?

NHSN launched as a voluntary, confidential HAI reporting system for hospitals conducting surveillance, benchmarking, and quality improvement for HAIs. Since 2006, state and federal agencies also use NHSN data have for public reporting purposes and, increasingly, to incentivize quality improvement through payment mechanisms. These new uses heightened the importance of complete and accurate NHSN data. Hospital boards, administrators, and clinical leadership need to trust their facilities' data to assess performance and manage change within their facilities; they also need to know that NHSN holds other facilities to the same high standards when reporting. Consumers seeking to make informed decisions about their healthcare expect that publicly reported data are valid. NHSN definitions are complex and sometimes require subjective interpretation. They may involve tracking and linking information from multiple hospital information systems (e.g., laboratory, admissions, and clinical data), coordinated data collection and interpretation, and data entry by multiple staff members. All these attributes introduce opportunities for variation and make it difficult to meet stakeholder's needs without taking additional steps to ensure data quality. The NHSN reporting landscape will continue to change over time as NHSN methods evolve, use of electronic medical records increases, and reporting requirements expand.

In the context of powerful incentives for facilities to “look good,” meaningful external validation is essential to assure NHSN surveillance meets its intended requirements, reported facility outcomes are appropriate, NHSN data are credible, and NHSN surveillance focuses on improving patient care and disease prevention. In the absence of meaningful external validation, healthcare facilities may fail to identify or report HAIs due to variation in effort, resources, and practices between facilities. which result in surveillance bias (“the harder you look the more you find”) and assessment bias (“we tend to see what we want to see”). For example, approaches to surveillance that create barriers to reporting, such as requiring agreement between multiple reporters or permission from authorities before reporting, can lead to lower measures of HAI rates without improving patient safety.^{1,2}

NHSN and reporting facilities must work together to ensure adequate resources for adherence to standard surveillance and reporting methods, optimal data accuracy and completeness, and appropriate application of patient mix risk adjustment so comparisons between facilities are fair and equal. Validation is an important step toward assuring NHSN data are actionable and motivate improved infection control efforts rather than strategies to avoid accounting for HAIs. Accurate, high quality NHSN data are important for setting infection prevention program priorities and measuring the impact of prevention efforts. Public health agencies at the local, state, territorial, and federal levels need these data to identify emergent HAIs and to measure prevention program success. Each of these stakeholders plays a role in assuring NHSN data quality.

External Validation

External validation is a survey and audit process conducted by an agency outside the reporting facility (e.g. state health department). One or more trained validators who work for the external agency review the facility's surveillance determinations and methods to evaluate surveillance program quality (e.g. knowledge and practices), data completeness, and reporting accuracy. Facilities can use findings from external validation to correct reporter misconceptions about NHSN definitions, criteria, and data requirements. External validation can help assure adherence to NHSN's specifications for HAI reporting by identifying and correcting shortcomings that would be difficult to address through internal validation alone. Understanding what led to reporting errors enhances reporting going forward. Facilities should help reporters correct and complete the validated data. Facilities should discuss and document common errors and challenging cases for teaching and to improve future reporting.

It is typically not possible nor necessary for validators to visit every facility in person or review every patient record in search of candidate HAIs. Sampling is a practical necessity, and sampling methods should strike a balance between resource availability and programmatic objectives.

2021 Validation Guidance

For 2021 data validation, algorithms specify using targeted sampling that allows efficient investigation of potential surveillance and reporting problems in facilities and medical records with high HAI exposure, where HAIs are most expected. Validators can assess exposure risk from increased device days, surgical procedures, or specified positive laboratory test results and target sampling methods by either high or low event reporting. Targeted samples do not typically produce generalizable information about the overall population. A favorable outcome under targeted sampling suggests that success would be even more likely in a probability sample representing the entire population at risk. Because NHSN holds all facilities, regardless of size, accountable for accurate reporting, validators should select a 5% random sample of additional facilities after selecting the targeted facility sample.

Chapter 2: Guidance for Conducting 2021 NHSN Validation

NHSN external validation includes six metrics that are consistent with Centers for Medicare & Medicaid Services (CMS) Inpatient Quality Reporting Program requirements:

1. Central line associated bloodstream infection (CLABSI) in validation locations
2. Catheter associated urinary tract infection (CAUTI) in validation locations
3. Colon (COLO) surgical site infection (SSI)
4. Abdominal hysterectomy (HYST) SSI
5. *Methicillin-Resistant Staphylococcus aureus* (MRSA) Bacteremia LabID Event
6. *Clostridioides difficile* infection (CDI) LabID Event

If unable to secure resources to complete the validation standard for all six HAIs listed above at the prescribed number of facilities, then NHSN recommends narrowing the scope of HAIs to be validated while maintaining the sample sizes for chosen metrics and the recommended number of facilities to derive robust information about performance.

Oversight agencies may choose to use experience and/or data analysis to prioritize which HAIs to validate. For example, if a facility completed CLABSI validation as recommended in 2020, agencies may seek to focus on other HAIs for 2021. Agencies may wish to focus validation on HAIs with unexpectedly high rates to assist facilities with prevention.

Agencies should still hold facilities not targeted for external validation audits using this suggested sampling method accountable for high quality surveillance and reporting programs, and for conducting internal validation activities. Agencies may request evidence of up to date NHSN reporter training (such as a 2021 certificate of successful completion produced by each of NHSN's multimedia training modules from all facilities) to assure appropriate reporter training without a site visit. Some agencies may wish to administer surveillance process surveys or request documentation of internal validation activities by facilities.

Recommended external validation for 2021 includes assessment of numerators, denominators, and risk-adjustment variables, with medical records audit focused on outcomes (numerators). Numerator quality can be optimized by a) reporter training (as demonstrated by completed certificates for 2021 online multimedia assessments), b) good surveillance practices (assessed by survey), and c) evidence of correct reporting (by an audit of medical records showing concordance of validator outcomes with events reported to NHSN). Denominators can be assessed by a) review of denominator data records, b) denominator collection practices surveys, and c) comparison of crude monthly COLO and HYST operative procedure counts in NHSN with ICD-10-PCS/and or CPT codes generated by the facility. Agencies should also review risk adjustment variables and documentation of internal validation work conducted by facilities.

This external validation guidance and toolkit recommends on-site medical record reviews by trained validators using a medical record abstraction tool that follows 2021 NHSN methods and definitions, with CDC serving as adjudicator of discordant outcomes when necessary. On-site validation provides optimal opportunity for validators to gain full access to any documented information used by reporters when conducting surveillance and strengthen relationships with reporting facilities through transparency. In addition, site visits encourage interaction, education, and understanding of the overall HAI surveillance program. Use of electronic medical records systems that are made available at a distance to validators is a feasible, though perhaps a sub-optimal alternative way to audit medical records. This approach may require technical expertise and iterative work with facilities to assure validator access to all relevant documentation. NHSN discourages remote review of copied medical records for external validation

program methodology, as copied material lacks complete data access and the interactivity that facilitates program capacity building. Ideally, validators will be either employed or contracted by agencies that have oversight responsibilities for patient safety and public health in the audited healthcare facilities, and across the continuum of healthcare. For ease of use and printing, Medical Records Abstraction Tools (MRATs) and Instructions for use of the MRATs are in a separate file under the tab “2021 External Validation Guidance and Toolkit”.

CDC-Recommended Validation Elements and Preferred Approach

Validation Element	Off-site	On- or Off-site	On-site
Validator training and assessment	X		
NHSN data analysis for completeness, timeliness, and quality	X		
Facility selection, request for line listings (CLABSI, CAUTI, MRSA bacteremia, and CDI), and monthly surgical procedure counts (COLO and HYST SSI)	X		
HAI Sampling Frame Development	X		
Medical Record Selection, NHSN data download, and arrangements for audit	X		
Facility Surveillance Practices Surveys (Appendix 2)		X	
Review of facility mapping, bed size			X
Medical Record Reviews (MRATS)			X
Post-review conference with Infection Preventionist (IP) re: surveillance practices and medical records audit discrepancies			X
Administration of additional denominator counting surveys, as needed		X	
Review of facility results, strengths, and weaknesses		X	
Follow-up corrections and report to IP and administration	X		

2.1 Assure or Update Validator Expertise in 2021 NHSN Validation

Surveillance and validation require rigorous adherence to the NHSN protocols, surveillance methods, and definitions as written. Persons conducting audits must be trained in NHSN specifications, remain up to date when changes are made, and commit to using appropriate NHSN methods and definitions to validate HAI data reported to the system. Validators need to familiarize themselves with the specific year's protocols for the validation period reviewed. In addition to reporter training resources, validator training resources are available on the NHSN website. The following trainings are available on the training website: <https://www.cdc.gov/nhsn/training/index.html>. They are listed in order of recommendation for validators:

Type of NHSN Training	Recommended Validator Standard	Where can I find this training?
Self-paced Interactive Training Modules	Assure that all 2021 validators successfully complete these courses for any NHSN component they will validate and provide copies of the certificates of completion.	Online courses provide instructional slides with detailed graphics, screen shots with step by step examples of form completion for instructional purposes, practice questions, and case study examples: https://www.cdc.gov/nhsn/training/continuing-edu/cbts.html
Training videos and slide sets	Slide sets and recorded presentations include case-studies to help validators	Presentations and case studies used to walk through difficult cases to learn to apply the NHSN HAI definitions accurately. Please begin using the NHSN

	implement the basic content presented in HAI training webinars.	Roadmap resources for the component or module you are validating: https://www.cdc.gov/nhsn/training/roadmap/index.html
Quick Learns	Quick Learns are educational videos/ demonstration that provide more in-depth explanation or clarification on a specific topic, issue, or FAQ.	Click on the NHSN Component to view available Quick Learns: https://www.cdc.gov/nhsn/training/index.html

Other opportunities for training include:

- CDC-sponsored trainings.
- NHSN blast emails, external partner calls, quarterly NHSN newsletter, and NHSN Patient Safety Component (PSC) Manual, which NHSN updates prior to January each year with any changes to methods and definitions.

Even after training, validators should be willing to seek help when needed from NHSN on definitions and criteria for challenging cases. If facilities and auditors cannot agree on case-status using documented information and the NHSN case definition as a gold standard, the case should be referred to CDC (NHSN@cdc.gov) for adjudication. Forms for tracking cases that result in discrepancies and require adjudication are found in Appendix [2.2](#).

Finally, although it is not required, duplicate medical record abstraction by another auditor (early in the process and periodically repeated) may be a useful adjunct to validator training and identify areas of difficulty to achieve improved inter-rater reliability.^{3,4}

2.2 Method of Facility Section

- See Chapter 3 and 4 for facility selection methodology. CDC recommends targeted validation to investigate and correct potential deficiencies in an efficient manner, given that most facilities have limited resources for validation. This approach also provides maximum opportunity to work with reporters to improve reporting.
- Cumulative Attributable Difference (CAD) is a second method of facility sampling for review. State health departments and other external agencies conducting validation of HAI data submitted to NHSN have the option to select either of the methods based on the state’s needs and priorities around HAI validation. Below we provide a summary, pros, and cons of both the methods to assist external agencies in selecting the appropriate method of facility and chart sampling.

	Method 1 - Prioritizing Facilities with Highest Likelihood of Event Occurrence	Method 2 - CAD Approach
Target criteria	This method prioritizes facility selection based on highest likelihood of event occurrence. It is more likely to select facilities with higher patient volume, and thus a higher predicted/expected number of events.	This method prioritizes facility selection by difference between predicted and observed number of events (CAD). It focuses on facilities with negative CAD values. These facilities reported zero or very few events and have a high predicted number of events.
What type of facilities are selected?	Focuses on larger healthcare facilities with high exposure volume, and thus high predicted/expected events.	Focuses on potential under reporters: facilities that reported very few events yet have a high predicted number of events.
Ranking algorithm	Facility ranking algorithm uses predicted events and facility standardized infection ratio (SIR) values for ranking and selection. SIR is a ratio of observed vs. predicted events and is subject to variability. A small facility with low predicted volume of events with even one observed event could have a high SIR value.	Facility ranking algorithm uses CAD. CAD metric is robust, stable and reflects the true facility HAI burden.

Which method should my agency use?	Agencies with no prior validation history should use Method 1 to determine HAI misclassification patterns. If external agencies are already aware of underreporting concerns, they may select Method 2.	Agencies with previous validation history that identified underreporting as a potential concern should use Method 2.
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2.3 Establish a mechanism for secure data transfer between facilities and the external validation agency

External validation agencies require data elements from facilities to build a sampling frame for medical record selection, including electronic files (spreadsheets) from laboratories that list positive blood specimens or other non-culture diagnostic tests that identify organism(s), positive quantitative urine cultures, and positive *C. difficile* tests with test dates, patient location(s) when collected, identified pathogens, and patient information to identify medical records for review. In addition, agencies may need assistance from facility medical records departments to identify hospital readmissions within the surveillance window (30 days for COLO and HYST) of audited surgical procedures. Some agencies have established secure File Transfer Protocol (FTP) sites for transfer of these sensitive data. Consider existing systems for secure data transfer and how to secure these data flow in both directions (to send line listings to characterize the sampling frame and to respond with the sample of medical records for review).

2.4 Develop and characterize the medical record sampling frame for each selected facility and each HAI to be validated, and for SSI assure a complete denominator

For CLABSI, CAUTI, MRSA Bacteremia LabID Event and positive *C. difficile* LabID Event, sampling frames derive from positive laboratory (blood specimen, urine culture, and CDI-positive specimen) line-listings in surveillance locations. NHSN encourages facilities to develop capacity to generate these lists electronically because recurring need for this capability is expected and creation of manual line-listings presents an excessive burden.

Facilities should report positive laboratory tests according to date of specimen collection, not date of result reporting.

To assure completeness of the laboratory line-listings, NHSN generally recommends laboratory data derive directly from the laboratory information management system and not from vendor software (such as data-mining programs). However, if convincing evidence exists that vendor software can provide complete laboratory data, vendor systems may provide convenient linkage to admission/discharge/transfer (ADT) data that would otherwise need to be created manually. This issue may need to be explored through individual discussions with facilities and by facilities with their vendors.

For SSI, sampling frames derive from procedures in NHSN. However, to assure the NHSN procedure sampling frame is complete, validators should use a monthly tally from the facility for COLO procedures and HYST procedures performed, based on ICD-10 procedure/CPT codes in discharge data. This data request may be made along with the line listing and the procedure number requests. If these numbers are reasonably close to the number of procedures listed in NHSN, validators can assume the procedure denominator data is relatively complete.

Structure of laboratory line listings

Validators need to be able to identify NHSN-reported HAIs on laboratory line listings. Facilities should report HAIs to NHSN using the medical record number (MRN) and may also use patient name. In most cases, matching reported HAIs to line listings will be based on MRN, gender, date of birth, and date of event. In some situations, validators may need more information from the IP about reported NHSN events to identify reported HAIs on the laboratory line listing (e.g. a request for additional personal identifiers of patients with NHSN-reported HAIs that can be linked to laboratory reports).

The selected sample of positive laboratory tests also will need to be linked to patient medical records for review. The patient MRN and laboratory test date from the line listing will be the primary identifiers for this purpose, but knowing patient date of birth, admission date, and possibly patient name may facilitate the medical records request for record audits. If the facility can provide these fields with the line listing, they should be requested.

CLABSI in validation locations

- From each selected facility, obtain a complete list of positive blood specimens collected from validation locations (VLs) in 2021 (which includes all positive blood specimens taken during VL stay, the day of departure from the VL, or the following 3 calendar days) to select the medical record sample before the site visit. A spreadsheet file (e.g. Excel) is recommended for ease of use.
- For VL blood specimens identifying organism(s), the MRN, admission date, laboratory specimen number, date of specimen collection (not date of report), resulting first organism (“Org 1”) genus and species, specific validation location, patient gender, and patient date of birth are required. Additional patient identifiers such as patient name may be helpful. If needed, ask the IP to translate specific patient location information on the laboratory line listings to mapped NHSN VLs, and assure that results for all locations are included. Be sure it is possible to distinguish neonatal intensive care unit (NICU) from adult/pediatric VLs on this line listing to stratify the CLABSI sample. No information about central line use should be requested; validators will screen for this information while reviewing records. See example of line list template in [Appendix 1.1](#) Letter requesting Site Visit and Line Listings for External Validation.

CAUTI in validation locations

- From each selected facility, obtain a complete list of positive urine cultures collected in VLs in 2021 (which includes all positive urine cultures taken during ANY VL stay, the day of departure, or the following calendar day) to select the medical record sample before the site visit. A spreadsheet file is recommended for ease of use. Limit positive urine cultures to those with no more than 2 identified pathogens and at least 10⁵ CFU/ml organisms.
- For positive urine cultures, the MRN, facility admission date, laboratory specimen number, specimen collection date, identity of organisms (up to two) and colony counts (CFU/ml), specific VL, patient gender, and patient date of birth are required. Additional patient identifiers such as patient name may be helpful. If needed, ask the IP to translate specific patient location information on the laboratory line listings to mapped NHSN validation locations, and assure that results for all VLs are included. Urine specimens with mixed flora, more than two organisms, no bacteria, or fewer than 10⁵ CFU/ml organisms will be rejected. No information about indwelling urinary catheter status should be requested; validators will screen for this information while reviewing records. See example of line list template in [Appendix 1.1](#) Letter requesting Site Visit and Line Listings for External Validation.

COLO Procedures

For each selected facility, use NHSN to determine the number of reported COLO procedures conducted in 2021. Enter the number of NHSN-reported COLO procedures in [Appendix 2.1](#) Numerator Validation, Sampling Frame Information.

HYST Procedures

For each selected facility, use NHSN to determine the number of reported HYST procedures conducted in 2021. Enter the number of NHSN-reported HYST procedures in [Appendix 2.1](#) Numerator Validation, Sampling Frame Information.

MRSA bacteremia LabID Event, facility-wide inpatient (FacWideIN)

- From each selected facility, obtain a complete list of blood specimens positive for methicillin-resistant *Staphylococcus aureus*. MRSA includes *S. aureus* cultured from any specimen that tests oxacillin-, ceftazidime-, or methicillin-resistant by standard susceptibility testing methods or by a laboratory test that is FDA-approved for MRSA detection. Include those collected in 2021 for inpatient location/emergency department (ED)/24-hour observation unit facility-wide to select the patient admissions/episodes of care for which review is planned. A spreadsheet format is recommended for ease of use. These laboratory line lists should include patient location at the time of specimen collection.
- For positive MRSA bacteremia LabID Event (FacWideIN), the MRN, facility admission date, laboratory specimen number, specimen collection date, documentation that specimen source was blood, organism genus and species, methicillin susceptibility information (organism ID may be shortened to MRSA, covering genus, species, and methicillin susceptibility requirements), specific inpatient or ED location/24-hour observation location, patient gender, 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 1.1](#) Letter requesting Site Visit and Line Listings for External Validation.

CDI LabID Event, FacWideIN

- From each selected facility, obtain a complete list of final *Clostridioides difficile* PCR-positive laboratory results collected in 2021 for inpatients facility-wide (excluding NICU, skilled care nursery, babies in labor/delivery/recovery/post-partum (LDRP) locations, and well-baby nurseries) plus ED/24-hour observation units to create a sample. 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. A spreadsheet format is recommended for ease of use. These laboratory line lists should include patient location at the time of specimen collection.
- 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, patient gender, 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 1.1](#) Letter requesting Site Visit and Line Listings for External Validation.

2.5. Notify facilities of the planned audit and request the required laboratory line listings

For chosen facilities, contact the IP and discuss the audit process, including the likely scope of the audit and how the audit sample will be drawn from eligible medical records. Discuss the request for blood specimens, urine cultures, and

C. difficile positive line listings for appropriate patient populations (with structures described above). If all six HAIs will be validated, up to 60 specific medical records will be requested each for CLABSI in VLs and CAUTI in VLs, up to 60 medical records each for COLO and HYST procedures with any subsequent admissions within 30 days following the procedure, and for LabID Event, access to either a) ADT data and complete inpatient and outpatient laboratory records for 60 specified episodes of care each for MRSA bacteremia and CDI LabID Event OR b) corresponding medical records that include these elements during on-site validation. Ask about the lead-time for the facility to generate the required line listings and how much lead-time the medical records department will need to arrange for medical record access. Ask how patient medical records can best be accessed onsite and how they are organized; this can affect the time required to abstract the records (for example, disorganized records on microfilm may be particularly difficult and time-consuming to abstract). Discuss the anticipated number of days and reviewers needed to complete the audit, based on experience or the guidance to follow. Request documentation that the facility's NHSN reporters have completed training on 2021 NHSN reporting methods and definitions. In addition, request a monthly breakdown of how many COLO and HYST procedures were conducted using ICD-10-PCS coded data if these will be validated. Consider a mutually agreeable due date for the laboratory line listings, dates for the medical record request, and proposed date(s) for the onsite audit. For the audit, request arrangements for medical records access including workspace, computer systems, terminals and passwords, microfilm readers, and (eventually) specific medical records. The laboratory line listings should be provided by the facility through a secure file transfer (for example, encrypted email, secure file transfer protocol [FTP] site, or encrypted file by courier or snail mail) as a sortable and searchable (e.g., .csv, Excel) file, and should include facility information such as facility name, CCN (CMS Certification Number), and NHSN orgID), contact name, contact phone, contact email, date of report, and timeframe of laboratory results. Compose a letter notifying the facility Chief Executive Officer (CEO), copied to the IP, that provides an overview of your authority to conduct validation (if applicable) or requesting voluntary access to medical records for the audit process, purpose of the audit, proposed dates for the audit, and specific data and accommodations needed from facility staff (see [Appendix 1.1](#) for an example letter). Explain the purpose of the audit (i.e., to assure accountability of all facilities in complete and accurate reporting of HAIs according to NHSN methods and definitions) and how validation results will be used and/or reported.

2.6 Select medical records (to be discussed in Chapters 3 and 4)

2.7 Download (“freeze”) the facility’s reported data from NHSN before disclosing which medical records were selected for the audit

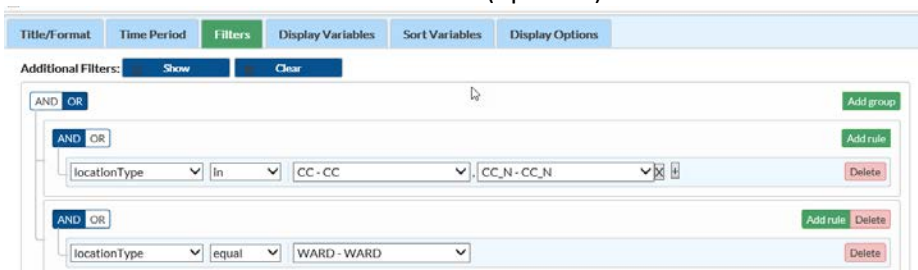
Do this after selecting the medical records sample to minimize downloads using NHSN Analysis Reports and the modifications described below to “freeze,” essentially take a snapshot of the data, and exporting the reported 2021 NHSN data.

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>.

CLABSI

Select “Device-associated Module” > “Central Line-Associated BSI”> “Line Listing – All CLAB Events” > “Modify Report”.
Suggested Modifications:

- Change the output title to “<Facility ID > Freeze Data <Freeze Date> CLABSI IN VALIDATION LOCATIONS, 2021”.
- Select Excel (.xls) or desired format.
- Select “Time Period” and use the drop-down box to set **eventDateYr** to 2021.
- Select “Filter” and use the drop-down boxes to select **locationType**, in, (“**CC_CC**”), (**CC_N-CC_N**); Select “Add group” for additional locations **OR** for each rule. See the screen shot below for an example.
- Select “Sort Variables” and “eventDate” (optional).



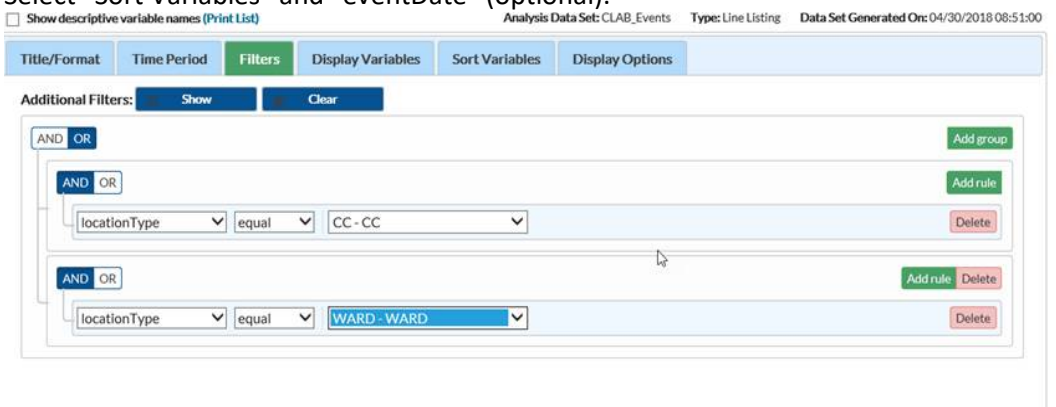
Note: Location type should reflect the locations being validated.

CAUTI

Select “Device-associated Module” > “Urinary Catheter-Associated UTI” > “Line Listing – All CAU Events” > “Modify Report”.

Suggested Modifications:

- Change the output title to “<Facility ID > Freeze Data <Freeze Date> CAUTI IN VALIDATION LOCATIONS, 2021”.
- Select Excel (.xls) or desired format.
- Select “Time Period” and use the drop-down box to set **eventDateYr** 2021.
- Select “Filter” and use the drop-down boxes to select **locationType (“CC_CC”)**; Click “Add Group” for additional locations. See the screen shot below for an example.
- Select “Sort Variables” and “eventDate” (optional).



Note: Location type should reflect the locations being validated.

COLO

Select “Procedure-Associated Module” > “SSI” > “Line Listing – All SSI Events” > “Modify Report”.

Suggested Modifications:

- Change the output title to “<Facility ID > Freeze Data <Freeze Date> COLO procedures, 2021”.

- Select Excel (.xls) or desired format.
- Select “Time Period” and use the drop-down box to set **procDateYr** to 2021.
- Select “Filter” and use the drop-down boxes to select **procCode**, then **equal**, then **COLO** from the next drop-down box (or **procCode=COLO**).
- Select “Sort Variables” and “procDate” (optional).

HYST

Select “Procedure-Associated Module” > “SSI,” > “Line Listing – All SSI Events” > “Modify Report”.

Suggested Modifications:

- Change the output title to “<Facility ID > Freeze Data <Freeze Date> HYST procedures, 2021”.
- Select Excel (.xls) or desired format.
- Select “Time Period” and use the drop-down box to set **procDateYr** to 2021.
- Select “Filter” and use the drop-down boxes to select **procCode**, then **equal**, then **HYST** from the next drop-down box (or **procCode=HYST**).
- Select “Sort Variables” and “procDate” (optional).

MRSA

Select “MDRO/CDI Module – LABID Event Reporting” > “All MRSA LabID Events” > “Line Listing for All MRSA Blood LabID Events” > “Modify Report”.

Suggested Modifications:

- Change the output title to “<Facility ID > Freeze Data <Freeze Date> **MRSA Blood LabID Events FacWideIN, 2021**”.
- Select “Excel” (.xls) or desired format.
- Select “Time Period” and use the drop-down box set **specDateYr** to 2021.
- Select “Filters” and verify the drop-down boxes read “mrsa”, “equals”, and “Y-Yes”.
- Add Rule and select “AND”, then use the drop-down boxes to select “SpecimenSource”, “equals”, and “(BLDSPC) - Blood specimen”.
- Select “Sort Variables” and “specimenDate” (optional).

CDI

Select “MDRO/CDI Module – LABID Event Reporting” > “All C. difficile LabID Events” > “Line listing of all C. difficile LabID Events” > “Modify Report”.

Suggested Modifications:

- Change the output title to “<Facility ID > Freeze Data <Freeze Date> **CDIF LabID Events, FacWideIN, 2021**”.
- Select “Excel” (.xls) or desired format.
- Select “Time Period” and use the drop-down box to set **specDateYr** to 2021.
- Select “Filters” and verify the drop-down boxes read “cdiff”, “equals”, and “Y-Yes”.
- Select “Sort Variables” and “specimenDate” (optional).

2.8 Request selected medical records in advance of the facility site-visit

Submit the medical records request to the facility in a secure fashion so they can arrange for access to the information for your visit.

Chapter: 3 Method 1 - Facilities and Medical Records Sampling: Prioritizing Facilities with Highest Likelihood of Event Occurrence

This is the first of two methods auditors may choose from for facility and medical records selection. If HAI's or other events will be validated in facility types other than acute care hospitals, separate rankings should be completed for acute care hospitals, long-term acute care hospitals (LTACHs), and inpatient rehabilitation facilities (IRFs). This will provide a system for assigning relative priority to each facility for each HAI. Even for those not planning to conduct validation, this ranking activity provides awareness of which facilities are highly exposed to HAI risk and those reporting high or low event outcomes. Additional analyses to evaluate data completeness, timeliness, and quality also are encouraged. Targeted sampling of hospitals performing the surgical procedures to be audited and of the surgical procedures themselves requires that risk-adjustment variables (e.g., ASA score, anesthesia, procedure duration) are complete. Analysis to assure completeness of these variables is recommended before facilities are ranked for SSI validation.

3.1 Determine the Minimum Facility Sample Size

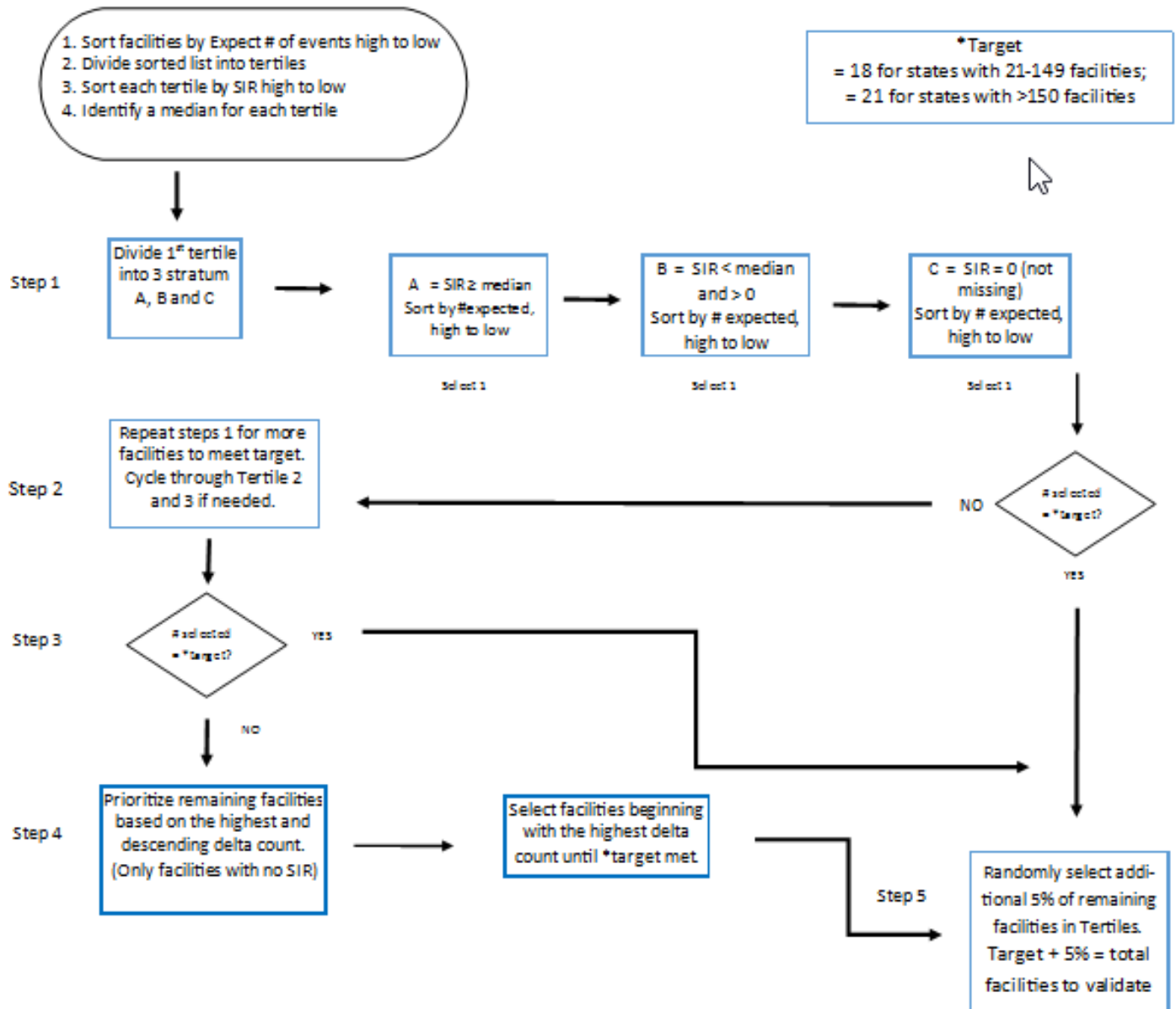
- This approach to facility selection is targeted to prioritize validation of facilities where HAIs are most expected. A recommended minimum number of facilities should be validated (with a recommended minimum number of medical records) for each selected HAI:
 - Smaller states/jurisdictions with 20 or fewer facilities should validate them all
 - Medium states with 21 to 149 facilities should select at least 18 targeted facilities plus a 5% random sample of remaining facilities
 - Larger states with 150 or more facilities should select at least 21 targeted facilities plus a 5% random sample of remaining facilities.
- Examples of facility selection calculation
 - a) **State A** DPH HAI coordinator has chosen to validate LabID CDI in Acute Care Hospitals (ACH). State A has 17 ACH. Based on validation guidelines all 17 facilities will be contacted to participate in the external validation.
 - b) **State B** DPH HAI coordinator has chosen to validate CLABSI in ACH. There are 125 ACH facilities in the state. Based on the validation guidelines the coordinator will need to select **18** targeted facilities and an additional 5% or **5** randomly selected facilities for a total of 23 facilities.
 - a. $18 + [(125-18) \times 0.05] = 23$ (rounding to the nearest whole number)
 - c) **State C** DPH HAI coordinator has chosen to validate SSI targeting COLO procedures in ACH. There are 185 ACH facilities in the state. Based on the validation guidelines the coordinator will need to select **21** targeted facilities and an additional 5% or **8** randomly selected facilities for a total of 29 facilities.
 - a. $21 + [(185-21) \times 0.05] = 29$ (rounding to the nearest whole number)

3.2 Apply the Facility Ranking Algorithm

- For each HAI, sort facilities based on predicted/expected number of events.
- After sorting, the top tertile (33%) of facilities will undergo further targeting and prioritization, based on performance, using the facility SIR relative to the median SIR for the top tertile group of facilities.
- If the minimum number of targeted facilities is not reached within the top tertile alone, the process should be repeated by targeting the second tertile, and (if necessary) the third.
- If additional facilities are needed to achieve the recommended minimum number, facilities without a calculated SIR may be considered for validation based on the "delta count", defined as the absolute difference between expected and observed NHSN Events reported to NHSN.

- For each HAI, all unselected facilities from all 3 tertiles will be subject to a 5% random sample in order to assure accountability for facilities that are not highly exposed.
- If you choose to validate multiple HAIs at your facilities then you will need to evaluate the facilities to be chosen based on where they rank after you've completed the ranking algorithm for each HAI individually.

Ranking Algorithm and Selection of Targeted facilities



Step 1. In the 1st 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 4 below).* Re-sort within each stratum A, B, and C, by # expected from highest to lowest. Assign sequential Targeted Selection Numbers to facilities, by selecting the highest available # expected from each stratum alternating A, B, and C. For example, facility #1 will be the facility with the highest # expected from stratum A, facility #2 the facility with the highest # expected from stratum B, and #3 the facility with the highest # expected from stratum C. Return to stratum A and assign #4 to the next facility in stratum A, assign #5 to the next facility in stratum B, and facility #6 will be the next facility in stratum C. Continue alternating strata until no facilities remain or the target number of facilities (18 or 21) is reached.

Step 2. If additional facilities are needed, repeat the process (step 1) using the second and then third tertile.

Step 3. If target # of facilities have been met cycling through tertile 1-3, proceed step 5.

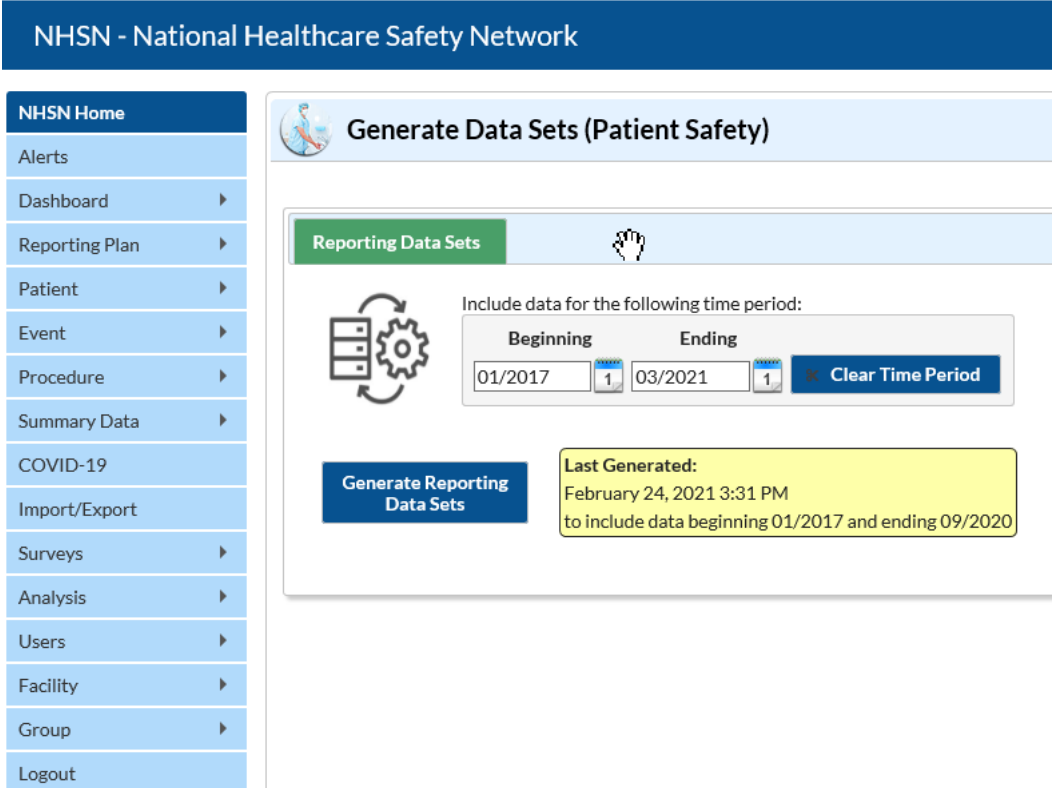
Step 4. If additional facilities are needed to complete the targeted number, prioritize them based on the highest and descending delta count (only for facilities without a calculated SIR).

Step 5. After the targeted selection is complete, ALL remaining facilities from ALL tertiles will be subject to random selection under the 5% rule.

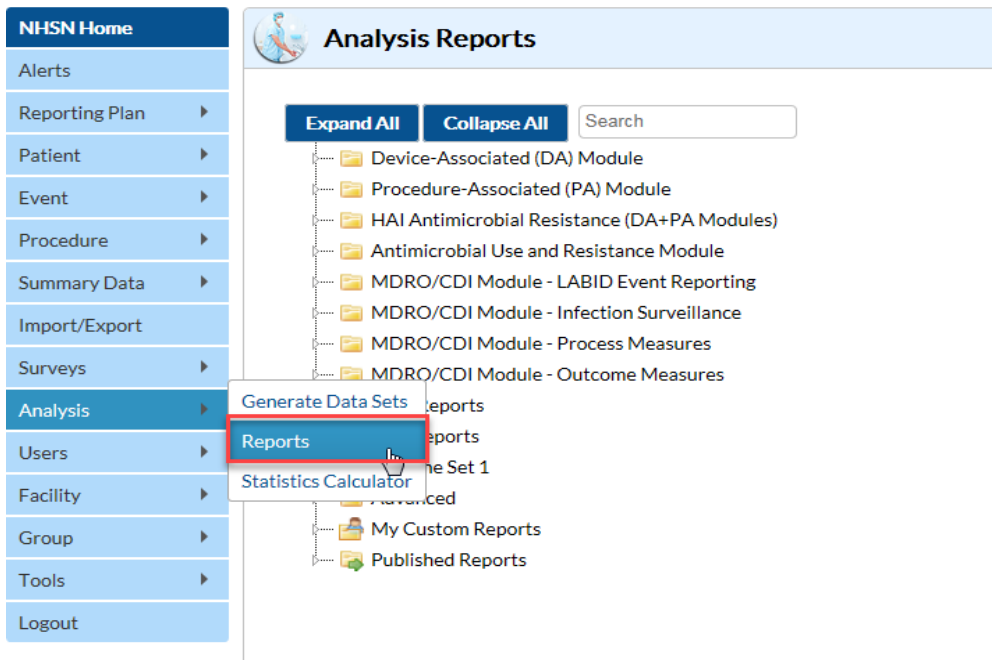
3.3 Step by step Targeted Facility Ranking and Selection

A. CLABSI IN VALIDATION LOCATIONS

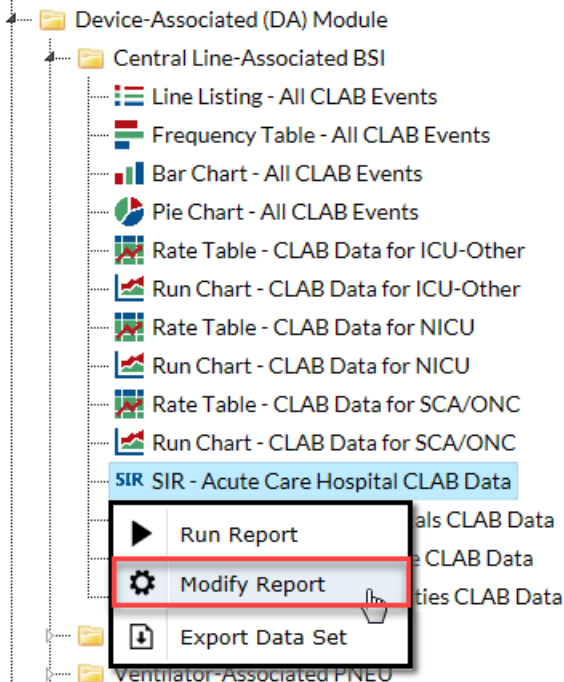
1. Generate new datasets in NHSN to ensure any data updates are included for analysis. On the NHSN Landing Page, navigate to Patient Safety Component --> [YOUR State Users' Group]. Select the "Analysis" tab and click "Generate Data Sets." Click the Generate New button. Allow the dataset generation process to complete; you can leave NHSN during the generation process.



2. After successful dataset generation, navigate to Analysis→Reports to display the tree view list of all analysis reports available within NHSN’s analysis tool.

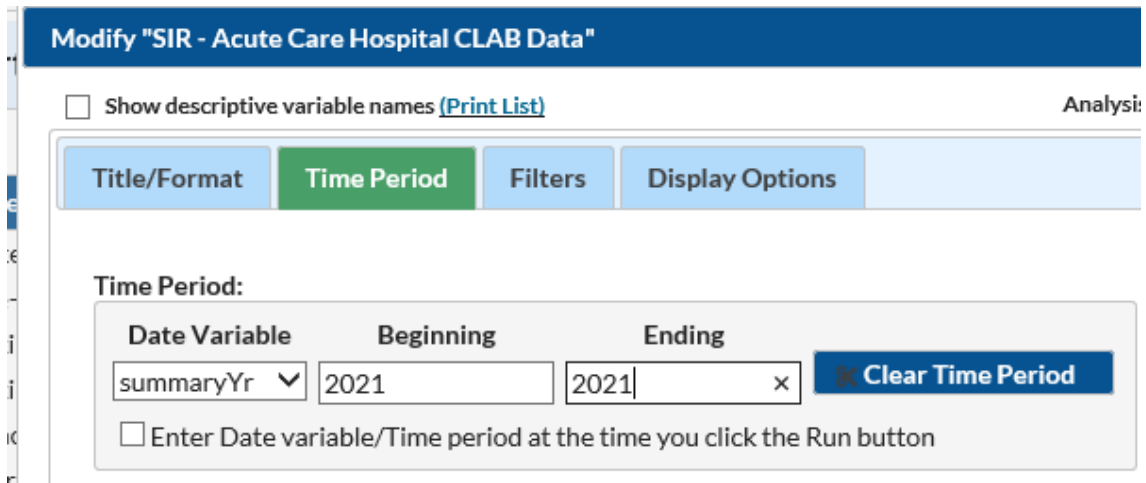


3. Use the tree view structure to navigate to the SIR report of interest. In this example (targeting for CLABSI), we will select the Device Associated Module, -> Central Line-Associated BSI, -> SIR Acute Care Hospital CLAB Data. This uses data reported to NHSN that has been shared with the group. Click the Modify button to proceed to the modification screen, which can be used to filter and export data from NHSN.



4. A modification screen will open titled “Modify ‘SIR- Acute Care Hospital CLAB Data’.” On the modification screen, 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. Use the “Time Period” option to limit the time period of data that is included in the report to be exported. Set “Date Variable” to SummaryYr, “Beginning” to 2021 and “Ending” to 2021:

4b. Navigate to the “Filters” tab. Select bsiPlan = Y. Add another rule by selecting “Location type” from the dropdown list.



Modify "SIR - Acute Care Hospital CLAB Data"

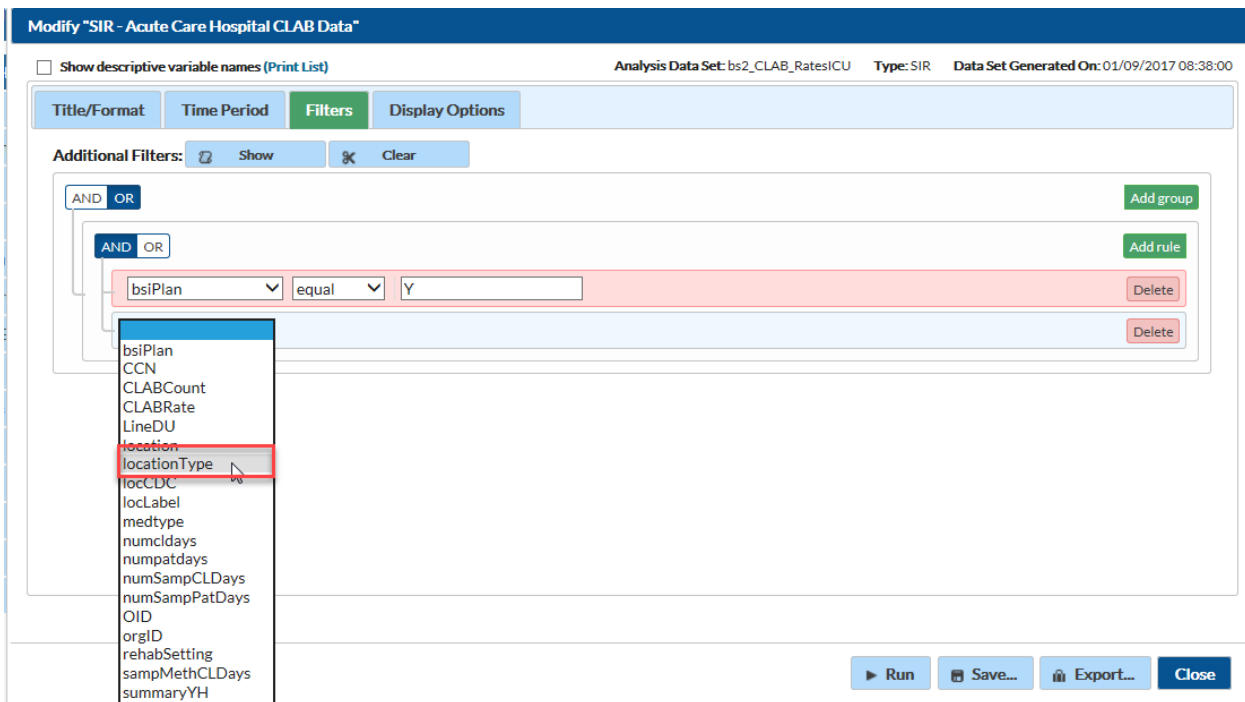
Show descriptive variable names ([Print List](#)) Analysis:

Title/Format **Time Period** **Filters** **Display Options**

Time Period:

Date Variable	Beginning	Ending
summaryYr	2021	2021

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



Modify "SIR - Acute Care Hospital CLAB Data"

Show descriptive variable names ([Print List](#)) Analysis Data Set: bs2_CLAB_RatesICU Type: SIR Data Set Generated On: 01/09/2017 08:38:00

Title/Format **Time Period** **Filters** **Display Options**

Additional Filters:

AND OR

AND OR

bsiPlan equal Y

locationType

- bsiPlan
- CCN
- CLABCount
- CLABRate
- LineDU
- location
- locationType
- locCDC
- locLabel
- medtype
- numcldays
- numpatdays
- numSampCLDays
- numSampPatDays
- OID
- orgID
- rehabSetting
- sampMethCLDays
- summaryYH

4c. After selecting “locationType”, set the next field to “in” and Value(s) to “CC-CC” and “CC_N-CC_N” to specify all ICU locations, adult and neonatal. Add additional validation locations by as needed. Scroll to the bottom of the pop-up screen and select “Save”.

Modify "SIR - Acute Care Hospital CLAB Data"

Show descriptive variable names (Print List) Analysis Data Set: bs2_CLAB_RatesICU Type: SIR Data Set Generated On: 01/04/2017 15:15:00

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

Additional Filters:

AND OR

AND OR

bsiPlan equal Y

locationType in

CC - CC , CC_N - CC_N , WARD - WARD , WARD_ONC - WARD_ONC

4d. Under the "Display Options" section, use the "Group by" option to view the data at a particular level of aggregation. By default, this is set to SummaryYH, (half-years). Change the Group by option to "SummaryYr".

Modify "ESTHER - SIR - Acute Care Hospital CLAB Data"

Show descriptive variable names (Print List) A

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

SIR Options

Group by: **summaryYr**

Cumulative
summaryYH
summaryYM
summaryYQ
summaryYr

- After making these modifications, scroll to the bottom of the modification screen. Click the Export button to export the data selected by your modifications to a different file format.
- Clicking the Export button will take you to the Export Analysis Data Set screen. Use the dropdown menu to select the file format to export the data. In this example, we will export to an Excel spreadsheet (*.xls) using data set modifications. Click the Export button to begin the export process. NHSN will create a .zip file with your data export in it and prompt you to specify a location to save the file on your computer.

Export Analysis Data Set

Analysis Data Set: bs2_CLAB_RatesICU

Export Format: **Excel spreadsheet (*.xls)**

Export Entire Analysis Data Set

Export Analysis Data Set using Modifications

- For CLABSI data, the exported SIR report file will be displayed at multiple levels of aggregation, which are outlined and displayed in the screenshot to follow.
- In Excel, select the aggregation level that provides a facility-specific SIR for all validation locations (shown below in black in Table 1.1). This level of aggregation will allow you to explore the level of exposure risk for

CLABSI in validation locations and measured performance at each facility. Select these rows and copy this information to a new spreadsheet. (Also, insert a row above your data and copy the header row so you can identify the variables on the new page). Arrange the facilities in rank order according to the predicted number of CLABSIs [numPred], (high to low), and create three new columns titled “Delta count”, “Stratum”, and “Targeted Selection Number.

9. Use Excel to calculate the Delta count for each facility/row. The formula in Excel is (=ABS[row cell under InfCount]—[row cell under numExp]). (You will use Delta count only if an SIR is not calculated by NHSN).
10. Select the top tertile (33%) of facilities by predicted number of CLABSI in validation locations. This “Top Tertile” of facilities where CLABSI in validation locations are most expected, may have the greatest potential for surveillance and prevention impact.
11. Within the top tertile, sort by SIR from highest to lowest, and identify the current median SIR for the top Tertile. (Recall that median is the “middle” value for the group). To sort just the top tertile, highlight the entire row for each facility in the top tertile, and click “Data, “Sort”; Column “Sort by” (select SIR), “Sort On” (values), and “Order” (highest to lowest).
12. 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 15 below).
13. Re-sort within each stratum A, B, and C, by numExp 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;” Column “Sort by” (select numExp), “Sort On” (values), and “Order” (highest to lowest). Repeat this process for the next two strata, one-by-one.
14. Assign sequential Targeted Selection Numbers to facilities, by selecting the highest available numExp from each stratum alternating A, B, and C. For example, facility #1 will be the facility with the highest numExp from stratum A, facility#2 the facility with the highest numExp from stratum B, and #3 the facility with the highest numExp from stratum C. Return to stratum A and assign#4) to the next facility in stratum A, assign #5 to the next facility in stratum B, and facility #6 will be the next facility in stratum C. Continue alternating strata until no facilities remain or the target number of facilities (18 or 21) is reached. If additional facilities are needed, repeat this process (steps 11-14) using the second and then third tertile based on exposure.
15. Once all hospitals with an assigned SIR have been prioritized, evaluate facilities with fewer expected events. In hospitals where NHSN does not calculate an SIR (because the predicted number of infections is less than one), a different method rather than the above method of stratifying by SIR should be used. This is because the value of a calculated SIR is exceedingly imprecise when the expected number of infections is less than one, and a single infection can result in a very high SIR. If additional facilities are needed to complete the targeted number, prioritize them based on the highest and descending delta count (only for facilities without a calculated SIR).
16. After the targeted selection is complete, ALL remaining facilities from ALL tertiles will be subject to random selection under the 5% rule.

This basic process can be followed with minor modifications for each of the six HAI metrics, to identify facilities that are highly exposed (and therefore at risk for HAIs) and to characterize their performance using the SIR to rank them for validation.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	infCount	numCLDays	numExp	SIR	SIR_pval	SIR95CI	summaryYr	locationtype	locdc	orgid	location	months			
2	6	2366	4.076	1.472	0.2269	0.540, 3.204	1/1/2014								
3	5	2344	4.012	1.246	0.3735	0.405, 2.908	1/1/2014	ICU-OTHER							
4	1	22	0.065				1/1/2014	NICU							
5	0	10	0.02				1/1/2014								
6	4	1195	2.271	1.761	0.1948	0.480, 4.510	1/1/2014								
7	0	1123	1.685	0	0.1854	, 2.189	1/1/2014								
8	1	22	0.065				1/1/2014								
9	1	16	0.037				1/1/2014								
10	3	414	0.664				1/1/2014								
11	2	1942	3.394	0.589	0.3409	0.071, 2.129	1/1/2014								
12	1	10	0.019				1/1/2014								
13	3	394	0.605				1/1/2014	ICU-OTHER							
14	0	20	0.059				1/1/2014	NICU							
15	1	1940	3.388	0.295	0.1482	0.007, 1.645	1/1/2014	ICU-OTHER							
16	1	2	0.006				1/1/2014	NICU							
17	1	10	0.019				1/1/2014	ICU-OTHER							
18	0	10	0.02				1/1/2014								
19	2	10	0.019				1/1/2014								
20	0	368	0.552				1/1/2014								
21	0	20	0.059				1/1/2014								
22	1	6	0.014				1/1/2014								
23	1	1175	2.233	0.448	0.3466	0.011, 2.495	1/1/2014								
24	0	755	1.133	0	0.3221	, 3.256	1/1/2014								
25	1	2	0.006				1/1/2014								
26	0	10	0.023				1/1/2014								
27	1	10	0.019				1/1/2014								
28	0	368	0.552				1/1/2014	ICU-OTHER							
29	0	10	0.02				1/1/2014	ICU-OTHER							
30	2	10	0.019				1/1/2014	ICU-OTHER							
31	0							ICU							
32	1							ICU-OTHER							
33	1							ICU							
34	0							ICU-OTHER							
35	0							ICU-OTHER							

This Excel spreadsheet illustrates seven different levels of aggregation in the NHSN ICU CLABSI download. Select the tier that identifies a facility-specific SIR for CLABSI combining all ICU location types.



B. CAUTI IN VALIDATION LOCATIONS

Note: Use the steps in “CLABSI IN VALIDATION LOCATIONS” as an example; a similar process will be used for ranking of facilities for CAUTI IN VALIDATION LOCATIONS, with the following exceptions:

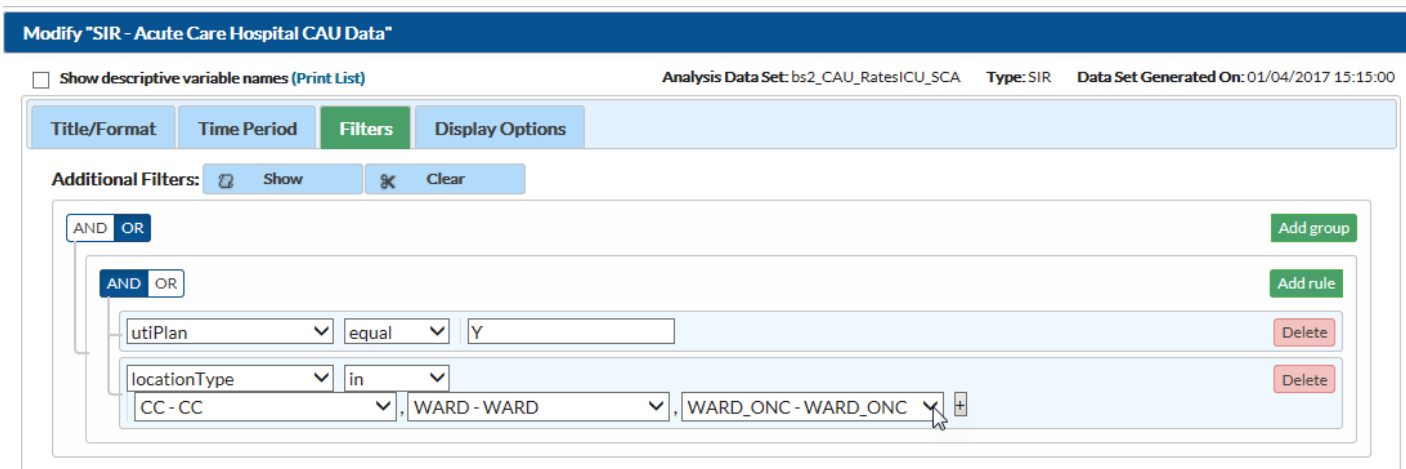
[Follow steps 1 and 2](#), as shown in “[CLABSI IN VALIDATION LOCATIONS](#)”.

3. Follow step 3 above, with the following modifications: select the Device Associated Module, -> Urinary Catheter-Associated UTI, -> SIR – Acute Care Hospital CAU Data. Select the modify button to proceed to the modification screen as before.

Follow step 4a, as shown in “[CLABSI IN VALIDATION LOCATIONS](#)”.

In part 4b, navigate to the “Filters” tab. Select utiPlan=Y. In the second line, add another rule by selecting “locationType”. After selecting “locationType”, set the next field to “equals” and Value(s) to “CC-CC”. (Omit “CC_N-CC_N” because you do not want to include NICU locations in the exposure calculations for CAUTI). Add additional validation locations by selecting “Add group”, “OR” then “add rule” Scroll to the bottom of the pop-up and select “SAVE”.

The selection box should resemble the screen shot below.



The screenshot shows the 'Modify "SIR - Acute Care Hospital CAU Data"' interface. At the top, it displays 'Analysis Data Set: bs2_CAU_RatesICU_SCA', 'Type: SIR', and 'Data Set Generated On: 01/04/2017 15:15:00'. Below this are tabs for 'Title/Format', 'Time Period', 'Filters', and 'Display Options', with 'Filters' selected. Under 'Additional Filters', there are 'Show' and 'Clear' buttons. The filter configuration area shows a hierarchical structure:

- Level 1: AND/OR selector, 'Add group' button.
- Level 2: AND/OR selector, 'Add rule' button.
- Level 3: Filter rule 1: 'utiPlan' dropdown, 'equal' dropdown, 'Y' text input, 'Delete' button.
- Level 3: Filter rule 2: 'locationType' dropdown, 'in' dropdown, and a list of values: 'CC - CC', 'WARD - WARD', and 'WARD_ONC - WARD_ONC'. A mouse cursor is pointing at the 'WARD_ONC - WARD_ONC' value. A 'Delete' button is to the right.

Follow steps 4d, 5, 6, and 7 as shown above. The exported SIR report Excel file will be displayed with multiple aggregation levels similar to the CLABSI data shown above.

In step 8, using Excel, select the aggregation level that provides a facility-specific SIR for all validation locations. This level of aggregation will allow you to explore the level of exposure risk for CAUTI in validation locations and measured performance at each facility. Copy this information to a new spreadsheet. Arrange the facilities in rank order according to “exposure”; the expected/predicted number of CAUTIs [numExp], (high to low), and create three new columns titled “Delta count,” “Stratum,” and “Targeted Selection Number.”

Complete steps 9-16 to assign a sequential Targeted Selection Number for CAUTI in validation locations to facilities and to draw a 5% random sample as before.

TARGETED FACILITY RANKING FOR COLO:

Note: Targeting surgical procedures requires that risk-adjustment variables in NHSN are complete. Please work with facilities to assure acceptable data quality and completeness before attempting to select facilities and records.

Note: Use the steps in [“CLABSI IN VALIDATION LOCATIONS”](#) as an example; a similar process will be used for ranking of facilities for COLO validation, with the following exceptions:

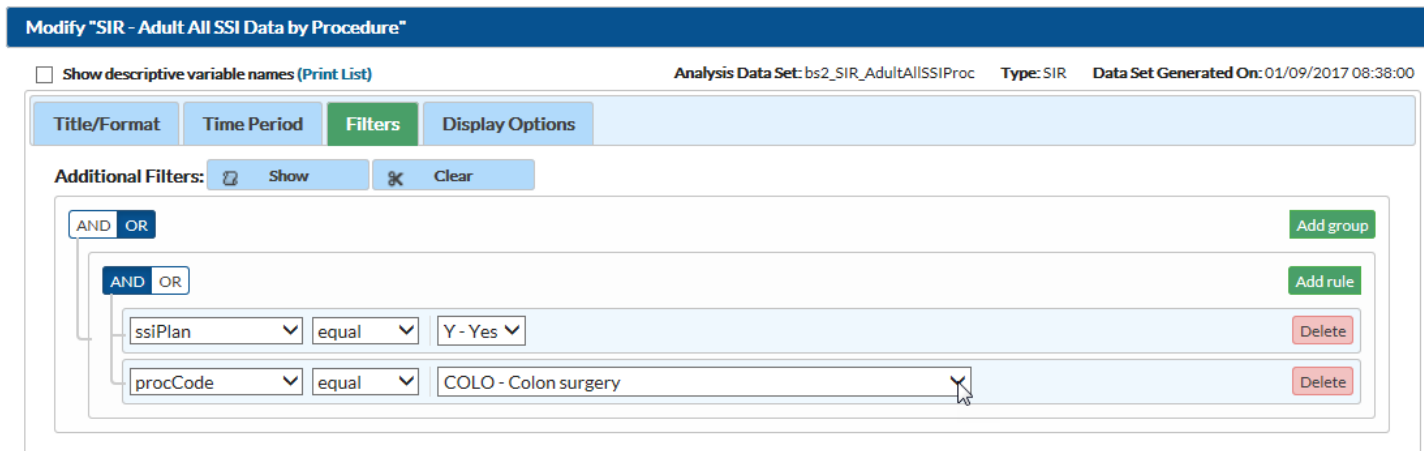
[Follow steps 1 and 2](#), as shown in [“CLABSI IN VALIDATION LOCATIONS”](#).

In step 3, select the Procedure-Associated Module, ->SSI, -> SIR- Adult All SSI Data by Procedure. Select the modify button to proceed to the modification screen as before.

Follow part 4a, as shown in [“CLABSI IN VALIDATION LOCATIONS”](#).

In step 4b, navigate to the “Filters” tab. Select ssiPlan = Y. In the second line, select “procCODE” from the drop-down options. Set the next file to “equals” and Value(s) to “COLO.” Select “SAVE.”

The selection box should resemble the screen shot below:



Follow steps 4d, 5, 6, and 7 as shown above. The exported SIR report Excel file will be displayed with multiple aggregation levels. A screen shot of an Excel spreadsheet is provided below to illustrate:

	A	B	C	D	E	F	G	H	I	J	K	L
1	summaryYr	procCount	infCountAll	numExpAll	SIRAll	SIRAll_pval	SIRAll95CI	procCode	orgid	outpatient	months	
2	1/1/2014	39	3	1.77	1.695	0.2614	0.350, 4.953	SIR for all facilities, all procedures				
3	1/1/2014	39	3	1.77	1.695	0.2614	0.350, 4.953	COLO	SIR for all facilities, specific procedures			
4	1/1/2014	37	2	1.638	1.221	0.4873	0.148, 4.411		10000			
5	1/1/2014	2	1	0.132					15164	SIR for each facility, all procedures		
6	1/1/2014	37	2	1.638	1.221	0.4873	0.148, 4.411	COLO	10000	*THIS IS THE LEVEL TO EVALUATE*		
7	1/1/2014	2	1	0.132				COLO	15164	SIR for each facility, specific procedures		
8	1/1/2014	37	2	1.638	1.221	0.4873	0.148, 4.411	COLO	10000	N		6
9	1/1/2014	2	1	0.132				COLO	15164	N		2

In step 8, using Excel, select the aggregation level that provides a facility-specific SIR for COLO SSIs (shown in black in the above screenshot). This level of aggregation will allow you to explore the level of exposure risk for COLO SSIs and measured performance at each facility. Copy this information to a new spreadsheet. Arrange the facilities in rank order according to “exposure”; the expected/predicted number of SSIs [numExp], (high to low), and create three new columns titled “Deltacount,” “Stratum,” and “Targeted Selection Number.”

Complete steps 9-16 to assign a sequential Targeted Selection Number for COLO SSI to facilities and to draw a 5% random sample as before.

D. TARGETED FACILITY RANKING FOR HYST:

Note: Targeting surgical procedures requires that risk-adjustment variables in NHSN are complete. Please work with facilities to assure acceptable data quality and completeness before attempting to select facilities and records.

Note: Use the steps in [“CLABSI IN VALIDATION LOCATIONS”](#) as an example; a similar process will be used for ranking of facilities for HYST validation, with the following exceptions:

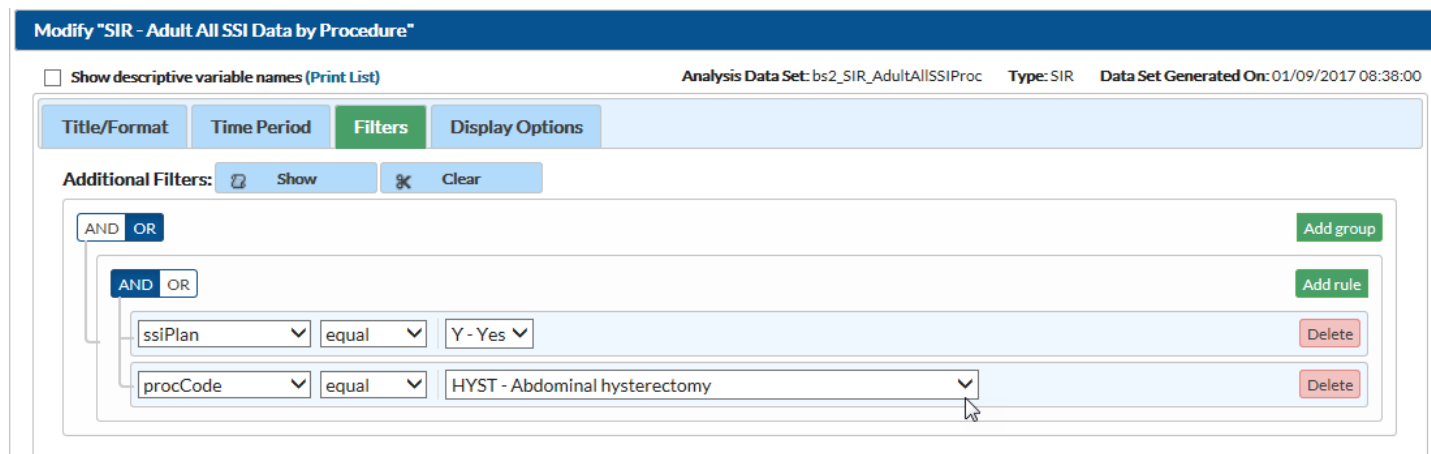
[Follow steps 1 and 2](#), as shown in [“CLABSI IN VALIDATION LOCATIONS”](#).

In step 3, select the Procedure-Associated Module, ->SSI, ->CDC-defined Output, ->SIR-In-Plan All SSI Data by Procedure. Select the modify button to proceed to the modification screen as before.

Follow step 4a, as shown in [“CLABSI IN VALIDATION LOCATIONS”](#).

In step 4b, navigate to the “Filters” tab. Select ssiPlan = Y. In the second line, select “procCODE” from the drop-down options. Set the next field to “equal” and Value(s) to “HYST.” Select “SAVE.”

The selection box should resemble the screen shot below.



The screenshot shows the 'Modify SIR - Adult All SSI Data by Procedure' interface. At the top, there is a header with the title and a 'Show descriptive variable names (Print List)' checkbox. Below the header, there are tabs for 'Title/Format', 'Time Period', 'Filters', and 'Display Options'. The 'Filters' tab is active. Underneath, there are 'Additional Filters' buttons: 'Show' and 'Clear'. The main filter area contains a tree structure with 'AND' and 'OR' operators. The first rule is 'ssiPlan' equal to 'Y - Yes'. The second rule is 'procCode' equal to 'HYST - Abdominal hysterectomy'. There are 'Add group', 'Add rule', and 'Delete' buttons for each rule.

Follow steps 4d, 5, 6, and 7 as shown in [“CLABSI IN VALIDATION LOCATIONS”](#). The exported SIR report Excel file will be displayed with multiple aggregation levels similar to the COLO data spreadsheet shown above.

In step 8, Using Excel, select the aggregation level that provides a facility-specific SIR for HYST SSIs. This level of aggregation will allow you to explore the level of exposure risk for HYST SSIs and measured performance at each facility. Copy this information to a new spreadsheet. Arrange the facilities in rank order according to “exposure”; the expected/predicted number of SSIs [numExp], (high to low), and create three new columns titled “Delta count,” “Stratum,” and “Targeted Selection Number.”

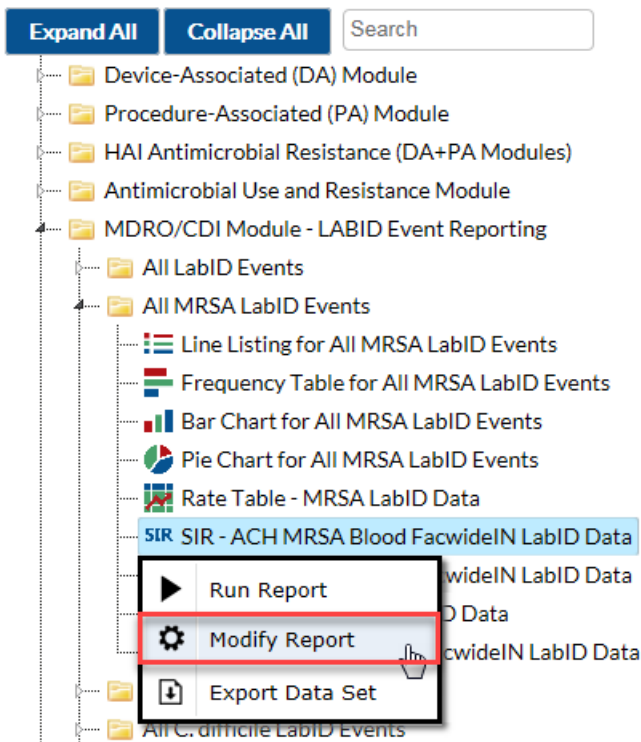
Complete steps 9-16 to assign a sequential Targeted Selection Number for HYST SSI to facilities and to draw a 5% random sample as before.

A. TARGETED FACILITY RANKING FOR MRSA BACTEREMIA LABID EVENT:

Note: Use the steps in “[CLABSI IN VALIDATION LOCATIONS](#)” as an example; a similar process will be used for ranking of facilities for MRSA Bacteremia LabID Event, with the following exceptions:

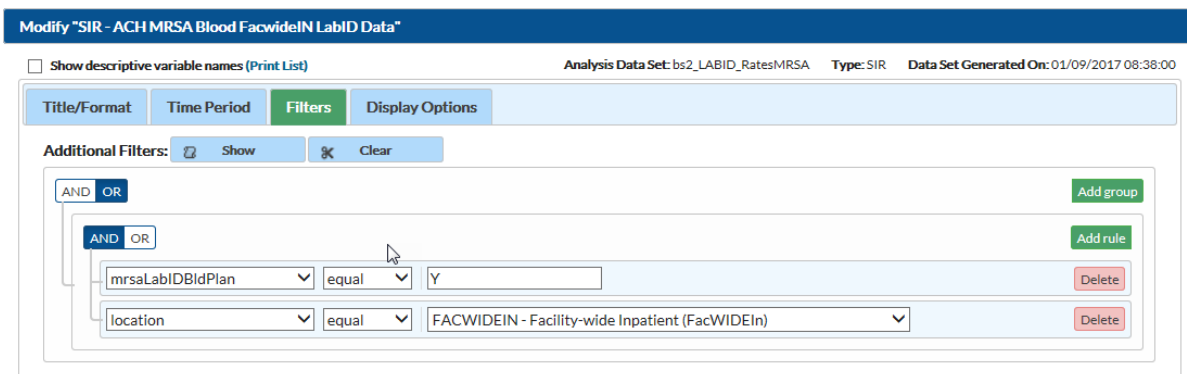
Follow steps 1 and 2, as shown in [CLABSI IN VALIDATION LOCATIONS](#).

In part 3, select the MDRO/CDI Module-LabID Event Reporting, -> All MRSA LabID events, -> SIR- ACH MRSA Blood FacwideIN LabID Data. Select the modify button as shown in the screen shot below.



Follow step 4a, as shown for CLABSI IN VALIDATION LOCATIONS above.

In step 4b, modify the selection criteria grid to analyze only IN-PLAN data. Click the first box in the top row, and select the variable “mrsaLabIDBidPlan”; set next field to “equal” and Value(s) to “Y”. In the second line, select “location” from the drop-down options. Set next field to “equal” and Value(s) to “FACWIDEIN” and select “SAVE.” See screen shot below.



NOTE: facilities that are conducting IN-PLAN MRSA all specimen surveillance are ALSO conducting IN-PLAN MRSA Bacteremia surveillance as a subset. NHSN includes these facilities under “mrsaLabIDBldPlan”=Y. Any surveillance that is not IN-PLAN will be excluded.

Follow steps 4d, 5 and 6, as shown for CLABSI in validation locations above.

For step 7, the exported SIR report Excel file for MRSA Bacteremia LabID Event will be displayed at several levels, and should look similar to the screenshot (for CDI LabID Event FACWIDEIN) shown above.

In step 8, Using Excel, select the aggregation level that provides a facility-specific SIR for MRSA Bacteremia LabID Event. This level of aggregation will allow you to explore the level of exposure risk for LabID Event and measured performance at each facility. Copy this information to a new spreadsheet. Arrange the facilities in rank order according to “exposure”; the expected/predicted number of LabID Events [numExpMRSA], (high to low), and create three new columns titled “Delta count,” “Stratum,” and “Targeted Selection Number.”

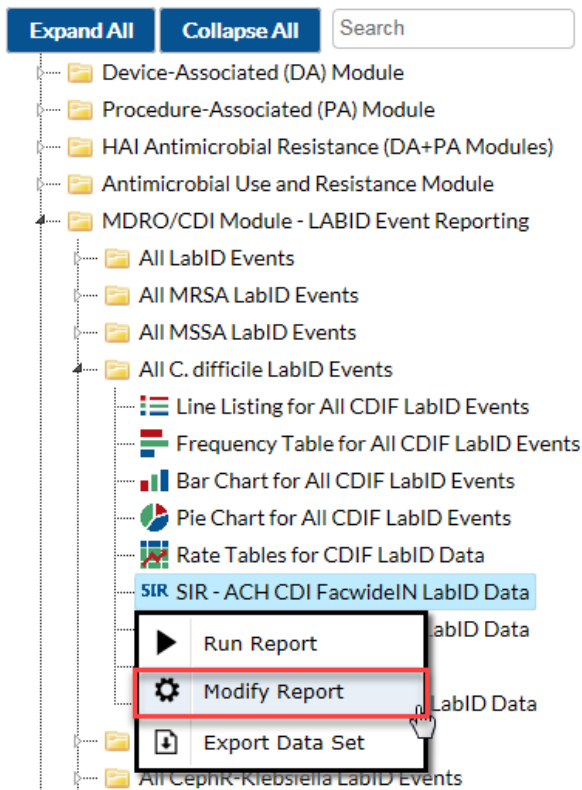
Complete steps 9-16 to assign a sequential Targeted Selection Number for LabID Events to facilities and to draw a 5% random sample as before.

B. TARGETED FACILITY RANKING FOR CDI LABID EVENT:

Note: Use the steps in [“CLABSI IN VALIDATION LOCATIONS”](#) as an example; a similar process will be used for ranking of facilities for CDI LabID Event, with the following exceptions:

[Follow steps 1 and 2](#), as shown in 3.2, [“CLABSI IN VALIDATION LOCATIONS”](#).

In step 3, select the MDRO/CDI Module-LabID Event Reporting, -> All C. difficile LabID events, -> SIR- ACH CDI FacwideIN LabID Data. Select the modify button as shown in the screen shot below.



Follow step 4a, as was shown for CLABSI IN VALIDATION LOCATIONS.

In step 4b, modify the selection criteria grid to analyze only IN-PLAN, FacWideIN data. Click the first box in the top row, and select the variable “cdfidLabIDPlan”, set the next field to “equal” and Value(s) to “Y”. In the second line, select “location” from the drop-down options. Set next field to “equal” and Value(s) to “FACWIDEIN” and select “SAVE.”

Modify "SIR - ACH CDI FacwideIN LabID Data"

Show descriptive variable names (Print List) Analysis Data Set: bs2_LABID_RatesCDIF Type: SIR Data Set Generated On: 01/09/2017 08:38:00

Title/Format Time Period **Filters** Display Options

Additional Filters:

AND OR

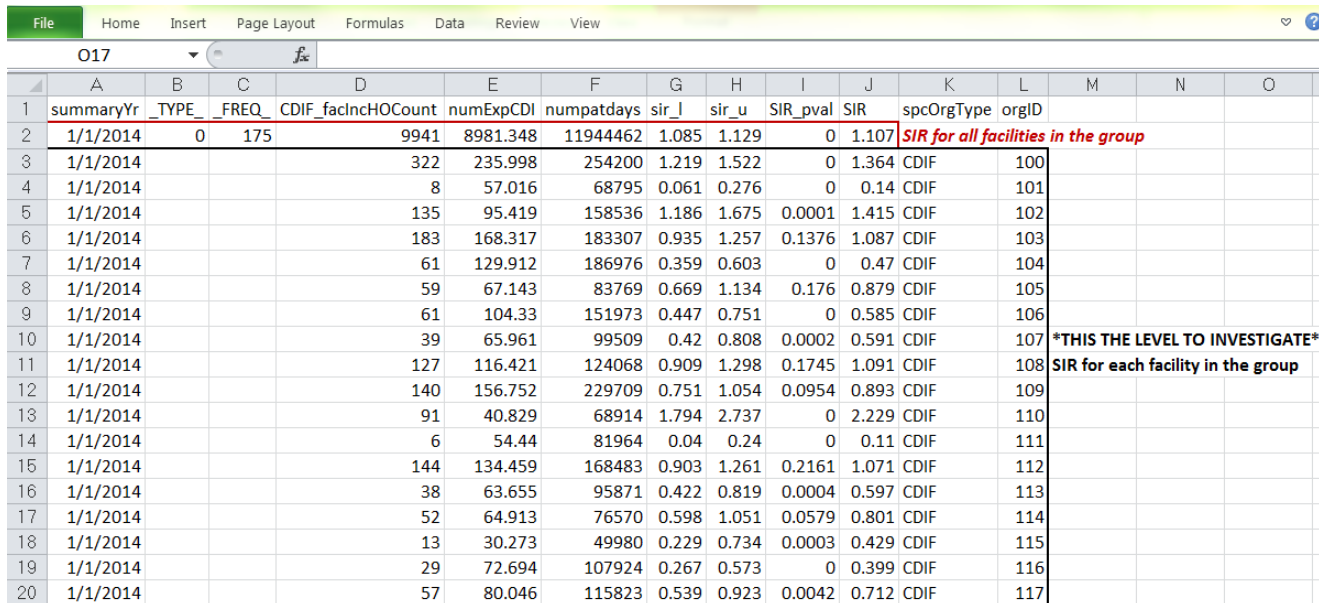
AND OR

cdfidLabIDPlan equal Y

location equal FACWIDEIN - Facility-wide Inpatient (FacWIDEIn)

Follow steps 4d, 5 and 6, as shown in [CLABSI IN VALIDATION LOCATIONS](#).

For step 7, the exported SIR report Excel file will be displayed at several levels, as illustrated in the screenshot below:



	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	summaryYr	TYPE	FREQ	CDIF	faclnCHOCCount	numExpCDI	numpatdays	sir_l	sir_u	SIR_pval	SIR	spcOrgType	orgID		
2	1/1/2014	0	175	9941	8981.348	11944462	1.085	1.129	0	1.107	SIR for all facilities in the group				
3	1/1/2014			322	235.998	254200	1.219	1.522	0	1.364	CDIF	100			
4	1/1/2014			8	57.016	68795	0.061	0.276	0	0.14	CDIF	101			
5	1/1/2014			135	95.419	158536	1.186	1.675	0.0001	1.415	CDIF	102			
6	1/1/2014			183	168.317	183307	0.935	1.257	0.1376	1.087	CDIF	103			
7	1/1/2014			61	129.912	186976	0.359	0.603	0	0.47	CDIF	104			
8	1/1/2014			59	67.143	83769	0.669	1.134	0.176	0.879	CDIF	105			
9	1/1/2014			61	104.33	151973	0.447	0.751	0	0.585	CDIF	106			
10	1/1/2014			39	65.961	99509	0.42	0.808	0.0002	0.591	CDIF	107	*THIS THE LEVEL TO INVESTIGATE*		
11	1/1/2014			127	116.421	124068	0.909	1.298	0.1745	1.091	CDIF	108	SIR for each facility in the group		
12	1/1/2014			140	156.752	229709	0.751	1.054	0.0954	0.893	CDIF	109			
13	1/1/2014			91	40.829	68914	1.794	2.737	0	2.229	CDIF	110			
14	1/1/2014			6	54.44	81964	0.04	0.24	0	0.11	CDIF	111			
15	1/1/2014			144	134.459	168483	0.903	1.261	0.2161	1.071	CDIF	112			
16	1/1/2014			38	63.655	95871	0.422	0.819	0.0004	0.597	CDIF	113			
17	1/1/2014			52	64.913	76570	0.598	1.051	0.0579	0.801	CDIF	114			
18	1/1/2014			13	30.273	49980	0.229	0.734	0.0003	0.429	CDIF	115			
19	1/1/2014			29	72.694	107924	0.267	0.573	0	0.399	CDIF	116			
20	1/1/2014			57	80.046	115823	0.539	0.923	0.0042	0.712	CDIF	117			

In step 8, Using Excel, select the aggregation level that provides a facility-specific SIR for CDI LabID Event (shown in black in the above screenshot). This level of aggregation will allow you to explore the level of exposure risk for LabID Event and measured performance at each facility. Copy this information to a new spreadsheet. Arrange the facilities in rank order according to “exposure”; the expected/predicted number of LabID Events [numExpCDI], (high to low), and create three new columns titled “Delta count,” “Stratum,” and “Targeted Selection Number.”

Complete steps 9-16 to assign a sequential Targeted Selection Number for LabID Events to facilities and to draw a 5% random sample as before.

3.4 Targeted Medical Record Sampling Overview

For sampling, a medical record refers to the record of a single facility inpatient admission, also referred to as an episode of care. For surgical procedures, the episode of care refers to the procedure and all associated medical encounters documented during the surveillance follow-up window. For each HAI to be validated, a sample size of 60 Medical Records/Episodes of Care per facility is recommended as a goal.

For CLABSI, CAUTI, COLO and HYST validation, up to 20 reported NHSN infection events will be reviewed. If more than 20 events have been reported to NHSN, 20 should be selected by random sampling. If less than 20 are reported, all events should be reviewed. In addition, a sampling frame of eligible (candidate) medical records will be developed for each HAI and from these 40 unreported “candidate events” will be selected, by targeting those with increased risk of event occurrence, where this is possible. Definitions of candidate events for each type of HAI and methods for targeting candidate events at increased risk for HAI are described below. Thus a total of (up to) 60 episodes of care containing reported or candidate events will be reviewed for each HAI per facility.

For MRSA bacteremia and CDI LabID Event validation, candidate events are defined by a positive laboratory test. Sixty (60) episodes of care will be selected based on presence of one or more qualifying laboratory tests during an episode of inpatient care, and information from the hospital laboratory and ADT system will be reviewed. Twenty (20) episodes of care will be reviewed to identify the FIRST reportable NHSN LabID Event, and 40 episodes of care will be reviewed to determine whether the SELECTED (non-first) laboratory event should have been reported to NHSN. If less than 20 are reported, all events should be reviewed.

Sample structure

- (Up to) 60 medical records each for CLABSI in validation locations, CAUTI in validation locations, COLO, and HYST, including
 - (Up to) 20 reported HAIs
 - (Goal of) 40 non-reported candidate HAIs. For CLABSI in validation locations, these will be stratified by NICU and adult/pediatric ICU locations, other validation locations, and will prioritize targeted pathogens. For CLABSI and CAUTI, many candidate cultures will be eliminated early because they do not have a device (central line or urinary catheter). For COLO and HYST, the medical record at the time of the surgical procedure will be reviewed, as well as any additional records during the surveillance window.
- (Goal of) 60 episodes of care each for candidate MRSA bacteremia LabID Events and candidate CDI LabID Events, including
 - (Up to) 20 “first” positive laboratory tests of the episode of care
 - (Up to) 40 “non-first” positive laboratory tests of the episode of care

Line listings required from facility

To identify unreported “candidate” CLABSI, CAUTI, MRSA bacteremia LabID Events and CDI LabID Events, a sampling frame of medical records and/or positive laboratory tests is needed and will require assistance from the facility being validated before the audit (see table below and specific instructions for medical records selection). For COLO and HYST SSIs the required sampling frame is derived from COLO and HYST procedures already entered and available in NHSN, however completeness of surgical risk-adjustment variables should be assured before sampling is conducted, because these variables are used for targeting.

Line Listings Required from Facilities for Sampling of CLABSI, CAUTI, MRSA Bacteremia and CDI LabID Events

HAI Event to be Validated	Request to Facility for Line Listing (detailed in Appendix 1.1)	Line Listing Will Define the Following Sampling Frame Elements
CLABSI in validation locations	Line listing ^a of blood specimens from validation locations and NICU where organism(s) was identified, with patient ID and admission date	<u>Episodes of care</u> (identified by patient ID and unique admission date) with one or more validation location blood specimen with organism(s) identified (include NICUs)
CAUTI in validation locations	Line listing ^a of positive urine cultures ^b from validation locations (non-NICU) with patient ID and admission date	<u>Episodes of care</u> (identified by patient ID and unique admission date) with one or more positive validation location urine culture(s) ^b (exclude NICUs)
MRSA bacteremia LabID Event	Inpatient ^c blood specimens positive for MRSA	<u>Episodes of care</u> with one or more inpatient ^c blood specimens positive for MRSA
CDI LabID Event	Inpatient ^c stools ^d -positive for <i>C. difficile</i> , excluding those from baby locations ^e	<u>Episodes of care</u> with one or more inpatient ^c stools ^d -positive for <i>C. difficile</i> , excluding those from baby locations ^e

^aLine listing of cultures should include all positive cultures taken during ANY validation location (VL) stay, the day of departure from the VL, or the following 1 calendar days after discharge

^bPositive urine cultures with no more than 2 identified pathogens, with at least one bacterium with greater than or equal to 10⁵ CFU/ml organisms

^cFor LabID Event, emergency department (ED) and 24 hour observation location specimens are included in FacWideIN. Specimens collected from other affiliated outpatient locations on the day of admission are considered inpatient specimens and attributed to the admitting location.

^dSurveillance guidance for laboratories recommends that *C. difficile* testing be done only on unformed stool specimens, and formed stool should be rejected

^eBaby locations include those with 80% or more infants (≤1 year); typically NICU, newborn nursery, and special care nursery. Babies in LDRP locations should also be excluded.

3.5 Step-by-Step Targeted Medical Record Selection

A. CLABSI in validation locations Targeted Medical Record Selection Process

1. From each selected facility, request a securely transmitted line listing of all positive blood specimens, from all validation locations reporting to NHSN, for the entire year, with required additional variables used for medical record identification and matching to NHSN reports (See [Appendix 1.1](#) for recommended line listing structure).
2. Assure the line listing includes positive blood specimens from all validation locations required to report CLABSIs to NHSN, using location mapping information in NHSN.
3. Assign a sequential number, beginning with 1, to each positive blood specimen.
4. Sort the list of blood specimens by MRN and admission date to generate clusters of blood specimens with same MRN and within the same admission date, also called unique episode of care.
5. Identify reported CLABSIs on the blood specimen line listing.
 - a) Using the NHSN CLABSI list and available patient information on blood specimen line listing, flag and mark blood specimens reported as CLABSIs. Create a new variable, “stratum” and assign these blood specimens and all other blood specimens in the same episode of care to stratum 1.
 - b) If reported CLABSIs are missing from the blood specimen line listing, the list may be incomplete. Investigate and correct this problem. Add omitted CLABSI records to the medical record review list.
6. Select simple random sample of (up to) 20 reported CLABSI in validation locations for review
 - a) Select stratum = 1.
 - b) Sort by random number, MRN, and hospital admission date.
 - c) Select the first 20 random numbers with unique episodes of care (defined by MRN and admission date) as the sample of reported CLABSI records.
 - d) If less than 20 targeted events review all episodes in stratum 1.
7. Identify unreported candidate CLABSI events and stratify by targeted pathogens
 - a) Select stratum not equal to 1.
 - b) Sort non-stratum 1 blood specimens by pathogen (focusing on Organism 1 only)
 - i. If the organism (Org 1) is a “Targeted Pathogen” (see list below), assign the positive blood specimen to stratum 2. If the organism (Org 1) is not a “Targeted Pathogen,” assign the positive blood specimen to stratum 3.
 - ii. Targeted Pathogens:
 - 1) *Candida spp., Torulopsis spp.* (yeast)
 - 2) *Enterococcus spp.*
 - 3) *Staphylococcus aureus* (includes MRSA, MSSA)
 - 4) Coagulase-negative staphylococcus (includes most staphylococcus spp. other than *S. aureus*, MRSA, MSSA)
 - 5) *Klebsiella spp., E. coli, or Pseudomonas spp.* (common gram negatives)
8. Among unreported candidate CLABSI events, use location information to identify NICU vs. adult/pediatric ICU records (If facility has no NICU, skip to step 10 below, and select 10 additional medical records from adult/pediatric ICUs for screening sample.).
 - a) Re-sort blood specimens by validation location type (NICU vs. other validation locations) and create a variable NICU (Yes/No). Assign NICU status to each blood specimen as appropriate.
9. Select the NICU screening sample.
 - a) Select NICU= Yes, and stratum = 2 (targeted pathogens)
 - b) Sort by random number, MRN, and admission date

- c) Select the first 10 random numbers with unique episodes of care (defined by MRN and admission date) as the sample of NICU records containing candidate CLABSIs.
 - d) If 10 NICU medical records with stratum 2 blood specimens are not available, supplement the NICU sample with NICU records with stratum 3 blood specimens (where NICU = Yes, and stratum = 3); take the initial medical records (lowest random numbers with unique MRNs) to total 10 selected medical records from NICU.
10. Select the non-NICU screening sample
- a) Select NICU = No, and stratum = 2 (targeted pathogens)
 - b) Sort by random number, MRN, and admission date
 - c) Select the first 30 random numbers with unique episodes of care (defined by MRN and admission date) as the sample of validation location medical records with candidate CLABSIs.
 - d) If 30 validation location medical records with stratum 2 blood specimens are not available, supplement the non-NICU medical record sample with stratum 3 blood specimen (where NICU= No, and stratum = 3); take the initial medical records (lowest random numbers with unique MRNs) to total 30 selected medical records from validation locations.
11. The final screening sample should contain: (up to) 20 medical records with reported CLABSIs, (up to) 40 medical records divided among NICU (if available) and other validation locations.
12. If medical records are not well balanced among different targeted pathogens, consider post-selection adjustment to include a variety of these organisms, in order to evaluate a variety of surveillance skills, as noted below.

Before requesting medical records for the audit, download (“freeze”) the facility’s reported data from NHSN

Why Target CLABSI Pathogens?

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

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

B. CAUTI IN VALIDATION LOCATIONS Medical Record Selection Process

1. From each selected facility, request a securely transmitted line listing of all positive urine cultures, from all validation locations reporting to NHSN, for the entire year, with required additional variables used for medical record identification and matching to NHSN reports (See [Appendix 1.1](#) for recommended line listing structure).
2. Assure the line listing includes appropriate positive urine cultures from all validation locations required to report CAUTIs to NHSN, using location mapping information in NHSN.
3. Assign a sequential number, 1 – x, to each positive urine culture.
Sort the list of urine cultures by MRN and admission date to generate clusters of urine cultures associated with recognizable patient records, also called unique episodes of care.
4. Identify reported CAUTIs on the urine culture line listing.
 - a) Using the NHSN CAUTI list and available patient information on urine culture line listing, flag and mark urine cultures reported as CAUTIs. Create a new variable, “stratum,” and assign these urine cultures and all other urine cultures in the same episode of care to stratum 1.
 - b) If reported CAUTIs are missing from the urine culture line listing, the list may be incomplete. Investigate and correct this problem. Add omitted CAUTI records to the medical record review list.
5. Select simple random sample of (up to) 20 reported CAUTI in validation locations for review.
 - a) Select stratum = 1
 - b) Sort by random number, MRN, and hospital admission date.
 - c) Select the first 20 random numbers with unique patient episodes of care (defined by MRN and admission date) as the sample of reported CAUTI records.
6. Identify unreported candidate CAUTI events.
 - a) Select stratum not equal to 1.
7. Select the screening sample
 - a) Sort by random number, MRN, and admission date (if available)
 - b) Select the first 40 random numbers with unique medical records (defined by MRN and admission date)
8. The final screening sample should contain: (up to) 20 medical records with reported CAUTIs, and (up to) 40 medical records without reported CAUTIs from validation locations.

Before requesting medical records for the audit, download (“freeze”) the facility’s reported data from NHSN

C. COLO Procedure Targeted Medical Record Selection Process

1. Using NHSN, download a line listing of all COLO procedures for 2021, following these steps:
 - a) Log In to NHSN for the facility being validated and the Patient Safety Module.
 - b) From the left-hand Navigation Bar, Click “Analysis” then “Reports.”
 - c) Select the folder titled “Advanced,” then “Procedure-level Data,” Modify.”
 - d) Select the “Line Listing – All Procedures,” Then the Modify Report button.
 - e) Change the Title to “Line Listing – COLO Procedures 2021,”
 - f) Under “Title/Format” Select Excel (xls), and consider whether you want to check the box for “Show Descriptive Labels.” This option will make the variable names longer (and more explicit), but is often not necessary if you know the variable names.
 - g) Select “time period,” then select ProcDateYr, for “Beginning” enter 2021, and for “Ending” enter 2021.
 - h) Select Filter do the following:
 - i. Under “add rule” use the drop down list and select “procCode”
 - ii. In the next drop down list select equals , and the next “COLO-Colon surgery”

- iii. Select “add rule” to add another line. Using drop down list, select “outpatient”, then equals “No”
- iv. select “ageAtProc”
- v. “ageAtProc”, equals or greater “18”
- i) Select “Display Variables select “Modify List”; retain the default Selected Variables: orgID, patID, DOB, gender, procID, procDate, and procCode. Add variables by double clicking from the left hand list: ProcDateYr, outpatient, ageAtProc (to assure that you have selected 2021 inpatient adult COLO procedures), anesthesia, asa, procDurationHr, procDurationMin, Scope, medAff, numBeds, swClass, and bs2_modelRiskAdultAll (variable that will be used to select procedures at higher risk to result in SSI).

- j) Select “Sort Variables; remove procCode from the right hand list by double clicking (all procedures will be COLO). Add procID by double clicking the variable in the left hand box; it will move to the right hand box. Click Save for future use if you wish: “Line Listing for COLO Procedures 2021.”
 - k) Select Run. You should see a line listing in Excel sorted by procID from lowest to highest.
2. Next, you will identify any of these procedures that have been reported to NHSN with an SSI. For this step, return to NHSN Analysis Output Options. This time, select the folders titled “Procedure-Associated Module,” “SSI.”
- a) Select “Line Listing – All SSI Events”, “then Modify Report.”
 - b) Under Title change to “Line Listing – COLO SSI Events 2021.”
 - c) Optional: decide if you want to use Variable Labels and check the box to show descriptions.
 - d) Under Format select Excel (xls).
 - e) Select “Time” select ProcDateYr, for “Beginning” enter 2021, and for “Ending” enter 2021.
 - f) Select “Filter” “Specify Other Selection Criteria” do the following:
 - i. Under “Add rule” select from the drop down box “procCode.”
 - ii. In the next field select “equals” from the drop down box then “COLO-Colon surgery” in the next.
 - iii. Click the “Add rule” button to add a line.
 - iv. From the drop down box select “outpatient.”
 - v. In the next field select “equals” from the drop down box then “No” in the next.
 - vi. Click Save
 - g) Under “Display Variables” retain the default Selected Variables: orgID, patID, DOB, gender, eventType, spcEvent, and procDate and procCode. Add the following: admitDate (this is date of admission for the procedure), eventID and eventDate. Remove the remaining variables by double clicking.
 - h) Select “Sort Variables” select linkedproc. This is the same variable as procID in the procedures file.
NOTE: if you do not find a linked procedure, this SSI has probably been entered off-plan. You can use the other variable (procDate, patID, etc.) to investigate this.
3. Returning to the procedures file; mark any procedure that has been reported with an SSI as a reported case. Select no more than 20. Review all SSI if less than 20. All others are considered Candidate SSIs. Select the 40 candidate SSIs with the highest SSI risk (“bs2_modelRiskAdultAll”) for review.

Before requesting medical records for the audit, download (“freeze”) the facility’s reported data from NHSN

D. HYST Procedure Targeted Medical Record Selection Process

1. Using NHSN, download a line listing of all HYST procedures for 2021, following the steps outlined above for COLO.
 - a. If you have saved your template for downloading the line list of COLO procedures, you can make a few small modifications to download the HYST procedures rather than starting over (where you have entered “COLO” replace it with “HYST”).
2. (As for COLO above), using NHSN, download a line listing of all HYST SSIs for 2021, following the steps outlines above, and replacing “COLO” with “HYST.”
3. (As for COLOs above) return to the HYST procedures file; mark any HYST procedure that has been reported with an SSI as a reported case. Select no more than 20. Review all SSI if less than 20. All others are considered candidate SSIs. Select the 40 candidate SSIs with the highest SSI risk (“bs2_modelRiskAdultAll”) for review.

Before requesting medical records for the audit, download (“freeze”) the facility’s reported data from NHSN

E. Strategy for Selection of MRSA Bacteremia LabID Events for Validation

1. From each selected facility, request a securely transmitted line listing of all positive MRSA blood cultures from all inpatient locations /ED/24 hour observations for the entire year, with required additional variables used for medical record identification and possible matching to NHSN reports (See [Appendix 1.1](#) for recommended line listing structure). Facilities should be STRONGLY encouraged to provide this in a spreadsheet (e.g. Excel) format.
2. Sort the line listing by specimen date. Assign a sequential number [1 to X] to each positive MRSA blood culture in the list. This will be used for random specimen selection.
3. Next sort the list by patientID, admission date, and specimen date. This allows you to identify individual episodes of patient care (a unique admission date and patientID) and to determine whether there is only one MRSA blood culture or multiple MRSA blood cultures during an episode of care.
4. Divide the original list into two lists: [A] first patient specimens (created by separating out all first specimens during a unique episode of care) and [B] non-first specimens (by separating out all remaining specimens). This may require some manual sorting.
5. Begin with list [B] (non-first specimens) to draw a random sample of 40 specimens that will be used to evaluate the SELECTED specimen and whether it should have been reported to NHSN. Sample only once from any episode of care.
6. Use list [A] (first patient specimens) to draw a random sample of 20 specimens that will be used to identify the FIRST REPORTABLE LabID Event during an episode of care. In this case, validators are looking for evidence of positive MRSA blood cultures that are not on the inpatient list, but which were collected on the date of admission from an affiliated outpatient location other than ED/ 24 hour observations, or during a recent admission with an eligible specimen from the same inpatient location within the prior 14 days.

Before requesting medical records or other data for the audit, download (“freeze”) the facility’s reported data from NHSN

F. Strategy for Selection of *C. difficile* Infection (CDI) LabID Events for Validation

1. From each selected facility, request a securely transmitted line listing of all positive *Clostridium difficile* stool specimens from all inpatient locations/ED/ 24 hour observations for the entire year, with required additional variables used for medical record identification and possible matching to NHSN reports (See [Appendix 1.1](#) for recommended line listing structure). Facilities should be STRONGLY encouraged to provide this in a spreadsheet (e.g. Excel) format.
2. Sort the line listing by specimen date. Assign a sequential number [1 to X] to each -positive CDI result in the list. This will be used for random specimen selection.
3. Next sort the list by patientID, admission date, and specimen date. This allows you to identify individual episodes of patient care (a unique admission date and patientID) and to determine whether there is only one inpatient CDI specimen or multiple inpatient CDI specimens during an episode of care.
4. Divide the original list into two lists: [A] first specimens (created by separating out all first specimens during a unique episode of care) and [B] non-first specimens (by separating out all remaining specimens). This may require some manual sorting.
5. Begin with list [B] (non-first specimens) to draw a random sample of 40 specimens that will be used to evaluate the SELECTED specimen and whether it should have been reported to NHSN. Sample only once from any episode of care.
6. Use list [A] (first patient specimens) to draw a random sample of 20 specimens that will be used to identify the FIRST REPORTABLE LabID Event during an episode of care. In this case, validators are looking for evidence of positive CDI results that are not on the inpatient list but which were collected on the date of admission from an affiliated outpatient location other than ED/ 24 hour observation or during a recent admission with an eligible specimen from the same inpatient location within the prior 14 days.

Before requesting medical records or other data for the audit, download (“freeze”) the facility’s reported data from NHSN

Note: For ease of use and printing, Medical Records Abstraction Tools (MRATs) and Instructions for use of the MRATs are located in separate documents under Supporting Documents on the Validation webpage

Chapter 4: Method 2 - Targeted Sampling of Facilities and Medical Records using Cumulative Attributable Difference (CAD) Approach

The targeted sampling of facilities and medical records described in [Chapter 3](#) recommends that facilities are selected using a targeted sampling approach to prioritize validation in facilities with higher volume of patients where HAIs are most expected. Recent reports of HAI data validation efforts have demonstrated that underreporting of HAI events continues to be a concern. Prioritizing validating among facilities sorted by “predicted/expected number of events” and SIR values, limits validation among relatively larger facilities with a computed value of SIR and excludes smaller size facilities where underreporting could potentially also exist.

An alternate method of prioritizing healthcare facilities uses the cumulative attributable difference (CAD) approach. CAD is defined as the difference between the observed number of HAI events and facility specific number of expected events. Among facilities with zero or very few reported events, a negative CAD value will be generated indicating that for the given time period fewer HAIs occurred than that are statistically predicted, and the SIR goal has been reached or exceeded. Larger negative values of CAD indicate a larger gap between the predicted and observed number of HAI events. Prioritization of facility selection based on highest negative CAD values can help assess the data accuracy among facilities with high predicted/expected and very few or no reported events during a time frame.

4.1 Ranking Algorithm for facility selection

A. Follow steps 1-7 of [Chapter 3 Step-by-Step Targeted Facility Ranking](#) using CLABSI as an example.

1. In Excel, select the aggregation level that provides a facility-specific SIR for all validation locations. This level of aggregation will allow you to explore the level of exposure risk for CLABSI in validation locations and measured performance at each facility.

4	1.71106	1030	0.1252	2.338	0.743, 5.639	IN-ACUTE:CC:M_PED		
2	3.18614	2824	0.5558	0.628	0.105, 2.074	IN-ACUTE:CC:NS		
7	9.78433	7188	0.3846	0.715	0.313, 1.415	IN-ACUTE:CC:NURS	SIRs for each location types	
9	17.3151	15646	0.0327	0.52	0.253, 0.954	IN-ACUTE:CC:S		
2	3.26009	2134	0.531	0.613	0.103, 2.027	IN-ACUTE:CC:T		
0	0.79606	670				IN-ACUTE:CC_STEP:NURS		
3	5.18805	4183	0.3493	0.578	0.147, 1.574	HOSP-GEN		
1	9.06437	7682	0.0013	0.11	0.006, 0.544	HOSP-GEN		
2	7.57817	6272	0.0235	0.264	0.044, 0.872	HOSP-GEN		
0	0.42346	562				HOSP-GEN		
0	0.7199	823				HOSP-GEN		
2	1.0873	1253	0.3934	1.839	0.308, 6.077	HOSP-GEN	"THIS IS THE LEVEL TO EVALUATE" Facility-specific SIRs combining all location types	
0	0.44531	591				HOSP-GEN		
1	1.05264	933	1	0.95	0.048, 4.685	HOSP-GEN		
13	18.5196	15267	0.1921	0.702	0.390, 1.170	HOSP-GEN		
0	0.15574	232				HOSP-GEN		
1	1.52725	1760	0.7659	0.655	0.033, 3.229	HOSP-GEN		
3	1.57237	1812	0.2846	1.908	0.485, 5.193	HOSP-GEN		
2	3.60045	3149	0.4283	0.555	0.093, 1.8 CC	HOSP-GEN	facility and location types	
1	1.5876	1034	0.7334	0.63	0.032, 3.1 CC_N	HOSP-GEN		
1	8.26831	7012	0.0026	0.121	0.006, 0.5 CC	HOSP-GEN		
0	0.79606	670			CC_N	HOSP-GEN		

2. Select these rows 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 page. Next, use the variable numPred (predicted events) to sort the facilities in descending rank order (high to low). After this step is completed, facilities will be arranged in the descending order of the numPred 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-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			100014	HOSP-GEN
8	9.542312	7958	0.6509	0.838	0.389, 1.592			100046	HOSP-GEN
1	9.064373	7682	0.0013	0.11	0.006, 0.544			100001	HOSP-GEN
2	7.578169	6272	0.0235	0.264	0.044, 0.872			100002	HOSP-GEN
7	5.689505	4581	0.5585	1.23	0.538, 2.434			100022	HOSP-GEN
4	5.504663	4879	0.558	0.727	0.231, 1.753			100027	HOSP-GEN
2	3.159258	2784	0.5651	0.633	0.106, 2.077			100010	HOSP-GEN
2	2.437844	2304	0.8601	0.82	0.138, 2.412			100049	HOSP-GEN
0	1.945079	1724	0.143	0	0, 1.540			100005	HOSP-GEN
3	1.572374	1812	0.2846	1.908	0.485, 5.111			100007	HOSP-GEN
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	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 the descending order of number of predicted infections (numPred) and compute the 75th percentile value of the variable numPred

- Using the *Percentile.inc* Excel function, generate a quartile distribution of variable column “numPred” for the validation period (minimum two quarters). At this step, the *Percentile.inc* function will generate 25th, 50th, 75th and 100th percentile values of the numPred column values. Look for the 75th percentile value of the numPred variable.
- Use the numPred value corresponding to the 75th percentile as the threshold for selection of facilities eligible for validation. This value corresponding to the 75th percentile allows selection of facilities of adequate size to obtain candidate events for onsite chart reviews. If this value is greater than 1, use the 75th percentile numPred value, otherwise use predicted=1 value. This will determine a threshold cut off of minimum predicted number of HAI events.

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			100014	HOSP-GEN
8	9.542312	7958	0.6509	0.838	0.389, 1.592			100046	HOSP-GEN
1	9.064373	7682	0.0013	0.11	0.006, 0.544			100001	HOSP-GEN
2	7.578169	6272	0.0235	0.264	0.044, 0.872			100002	HOSP-GEN
7	5.689505	4581	0.5585	1.23	0.538, 2.434			100022	HOSP-GEN
4	5.504663	4879	0.558	0.727	0.231, 1.753			100027	HOSP-GEN
2	3.159258	2784	0.5651	0.633	0.106, 2.077			100010	HOSP-GEN
2	2.437844	2304	0.8601	0.82	0.138, 2.412			100049	HOSP-GEN
0	1.945079	1724	0.143	0	0, 1.540			100005	HOSP-GEN
3	1.572374	1812	0.2846	1.908	0.485, 5.111			100007	HOSP-GEN
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	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

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

- Create a subset of facilities that includes facilities with predicted number of HAI 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 the validation sample. This will be the facility-sampling frame.
- If the sampling frame consists of less than or equal to 30 facilities, then select all facilities for validation. (In the example above, since the number of facilities with numPred value >5.5 is less than 30, all the facilities are selected for validation)



7. If sampling frame consists of greater than 30 facilities, select 30 facilities based on the criteria described in section C. below.

B. Observed Events

- Since CAD approach focuses on the difference between the predicted number of HAIs and actual observed HAIs (reported), the step B involves computing the pooled estimation of observed events (infCount) across the validation locations. The infCount is an aggregated count of observed HAIs for individual validation locations to create a “pooled aggregate” observed HAIs.
- Next, create a column titled “CAD” next to numPred and compute the CAD values for each line by subtracting numPred value from infCount (observed – predicted).

C. 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:
 - Stratum 1: Includes all facilities in the sampling frame that had zero infCount value, i.e., 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, i.e., non-zero reported pooled aggregate observed events for the validation time frame
- 2) Stratum 1 (where facility reported zero events): If the facility reported zero HAI events in NHSN, then CAD value will be negative. The highest negative values will be for facilities with greater predicted/expected and zero events reported. Use the computed CAD values for facilities in stratum 1 and sort them in descending order of negative values of CAD. After this step, facilities with the highest negative CAD value should be at the top. Select the first 15 facilities from Stratum A.

infCount	numPred	CAD	numclday	SIR_pval	SIR	sir95ci	locationTy	locCDC	orgID	facType
1	9.064373	-8.06437	7682	0					100001	HOSP-GEN
2	7.578169	-5.57817	6272						100002	HOSP-GEN
13	18.51959	-5.51959	15267						100008	HOSP-GEN
8	9.542312	-1.54231	7958						100046	HOSP-GEN
4	5.504663	-1.50466	4879						100027	HOSP-GEN
10	9.736101	0.263899	8387						100014	HOSP-GEN
7	5.689505	1.310495	4581						100022	HOSP-GEN
22	15.32671	6.673286	9910	0.2					100030	HOSP-CHLD

Compute the CAD values for facilities in the sampling frame. Sort the CAD values in descending order (highest negative 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): Among facilities with non-zero events, this option could lead to CAD values from positive to negative. Sort the facilities in descending order of negative values of CAD. The sorted list will include facilities with the highest negative CAD at the top and could also include facilities with positive CAD values. Select the first 15 facilities from stratum 2.
- 4) If there are insufficient facilities in either of the strata, over sample from the other strata to complete the required number of facilities for the validation sample.

Facility Sampling Using CAD Approach

- Generate the quartile distribution of predicted HAIs for the facility
- Find the 75th percentile value of predicted HAI
- If value > 1, then use the value corresponding to 75th percentile as the threshold, otherwise use value = 1
- Select all the facilities with predicted events > 75th percentile threshold value or 1 (whichever is higher) and create a subset of facilities in state to form the validation sampling frame.



If subset is ≤ 30 facilities – validate all
If subset > 30 facilities, facility selection



Calculate the pooled aggregate observed events among the facilities in sampling frame



Stratum 1: Zero events reported

- All values negative CAD
- Highest negative CAD: High predicted/zero events
- Sort – descending order absolute CAD values

Stratum 2: Non-zero events reported

- CAD values: negative and positive
- Sort – descending order absolute CAD values
- Select top 15 facilities

4.2 Medical Records Selection Overview

- 1) **Before requesting medical records or other data for the audit, download (“freeze”) the facilities reported data from NHSN.** See Chapter 2.7 for detailed step by step instructions for each HAI.
- 2) Request facilities to send line lists of candidate HAI cases from the validation locations for the validation timeframe. These line lists will include positive blood and urine cultures, COLO and HYST procedures, positive CDI results and positive MRSA blood specimen results. Facilities should be encouraged to provide the line lists in an Excel template (Refer to [Appendix 1.1](#)).
- 3) For each HAI with reported events in validation locations:
 - Select all medical records for which events have been reported to NHSN in the validation time frame.
 - Randomly select additional medical records for a total of 40 medical records for candidate cases.
- 4) For HAIs with no reported event in validation locations:
 - Randomly select 40 medical records for review for each HAI candidate event.
- 5) If 40 medical records for candidate cases are not available for the validation timeframe, select the maximum number of eligible records available or alternatively consider increasing the validation timeframe to four quarters.

Note: For ease of use and printing, Medical Records Abstraction Tools (MRATs) and Instructions for use of the MRATs are located in separate documents under Supporting Documents on the Validation webpage

Chapter 5: Activities During and After the Facility Site Visit

Suggested Tools to bring along for validation site-visits

- Letter of introduction, state ID badge or other authorization
- 2021 NHSN PSC Manual
 - Before visit: Tag/highlight case definitions
 - Tag/highlight location descriptions for patient location mapping
- Information about the facility:
 - Facility's most recent NHSN Annual Survey
 - List of surveillance locations with demographics
 - List of medical records requested for screening
 - Confidential list of HAIs reported by facility to NHSN (assure that validators are blinded until after review is completed)

Multiple copies of blank medical record abstraction tools **under Supporting Documents on the**

Validation webpage <https://www.cdc.gov/nhsn/validation/index.html#ui-id-3>

- Copies of 2021 NHSN checklists available at <https://www.cdc.gov/nhsn/hai-checklists/index.html>
- External Validation Documentation Form ([Appendix 2.1](#))
- Blank audit discrepancies reports ([Appendix 2.2](#))
- Copies of Methods Surveys and form to collect contact information ([Appendix 3](#))
- Miscellaneous tools: Straight edge (e.g.: ruler) for reading data printouts, stapler, binder clips, pens, highlighters, sticky notes, tape flags

Please note that some of the listed tools are templates that should be adapted to the facility and state before copies are made.

Request documentation of current NHSN reporter training

NHSN reporters should have documentation of successful completion of the online, self-paced multimedia training modules for HAIs they oversee. This is an opportunity to establish or reinforce state expectations for this annual update.

Review risk adjustment variables:

For CLABSI and CAUTI, review validation location mapping, location bed size, and teaching hospital status. For MRSA bacteremia and CDI LabID Event reporting, review location mapping facility-wide if this has not been done to the state's satisfaction in the past 3 years. Otherwise, review changes since the last facility-wide review.

Bring a copy of the facility NHSN Annual Survey, and review the ICU location mapping and bed size information with the IP, along with an up-to-date list of CDC locations and descriptions (see http://www.cdc.gov/nhsn/forms/instr/57_103-TOI.pdf and 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 assure that facility teaching hospital status is accurate in the NHSN Annual Survey.

For COLO and HYST, many risk adjustment variables can be validated as part of the medical record review process. The medical record abstraction forms for COLO and HYST include fields for ASA score, patient age, and other risk

adjustment variables, as well as SSI outcome. Validation of risk adjustment variables is recommended to assure that sampling has appropriately targeted high-risk procedures.

Review denominator methods and documentation

CLABSI and CAUTI denominator counting methods

Surveillance and denominator data collection surveys found in [Appendices 3.1](#) through [3.4](#) may be administered to the IP contact before or during the site visit; however it may be impractical to interview multiple denominator data collectors during the site visit. In this case, collecting contact information during the site visit may be advisable for subsequent administration of surveys by telephone ([Appendix 3.2](#)). This allows time at the facility to be used efficiently and accommodates interviews with individuals who may work at other times (e.g. the night shift).

In many facilities, the same person will collect denominator data for device-associated infections (including CLABSI and CAUTI) concurrently. Because of this, the denominator counting survey for CLABSI and CAUTI in [Appendix 3.3](#) may be administered for each metric separately or for both combined. Knowledge of definitions and counting methods is important even in facilities where denominators are reported electronically in order that spot-checks can be conducted periodically. A form for facilities to document required internal validation of electronic denominator counting is provided in [Appendix 3.1](#).

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

CLABSI and CAUTI denominator records

While visiting, request original records of denominator data collection paperwork, which can provide insight into the frequency, reliability, and consistency of this task and how omissions are handled (NHSN provided guidance for missing device-associated denominator data in September 2013

http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf). Consider whether patient days and central-line days data appear as anticipated when manually counted each day: different ink, different but similar numbers.

Determine for what percent of day's data are missing and what was done for reporting on those days. Findings should be documented in [Appendix 2.1](#). This data is best assessed on site.

Electronically collected CLABSI and CAUTI denominators

Unexamined electronic denominator counting may be a source of error in HAI reporting.^{5,6} If the facility uses electronic denominator data collection, obtain documentation of their denominator validation process and any periodic spot checks. NHSN specifies that electronic denominator counts should fall within 5% of manual counts for three consecutive months before electronic counts can be used ([See Appendix 3.1](#)). [This may be examined post visit.](#)

If documentation of electronic denominator validation is not available, the facility should resume manual counting (and assure staff training), to re-validate electronic counts, and to retain evidence of valid electronic counting (within 5% for 3 months). Facilities should conduct periodic spot checks even after formal validation to prevent lost information due to changing medical records systems or other disruptions. Accurate electronic denominator reporting may require iterative programming corrections in consultation with IT support until accuracy is established.^{7,8}

Completeness and accuracy of SSI (COLO and HYST) denominators

Evaluate the information in [Appendix 2.1](#), sections "Denominator Validation COLO" and "Denominator Validation HYST" (this information was gathered during preparation for the facility site visit). If there appear to be large differences in the number of procedures identified by these two data sources, discuss this with the IP. Consider matching a subset of records between the two systems and examining un-matched records to explore potential reasons for this discrepancy. In particular, all procedures meeting the NHSN procedure definition should be entered, regardless of pre-existing

infection / wound class or incision closure method. If the two systems generate roughly similar data, the NHSN procedure denominator should be considered complete.

Electronically collected MRSA bacteremia and 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 or not 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. One consideration is the facility’s ability to capture “observation” patients within inpatient locations electronically. Electronic ADT data often are found to be more accurate than electronic billing data in this regard. Note that patient counts should differ for MRSA bacteremia LabID Event and CDI LabID Event denominators because CDI denominators exclude patients in infant locations. This internal validation process can be conducted by facilities when requested or required.

Structured Medical Records Review

Validator blinding and consultation at the facility site-visit

Validator blinding as to HAI status is required and is normally 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 2021 Medical Records Abstraction Tool processes. These tools include algorithms and logic designed to establish presence or absence of required criteria for case definitions and to provide support to avoid common errors.

For CLABSI validation, when consideration is given to an alternative primary site infection leading to secondary bloodstream infection, use of an appropriate NHSN checklist (available at <https://www.cdc.gov/nhsn/hai-checklists/index.html>) is highly recommended. These checklists provide a structure to record required elements from the NHSN Patient Safety Component Manual’s Chapter 17 criteria. The NHSN checklists are also useful for surgical site infection (SSI) validation when documenting organ/space SSIs. The checklists exist for multiple infection types (derived from the NHSN manual Chapter 17), and in multiple dated versions. Be sure the selected version is for 20212021 definitions.

If working on paper, bring enough copies of the medical records abstraction tools to complete a separate form for each medical record. After all medical records have been abstracted by validators, events reported to NHSN should be revealed and a meeting arranged with IPs / NHSN reporters to discuss any discrepancies between validator outcomes and reported outcomes, while medical records are readily available.

Discussion of audit results with IP

Whether or not reporting errors are identified, review the data with the IP to assure transparency and provide opportunity for discussion and feedback. If case-determinations are discordant, determine whether reporters or auditors missed any documented information that would affect the correct result (undocumented information should not be considered). Use NHSN criteria as the gold standard. For difficult cases, seek adjudication from CDC.

Look carefully for systematic reporting errors or misconceptions that could affect reporting beyond the reviewed medical records. If systematic errors are found, the facility should be asked to re-review and correct affected data, not just those records reviewed by auditors. These errors should be re-assessed during the next audit to evaluate improvement.

Use errors as learning opportunities for reporters and validators. These discussions may provide insight into the soundness of the facility's surveillance processes and competencies, and topics where additional training may be useful. Leave a copy of expected changes to NHSN data with the IP and agree to a deadline for changes to be made (see [Appendix 2.2](#)). An exit interview with a facility C-suite administrator (e.g., CEO or CMO) would rarely be needed, unless a process improvement plan is indicated.

Post-visit

Denominator data collection surveys ([Appendix 3.3](#)) may be completed after the visit.

Document validation findings (e.g., using [Appendix 2.2](#)) to create a facility summary report.

A follow-up letter to the IP and facility C-suite administrator will close the communication loop and provide valuable feedback. Send a letter thanking them, recognizing all participants in the audit, and documenting results, necessary corrections, and recommendations. When appropriate, identify systematic strengths as well as problems with resources and support for surveillance, data collection, and reporting ([Appendix 1.3](#)).

If the facility was required to change data in NHSN or to re-review information due to systematic errors, follow-up with the facility and assure corrections are made by the agreed upon deadline.

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Appendix 1: Letter Templates

Appendix 1.1: Sample Letter Requesting Site Visit and Line Listings for External Validation

Please customize this template to meet your state's needs

Dear *[Name of CEO]*

Cc: *[Name of IP]*

The *[Health Department]* will conduct an audit of surveillance practices and reporting of healthcare-associated infections in *[multiple/all]* hospitals statewide, focusing on 6 different metrics for 2021 data. These include the metrics designated by the CMS Inpatient Quality Reporting Program: central line-associated bloodstream infections (CLABSI) and catheter-associated urinary tract infections (CAUTI) in validation locations, surgical site infections (SSI) following colon (COLO) and abdominal hysterectomy (HYST) procedures, and proxy measures for MRSA bacteremia (MRSA bacteremia LabID Event) and *Clostridium difficile* infection (CDI LabID Event). *[Modify metrics as indicated]* Participation in the audit is *[Select as appropriate]*

- *[obligatory, to assure compliance with state healthcare-associated infection (HAI) reporting legislation and assure that facilities are accurately identifying and reporting healthcare-associated infections]. OR*
- *[voluntary, but may be of value to you in preparation for CMS validation activities, and by assuring that all state facilities are held to a high standard of accountability]. [Facilities that participate will be acknowledged by the SHD in the following way_____. Facilities that choose not to participate will also be identified in the following way_____.]*
- *[Modify as per state decision]: The individual results of SHD validation will be shared with your infection prevention staff and you [but will / will not be shared in the following additional ways]. Pooled results of SHD validation will be shared publically, but will not identify individual facilities.*

A site visit has been tentatively scheduled for *[Day and Date]* with *[Name of IP]*, Infection Preventionist, who has also been asked to assist with generating 4 line listings (described below) of eligible medical records for review, and two reports of monthly surgical procedures. Successful preparation for the audit will require the assistance of the microbiology laboratory, medical records system, and IT to generate specified line listings ahead of time that will be used to select medical records for review, and later assistance from medical records personnel to make medical records available for review at the time of the audit.

At this time, we request your support for production of the following 4 microbiology laboratory-based line listings, coordinated through the IP, and transmitted to us securely via FTP *[FTP site]* in a spreadsheet (e.g. Excel) file format. Please note that these lists must include information about facility admission date, which may require coordination of microbiology data with another hospital data system. The line listings will be due by *[Date]*. If questions arise, we can be reached at the following number *[XXX-XXX-XXXX]*:

Requested Line Listings

- 1) A complete list of validation location blood specimens identifying organism(s) for 2021, with additional variables based on the template below. NICUs should be included.

Template positive blood culture line listing (*indicates required data):

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Blood Organism 1 Genus and Species	*Specific validation patient Location	*Gender	*Date of Birth	First Name	Last Name
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- 2) A complete list of positive urine cultures from validation locations for 2021, with additional variables based on the template below. NICUs should not be included. If possible, limit positive urine cultures to those with no more than 2 identified pathogens and at least 10⁵ CFU/ml which must include one bacterium.

Template positive urine culture line listing (*indicates required data, †indicates conditionally required data):

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Urine Organism 1 Genus and Species	*Urine Colony Count 1 (CFU/ml)	†Urine Organism 2 Genus and Species	†Urine Colony Count 2 (CFU/ml)	*Specific validation Location	*Gender	*Date of Birth	First Name	Last Name
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- 3) A complete list of blood cultures positive for methicillin-resistant *Staphylococcus aureus* (MRSA), among inpatients facility wide for 2021, with additional variables based on the template below.

Template positive MRSA bacteremia, FacWideIN line listing (*indicates required data):

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Blood Organism Genus and Species (documenting <i>S. aureus</i> or MRSA)	*Documentation of Methicillin-Resistance (susceptibility test result or MRSA)	*Specific Mapped NHSN Location	*Gender	*Date of Birth	First Name	Last Name
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- 4) A complete list of -positive *Clostridium difficile* stool specimens among inpatients facility-wide for 2021, with additional variables based on the template below. Please include only final results for testing that is conducted following multiple steps.

Template positive C. difficile assay FacWideIN line listing (*indicates required data):

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Result of CDI Test	* Specific Mapped NHSN Location	*Gender	*Date of Birth	First Name	Last Name
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The line listings will be due by [day and date in advance of site visit] so that we may select medical records for review from among candidate records. We will then communicate our selected records to infection prevention so that they can be made available for the audit. In addition, we request a monthly count of selected 2021 inpatient surgical procedures performed in your facility based on the following ICD-10-PCS/ICD-10-PCS procedure codes:

Procedure Class	COLO Procedures	HYST Procedures
ICD-10-PCS/CPT Procedure Codes:		
2021 Month	Number of Procedures	Number of Procedures
January		
February		
March		
April		
May		
June		
July		
August		
September		
October		
November		
December		

During our visit, we will be available to describe the process and evaluation tools, as well as answer any questions you may have about the state health department’s HAI data validation program.

If your healthcare facility has initiated or completed conversion to an electronic medical record system, we will need a means of accessing these records during our visit, including any diagnostic/laboratory results, clinical documentation and ICD-10-PCS codes related to these patients.

Should there be any scheduling difficulties, please contact me directly, either by phone [phone number] or email [email].

HAI Program Director /Regional Representative

cc: IP name

enc.

Appendix 1.2: Sample Letter Requesting Availability of Medical Records for Audit

Please customize this template to meet your state's needs

Dear *[Name of IP]*

As we discussed in our letter of [date], the *[Name of Health Department]* plans to audit surveillance practices and reporting of healthcare-associated infections for 2021 in multiple hospitals including your own. Thank you for your recent assistance in procuring the required line listings for medical record selection.

In the list below, we have identified the [XXX] medical records we would like to review during the audit, scheduled for [date(s)]. We appreciate your assistance in assuring that our team of [X] reviewers will have access to adequate working space, any necessary system passwords, and to these records when we visit. If your healthcare facility has initiated or completed conversion to an electronic medical record system, we will need a means of accessing these records including any diagnostic/laboratory results, clinical documentation, and ICD-10-PCS codes related to these patients during our visit.

We look forward to visiting your facility and working with you in person. If questions arise, we can be reached at the following number [XXX-XXX-XXXX]:

Appendix 1.3: Example Validation Follow-up Letters, With and Without Identified Problems

(Courtesy of New York State Department of Health)

Please feel free to adapt these templates to meet your state's needs

Version One: Problems identified. Letter should be adapted to circumstances.

Dear CEO Name,

The [Department of Health] Healthcare Associated Infection (HAI) Reporting Program completed an audit site visit at your facility for [year] at your facility. We wish to thank you and your staff, particularly the Infection Control, Microbiology, and Medical Records staff for their cooperation and the effort they contributed during our review and audit process.

The purposes of this audit were initially presented to you in the letter of notification. Based upon our review of X medical records during the audit, there were [e.g.: X missed and unreported central line-associated bloodstream infections (CLABSIs), and X missed and unreported surgical site infections (SSIs), including (X types), and X CLABSIs and X SSIs that need to be deleted from the NHSN database].

We observed the following trends that may contribute to surveillance inaccuracies: [e.g.: Of the X colon procedure records reviewed as entered in the NHSN database, X were not NHSN colon procedures. The reporting of non-colon procedures is an infection control program surveillance system issue. In addition, infection control was not made aware of X bloodstream infections identified by the microbiology laboratory, which may have resulted in omissions.]

We reviewed the reporting requirements with [Name of IP] and [she] will be reporting the missing SSIs and deleting the non-NHSN colon and HYST procedures. Each record requiring corrections was reviewed with [Name of IP] and a list of a data entry edits to be made in NHSN was provided to [her]. All data errors and missed data entry must be edited in NHSN data base within 30 days of this notice.

The infection preventionist/infection prevention manager continues to enter surgical procedure data into NHSN manually, which is a labor-intensive method for larger hospitals. Data entry could be done by a clerical person with Infection Control oversight or by electronic submission after editing of the source data for accuracy by infection control staff. Additional IT support would be required to make this possible.

We investigated your facility's notification of other hospitals when patients who underwent procedures there were admitted to your hospital with surgical site infections during the post-operative period, and we found it to be lacking. [Stipulate state requirements if they exist]. Please note that such notifications are necessary for complete surveillance of SSIs statewide, and permitted under HIPAA for the purpose of healthcare operations. We also reviewed the timeliness of your reporting and found it acceptable.

Given the issue identified with colon procedure reporting, we request your hospital review all 2021 inpatient colon procedures entered in NHSN to validate they are NHSN colon procedures. A follow-up communication as to your findings and action plans to eliminate reporting non-NHSN colon procedures should be sent to my attention no later than [Date]. Your response can be faxed or electronically sent to me. If you need any additional information or have any further questions regarding this site visit please contact me directly at [phone, fax, email].

Version Two: No problems identified. Letter should be adapted to circumstances.

Dear CEO name,

The [Department of Health] Hospital Acquired Infection (HAI) Reporting Program completed an audit site visit for [year] at your facility. We wish to thank you and your staff, particularly the Infection Control, Microbiology, and Medical Records staff for their cooperation and the effort they contributed during the review and audit process.

The purposes of this audit were initially presented to you in the letter of notification. Based upon our review of X medical records, no significant compliance issues were detected. During our [date] audit, we identified [one colon surgical site infection (SSI) and two colon procedures that need to be deleted from the NHSN database]. There were no unreported infections identified in the medical records reviewed during this audit visit. We also reviewed the timeliness of reporting and have found it to be acceptable.

There continues to be only one individual, [Name], with access to manage and report in the NHSN data system. In our [specify past years] post-audit letters, we recommended to select another NHSN user to receive administrative access, to serve as a backup to the infection preventionist (IP). We continue to strongly recommend your facility add another NHSN administrative user as soon as possible. The NHSN administrative user role should be reviewed with this individual periodically during the year to ensure that your facility will be able to meet the regulatory requirements for data submission should your IP be unable to work for any reason.

We also investigated your facility's notification of other hospitals when patients who underwent procedures there were admitted to your hospital with surgical site infections during the post-operative recovery period and found it to be adequate. *[Stipulate requirements if they exist]*. Please note that such notifications are necessary for complete surveillance of SSIs statewide, and permitted under HIPAA for the purpose of healthcare operations.

The infection prevention manager continues to manually enter surgical procedure data into NHSN. Data entry could be done by a clerical person with Infection Control oversight. NHSN does provide for electronic submission of denominator procedure data into their reporting database and may be an option when your OR documentation becomes electronic.

We have discussed infection definitions, reporting, and data entry issues or concerns that [Name of IP] may have had, in an ongoing effort to support the [state] HAI mandatory reporting. There are some data entry corrections to be made by your staff in the NHSN reporting system. A list of each record requiring data edits was reviewed with [Name of IP]. The data entry corrections should be completed within 30 days of the audit visit.

[Name of IP] is also a member of our State HAI public reporting Technical Advisory Workgroup. I would like to take this opportunity to thank you for supporting her membership and attendance at the semiannual workshop meetings. Her contributions to this workgroup are valued by the HAI public reporting program.

If you need any additional information or have any further questions regarding this site visit please contact me directly at [phone, fax, and email.]

APPENDIX 2: Surveillance Surveys

Appendix 2.1: External Validation Data Form

State Health Department Validation Record

Page 1 of 6 (Validation record completed at the of the validation)

*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)

*Sampling version: CDC Version 1 (Targeted Sampling) CDC Version 2 (Cumulative attributable difference)

*Data for year: 2021

*HAI validated at this facility, and reason:

CLABSI (Validation locations, includes NICUs if applicable)
 CAUTI (Validation locations, excludes NICUs)
 COLO (DI/OS SSI)
 HYST (DI/OS SSI)
 MRSA bacteremia LabID event
 CDI LabID event

Reason:

All facilities are validated Targeted facility 5% random sample facility

Numerator Validation

*Sampling information for numerator audit at this facility

Event	Sampling frame elements	Sampling Frame (# episodes or procedures eligible for review for year)	Total # events from facility reported to NHSN for year (before validation)
**CLABSI (including NICU)	Medical records with positive blood specimen(s)	_____	_____
**CAUTI (excluding NICU)	Medical records with positive urine culture(s)	_____	_____
**DI/OS ^a COLO SSI	COLO procedures	_____	_____
**DI/OS ^a HYST SSI	HYST procedures	_____	_____
**MRSA bacteremia LabID event	Inpatient ^b blood specimens positive for MRSA	_____	_____
**CDI LabID event	Inpatient ^b stools -positive for C. difficile, excluding those from "baby locations"	_____	_____

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

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

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

Public reporting burden of this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Reports Clearance Officer, 1600 Clifton Rd., MS D-74, Atlanta, GA 30333, ATTN: PRA (0920-0666).
CDC 57.600 (Front) v8.3

State Health Department Validation Record

Page 2 of 6

Numerator Validation (continued)

*Facility audit results, numerators

**CLABSI in validation locations (including NICU):

Facility determination	Audit-CLABSI Yes	Audit-CLABSI No
Date-matched CLABSI reported	a. ____	b. ____
Date-matched CLABSI NOT reported	c. ____	d. ____

**CAUTI in validation locations (excluding NICU):

Facility determination	Audit-CAUTI Yes	Audit-CAUTI No
Date-matched CAUTI reported	a. ____	b. ____
Date-matched CAUTI NOT reported	c. ____	d. ____

**DI/OS COLO SSI:

Facility determination	Audit-DI/OS SSI Yes	Audit-DI/OS SSI No
Date-matched DI/OS SSI reported	a. ____	b. ____
Date-matched DI/OS SSI NOT reported	c. ____	d. ____

**DI/OS HYST SSI:

Facility determination	Audit-DI/OS SSI Yes	Audit-DI/OS SSI No
Date-matched DI/OS SSI reported	a. ____	b. ____
Date-matched DI/OS SSI NOT reported	c. ____	d. ____

**MRSA bacteremia LabID event:

Facility determination	Audit-MRSA bacteremia LabID event	Audit-MRSA bacteremia NOT reportable LabID event
Date-matched MRSA blood specimen reported as LabID event	a. ____	b. ____

Date-matched MRSA blood specimen NOT reported as LabID event

c. ____

d. ____

****CDI LabID event:**

Facility determination	Audit-CDI test reportable LabID event	Audit-CDI test NOT reportable LabID event
Date-matched CDI test reported as LabID event	a. ____	b. ____
Date-matched CDI test NOT reported as LabID event	c. ____	d. ____

State Health Department Validation Record

Page 3 of 6

Denominator Validation: Central Line and Patient days for CLABSI

**Which method was used by this facility for CLABSI in validation locations denominator (patient days and central line days) counting for this year?

- Manual counting (Daily / Weekly sampling) Electronic counting Both manual and electronic counting

**Has this facility completed an internal validation of CLABSI in validation locations denominator data for this year? Yes No

Note: Validation of manual denominator data counting requires either:

- *Method A – Concurrent dual counting (with more experienced counter as reference) for ≥ three months OR*
- *Method B – Concurrent patient days data (ADT-Admission/Discharge/Transfer or other reference) and manual counting for ≥ three consecutive months*

Validation of electronic denominator data counting requires:

- *Method C – Concurrent manual denominator counting (reference) vs. electronic data for ≥ three months*

++ Only ICU and ward location types with an average of 75 or more central line-days per month are eligible to use this method.

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

Location of validation	Month of validation	Validation method	Count 1	Count 2
		A, B, or C		
		A, B, or C		
		A, B, or C		
		A, B, or C		
		A, B, or C		

Note:

If Method A is chosen, Count 1 should be "Usual Count" and Count 2 should be "Expert (Referent) Count";

If Method B is chosen, Count 1 should be "Usual Count" and Count 2 should be "Patient days (Referent) Count";

If Method C is chosen, Count 1 should be "Manual Count" and Count 2 should be "Electronic Count."

Denominator Validation: Catheter and Patient Days for CAUTI

**Which method was used by this facility for CAUTI in validation locations denominator (patient days and catheter days) counting for this year?

- Manual counting Electronic counting Both manual and electronic counting ++Weekly sampling

**Has this facility completed an internal validation of CAUTI in validation locations denominator data for this year? Yes No

Note: Validation of manual denominator data counting requires either:

- *Method A – Concurrent dual counting (with more experienced counter as reference) for ≥ three months OR*
- *Method B – Concurrent patient days data (ADT-Admission/Discharge/ Transfer or other reference) and manual counting for ≥ three consecutive months*

Validation of electronic denominator data counting requires:

- *Method C – Concurrent manual denominator counting (reference) vs. electronic data for ≥ three months*

++ Only ICU and ward location types with an average of 75 or more central line-days per month are eligible to use this method.

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

Location of validation	Month of validation	Validation method	Count 1	Count 2
		A, B, or C		
		A, B, or C		

		A, B, or C		
		A, B, or C		
		A, B, or C		

Note:

If Method A is chosen, Count 1 should be "Usual Count" and Count 2 should be "Expert (Referent) Count";
 If Method B is chosen, Count 1 should be "Usual Count" and Count 2 should be "Patient-level (Referent) Count";
 If Method C is chosen, Count 1 should be "Manual Count" and Count 2 should be "Electronic Count."

State Health Department Validation Record

Page 4 of 6

Denominator Validation: COLO

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

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

Denominator Validation: HYST

**Document number of HYST procedures from two systems by month:

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

Location Validation: MAPPING

NHSN inpatient location validation

**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

--	--	--	--

**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): _____

State Health Department Validation Record

Page 5 of 6

Denominator Validation: MRSA bacteremia LabID event & CDI LabID event

**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:

MRSA bacteremia LabID event					
Location of validation	Month of validation	Admissions		Patient Days	
		Usual count	Manual count	Usual count	Manual count

CDI LabID event ^c					
Location of validation	Month of validation	Admissions		Patient Days	
		Usual count	Manual count	Usual count	Manual count

^cExcludes 'baby locations'

Risk Adjustment Variable Validation

**ICU mapping (CLABSI in validation locations [includes NICUs], CAUTI in validation locations [excludes NICUs])

Number of ICU locations correctly mapped as ICUs in NHSN (includes NICUs): _____



Number of validation locations incorrectly mapped (includes NICUs): _____

Number of ICUs (includes NICUs) omitted from ICU mapping: _____

Number of ICU mapping errors (ICUs vs. non-ICUs): _____

****Teaching hospital affiliation (CLABSI in validation locations, CAUTI in validation locations , MRSA bacteremia LabID event, CDI LabID event)**

Facility teaching hospital affiliation reported on 2021 NHSN annual facility survey:

Non-teaching Major Graduate Undergraduate N/A (IRF & LTACH)

Is facility teaching hospital affiliation correct? Yes No

****ASA score (COLO, HYST)**

Number (% of audited) correct for
COLO: _____

Number (% of audited) correct for
HYST: _____

State Health Department Validation Record

Page 6 of 6

Risk Adjustment Variable Validation (continued)

****Patient age (COLO, HYST)**
 Number (% of audited) correct for
 COLO: _____
 Number (% of audited) correct for
 HYST: _____

****Facility bed size (all inpatient locations, including 'baby locations') (MRSA bacteremia LabID event, CDI LabID event)**
 Facility bed size reported on 2021 NHSN annual facility
 survey: _____
 Validated bed size: _____

Custom Fields

Label	Label
_____ / ____ / ____	_____ / ____ / ____
—	—
_____	_____
—	—
_____	_____
—	—
_____	_____
—	—

Comments

Appendix 2.2: (Optional) Templates for Audit Discrepancies Discussion with Facilities

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

(Instructions: For each HAI Event with discordant outcome between reporters and validators, record the following [first row-enter hospital report; second row-enter recommended changes]. Use the Comment area to document reasons for error, e.g.: overlooked candidate culture; confusion re common commensals; did not meet alternative primary definition, not an 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). H=hospital; V=validator

Central line-associated Bloodstream Infection (CLABSI) Discrepancies

Pt. ID		Positive blood culture event: first culture date	Select One:			If LCBI, Event date	If LCBI, MBI* LCBI?				
			Not candidate CLABSI	Alternative primary (specify)	LCBI1, LCBI2, LCBI3*						
	H										
	V										
Comment:											
	H										
	V										
Comment:											
	H										
	V										
Comment:											
	H										
	V										
Comment:											

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

Catheter-associated Urinary Tract Infection (CAUTI) Discrepancies

Pt. ID		Positive urine culture event: first culture date	Select One:			If UTI, Event date	POA, HAI or neither	Urethral catheter >2d?	Location of attribution	CAUTI IN VALIDATION LOCATIONS Y/N
			Not candidate CAUTI	SUTI 1a, SUTI 2a, ABUTI*	Did not meet UTI criteria (specify below)					
	H									
	V									
Comment:										
	H									
	V									
Comment:										
	H									
	V									
Comment:										
	H									
	V									
Comment:										
	H									
	V									
Comment:										

****SUTI 1a, 2a, (NHSN): types of symptomatic urinary tract infection. ABUTI (NHSN): asymptomatic urinary tract infection. See definitions NHSN PSC Manual Chapter 7.***

Surgical Site Infection (SSI) Following Colon Procedure (COLO) Discrepancies

Pt. ID		Procedure Date:	Surveillance window closed Date:	Select One:			If SSI, Event date	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
	H													
	V													
Comment:														
	H													
	V													
Comment:														
	H													
	V													
Comment:														
	H													
	V													
Comment:														
	H													
	V													
Comment:														
	H													

	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.														

Surgical Site Infection (SSI) Following Abdominal Hysterectomy Procedure (HYST) Discrepancies

Pt. ID		Procedure Date:	Surveillance window closed Date:	Select One:			If SSI, Event date	Attributable to HYST? 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
	H													
	V													
Comment:														
	H													
	V													
Comment:														
	H													
	V													
Comment:														
	H													
	V													
Comment:														
	H													
	V													
Comment:														

	H													
	V													
Comment:														
<p><i>*SI, DI, O/S SSI (NHSN): depth (superficial incisional, deep incisional, organ/space) of surgical site infections.</i></p> <p><i>†ASA score: American Society of Anesthesiologists Score</i></p> <p><i>‡ SW class: Surgical wound class. See definitions NHSN PSC Manual Chapter 9.</i></p>														

Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia LabID Event Discrepancies

Pt. ID		Admission Date	Date of first reportable LabID Event during this inpatient stay	NHSN location of LabID Event	Positive MRSA blood culture on date of admission? Y/N	Prior MRSA blood from same location within prior 14 days? Y/N	Other reason for error
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							

Clostridium difficile Infection (CDI) LabID Event Discrepancies

Pt. ID		Admission Date	Date of first reportable LabID Event during this inpatient stay	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
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							



	H						
	V						
Comment:							

Appendix 3: Surveillance Surveys

(Designed for External Validation of Surveillance Processes)

Appendix 3.1: Documentation of Electronic CLABSI/CAUTI Denominator Validation

OrgID/Name of Hospital: _____ Date of Survey: _____

Instructions: NHSN requires that the monthly electronic denominator count falls within a 5% tolerance interval of the monthly manual denominator count for 3 consecutive months before reporting electronic denominator counts for CLABSI/CAUTI. This validation is not conducted during the external survey. The facility is expected to have a copy of this internal validation comparing manual counts to electronic counts available for the auditor to review. *If there is no electronic denominator counting at this facility, skip this survey. If electronic device denominator counting is used for reporting at this facility, document the NHSN-required validation results below:*

Initial electronic denominator validation (when electronic denominator reporting began):

Location name:		Manual count	*Calculated 5% tolerance interval	Electronic count
Month/year:	Patient days			
	Central line days			
	Indwelling urinary catheter days			
Location name:				
Month/year:	Patient days			
	Central line days			
	Indwelling urinary catheter days			
Location name:				
Month/year:	Patient days			
	Central line days			
	Indwelling urinary catheter days			

If available, please document additional information for any more recent electronic denominator validation:

Location name:		Manual count	*Calculated 5% tolerance interval	Electronic count
Month/year	Patient days			
	Central line days			
	Indwelling urinary catheter days			
Location name:				
Month/year	Patient days			
	Central line days			
	Indwelling urinary catheter days			
Location name:				
Month/year:	Patient days			
	Central line days			

	Indwelling urinary catheter days			
<p>*Equation for calculating 5% tolerance interval is: manual count ± (manual count * 0.05). Example calculations where manual count = 164 and electronic count = 178: Eligible 5% tolerance interval = [164±(164*0.05)]=155.8 to 172.2 Electronic count 178 falls outside the tolerance interval.</p>				

Appendix 3.2: Contact Information for Manual CLABSI/CAUTI Denominator Validation

Please feel free to adapt this template to meet your state’s needs
<i>NOTE: If facility assures annual training updates for denominator counters, and three or more denominator counters show proficiency on the survey in part 4, or if facility has already internally surveyed denominator counter proficiency, this can serve as evidence of proficiency.</i>

OrgID / Name of Hospital _____ Date of Survey _____

Instructions: Collect contact information for persons directly responsible for denominator collection in surveillance locations and administer the survey (in part 4 below) later, by telephone.

ID	Name of data collection professional	Surveillance locations covered	CLABSI CAUTI Both	Work hours/ Preferred time for telephone survey	Phone number(s)	Supervisor
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
Etc.	To be expanded as needed....					



Appendix 3.3: CLABSI and CAUTI Denominator Counting Survey (with Key)

<p><i>Instructions: Administer in person or by telephone, directly to individuals responsible for denominator counting. This form is divided into 3 sections for facilities where these tasks are performed by different persons. The first section, PATIENT DAYS, contains questions applicable to both CLABSI and CAUTI denominator collection (questions 1-9). The second section, CENTRAL LINE DAYS, contains questions applicable to CLABSI denominator collection (questions 10-22). The third section, INDWELLING URINARY CATHETER DAYS, contains questions applicable to CAUTI denominator collection (questions 23-29).</i></p>				
Facility OrgID:	Name/ID of individual interviewed:	Position: <input type="checkbox"/> IP <input type="checkbox"/> Clerical <input type="checkbox"/> Nursing <input type="checkbox"/> Other (explain)	Interviewer initials:	Date of survey:
(circle one): CLABSI, CAUTI, BOTH		NHSN location(s) covered:		
PATIENT DAYS (for both CLABSI and CAUTI denominator counters)			Answer Key:	
1. How are patient days usually collected? (choose one)			<p><i>If using weekly: Once weekly sampling of denominator data to generate estimated central line days, may be used as an alternative to daily collection in non-oncology ICUs and wards. Sampling may not be used in SCA/ONC locations or NICUs. During the month, the number of patients in the location (patient-days) and the number of patients with at least one central line of any type (central line days) is collected on a designated day each week (for example, every Tuesday), and at the same time each day.</i></p> <p><i>The average number of device days per month must be greater than or equal to 75 device days if using weekly denominator collection method.</i></p>	
Electronically (document the software system utilized and skip to Q8):				
Manually (daily/weekly)				
Some units electronic and some units manual				
Comment:				
2. Is there a specified time when the denominator count is taken?		<input type="checkbox"/> Yes <input type="checkbox"/> No		<i>The answer should be Yes</i>
3. When is it done?			<i>Counts should be done at a specific time daily, preferably at nearly the same time throughout the facility to avoid errors when patients transfer</i>	
4. Describe the method used to count patient days :			<p><i>From NHSN: Denominator data (patient days and device days) should be collected at the same time, every day, for each location performing surveillance to ensure that differing collection methods don't inadvertently result in device days being > patient days.</i></p>	
Count the number of <u>patients</u> assigned to a unit bed <u>at the same time</u> central line/indwelling urinary catheter counts are conducted				
Other (specify):				



5. When reporting monthly patient day total, what is done if there are missing patient day data? (<i>choose one</i>)		NHSN issued specific guidance on imputing values for missing data in September 2013 (http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf)
	Report the sum of available daily counts with no adjustment for missing data	
	Estimate or re-create missing data from existing information using our own methods	
	Impute missing values using recent CDC/NHSN guidance	
	Other (specify):	
6. Which best describes your training for denominator (patient days and central line or catheter days) counting? (<i>select all that apply</i>)		
	No specific training was provided	Formal training by NHSN or NHSN-trained IP is recommended due to technical aspects of definitions (e.g., central line, permanent line, temporary line) and methods (e.g., when to count lines, how many to count).
	Peer training (person who previously counted explained their approach to new staff)	
	Formal training by IP	
	Formal training by NHSN (e.g., online training)	
	Annual training updates	
	Other (describe):	
7. Which staff member counts patient days and central line or catheter days when the “regular” data collector(s) is/are not working?		<input type="checkbox"/> IP <input type="checkbox"/> Another trained counter <input type="checkbox"/> Nobody <input type="checkbox"/> Other (specify)
8. Does your facility have a mechanism in place for quality control of denominator data? (<i>Select one</i>):		
	(<i>Electronic data</i>) Yes, data submitted electronically is periodically checked using manual methods	
	(<i>Manual data</i>) Yes, manually collected data are periodically counted by more than one staff member	
	Yes, other (<i>explain</i>)	
	No formal quality control process	
9. Which staff member(s) is/are responsible for entering validation locations patient days and central line or catheter day data into NHSN?		<input type="checkbox"/> IP <input type="checkbox"/> Counter <input type="checkbox"/> Clerical <input type="checkbox"/> Other (specify)

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

11. Identify the method used to count central line days : (choose one)		A daily count of <u>the number of patients with a central line in the patient care location during a time period, which is summed for the monthly total</u>
	Count the number of patients with at least one central line at the time surveillance rounds are conducted	
	Count the number of central lines that are in place at the time surveillance rounds are conducted	
	Count the number of central lines that are in use at the time surveillance rounds are conducted	
	Other (specify):	
12. When reporting monthly central line day total, what is done if there are missing central line day data? (choose one)		NHSN issued specific guidance on imputing values for missing data in September 2013 (http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf)
	Report the sum of available daily counts with no adjustment for missing data	
	Estimate or re-create missing data using existing information (e.g., medical records), then sum	
	Impute missing values using recent CDC/NHSN guidance for missing denominator data	
13. A patient has a radial arterial line and a peripheral IV. How many central line days are counted for this patient on this day?		Zero. The radial arterial line and peripheral IV are not central lines.
14. A patient has a temporary central line and a permanent central line that have both been used during this hospitalization. How many denominator device line days are counted for this patient on this day?		One. Although the patient has two central lines, a device day is defined as the number of patients who have the device, not the number of devices.
15. The patient above with the temporary central line and the permanent central line is on an oncology ward. Should you report one temporary line day, one permanent line day, or both a temporary and a permanent line day?		When a patient in an oncology location has both temporary and permanent lines, the line day is reported as a temporary line day. (This information is detailed in the NHSN PSC Manual, Instructions for Form 57.1171)

16. A patient has a port-a-cath that has not been accessed during this hospital stay, and a peripheral IV that is in use. How many denominator device days are counted for this patient on this day?	<i>One. Beginning in January 2021, central lines that are present on admission should be included in denominator device day counts beginning on the day of admission to an inpatient location. This is regardless of access of the central line. The peripheral IV is not a central line.</i>
17. A port-a-cath was inserted during this admission for planned chemotherapy. It is not in use. How many denominator device days are counted for this patient on this day?	<i>One. If a central line was accessed via placement in an inpatient location during the current admission, it is counted in the denominator device day count each day that it remains in place, whether in use or not.</i>
18. A patient has a central line that was accessed for a blood draw in the ICU yesterday but is not currently in use, and a peripheral IV that is in use. How many central line days are counted for this patient on this day?	<i>One. The central line was accessed in an inpatient location during this stay. All central lines should be included in denominator device day counts once the patient locates to an inpatient location. This is regardless of access of the central line.</i>
19. A patient has a central line that was accessed once for a blood draw in the ED during evaluation leading to admission. The patient is now admitted to an inpatient location, but the line is not currently in use. How many denominator device days are counted for this patient on this day?	<i>One. All central lines should be included in denominator device day counts once the patient locates to an inpatient location. This is regardless of access of the central line.</i>
20. If a central line is removed at 2PM and replaced at 8PM. The central line day count is done at 5PM, should the line be counted?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <i>No. Central line must be in place at time of count.</i>

NICU-Specific Central Line Questions (Optional: Check here and skip section if NICU questions do not apply to your job) <input type="checkbox"/>		
21. When reporting central line (CL) days, in neonates, which neonatal weight is used for reporting? (select one)	<input type="checkbox"/> Birth weight <input type="checkbox"/> Current weight	<i>Birth weight</i>
22. Neonates with both a CL and an umbilical catheter (UC) are included in the daily count as: (select one)	<input type="checkbox"/> UC only <input type="checkbox"/> CL only <input type="checkbox"/> 2 separate lines	<i>CL only. No separate reporting of UCs; UCs are considered CLs. Although the patient has two central lines, a device day is defined as the number of patients who have the device, not the number of devices. When reporting the central line, it should be stratified by birth weight.</i>

Indwelling Urinary Catheter Days (for indwelling urinary catheter counters only)	
23. How are indwelling urinary catheter days collected for the units you oversee? (choose one)	
Electronically (specify <i>software system utilized</i>):	
Manually (daily/weekly)	
Some units electronic and some units manual	
Comment:	
24. Identify the method used to count indwelling urinary catheter days : (choose one)	<p>Count the number of patients on the unit with an indwelling catheter or indwelling three-way (infusion) catheter used for bladder irrigation.</p> <p>Note: Indwelling urinary catheter: A drainage tube that is inserted into the bladder through the urethra, left in place, and connected to a drainage bag, including urinary catheters that are used for intermittent or continuous irrigation, but excluding suprapubic, condom, or straight in-and-out catheters.</p>
Count the number of patients on the unit with a urine collection bag	
Count the number of patients on the unit with a urinary catheter or condom catheter	
Count the number of patients on the unit with a urinary catheter, condom catheter, or suprapubic catheter	
Count the number of patients on the unit with a urinary catheter or indwelling urethral three-way (infusion) catheter used for bladder washes	
Other (specify):	
25. When reporting monthly indwelling urinary catheter day total, what is done if there are missing catheter day data? (choose one)	<p>NHSN issued specific guidance on imputing values for missing data in September 2013</p> <p>(http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf)</p>
Report the sum of available daily counts with no adjustment for missing data	
Estimate or re-create missing data using patient information (e.g., medical record), then sum	
Impute missing values using recent CDC/NHSN guidance for missing denominator data	
26. A patient has a draining ureteral stent and a Foley catheter; each one connected to a collection bag. How many urinary catheter days are counted for this patient on this day?	<p><i>One. Ureteral stents are not counted because they are not urethral catheters. A patient can only be counted for 1 urinary catheter each day.</i></p>
27. A patient has a three-way indwelling urinary catheter used for irrigation after surgery to prevent blood in the bladder from clotting, and to provide for urinary drainage. How many urinary catheter days are counted for this patient on this day?	<p><i>One. Catheters to be counted include indwelling urethral catheters used for intermittent or continuous irrigation, as well as those used for drainage.</i></p>
28. A patient on the unit has a supra-pubic urinary catheter. How many urinary catheter days are counted for this patient on this day?	<p><i>Zero. Supra-pubic catheters are not urinary catheters because they enter the bladder through the abdominal wall.</i></p>

29. A patient's indwelling urinary catheter is removed at noon and replaced at 5PM. Daily indwelling urinary catheter counts take place at 2PM. How many urinary catheter days are reported for this patient on this day?

None. There was no indwelling urinary catheter at the time of the daily denominator count. NOTE: However, if this patient develops a bloodstream infection attributable to a urinary tract infection, this day will count as one of two required catheter days to establish CLABSI criteria, because the catheter need only be in place for part of the two days to meet this criterion.

Appendix 3.4: Surgical Procedure and SSI Surveillance Methods Survey (with Key)

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: <input type="checkbox"/> IP <input type="checkbox"/> 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? (<i>choose one</i>):		<input type="checkbox"/> Electronic (skip to Q3) <input type="checkbox"/> Manual <input type="checkbox"/> Other (comment): _____		
2) If manual, who has primary responsibility for surgical procedure data entry to NHSN? (<i>choose one</i>):		<input type="checkbox"/> IP <input type="checkbox"/> Clerical/support staff <input type="checkbox"/> Clerical/support staff with IP oversight <input type="checkbox"/> Other _____	<i>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.</i>	
3) What source(s) of information does your facility NORMALLY use to identify COLO and/or HYST procedures? (<i>choose all that apply</i>):		<input type="checkbox"/> The complete OR records/reports system <input type="checkbox"/> Selected flagged/filtered OR records/reports based on key words <input type="checkbox"/> CPT codes assigned by surgeons <input type="checkbox"/> ICD-10-PCS/CPT operative procedure codes assigned by coders after discharge <input type="checkbox"/> Vendor system using OR records (specify) _____ <input type="checkbox"/> Vendor system using ICD-10-PCS operative procedure codes assigned after discharge (specify) _____ <input type="checkbox"/> Vendor system using both OR records and ICD-10—PCS/CPT operative procedure codes assigned after discharge (specify) _____ <input type="checkbox"/> Other _____	<i>ICD-10-PCS/CPT operative procedure codes are required to determine the correct NHSN operative procedure category to be reported.</i> <i>ICD-10-PCS/CPT operative procedure codes should be assigned by a professional medical coder.</i> <i>If there are questions regarding the accuracy of an assigned operative procedure code, these questions should be reviewed with your professional medical coder.</i>	
4) How are you ensuring that all qualifying inpatient COLO and/or HYST procedures are included in your denominator data?		<input type="checkbox"/> No systematic way <input type="checkbox"/> Review only CPT operative procedure codes <input type="checkbox"/> Review only ICD-10-PCS operative procedure codes <input type="checkbox"/> Review both CPT and ICD-10-PCS operative procedure codes <input type="checkbox"/> Cross-reference*(multiple) data sources (explain): _____ <input type="checkbox"/> Other _____	<i>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.</i> <i>Instances such as a facility using CPT codes for what they consider is an 'outpatient' procedure but the procedure actually meets</i>	

		<p><i>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.</i></p> <p><i>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.</i></p> <p><i>A vaginal hysterectomy procedure may qualify as an abdominal hysterectomy (HYST) if an abdominal incision is made. A medical coder may correctly assign laparoscopic vaginal hysterectomy procedure codes based on route of detachment but for the purpose of NHSN SSI reporting, hysterectomy procedure codes that involve an incision made into the abdomen, including trocar insertion, are listed in the abdominal hysterectomy (HYST) category. The correct hysterectomy procedure codes should be assigned by a medical record coder using current guidelines and conventions.</i></p> <p><i>*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></p>
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<p>5) If you are following inpatient procedures under what circumstances do you remove COLO and/or HYST procedures from NHSN? <i>(choose all that apply):</i></p>	<p><input type="checkbox"/> a. COLO or HYST ICD-10-PCS/CPT operative procedure code was not assigned to the operative procedure</p> <p><input type="checkbox"/> b. COLO or HYST ICD-10-PCS/CPT operative procedure code was assigned, but IP believes coder assigned COLO or HYST code in error</p> <p><input type="checkbox"/> c. Incision not primarily closed in OR</p> <p><input type="checkbox"/> d. The admission and discharge date were the same calendar date (NHSN outpatient operative procedure)</p> <p><input type="checkbox"/> e. Infection was present at the time of surgery (PATOS)</p> <p><input type="checkbox"/> f. COLO wound class = Clean (C)</p> <p><input type="checkbox"/> g. ASA score = 6</p> <p><input type="checkbox"/> h. Other _____</p>	<p>Correct Answers: a, d, f, g</p> <p><i>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</i></p> <p>a) no appropriate ICD-10-PCS/CPT procedure code assigned,</p> <p>d) not an inpatient operative procedure) (if facility is <u>only</u> following inpatient procedures on monthly reporting plan),</p> <p>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 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.</p> <p>g) ASA score = 6</p> <p>.....</p> <p>Note:</p> <p><i>Facilities should keep clear and accurate documentation when procedures are excluded from NHSN reporting.</i></p>
<p>6) If the operative procedure report details do not match the listed ICD-10-PCS/CPT procedure codes, what should you do?</p>	<p><input type="checkbox"/> a. Review coding assignment with the facility medical coder</p> <p><input type="checkbox"/> b. Query NHSN</p> <p><input type="checkbox"/> c. Other</p>	<p><i>For validation purposes, NHSN recommends that IPs should bring coding mismatches to coders for review and should not over-ride coders' decisions.</i></p> <p><i>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</i></p>



		<i>documentation should be maintained in these instances.</i>
7) Which of the following are consistent with the definition of primary wound closure? (<i>check ALL that apply</i>)	<input type="checkbox"/> a. Complete closure of skin with suture <input type="checkbox"/> b. Partial closure of skin with staples <input type="checkbox"/> c. Closure of skin except for wick/drain through incision <input type="checkbox"/> d. Closed fascia with incision loosely closed at the skin level <input type="checkbox"/> e. Closed fascia, with skin layer left open	<p>Correct answers: a, b, c, d</p> <p><i>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.</i></p> <p><i>The closure of the surgical wound in a way which leaves the skin level completely open following surgery is a non-primary closure (e).</i></p> <p><i>All procedures, regardless of closure method, must be reported to NHSN.</i></p>
8) Does your facility conduct NHSN analysis to look at longitudinal trends for COLO or HYST SSIs and procedures?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<i>This is recommended practice for facility use of NHSN data</i>
9) What would you do if your procedure denominator this month was dramatically higher from one month to the next?	_____	<i>Recommended: investigate this aggregate data by exploring the data at a patient/procedure level to identify the reason.</i>

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:	(circle one): COLO, HYST, BOTH
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)		<input type="checkbox"/> Report the SSI to NHSN <input type="checkbox"/> Report the SSI to "hospital A" <input type="checkbox"/> Report the SSI to the health department <input type="checkbox"/> No external reporting Comment: _____
11) If you do not report the SSI to "hospital A", why not? (choose all that apply)		<input type="checkbox"/> HIPAA concerns <input type="checkbox"/> Not a priority for IP program <input type="checkbox"/> Logistically difficult (which hospital, who to contact) <input type="checkbox"/> Not required Comments: _____
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)		<input type="checkbox"/> Ask the IP for help completing the NHSN report <input type="checkbox"/> Document in your tracking records <input type="checkbox"/> Report the SSI to NHSN <input type="checkbox"/> Ask the IP to report the SSI to NHSN <input type="checkbox"/> No internal reporting or documentation 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.

Best practice is to report to "hospital A" If facility cites HIPAA concerns, consider sharing [Appendix 4](#), 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.

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.) Include relevant details in the patient medical record.



<p>13) What methods are routinely and systematically used to identify possible SSI? (Check all that apply)</p>	<p>Reports/Rounds:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Emergency department line lists with diagnoses <input type="checkbox"/> Admissions line lists with diagnoses <input type="checkbox"/> Patient chart review for signs and symptoms of SSI <input type="checkbox"/> Surgical ward rounds – talk to primary care staff <input type="checkbox"/> Clinician/healthcare professional notes <input type="checkbox"/> Positive laboratory cultures from inpatients <input type="checkbox"/> Positive laboratory cultures from ED <input type="checkbox"/> Positive laboratory cultures from outpatient clinics <input type="checkbox"/> Pharmacy reports (antibiotic starts or continuations) <input type="checkbox"/> Other <hr/> <p>Surgical service information:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Inpatient returns to surgery <input type="checkbox"/> Surgical service readmissions <p>ADT/Medical Records Data Mining:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Readmissions within one month of discharge <input type="checkbox"/> Extended LOS <input type="checkbox"/> Discharge diagnostic coding (for example, ICD-10-CM Infection Diagnosis Codes to prompt further review) <input type="checkbox"/> Other/Comment: 	<p><i>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</i></p>
<p>14) How does your facility conduct post-discharge surveillance for SSIs? (check all that apply)</p>	<ul style="list-style-type: none"> <input type="checkbox"/> IP does not have a formal post-discharge surveillance plan <input type="checkbox"/> IP conducts patient survey by mail <input type="checkbox"/> IP conducts patient survey by telephone <input type="checkbox"/> IP provides line list of patients to surgeon for response <input type="checkbox"/> Surgeon indicates SSIs identified at surgical follow-up <input type="checkbox"/> Surgeon surveys patient by mail <input type="checkbox"/> Surgeon surveys patient by telephone 	<p><i>It is important to perform post-discharge surveillance as the majority of SSI's may be detected this way.</i></p>

	<input type="checkbox"/> IP reviews surgical clinic / wound clinic information <input type="checkbox"/> IP reviews surgical patient records within a time period that aligns with the operative procedure category surveillance period. <input type="checkbox"/> Other/ Comment: _____	
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?	<input type="checkbox"/> COLO <input type="checkbox"/> HYST <input type="checkbox"/> Both <input type="checkbox"/> Neither	Correct answer: a Refer to SSI Event Reporting Instruction #9. Since SSI attribution is not clear, the procedure which is higher on the 2021 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.

Appendix 3.5: LabID Event Surveillance Methods Survey (with Key)

OrgID / Name of Hospital _____

Date: _____

LabID Event Surveillance Methods Survey				
<i>Instructions: Administer this survey to the person who oversees NHSN LabID Event reporting</i>				
Denominator Data Collection Questions				
Name of individual interviewed:	Position:	<input type="checkbox"/> FacWideIN MRSA bacteremia <input type="checkbox"/> 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			<input type="checkbox"/> True <input type="checkbox"/> False	T
2) For CDI reporting, the denominator should include all completed CDI tests			<input type="checkbox"/> True <input type="checkbox"/> 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			<input type="checkbox"/> True <input type="checkbox"/> False	F (all patients housed in inpatient locations)
4) For CDI reporting pediatric locations should be excluded from FacWideIN reporting			<input type="checkbox"/> True <input type="checkbox"/> False	F (NICU and well-baby locations and babies on LDRP are excluded for CDI)
5) For MRSA bacteremia reporting baby locations (NICU, newborn nursery, etc.) should be excluded from the denominator			<input type="checkbox"/> True <input type="checkbox"/> False	F (no location exclusions for MRSA)
LabID Event (Numerator) Data Collection Questions				
Name of individual interviewed:	Position:	<input type="checkbox"/> FacWideIN MRSA bacteremia <input type="checkbox"/> FacWideIN CDI	Interviewer initials:	Date of survey:
6) For FacWideIN reporting, one monthly numerator for Events is reported at the facility-wide level			<input type="checkbox"/> True <input type="checkbox"/> False	F (events are reported by location)
7) For CDI reporting, the numerator should include –toxin positive CDI results conducted on formed stool specimens			<input type="checkbox"/> True <input type="checkbox"/> False	F (laboratories should only process and report results for unformed stools)
8) A second event is always reported if >14 days have passed from the most recent positive MRSA bacteremia or -positive CDI test result			<input type="checkbox"/> True <input type="checkbox"/> False	T
9) A second event is only reported if >14 days have passed from the most recently reported LabID event			<input type="checkbox"/> True <input type="checkbox"/> False	F (If the patient changes location, a second event is reported even within 14 days of prior event)
10) A second event is only reported if the patient changes location OR >14 days have passed since the most recent positive MRSA bacteremia or -positive CDI test in the same location			<input type="checkbox"/> True <input type="checkbox"/> False	T
11) Only reportable CDI LabID Events should be entered into NHSN			<input type="checkbox"/> True	T

	<input type="checkbox"/> False	
Policy Question		
12) 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?	<input type="checkbox"/> Unformed stool specimens only <input type="checkbox"/> All stool specimens	Recommended policy is to only process unformed stool specimens for CDI

Appendix 3.6: LabID Event Facility-Wide Inpatient (FacWideIN)

Denominator Validation Template

Please feel free to adapt this template to meet your state’s needs

Electronically collected MRSA bacteremia and 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.

MRSA Bacteremia 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/pscmanual_current.pdf, and http://www.cdc.gov/nhsn/forms/instr/57_127.pdf).

Remember that for MRSA bacteremia **both mothers and babies** are counted in LDRP locations.

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

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

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

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

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/pscmanual_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 \pm (Usual Count * 0.05).

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

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

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

Appendix 4: Facility/Provider to Facility/Provider Communications under HIPAA: Questions and Answers

Note: The following document was developed by CDC scientists and lawyers in collaboration with HHS Office of Civil Rights (OCR) program and legal staff, who oversee administration of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This information may not be modified without express permission of OCR.

Facility/Provider to Facility/Provider Communications under HIPAA: Questions and Answers

Health care providers [i.e., individual clinicians and facilities (including hospitals and other health care facilities such as nursing homes and rehabilitation facilities)] are increasingly active in addressing concerns about patient safety and minimizing patients' risks of adverse healthcare events. In an era when the public, policymakers, and many health care providers seek greater transparency and accountability in healthcare, these efforts include but are not limited to new or renewed emphasis on information sharing among providers themselves about adverse events that are a consequence of a care process, care process omission, or some other risk exposure during a health care episode, such as exposure to an infectious agent.

Health care providers have raised questions as to whether the HIPAA Privacy Rule permits information sharing between individual providers and/or facilities for patient safety-related purposes. This guidance assumes that the provider seeking to share such patient information is a HIPAA covered entity. While any health care provider may be faced with these questions, they tend to arise more frequently at the facility level. The term "patient" is also used here to encompass persons residing in nursing homes or other facilities, where they are often referred to as "residents." "Source facility" or "source provider" refers to the health care facility or individual provider that first cared for the patient. Protected health information ("PHI") is individually identifiable health information, such as information that identifies (or can be used to identify) a patient.

Question One

Does HIPAA permit a health care facility to share PHI with the source facility where a patient was previously treated or where a patient previously resided, without the patient's authorization, for purposes of providing notification of an infection with potential infection control implications at the source facility?

In these scenarios a resident of a nursing home is admitted into a hospital, certain medical conditions are diagnosed, and the hospital wants to disclose this health information back to the nursing home.

- A practitioner at the hospital diagnoses a patient's tuberculosis and wants to inform the nursing home so that the staff there can quarantine the coughing roommate of the index case.
- The patient is admitted with sepsis and later dies in the hospital. Blood cultures drawn at admission grow group A streptococcus. The hospital seeks to disclose that this patient was diagnosed with invasive group A streptococcal infection (which causes serious outbreaks in nursing homes) to the nursing home for infection control purposes, even though the patient will not be returning.
- The hospital diagnoses the patient with influenza early in the flu season and wants to disclose this diagnosis to the nursing home for infection control purposes.

In each scenario the hospital will want to disclose the name of the patient so the nursing home can verify that this patient had been a resident in their home and the date and location of service.

Answer One

The HIPAA Privacy Rule permits a covered health care provider to use or disclose PHI for treatment purposes without the authorization of the patient. (Generally, disclosures of psychotherapy notes require written patient authorization, but these notes do not appear relevant here.) 45 CFR 164.506(c) and 164.508(a)(2). “Treatment” is defined to include the provision, coordination, or management of “health care” and related services. 45 CFR 164.501. “Health care” is defined to include preventive care. 45 CFR 160.103. Treatment refers to activities undertaken on behalf of individual patients. While in most cases, the information regarding an individual is needed for the treatment of that individual, the HIPAA Privacy Rule also allows the information regarding one individual (e.g., a patient) to be used or disclosed for the treatment or preventive care (e.g., vaccinations or quarantine) of other persons (e.g., patients at risk).

In these scenarios, the patient (and former nursing home resident) has or had a medical condition while at the nursing home that may directly impact the health of certain or all residents at that facility. In some cases, the nursing home did not know of this condition, or the condition had not manifested itself at the time the patient was at the nursing home. The hospital may disclose PHI of the patient (and former nursing home resident) to the nursing home for treatment purposes involving other residents.

A distinction is made between use and disclosure of PHI for treatment purposes with regard to the “minimum necessary” requirement. The “minimum necessary” requirement does not apply to disclosures of PHI for treatment purposes, and the disclosures discussed above are treatment disclosures that are permitted under the HIPAA Privacy Rule.

After PHI is disclosed to the nursing home, the information may be used for the provision of treatment to the nursing home residents. For example, preventive measures, such as cohorting, isolation, or prophylaxis of specific patients who may be at risk at the nursing home, are considered treatment under the Privacy Rule. The uses of PHI by the nursing home for treatment purposes in the above scenarios are subject to the Privacy Rule’s “minimum necessary” requirement, and the nursing home’s minimum necessary policies. A nursing home, as a covered entity, must identify those persons or classes of persons in its workforce who need access to PHI, and for each such person or classes of person, the category or categories of PHI to which access is needed, and any conditions appropriate to such access. 45 CFR 164.514(d)(2). For more information on the “minimum necessary” requirement, see: http://www.hhs.gov/ocr/privacy/hipaa/faq/minimum_necessary/207.html.

Question Two

Under HIPAA, is a health care facility permitted to share PHI with another health care facility that previously treated or housed a patient, without that patient’s authorization, for purposes of notifying this source facility of a potential complication of care related to the health care

provided at the source facility so as to monitor and improve care and prevent future complications?

- A hospital identifies a surgical site infection (SSI) that is probably attributable to an ambulatory surgical care facility and/or surgeon that performed the surgery within the past 12 months. The hospital seeks to notify the ambulatory surgical care facility about the SSI, or in a given situation, notify the surgeon directly.
- A patient is admitted to Hospital B with a surgical site infection (SSI) after an operation at another hospital (Hospital A), where the patient had been operated on and then discharged without signs or symptoms of infection. Because of federal requirements (e.g., the Centers for Medicare and Medicaid Services' Inpatient Quality Reporting program requirements) or state law or policy, both hospitals are committed to reporting all SSIs following the type of operation performed on the patient. Hospital B seeks to report the SSI to Hospital A, where the SSI is presumed to have originated, so that Hospital A can fully account for SSIs attributable to its care.

Answer Two

The HIPAA Privacy Rule permits a covered entity to use or disclose PHI for certain “health care operations” purposes without the authorization of the patient. 45 CFR 164.506(c). This includes a covered entity disclosing PHI to another covered entity for certain purposes if each entity either has or had a relationship with the individual who is the subject of the information, and the PHI being disclosed pertains to the relationship. 45 CFR 164.506(c)(4). Of relevance here, disclosures are permitted for the purpose of the covered entity receiving the information “conducting quality assessment and improvement activities; . . . population-based activities relating to improving health [and] protocol development.” 45 CFR 164.501 (definition of “health care operations”). Only the minimum amount of PHI necessary for the particular health care operations purpose may be disclosed.

The disclosures discussed above are health care operations disclosures that are permitted under the HIPAA Privacy Rule. In these scenarios we assume that the hospitals sharing the PHI, the ambulatory surgical care facility, and the surgeon are all HIPAA covered entities. The hospitals disclosing the PHI would be sharing information regarding a patient who the surgical facilities (either the ambulatory care facility or the hospital) and/or surgeon had treated, and the communication is in regard to the treatment that had been provided. The disclosures are so that the surgical facilities and/or surgeon can monitor and improve the quality of care provided. This falls under “conducting quality assessment and improvement activities,” and perhaps “population-based activities relating to improving health,” and/or “protocol development.” In these scenarios, information regarding the patient with an SSI can be shared with the surgical facilities and/or surgeon. While only the minimum amount of information regarding the patient may be disclosed, in these scenarios the identity of the patient may be shared because it is needed to investigate the cause of the infections (e.g., the dates and locations of care, and the staff involved.) There is likely to be no need to share health information regarding these patients that is unrelated to investigating the SSI.



For additional information regarding disclosures for treatment and healthcare operations purposes, see:
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/usesanddisclosuresfortpo.html>.

