

2023 NHSN Patient Safety External Validation Toolkit

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About the 2023 NHSN Patient Safety External Validation Toolkit

The 2023 NHSN Patient Safety External Validation Toolkit provides guidance for NHSN data validation. CDC provides 2023 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. CLABSI validation is applicable for acute care hospitals and long-term acute care hospitals (LTACHs) and CAUTI validation is applicable for acute care hospitals, LTACHs, and inpatient rehabilitation facilities (IRFs).

The purpose of validation is to ensure 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 ensure 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 ensure 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 validators. Recommended sample sizes attempt to balance feasibility with accuracy for HAI metrics at the facility level. Survey tools assess reporter knowledge and facility practices required to conduct adequate surveillance.

For 2023 data validation, NHSN specified three methods for sampling of facilities— two targeted and one random. State health departments and other external validators are encouraged to select the method based on their validation priority. The first targeted sampling method 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. The second targeted method, the cumulative attributable difference approach, aims to target facilities that have a high number of predicted events, but few or zero events reported. There are two important limitations to keep in mind with targeted sampling. Precision measures 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. The third method, stratified random sampling, aims to produce a representative sample to measure inter-rater reliability of the measure(s) in the jurisdiction undergoing validation. All three methods are summarized in section 2.2.

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 with the subject line “External Validation Toolkit.”

Acknowledgements and Thanks: NHSN adapted many aspects of this document from states conducting validation. However, the 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

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-BASED LOCATIONS*	(NHSN) Neonatal Intensive Care Units (NICU), Specialty Care Nurseries (SCN), babies in LDRP (Labor, Delivery, Recovery, and Post-partum), well-baby nurseries, or well-baby clinics.
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, that is, 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 3 rd 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) A drainage tube that is inserted into the urinary bladder through the urethra, is left in place, and is connected to a drainage bag (including leg bags). These devices are also often called Foley catheters. Indwelling urinary catheters (IUC) that are used for intermittent or continuous irrigation are also included in CAUTI surveillance. Condom or straight in-and-out catheters are not included nor are nephrostomy tubes, ileoconduits, or suprapubic catheters unless an IUC is also present.
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*	(NHSN) Labor, Delivery, Recovery, and Post-partum. A type of NHSN location in an acute care facility.
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, that is, 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 performed in that location.
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 (CLABSI, CAUTI, VAE) and LabID Events.

PDS	Post-discharge surveillance.
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.
QIO	Quality Improvement Organization.
REPORTER	Infection Preventionist or other designated NHSN user inputting a facility's reportable HAI events into the NHSN database.
SAMPLING FRAME	Derived from positive laboratory line listings (blood culture, urine culture, and CD-positive specimen) or line listing of COLO and HYST procedures already entered and available in NHSN during the validation timeframe from which medical records are selected for validation.
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.
SURVEILLANCE	The term "surveillance location", abbreviated SL, is used in the toolkit to indicate that
SUTI*	(NHSN) Symptomatic UTI. SUTI 1a and 2a are CAUTIs; SUTI 3 and 4 may be CAUTIs; SUTI 2a and 2b cannot be CAUTIs
TARGETED SAMPLE	In this document, a targeted sample is a purposive sample taken to target facilities at higher risk for HAI.
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.
VALIDATOR	Member of external agency that reviews a facility's surveillance determinations and methods to evaluate surveillance program quality, data completeness, and reporting

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

Chapter 1: Purpose and Goals of External Validation

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

1.1 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 for public reporting purposes and to incentivize quality improvement through payment mechanisms. These 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 (for example, 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 stakeholders' needs without taking additional steps to ensure data quality. The NHSN reporting landscape will continue to change over time as NHSN methods evolve and reporting requirements expand.

In the context of powerful incentives for facilities to “look good,” meaningful external validation is essential to ensure 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.

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 guaranteeing NHSN data are actionable and motivate improved infection prevention and 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 ensuring NHSN data quality.

1.2 What is External Validation?

External validation is a survey and review process conducted by an agency outside the reporting facility (for example 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 (for example 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 ensure 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. Validators should help reporters correct and complete the validated data. Validators should document and discuss with reporters 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 their jurisdiction in person or review every patient record in search of candidate HAIs, which is why facilities and medical records are selected from sampling frames (described further in section 2.6). Sampling is a practical necessity, and sampling methods should strike a balance between resource availability and programmatic objectives.

1.3 Goals of NHSN External Validation

Evaluate facility NHSN HAI Event surveillance practices:

- Assess staff understanding of the Event Protocol(s)
- Assess data collection and reporting methods
- Identify common barriers to complete and accurate data collection and reporting

Educate facility staff on NHSN HAI Event Surveillance:

- Improve staff understanding of the methods and definitions in the Event Protocol(s)
- Improve staff data collection and reporting practices
- Increase staff awareness of reporting resources

Assess and improve the quality of HAI Event data reported to NHSN:

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

Provide feedback to CDC to support continuous improvement of public resources in order to:

- Improve this Toolkit and the corresponding documents
- Develop optimal and standardized data evaluation methods
- Improve existing NHSN HAI event surveillance and reporting resources, such as training materials, reporting instructions, and frequently asked questions (FAQs) to address common areas of confusion

Chapter 2: Overview for Conducting 2023 NHSN External Validation

NHSN Patient Safety 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 surveillance locations**
2. **Catheter associated urinary tract infection (CAUTI) in surveillance 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**

Oversight agencies may choose to use experience and/or data analysis to prioritize which HAIs to validate. For example, if an agency recently completed CLABSI validation, they may seek to focus on other HAIs for 2023. Alternatively, agencies may wish to focus validation on HAIs with unexpectedly high rates to assist facilities with prevention.

Agencies should still hold facilities not selected for external validation, using one of the suggested sampling methods, 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 2023 certificate of successful completion produced by each of NHSN's multimedia training modules from all facilities) to ensure 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 2023 includes assessment of event determination and risk-adjustment variables, with medical records review focused on HAI event determination. Numerator (HAI events) quality can be optimized by a) reporter training (as demonstrated by completed certificates for 2023 online multimedia assessments), b) good surveillance practices (assessed by survey), and c) evidence of correct reporting (by a review of medical records showing concordance of validator outcomes with events reported to NHSN). Denominator (for example, device days) accuracy 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 additional risk adjustment variables and documentation of internal validation work conducted by facilities.

Because of advances in electronic medical records (EMRs) and telecommunication, many validation elements can now be performed either on- or off-site. However, this external validation toolkit recommends on-site medical record reviews by trained validators using a medical record abstraction tool (MRAT) that follows 2023 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 EMR systems that are made available at a distance to validators is a feasible, alternative way to review medical records. 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 validated healthcare facilities, and across the continuum of healthcare.

Steps for External Validation:



CDC-Recommended Validation Elements and Preferred Approach

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

Project Timeline

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

External Validation Project Steps Total estimated duration ~26 weeks	Project Duration
1) Preparation (estimated duration 4 weeks) <ul style="list-style-type: none"> <input type="checkbox"/> Read the 2023 NHSN Patient Safety External Validation Toolkit in its entirety. <input type="checkbox"/> Determine which HAI(s) your jurisdiction will validate. <input type="checkbox"/> Read the 2023 NHSN HAI-specific External Validation Toolkit(s) in its entirety. <input type="checkbox"/> Ensure validators are trained in NHSN protocol(s), HAI Event Surveillance, and validation tools. <input type="checkbox"/> Determine the method of facility selection and number of facilities that will be included in the project. <input type="checkbox"/> Determine the validation timeframe (which months of NHSN data will be validated). <input type="checkbox"/> Determine when the site visits will occur. <input type="checkbox"/> Download facility SIR lists from NHSN. <input type="checkbox"/> Select facilities to be included in the validation project. <input type="checkbox"/> Download (“freeze”) facility NHSN data. <input type="checkbox"/> Customize Template Letters 1 and 2 (Appendix 1) for your organization and project parameters. <input type="checkbox"/> Optional: Consider hosting webinar for jurisdiction/selected facilities to describe validation process and its benefits. 	
2) Solicit Facility Participation (estimated duration 4 weeks) <ul style="list-style-type: none"> <input type="checkbox"/> Contact Facility Infection Preventionist, using Template Letter 1 (Appendix 1.1), to describe the validation project and invite them to participate. <input type="checkbox"/> Send Template Letter 2 (Appendix 1.2) to Facility Leadership (i.e. CEO, CMO) of the selected facilities requesting site visit and line listing(s). <input type="checkbox"/> Establish mechanism of secure data transfer between facility and external validation agency. <input type="checkbox"/> Develop medical record sampling frame from facility-provided line listing(s). <input type="checkbox"/> Select medical records from sampling frame for review. <input type="checkbox"/> Document facilities that decline to participate and reasons why. 	
3) Confirm Site Visits (estimated duration 2 weeks) <ul style="list-style-type: none"> <input type="checkbox"/> Send Template Letter 3 (Appendix 1.3) to Facility IP to confirm the details of each visit and request selected medical records to be available on the day of the site visit. <input type="checkbox"/> Optional: Determine which survey(s) will be utilized (HAI-specific EVT) and send to facilities to complete prior to site visit – may be included with Template Letter 3. Surveys may also be completed during or after site visit. 	

<p>4) Prepare for Each Site Visit (estimated duration 1 day per site)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Print copy of facility's most recent NHSN Annual Survey. <input type="checkbox"/> Have extra materials (e.g., calendar, pens, etc.) ready. <input type="checkbox"/> If abstracting directly into REDCap medical record abstraction tool (MRAT), have a laptop/device with internet access available and bring device's charger; OR if abstracting manually on paper, be sure to print enough copies of the MRAT for the selected medical records. <input type="checkbox"/> Contact Facility IP a few days before the site visit to confirm. Ensure that space and computer access is ready (if performing validation onsite), selected medical records will be available, staff will be available for survey administration and intermittent questions throughout day, and arrange meeting time. 	
<p>5) Conduct Site Visits (estimated duration 6-12 weeks)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Conduct greetings and introductions. <input type="checkbox"/> Request documentation of current NHSN reporter training. <input type="checkbox"/> Conduct chart review/abstraction and enter data into MRAT. <input type="checkbox"/> Review any additional reported events from NHSN line listing not found. <input type="checkbox"/> Conduct Facility Debrief to discuss survey findings and chart review findings. 	
<p>6) Post-site Visits: Facility follow-up and Data Summary and Dissemination (estimated duration 4 - 8 weeks)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Upon completion of each site visit, summarize findings and customize Template Letter 4 (Appendix 1.4) and send to Facility Leadership and IP. <input type="checkbox"/> Follow-up ~4 weeks post-site visit to ensure any identified errors were corrected. <input type="checkbox"/> Export deidentified data from REDcap and send to CDC. <input type="checkbox"/> Analyze aggregated data from all facilities that participated in the project. <input type="checkbox"/> Write a state/jurisdiction summary report, disseminate findings to key stakeholders (i.e. participating facilities, CDC). 	

2.1 Ensure or Update Validator Expertise in 2023 NHSN Protocols

Surveillance and validation require rigorous adherence to the NHSN protocols, surveillance methods, and definitions as written. Persons conducting validation 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](#). Training resources are listed below in order of recommendation for validators:

Type of NHSN Training	Recommended Validator Standard	Where can I find this training?
Self-paced Interactive Training Modules	Ensure that all 2023 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 implement the basic content presented in HAI training webinars.	Presentations and case studies used to walk through difficult cases to learn to apply the NHSN HAI definitions accurately. Please begin using the NHSN 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 validators 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) with the subject line "case review for adjudication." Forms for tracking cases that result in discrepancies and require adjudication are found in Section 6 of the corresponding HAI-specific EVTs.

2.2 Methods of Facility Selection

See [HAI-specific EVTs](#) for step-by-step instructions for facility selection methodology.

Below is an overview of the three facility selection method options that CDC provides to agencies. State health departments and other external agencies conducting validation of HAI data submitted to NHSN have the option to select a method based on the jurisdiction's needs and priorities around HAI validation. Here we provide a summary, pros, and cons of the methods to assist external agencies in selecting the appropriate method of facility selection:

Method 1: Prioritizing Facilities with Highest Likelihood of Event Occurrence

This is the first of three methods validators may choose from for facility selection. 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 are also encouraged. Targeted sampling of hospitals performing the surgical procedures to be validated and of the surgical procedures themselves requires that risk-adjustment variables (for example, ASA score, anesthesia, procedure duration) are complete. Analysis to ensure completeness of these variables is recommended before facilities are ranked for SSI validation.

Method 2: Cumulative Attributable Difference (CAD) Approach

HAI data validation efforts have demonstrated that underreporting of HAI events continues to be a concern. Prioritizing validating among facilities sorted by “predicted number of events” and SIR values (Method 1 approach) limits validation to relatively larger facilities with a computed value of SIR and excludes smaller size facilities where underreporting may 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 number of predicted events at each facility. 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 were reported than statistically predicted, and the SIR goal had 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 and very few or no reported events during a time frame.

Method 3: Stratified Random Sampling

The third method validators may choose from for facility selection provides a system for stratified random sampling with the aim of producing a representative sample of facilities and allows for the measurement of inter-rater reliability between the facilities and the validators in the jurisdiction undergoing validation.

External Validation Facility Selection Methods Comparison			
	Method 1 - Prioritizing Facilities with Highest Likelihood of Event Occurrence	Method 2 – Cumulative Attributable Difference (CAD)	Method 3 - Stratified Random Sample
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.	This method prioritizes selecting facilities randomly to create representative estimates.
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.	Focuses on reviewing a representative sample of the state/jurisdiction
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.	No facility ranking algorithm used. Facilities are stratified by bed size.
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 Methods 2 or 3.	Agencies with previous validation history that identified underreporting as a potential concern should use Method 2.	Agencies who wish to evaluate a representative sample of their jurisdiction should use Method 3.
Number of facilities	<ul style="list-style-type: none"> 20 or fewer facilities: validate them all 21 to 149 facilities: at least 18 targeted facilities plus a 5% random sample of remaining facilities 150 or more facilities: select at least 21 targeted facilities plus a 5% random sample of remaining facilities. 	<ul style="list-style-type: none"> Fewer than 30 facilities: validate them all 30 or more facilities: 30 facilities, distributed between Stratum 1 and 2 	<ul style="list-style-type: none"> Fewer than 30 facilities: validate them all 30 or more facilities: 30 facilities, distributed between Stratum 1 and 2
Charts per facility	40	40	40

General guidelines for facility selection applicable to all methods:

This section provides an overview of the facility selection process. The specific step-by-step instructions with screenshots can be found in the HAI-specific toolkits. If HAIs 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.

Step 1: Download NHSN SIR Facility List

1. Generate datasets in NHSN
2. Modify report for specific HAI
3. Export data into spreadsheet

Step 2: Determine minimum facility sample size

Method 1

1. 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 for each selected HAI:
 - a. Smaller states/jurisdictions with 20 or fewer facilities should validate all facilities.
 - b. Medium states with 21 to 149 facilities should select at least 18 targeted facilities plus a 5% random sample of remaining facilities.
 - c. 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

1. **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.
2. **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.

$$18 + [(125-18) \times 0.05] = 23 \text{ (rounding to the nearest whole number)}$$
3. **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.

$$21 + [(185-21) \times 0.05] = 29 \text{ (rounding to the nearest whole number)}$$

Method 2

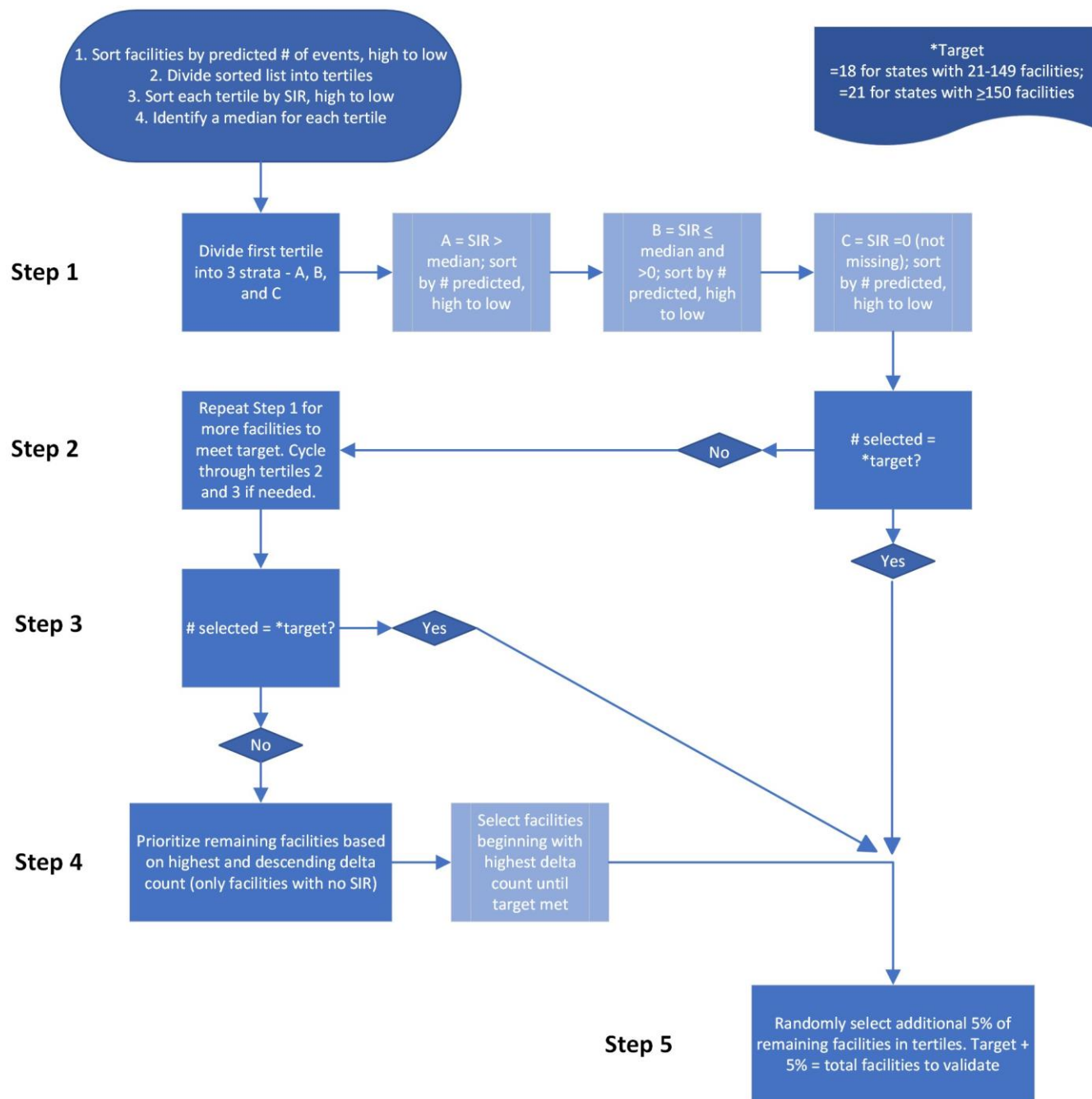
1. If fewer than 30 facilities, validate them all.
2. If 30 or more facilities, validate 30 distributed between stratum 1 and stratum 2 according to ranking algorithm.

Method 3

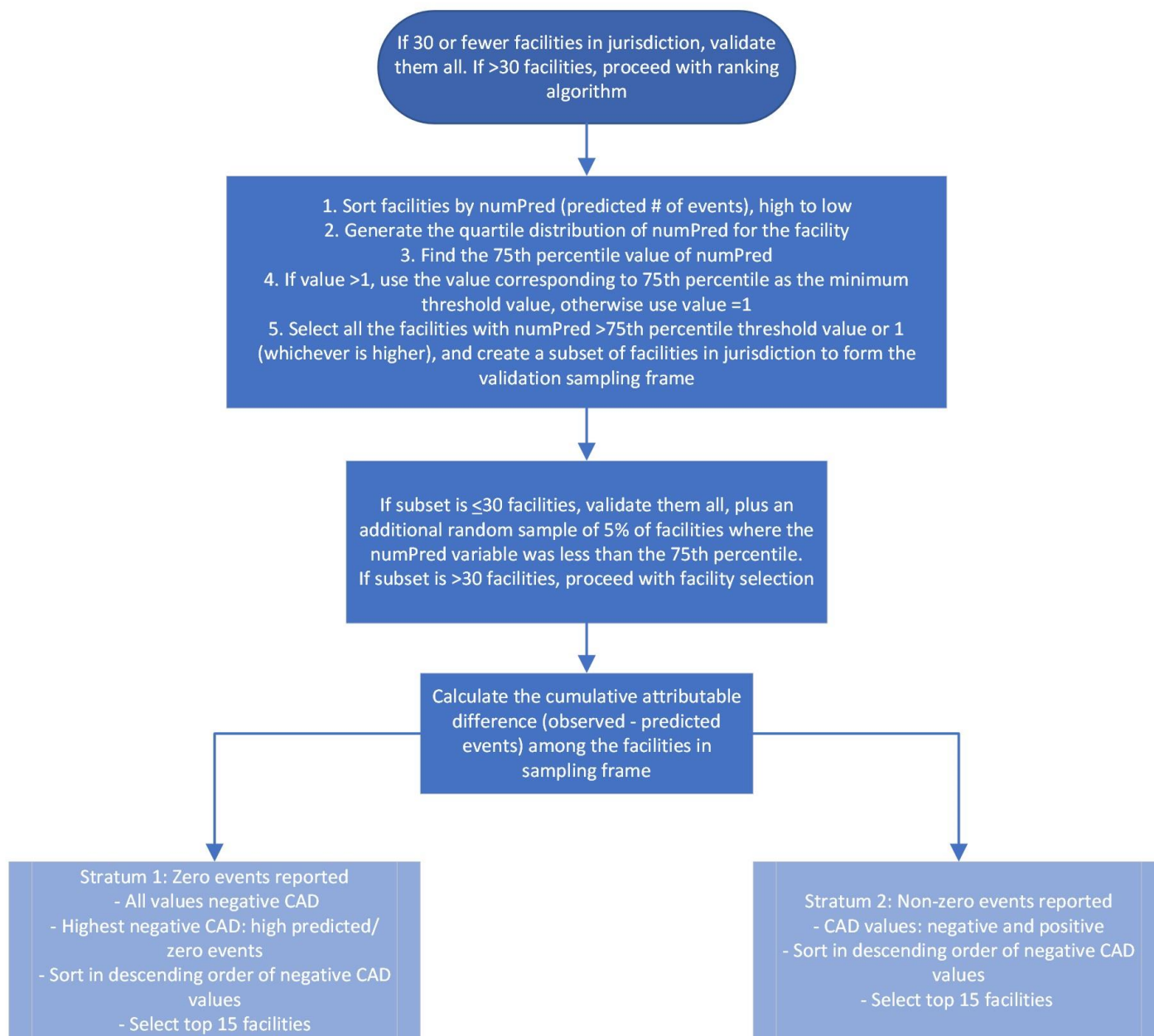
1. If fewer than 30 facilities, validate them all.
2. If 30 or more facilities, validate 30 distributed between stratum 1 and stratum 2 according to stratification algorithm.

Step 3: Apply facility ranking/stratification algorithm

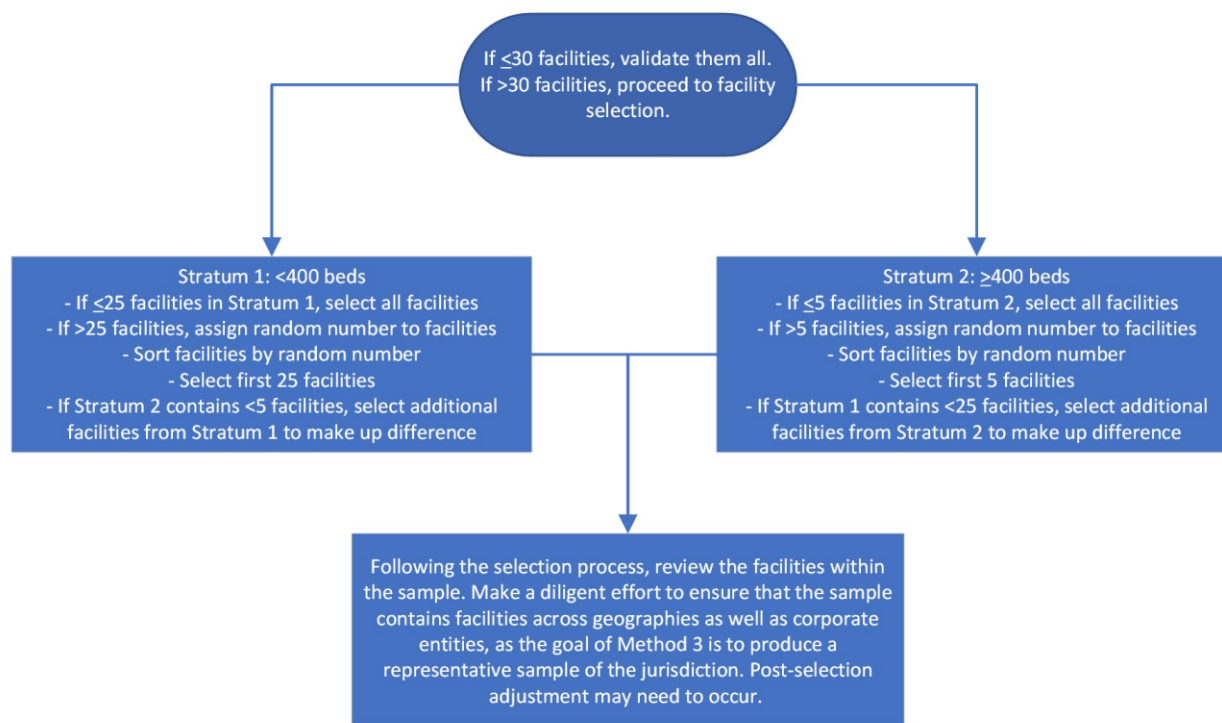
Facility Selection Method 1



Facility Selection Method 2



Facility Selection Method 3



2.3 Download (“freeze”) the facility’s reported data from NHSN

See [HAI-specific EVTs](#) for step-by-step instructions on how to download reported data from NHSN.

Before selecting the medical records sample, use the NHSN Analysis Reports and the modifications described in the HAI-specific EVTs to “freeze” each facility’s reported data, essentially taking a snapshot of the data, which can then be exported.

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

For chosen facilities, contact the IP inviting them to participate in the validation project ([Appendix 1.1](#)), including the likely scope of the validation and its importance to data quality improvement. Emphasize that external validation is not related to any regulatory surveys and highlight the benefits of external validation to the facility.

After the initial invitation is sent to the facility IP, compose a letter notifying the facility leadership (i.e. CEO, CMO) of their selection to participate in validation, 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 validation process, purpose of the validation, proposed dates for the validation, and specific data and accommodations needed from facility staff ([Appendix 1.2](#)). Explain the purpose of validation (that is, to ensure 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. Describe the request for blood cultures, urine cultures, and/or *C. difficile* positive line listings for appropriate patient populations (with structures described below). 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. 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 and how they are organized; this can affect the time required to abstract the records. Discuss the anticipated number of days and reviewers needed to complete validation, based on experience or the guidance to follow.

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, sex, date of birth, and date of culture/specimen collection. In some situations, validators may need more information from the IP about reported NHSN events to identify reported HAIs on the laboratory line listing (for example a request for additional personal identifiers of patients, such as patient name, with NHSN-reported HAIs that can be linked to laboratory reports). If the facility can provide these fields with the line listing, they should be requested.

The line listings should be sortable and searchable (for example, .csv, Excel) files, 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. 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 surgical procedures being validated.

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

To ensure 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 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. Consider a mutually agreeable due date for the laboratory line listings, dates for the medical record request, and proposed date(s) for the onsite validation. For the validation, request arrangements for medical records access including workspace, computer systems, terminals and passwords and (eventually) specific medical records.

2.5 Establish a mechanism for secure data transfer between facilities and the external validation agency

External validation agencies require data elements from facilities to build the 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. Some agencies have established secure file transfer (for example, encrypted email, secure file transfer protocol [FTP] site, or encrypted file by courier or snail mail) 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 develop the sampling frame and to respond with the sample of medical records for review).

2.6 Develop the medical record sampling frame for each facility

For CLABSI, CAUTI, MRSA Bacteremia LabID Event and positive *C. difficile* LabID Event, sampling frames derive from positive laboratory (blood culture, urine culture, and CD-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.

Note: The term “surveillance locations,” abbreviated SL, is used in the toolkit to indicate that only in plan NHSN-reporting locations (part of monthly reporting plan) will be included for the validation efforts for CLABSI and CAUTI.

- Validation of CLABSI in NHSN-reporting surveillance locations: includes NICU locations
- Validation of CAUTI in NHSN-reporting surveillance locations: excludes NICU locations
 - NICU is considered off plan (not part of CAUTI monthly reporting plan), and therefore not a mandatory reportable surveillance location for CAUTI.

For SSI, sampling frames derive from procedures reported in NHSN. However, to ensure the NHSN procedure sampling frame is complete, validators should use a monthly tally from the facility for COLO procedures 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.

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 1.2)	Line Listing Will Define the Following Sampling Frame Elements
CLABSI	Line listing ^a of blood cultures from NHSN-reporting surveillance locations, including NICU, where organism(s) was identified, with patient MRN and admission date	<u>Episodes of care</u> (identified by patient MRN and unique admission date) with one or more surveillance location blood culture with organism(s) identified (include NICUs)
CAUTI	Line listing ^a of positive urine cultures ^b from NHSN-reporting surveillance locations (non-NICU) with patient MRN and admission date	<u>Episodes of care</u> (identified by patient MRN and unique admission date) with one or more positive surveillance 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 stool specimens ^d positive for <i>C. difficile</i> , excluding those from baby locations ^e	<u>Episodes of care</u> with one or more inpatient ^c stool specimens ^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 surveillance location (SL) stay, the day of transfer from the SL, or the following calendar day after transfer

^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.

2.7 Select medical records for validation

See [HAI-specific EVTs](#) for step-by-step instructions on how to conduct medical record selection.

Once the requested laboratory line listings have been received, proceed with the medical record selection process corresponding with the HAI(s) being validated. There is a single method for medical record selection, which aims to provide a representative sample of records to review for each facility being validated. Follow the step-by-step process described in the HAI-specific toolkits.

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

When the medical record selection process is complete, inform the IP of the selected records ([Appendix 1.3](#)), and submit the medical records request to the facility in a secure fashion so they can arrange for access to the information for your visit.

If more than one HAI will be validated, up to 40 specific medical records should be requested for **each** HAI reviewed: for CLABSI and CAUTI, up to 40 medical records **each** for COLO and HYST procedures with any subsequent admissions within 30 days following the procedure, and for LabID Events, access to either a) ADT data and complete inpatient and outpatient laboratory records for 40 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.

Chapter 3: Activities During and After the Facility Site Visit

Suggested Tools to bring along for validation site visits

- 2023 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 review
 - Confidential list of HAIs reported by facility to NHSN (ensure that validators are blinded until after review is completed)

It is recommended that validation data are directly entered into the REDCap MRAT. However, if conducting abstractions on paper, be sure to have multiple copies of blank MRATs found **under**

Supporting Documents on the Validation webpage

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

- 2023 NHSN checklists available at <https://www.cdc.gov/nhsn/hai-checklists/index.html>
- Validation discrepancies reports (Section 6 of HAI-specific EVT)
- Methods Surveys and form to collect contact information (Section 6 of HAI-specific EVT)

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

3.1 Request documentation of current NHSN reporter training

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

3.2 Structured Medical Records Review

Validator blinding and consultation at the facility site-visit

Validator blinding as to HAI status is recommended 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 2023 MRATs. 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.

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. 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 2023 definitions.

It is recommended that validators utilize REDcap MRAT templates for ease of data entry and exporting; however, if working on paper, bring enough copies of the MRATs 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.

3.3 Review risk adjustment variables, denominator methods, and documentation

See [HAI-specific EVT](#)

It is recommended to bring a copy of the facility's most recent NHSN Annual Survey to review risk adjustment variables (teaching hospital affiliation, bed count, number of patient days, and number of admissions). Download and print a copy of the Annual Survey if this has not been done already. Location mapping should also be validated at this time.

For location mapping validation, review data for each surveillance location entered into NHSN using up-to-date information on patient demographics by location (objective data may be available from bed control or a chief nursing officer) to confirm the CDC location label assigned meets the CDC 80% rule for the assigned CDC location description (See NHSN PSC Manual Chapter 15, available at https://www.cdc.gov/nhsn/pdfs/pscmanual/pcsmanual_current.pdf).

Complete the denominator collection and surveillance methods surveys for the corresponding HAIs, found in section 6 of the HAI-specific toolkits. Surveys may be administered prior, during, or after the site visit.

3.4 Creation of Facility Summary Report

To utilize the pre-built SAS code to generate a facility summary report (recommended), go to [2023 PSC Data Validation Resources | NHSN | CDC](#), Additional Resources, Statistical Tools, and select the Patient Safety Component HAI Summary Report. This code pulls from the validation data that was entered in the REDCap MRATs. Before running the SAS code, review the instructions at the top of the code. Be sure to download and save the REDCap data to a secure location.

If completing validation on paper, validators may utilize the optional HAI Validation Summary template, found in the HAI-specific toolkits, to create the facility summary report. This form summarizes each of the HAI reporting domains: numerators, denominators, and risk adjustment variables.

3.5 Discussion of validation results with IP

Whether or not reporting errors are identified, review the data with the IP to ensure transparency and provide opportunity for discussion and feedback. If case-determinations are discordant, determine whether reporters or validators 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 by logging into SAMS and submitting a case through the ServiceNow portal, or emailing nhsn@cdc.gov with the subject line “case review for adjudication.”

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 validators. These errors should be re-assessed during a subsequent review by validators 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. An exit interview with a facility C-suite administrator would rarely be needed, unless a process improvement plan is indicated.

3.6 Post-visit

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 validation project, 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 1.4](#)).

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 ensure corrections are made by the agreed upon deadline.

Once the jurisdiction's validation project is complete, send facility data from REDCap to CDC. Step-by-step instructions on how to export and where to send the de-identified dataset can be found at [2023 PSC Data Validation Resources | NHSN | CDC](#), Additional Resources, Training Materials, and select How to Export Data from REDCap. If jurisdiction is not using REDCap to collect abstracted data, contact the NHSN Validation team by logging into SAMS and submitting a case through the ServiceNow portal, or by emailing nhsn@cdc.gov, with "External Validation Toolkit" as the subject, for alternate methods of data transfer.

Analyze aggregated data from all facilities that participated in the project – these data should be used to write and publish a state/jurisdiction summary report and be disseminated to key stakeholders.

Appendix 1: Letter Templates

Appendix 1.1: Introduction/Invitation Letter

<<Insert Date >>

<<Facility Name>>

<<Facility Street Address>>

<<Facility City, State, Zip>>

Dear <<Name of Facility Infection Preventionist>>:

I am inviting you to help in a data quality evaluation of hospital data that are reported to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). This evaluation is being conducted by <<agency/group conducting evaluation>> to learn how NHSN HAI Event surveillance data collection procedures are understood and carried out in hospitals, as well as to identify and address barriers to reporting complete and accurate data.

We are contacting you because your facility is among a subset of facilities within <<Network/state/area>> that are expected to have, on average, more data to review, or that are part of a random sample. To conduct validation, staff from <<agency/group conducting validation>> will be visiting several facilities in <<geographic area>> during <<time period month(s)/year of visits>>.

These site visits include three main activities:

1. A standardized survey to evaluate surveillance practices within your facility.
2. A review of pre-selected patient medical records, including both paper charts and any electronic records, to assess the completeness and accuracy of the data reported to NHSN.
3. Education for facility staff about Event surveillance, use of the NHSN system, and common reporting omissions and errors and their causes.

It is anticipated the visit will be completed within one to two days. On the day(s) of the visit, <<agency/group conducting validation>> staff will need a space to review patient charts and access the facility's electronic medical records systems.

Validation of the data is critical to ensure they are complete and accurate. The findings from this evaluation will be used to identify, correct, and prevent common reporting errors. Your participation is vital to these surveillance support and data quality improvement efforts.

This evaluation is not related to any regulatory surveys; no observations will be made of infection control practices or other aspects of patient care during the site visit. The identities of participating facilities will remain confidential, and all patient identifiable information will be maintained securely and remain confidential. All visits will be scheduled – no unannounced visits will occur.

In return for your facility's participation, you will have the following opportunities:

- obtain confidential feedback about your facility's NHSN reporting,
- interact one-on-one with a NHSN surveillance expert who can address any questions you may have about reporting,

- provide feedback about your experience with event data collection and reporting that will be used to help inform changes that will improve future reporting efforts, and
- may be of value to you in preparation for CMS validation activities.

Please confirm your interest in participation by contacting me with available dates for a site visit during the months of <<*site visit time period*>>. Once you confirm your participation, we will contact you, as well as an administrative leader within your facility, to schedule a mutually agreeable date for the site visit and ask you to prepare some information on the patients at your facility during <<*evaluation period*>>.

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

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

Sincerely,

<<*Primary Contact's Name*>>

<<*Primary Contact's Title*>>

<<*Agency/Group's Contact Information*>>

Appendix 1.2: Sample Letter Requesting Site Visit and Line Listings for External Validation

Please customize this template to meet your jurisdiction's needs

To: <<Name of Facility Leader (i.e. CEO)>>

Cc: <<Name of IP>>

The <<agency/group conducting evaluation>> will conduct a review of surveillance practices and reporting of healthcare-associated infections in <<multiple/all>> hospitals statewide, focusing on 6 different metrics for 2023 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 surveillance locations, surgical site infections (SSI) following colon (COLO) and abdominal hysterectomy (HYST) procedures, and proxy measures for MRSA bacteremia (MRSA bacteremia LabID Event) and *Clostridioides difficile* infection (CDI LabID Event). <<Modify metrics as indicated>> Participation in the audit is

[Select as appropriate]

- <<obligatory, to ensure compliance with state healthcare-associated infection (HAI) reporting legislation and ensure that facilities are accurately identifying and reporting HAIs>>. OR
- <<voluntary, but may be of value to you in preparation for CMS validation activities, and by ensuring 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 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 the statewide validation project will be shared publicly, as well as with CDC, 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 site visit 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 validation.

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 (for example 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

A complete list of surveillance location blood cultures identifying organism(s) for 2023, with additional variables based on the template below. NICUs should be included (if applicable). Line listing of cultures should include all positive cultures taken during ANY surveillance location (SL) stay, the day of transfer from the SL, or the following calendar day after transfer.

1)

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 surveillance patient Location	Sex	*Date of Birth	First Name	Last Name
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A complete list of positive urine cultures from surveillance locations for 2023, 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. Line listing of cultures should include all positive cultures taken during ANY surveillance location (SL) stay, the day of transfer from the SL, or the following calendar day after transfer.

2)

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 surveillance Location	Sex	*Date of Birth	First Name	Last Name
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Note: The term “surveillance locations”, abbreviated SL, is used in the toolkit to indicate that only in plan NHSN-reporting locations (part of monthly reporting plan) will be included for the validation efforts for CLABSI and CAUTI.

- Validation of CLABSI in NHSN-reporting surveillance locations: includes NICU locations
- Validation of CAUTI in NHSN-reporting surveillance locations: excludes NICU locations
 - NICU is considered off plan (not part of CAUTI monthly reporting plan), and therefore not a mandatory reportable surveillance location for CAUTI.

A complete list of blood specimens positive for methicillin-resistant *Staphylococcus aureus* (MRSA), among inpatients facility-wide FacWideIn) for 2023, with additional variables based on the template below. 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.

3)

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	Sex	*Date of Birth	First Name	Last Name
------	--------------------------	-----------------------------	---------------------------	--	---	--------------------------------	-----	----------------	------------	-----------

- 4) A complete list of positive *Clostridioides difficile* stool specimens among inpatients facility-wide (FacWideIN) for 2023, with additional variables based on the template below. 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. 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	Sex	*Date of Birth	First Name	Last Name
------	--------------------------	-----------------------------	---------------------------	---------------------	---------------------------------	-----	----------------	------------	-----------

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 validation. In addition, we request a monthly count of selected 2023 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:		
2023 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 validation 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 1.3: Sample Letter Requesting Availability of Medical Records for Validation

Please customize this template to meet your jurisdiction's needs

Dear <<Name of IP>>

As we discussed in our letter of <<date>>, the <<agency/group conducting evaluation>> plans to validate surveillance practices and reporting of healthcare-associated infections (HAIs) for 2023 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 validate during review, scheduled for <<date(s)>>. We appreciate your assistance in ensuring that our team of <<X>> reviewers will have access to adequate working space, any necessary system passwords, and access 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. If questions arise, we can be reached at the following number <<XXX-XXX-XXXX>>:

Sincerely,

<<Primary Contact's Name>>

<<Primary Contact's Title>>

<<Agency/Group's Contact Information>>

Appendix 1.4: 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 jurisdiction's needs

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

Dear <<Facility Leader (i.e. CEO) Name>>,

The <<agency/group conducting evaluation>> Healthcare Associated Infection (HAI) Reporting Program completed a validation site visit at your facility for <<year>> at your facility. We wish to thank you and your staff, particularly the Infection Prevention, Microbiology, and Medical Records staff for their cooperation and the effort they contributed during our review and validation process.

The purposes of validation were initially presented to you in the letter of notification. Based upon our review of <<X>> medical records during the review, there were <<for example: 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: <<for example: 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 <<he/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 <<him/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 2023 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>>.

Sincerely,

<<Primary Contact's Name>>

<<Primary Contact's Title>>

<<Agency/Group's Contact Information>>

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

Dear <<Facility Leader (i.e CEO) name>>,

The <<agency/group conducting evaluation>> Hospital Acquired Infection (HAI) Reporting Program completed a validation 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 validation 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>> review, 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 validation. 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-validation 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 <<jurisdiction>> 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 validation 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>>.

Sincerely,

<<Primary Contact's Name>>

<<Primary Contact's Title>>

<<Agency/Group's Contact Information>>

Appendix 2: 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 [that is, 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 (for example, a patient) to be used or disclosed for the treatment or preventive care (for example, vaccinations or quarantine) of other persons (for example, 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 (for example, 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 (for example, 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>.