National Healthcare Safety Network (NHSN) Validation Guidance and Toolkit 2012

Validation for Central Line-Associated Bloodstream Infection (CLABSI) in ICUs

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

NHSN
National Healthcare Safety Network

Healthcare-associated Infections
HAI Elimination

Contents

National Healthcare Safety Network (NHSN) Validation Guidance and Toolkit 2012; Validation for Central Line-Associated Bloodstream Infection (CLABSI) in ICUs

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About the 2012 NHSN Validation Guidance and Toolkit

Purpose: This first release of the NHSN Validation Guidance and Toolkit provides recommended approaches to investigate and enhance the accuracy and completeness of 2012 NHSN CLABSI data, including suggestions for internal quality assurance by reporting facilities, and methods for surveys and on-site audits by health departments (or their agents) to assess use of NHSN methods and definitions. Because CDC makes changes to NHSN definitions, criteria, and surveillance methods in response to field experience, user input, and new knowledge of infections and how they are diagnosed, tools and guidance for HAI data validation are likely to evolve. In this first version of guidance, targeted external validation, aimed at facilities with higher risk of CLABSI due to exposure to more central line days or higher risk patient populations, is recommended for efficient assurance of data quality under constrained resources. Facilities at lower risk for CLABSI will also have some opportunity to undergo validation as part of a 5% random sample. The recommended methods are considered an initial step toward building a validation program with capacity for probability sampling. We include tools for internal investigation of data quality by facilities reporting to NHSN, surveys to evaluate knowledge and use of surveillance methods, and a step-by-step external auditing approach in the toolkit.

States that are beginning a CLABSI validation program are encouraged to use the methods and tools recommended herein, which are intended to promote a robust national standard for CLABSI validation. States with existing validation programs are encouraged to investigate the guidance and toolkit, to incorporate any elements of the toolkit that may be missing from their current approach, and to consider ways to meet or exceed the goals recommended in the national standard as well as their own validation program goals. This guidance is not meant to supersede existing robust validation programs.

Intended Audience: This document is designed for use by infection preventionists and quality professionals at healthcare facilities that report to NHSN, state health department personnel (and/or their agents) who work with healthcare facilities to assure high-quality, actionable surveillance data to enhance patient safety, and other groups that seek to enhance NHSN data quality for surveillance, reimbursement, quality improvement, research or public reporting purposes.

Comments and Feedback Welcome:

This document presents a methodological approach that draws upon prior validation efforts and that that will benefit from the additional experience of those who conduct validation. Future versions of this guidance document will provide updated validation methods that refine or extend this initial iteration. Future guidance for validation of additional HAIs is anticipated. Please direct any comments or suggestions for improvement to the NHSN Helpdesk: NHSN@cdc.gov

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The guidance and toolkit recommendations are the sole responsibility of the Centers for Disease Control and Prevention (CDC) and should not be regarded as having the receiving the endorsement of any individuals or organizations outside of CDC.

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Abbreviations, Terms, and Acronyms Used in this Document

ADT	Admissions/discharges/transfers
AUDIT	On-site medical record review to evaluate concordance of reported data with findings using NHSN methods
BSI	Bloodstream infection
CCN	CMS facility identifier
CDC	Centers for Disease Control and Prevention
CEO	Chief executive officer
CL	Central line
CLABSI*	(NHSN) Central line-associated bloodstream infection
C-SUITE	Senior executives (of a healthcare facility)
CMS	Centers for Medicare & Medicaid Services
DOB	Date of birth
DOH	Department of health
EMR	Electronic medical record
EXTERNAL VALIDATION	Survey and audit process by external agency to assure quality of NHSN surveillance and reporting
GI*	(NHSN) Gastrointestinal system infection
HAI*	(NHSN) Healthcare-associated infection
IAB*	(NHSN) Intra-abdominal infection; a subset of GI*
INTERNAL VALIDATION	Active efforts by a reporting facility to assure completeness and accuracy of NHSN data
IP	Infection preventionist
IT	Information technology
LCBI 1,2,3*	(NHSN) laboratory-confirmed bloodstream infection criteria
LOS	Length of stay (days)
MRN	Medical record number
MRSA, MSSA	Methicillin-resistant *Staphylococcus aureus,* Methicillin-susceptible *Staphylococcus aureus*
NICU	Neonatal intensive care unit
NP	Nasopharyngeal
NHSN	National Healthcare Safety Network
OrgID*	(NHSN) NSHN facility identifier
PDS	Post-discharge surveillance
POA	Present on admission
PROBABILITY SAMPLE	Sample based on randomization or chance that allows calculation of confidence intervals regarding how well the overall population is likely to be represented
PURPOSIVE SAMPLE	Sample taken with a purpose in mind (See also, targeted sample)
QIO	Quality Improvement Organization
SIR	Standardized infection ratio
TARGETED SAMPLE	In this document, purposive sample taken targeting facilities at higher risk for CLABSI or medical records at higher risk for misclassification of CLABSI status (See also, purposive sample)
TERTILE	Lowest, middle, or highest one-third of a group
UTI*	Urinary tract infection
VALIDATION	Assurance that reported NHSN surveillance data meet requirements for which they were intended

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

Chapter 1 Overview

This section contains

VALIDATION Assurance that reported NHSN surveillance data meet requirements for which they were intended

The American Society for Quality defines validation as "the act of confirming a product or service meets the requirements for which it was intended."[1] In discussing validation of National Healthcare Safety Network (NHSN) surveillance data, we extend the concept of validation to include assurance of NHSN data quality, by recommending documentation and correction of identified and systematic reporting errors. NHSN validation addresses the three domains in reporting of healthcare-associated infections (HAIs): denominators, numerators, and risk adjustment variables. For central line-associated bloodstream infections (CLABSIs), validation of denominator quality uses a survey to assess knowledge and practices of those counting patient days and central line days, review of manual denominator data entry logs for completeness, documentation that electronically derived denominators have been validated within 5% of manual denominators, and longitudinal data analysis. Risk adjustment variables (patient care location mapping, bed-size and medical school affiliation) are validated during an on-site survey. Completeness and accuracy of numerator data are validated through an on-site audit of medical records that requires several steps:

- Sampling of facilities
- Sampling of medical records within selected facilities
- Medical record abstraction
- Comparison of reported information with audit findings and outcomes, with calculation of sensitivity, specificity, and predictive value positive of facility reports.

Upon completion, a validation summary report is developed for the facility, addressing the three surveillance domains, with recommendations for past data correction, surveillance program improvements, and/or additional surveillance program support when appropriate.

Because the audit sample is targeted and un-weighted, aggregated analytic findings are not necessarily indicative of NHSN data quality throughout the state. Ideally, state health departments would be able to aggregate facility-level findings to provide a quantitative indicator of NHSN data quality for the population under surveillance. For this reason future versions of this guidance may recommend a standardized method for a probability sample.

Why Validate?

NHSN and its precursor, the National Nosocomial Infection Surveillance System (NNIS), were launched as voluntary, confidential HAI reporting systems for hospitals conducting internal surveillance, benchmarking, and quality improvement for HAIs. Since 2006, NHSN data have been used by state and federal agencies for public reporting purposes, and these data will soon be used to financially incentivize quality improvement by setting reimbursement rates. Therefore, the completeness and accuracy of the data have become increasingly important. Hospital boards, administrators, and clinical leadership need to trust their own facility's data to assess performance, and to know that other facilities are held to the same high standards. Consumers expect that publicly reported data are valid. These requirements are challenging because NHSN definitions are complex and may involve tracking and linking information from multiple hospital systems (e.g., laboratory, admissions, and clinical data); coordinated data collection, interpretation, and entry by multiple staff members; and sometimes require subjective interpretation, all of which

1 The American Society for Quality, Quality Glossary, http://asq.org/glossary/v.html, accessed Oct 2, 2012

add opportunity for variation. This complex landscape will continue to change over time with anticipated co-evolution of NHSN methods, increasing use of electronic health records, and expanded reporting requirements. In the context of powerful inducements for facilities to "look good", meaningful external validation is essential to assure that NHSN surveillance meets the requirements for which it was intended; that outcomes for reporting facilities are appropriate, that NHSN data are credible, and that the focus of NHSN surveillance will be better patient care.

In order to provide for fair comparison of facilities, standard surveillance and reporting methods must be adequately resourced and adhered to, data accuracy and completeness must be optimized, and risk adjustment for patient mix applied appropriately. Validation is an important step toward assuring that reported NHSN data are actionable and motivate improved infection control efforts rather than strategies to avoid accountability for HAIs.

Accurate, high quality NHSN data are important to infection preventionists for setting prevention priorities and measuring the impact of their prevention activities. These data also are important to facilities, practitioners, and the public as a means of assuring credible facility comparisons and compensation decisions, and improving healthcare outcomes. Further, public health agencies at the local, state and federal levels need these data to identify HAI problems and to measure prevention program success. Each of these data users also has a role and a stake in assuring quality of NSHN data.

Validation should strive to address data quality across several components that comprise HAI measures. This includes the completeness and accuracy of (1) the population denominator at risk for the HAI, (2) identified cases, and (3) reported data elements, including those used for risk adjustment.

Types of Validation

"Intrinsic validation" is an automated process built into a computer application that controls the values and types of data that are entered into the system. Point-of-entry validation is a process for routinely checking whether data are reasonable, complete, consistent, and formatted in accordance with system requirements. Intrinsic validation of data entered into NHSN serves as a means for detecting and preventing some input errors However, intrinsic validation does not prevent all errors and does not assure the quality and completeness of HAI case ascertainment or the caliber of numerator and denominator data acquisition.

"Internal validation" is a systematic process that enables facility personnel themselves to assess whether sound surveillance methods, optimal healthcare data sources, and the highest caliber data abstraction and entry are in use when numerator and denominator records are completed and submitted to NHSN. Investigations of surveillance practices and analysis and follow-up of aberrant or outlying results are the main methods of internal validation. Modifiable analysis tools in NHSN including line listings, charts, frequency tables, rate tables, and standardized infection ratio (SIR) tables are provided to simplify the job of exploring current NHSN data for duplicate or outlying elements. Longitudinal trends can be explored using run charts. As NHSN group users, state health departments can also prompt facilities to conduct internal validation when they identify aberrant NHSN data. Internal validation for CLABSI is discussed in Chapter 2.

"External validation" is a survey and audit process conducted by an agency outside the reporting facility (e.g. health department), in which a facility's surveillance determinations and methods are assessed by one or more validators who work for the agency and who are trained to evaluate completeness and accuracy of reporting. External validation complements internal validation by systematically reinforcing the obligation of facilities to conduct complete and accurate surveillance. Findings from external validation can be used to correct misconceptions about NHSN definitions, criteria, and data requirements. As a result, external validation can help assure adherence to NHSN's specifications for HAI reporting, in large part by identifying and correcting shortcomings that can be difficult to address through internal validation alone. Corrections to past data should be required, and helping reporters understand what led to the errors enhances the likelihood of better reporting in future. Challenging cases and lessons learned can be documented and built into teaching programs and shared with other reporting facilities to improve future reporting elsewhere. Chapter 3 of this document focuses on a standardized approach to external validation of CLABSI.

Sampling in External Validation

Sampling of hospitals and medical records for review can be done in a variety of ways to meet different goals. It is typically not possible or necessary for validators to visit every facility and review every patient record in search of candidate HAIs. Sampling is a practical necessity, and it should serve the purpose of providing an adequate test of proficiency in surveillance methods and accuracy in case-classification. This first version of the NHSN Guidance and Toolkit primarily recommends use of **targeted sampling** (a type of purposive sampling) for efficient investigation of likely surveillance and reporting

problems in facilities where CLABSIs are most expected, based on increased central line days and/or high-risk patient care locations. In recommending an un-weighted targeted sample, the ability to derive generalizable information about the population as would be possible with **probability sampling** is compromised. Although there are different ways to devise a targeted sample for HAI data validation, we propose a single algorithm derived from targeted sampling strategies already in use that is methodologically sound, meets the need for a standard approach, and is achievable in states throughout the U.S. regardless of their HAI data validation experience. States are encouraged to begin healthcare facility and medical record sampling using this method and to make the most of their available resources. States with sufficient resources to do more should not be constrained by the algorithm if they want to pursue more ambitious goals. Because all facilities should be held accountable for accurate reporting, facilities at lower risk for CLABSIs will also be eligible for auditing as part of a 5% random sample of facilities that is drawn after the higher risk facilities have been selected by targeting.

Chapter 2 Internal Validation of CLABSI Data Quality

INTENDED AUDIENCE Reporting facilities

This section contains

- Intrinsic Data
- Internal Validation
  - Facility info
  - Suggestions
- Tools

Intrinsic Data Quality

Data cross-checks and rules built into NHSN's web interface for data entry are designed to reduce keystroke errors and provide an internal mechanism for assuring valid data are entered. Examples of data cross-checks and rules for CLABSI data entries are listed in Table 1.

Table 1: Selected NHSN Date Entry Checks for CLABSI (2012)

TOPIC	Data Entry Check
DATES	Date of birth must be ≥ 01/01/1890 and ≤ current date Date of birth must be ≤ event date Date of birth must be ≤ admission date Event date must be ≥ admission date
DROPDOWN MENUS	Location of attribution for CLABSI event Pathogen identity
EVENTS	Logic to populate common commensal vs. pathogen lists Required fields given monthly reporting plan Limit maximum number of feasible events per patient, per date (e.g., only one BSI can be reported per patient per date)
SUMMARY DENOMINATORS	Format of denominator screen is driven by mapped locations Patient days must be ≥ device days for a given location

Internal Validation of CLABSI Data Quality

INTERNAL VALIDATION Active efforts by a reporting facility to assure completeness and accuracy of NHSN data

Although data cross-checks and rules that support data quality are built into NHSN, CLABSI data are subject to error in case-ascertainment, case-classification (primary vs. secondary) location of attribution, denominator reporting, and risk adjustment variables. High quality CLABSI surveillance requires that facilities assure accurate collection of denominator data (patient days and central line days), risk-adjustment variables (e.g., patient care location mapping, medical school affiliation), and recognize and correctly classify all potential CLABSI events in surveillance locations.

Recommended facility surveillance program competencies

Note: At most facilities, the infection preventionist (IP) is the team leader who coordinates collection and review of necessary information for HAI surveillance and reporting. The expanding requirements for HAI reporting, and the associated need for data completeness and accuracy, have complicated and expanded the role of the IP, and in many cases require the assistance and coordination of multiple partners within the facility. In order to preserve IP time and resources for the essential task of disease prevention activities, delegation or automation of selected surveillance tasks should be considered. Examples might include delegation of denominator counting in surveillance locations or data entry, or developing capacity for electronic denominator uploads. Team members conducting surveillance tasks need to be guided and trained to use correct methods and definitions for their assigned tasks, and held to high standards of accountability. We have used the term IP to indicate the leader of the infection control team in the following guidance.

The infection prevention team leader (IP) should strive to assure the following facility-level competencies for NHSN surveillance and validation activities:

- Ability to generate correct denominator data (line days and patient days)
  - ◊ If denominator data are electronic, documentation that electronic counts have been appropriately validated for at least 3 months, relative to manual counts (per NHSN protocol: http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf, page 4–6).
- Ability to identify all candidate CLABSI events in real time (awareness of positive blood cultures in surveillance locations among patients with central lines)
- Capacity to produce a complete list of positive blood cultures collected from patients assigned to specific facility location(s), to facilitate internal (or external) audits
- Routine assessment and tracking of candidate CLABSI events (ideally, by keeping a line listing of candidate CLABSI events and relevant decisions leading to reporting outcomes)
- Ability to correctly apply CLABSI case-definitions (ideally, as assessed by external validation), including ability to differentiate between primary and secondary bloodstream infections following NHSN protocols. Of note, NHSN definitions for alternative primary infection sites must be met in order to invoke alternative primary site designations (see TN checklists, Appendix 5)
- Assurance of appropriate risk adjustment elements (surveillance location mapping, medical school affiliation); see http://www.cdc.gov/nhsn/forms/instr/57_103-TOI.pdf and http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions_current.pdf
- Minimized data entry error (as correlated with NHSN reports)

Suggestions for IPs coordinating internal validation of NHSN data quality

Validation planning

Consider how you will conduct internal validation as you plan for NHSN surveillance, and how often you will need to check data quality. Ideally, CLABSI validation will have elements that are conducted annually (such as review of patient care location demographics and mapping during the NHSN annual survey), monthly (such as quality of uploaded denominator data), and daily to weekly (such as spot checks of denominator counting) as you conduct daily surveillance for events. Changes to facility systems (new patient care locations, modifications to electronic medical records systems) should trigger proactive investigation of effects on data quality.

Mapping, bed size, and medical school affiliation

- Review your facility patient care location demographics and bed size with regard to current NHSN location descriptions. Use this information to validate location mapping information in NHSN (found in the NHSN Annual Survey). Be sure all reporting locations are

mapped to locations according to the NHSN protocol. This is important because it can affect benchmarks, risk adjustment, and reporting to CMS. It is important to map correctly before reporting data, because data linked to mis-mapped locations cannot be easily corrected. If you have questions, contact NHSN support: NHSN@cdc.gov.

- Review NHSN definitions for medical school affiliation, and assure that facility medical school affiliation status is accurate in NHSN.

Assuring optimal data collection methods, source data, correctness and completeness of reported NHSN data

Denominators

- Assure that those responsible for manual denominator collection know methods and definitions, such as the NHSN definition of a central line and methods for enumerating central line days. Know when the daily counts routinely take place and conduct periodic spot checks of manual denominator counting accuracy. Review daily logs to determine frequency of omissions. Ideally, this should be done on a rotating basis by location, so that each location is spot-checked periodically.
- Review how you and your team will appropriately handle missing denominator data for surveillance locations.
- If transitioning from manual to electronic denominator data collection, assure electronic data counts are within 5% of manual data collection (accurate correlation is required for 3 months; see Facility Self-validation Tool, Appendix 1). Conversion to electronic denominator data collection can be challenging and require focused efforts engaging information technology staff,[2] but is required by NHSN protocol (http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf, page 4–6).
- If already conducting electronic denominator collection, suggest that each location re-validate by manual counting one month per year, to assure continued accuracy. Ideally, this will occur on a rotation, so that any centralized changes to hospital systems that affect electronic denominator collection in all locations can be identified early. Assure accuracy of the manual count for this exercise.

Numerators

- During surveillance, IPs should be aware of and investigate ALL positive blood cultures in their facility for possible CLABSIs. Keeping a record of decisions about CLABSI status for positive blood cultures in surveillance locations will document IP engagement, which may be useful during in an audit process. Most blood cultures will not require in-depth review before CLABSI is ruled out; one approach to efficient review designed specifically for ICU CLABSI is found in the Medical Record Abstraction Tool (Appendix 5).
- For BSI events that initially meet criteria for CLABSI, but for which an alternative primary infection is being considered, using the Tennessee Audit Checklists (Appendix 5) is recommended to assure accurate case-classification. These checklists are available in dated versions that follow changes in NHSN definitions; use of the correct version is necessary.
- To assure that CLABSI events are not overlooked, IPs should request a summary line listing of positive blood cultures for surveillance locations at least annually to compare against their list of previously investigated blood cultures. If positive blood cultures are identified by the line listing that were not reported to infection control in real time, this should be investigated and corrected, as an essential component of comprehensive infection control. If the IP has investigated positive blood cultures or reported CLABSIs that are NOT found on the summary list from the microbiology laboratory, this should be investigated and corrected.

Investigating reported data through NHSN analysis

- Explore NHSN CLABSI data by location and pathogen. As a start, run pre-programmed NHSN data quality output programs in NHSN Analysis. These programs are modifiable so that you can look at data in different ways. Updated guidance for using NHSN analysis programs is available on the NHSN website(http://www.cdc.gov/nhsn/PS-Analysis-resources/reference-guides.html), including analysis quick reference guides for how to modify many aspects of analysis. These include methods to generate line listings, frequency tables, rate tables, SIR tables, bar charts, pie charts, longitudinal run charts, and statistical calculations.
- Explore location-specific CLABSI rates, SIRs, and CL utilization ratios, using the NHSN Rate Table option. Use this information to plan for prevention activities.
- Review longitudinal reports of CL days and patient days, longitudinal trends in numerators and denominators, SIRs, and investigate inconsistencies.

Tools for Internal Validation of CLABSI

Appendices 1, 2, 5

2 Chernetsky Tejedor SC, Garrett G, Jacob J, Stein J, Phillips L, Meyer E, Dent Reyes M, Robichaux C, Steinberg JP. Electronic documentation of central line-days; validation is essential. Presented at SHEA 2011 Annual Scientific Meeting, Abstract 308.

Chapter 3 External Validation of CLABSI in ICUs; Denominator Methods Survey and Auditing of ICU CLABSI Determinations

INTENDED AUDIENCE State Health Departments and other NHSN Auditors

AUDIT	On-site medical record review to evaluate concordance of reported data with findings using NHSN methods
EXTERNAL VALIDATION	Survey and audit process by external agency to assure quality of NHSN surveillance and reporting
TARGETED SAMPLE	In this document, purposive sample taken targeting facilities at higher risk for CLABSI or medical records at higher risk for misclassification of CLABSI status

Overview

External validation of NHSN CLABSI data is conducted by an agency outside the reporting facility. This guidance and toolkit recommends an external validation process that is conducted on-site at reporting facilities by trained validators, using NHSN methods and definitions as the gold standard, with CDC acting as adjudicator when necessary. Ideally, validators are either situated at or contracted as agents of a state or local health department that has oversight responsibilities for patient safety and public health in the healthcare facilities located in its jurisdiction. Recommended external validation includes review of patient care location mapping and other variables used for risk adjustment, and an audit of medical records to assess concordance of reported facility determinations and auditor determinations of CLABSI numerators. It also includes a denominator collection survey that may be administered off-site.

CDC Perspective on External Validation Programs

At least some external validation should be done annually to encourage accountability for accurate reporting, and what is done should be quantified to allow reliability of reported data to be assessed. CDC includes information about validation in the annual National and State Healthcare-Associated Infections Standardized Infection Ratio Report. Every eligible facility should be at some risk for auditing, but it is unlikely that every facility will be reached by validators every year or that every medical record will be sampled. Taking resource constraints into account, we propose methods for states to gain external validation experience, while targeting available resources efficiently and where they are likely to provide meaningful impact. External validation of NHSN data, such as through a systematic audit, is relatively new. The initial publication of CDC's recommendations for external validation of NHSN data is intended to serve as a

This section contains

starting point. Field experience and further development of CDC's recommendations will be needed to ensure that the validation methods are optimized and operationalized to the fullest extent. Feedback from validators is requested during and after implementation.

The algorithm that follows is intended to set meaningful goals that are achievable, standardize a methodological approach that can be used widely, and serve as a starting point for states that are beginning auditing and validation. States that have many facilities will be asked to reach a larger number but a smaller proportion of facilities than states with fewer facilities.

Before the Audit

Assure or update auditor expertise

Surveillance and validation require rigorous adherence to standard NHSN protocols, surveillance methods, and NSHN definitions as written. NHSN specifications are updated at least annually and are often nuanced. Persons conducting audits must be trained in NHSN specifications, remain up-to-date when changes are made, and commit to using current NHSN methods and definitions to validate HAI data reported to the system.

Experience working in infection control is an advantage for auditors but does not necessarily assure (and cannot substitute for) rigorous implementation of current NHSN definitions and surveillance methods. When clinical experience is at odds with surveillance case-definitions, it must be set aside for reporting and validation. All auditors should demonstrate attention to detail and have experience in conducting systematic record reviews. Developing expertise in NHSN takes time, effort, and mentoring. Willingness to seek help when needed from NHSN on definitions and criteria is important in assuring that a standard approach is used to determine whether or not a difficult case meets NHSN specifications for an HAI. If facilities and auditors cannot agree on case-status using the NHSN case-definition, the case should be referred to CDC for adjudication. Forms for tracking problems, discrepancies and cases requiring adjudication are found in Appendix 6 and Appendix 8.

A certification process for auditors does not yet exist. However, currently available training exercises and other resources designed for NHSN reporters should be considered as basic to auditors. These include:

- A variety of on-line resources, including interactive case-studies that test basic NHSN skills at http://www.cdc.gov/nhsn/training/. For these exercises, ALL NHSN users are expected to attain 80% or better; auditors should also understand and be able to explain these case-studies.
- CDC-sponsored trainings.
  - NHSN blast emails (delivering updates every January), State Users calls, the NHSN newsletter, and the NHSN Manual with information on updated methods and definitions.
  - Review and use of the ICU CLABSI Medical Record Abstraction Tool and the Tennessee validation checklists (Appendix 5).

To assure that NHSN auditors are achieving uniformly high standards, CDC plans to conduct repeat abstraction of a subset of records in several validating states each year. In order to develop auditor training materials, all states conducting validation are encouraged to identify or compose one or two challenging case-studies annually, derived from discordant (auditor vs. reporting facility) and contested cases, and submit them to the NHSN help desk (NHSN@cdc.gov) for review.

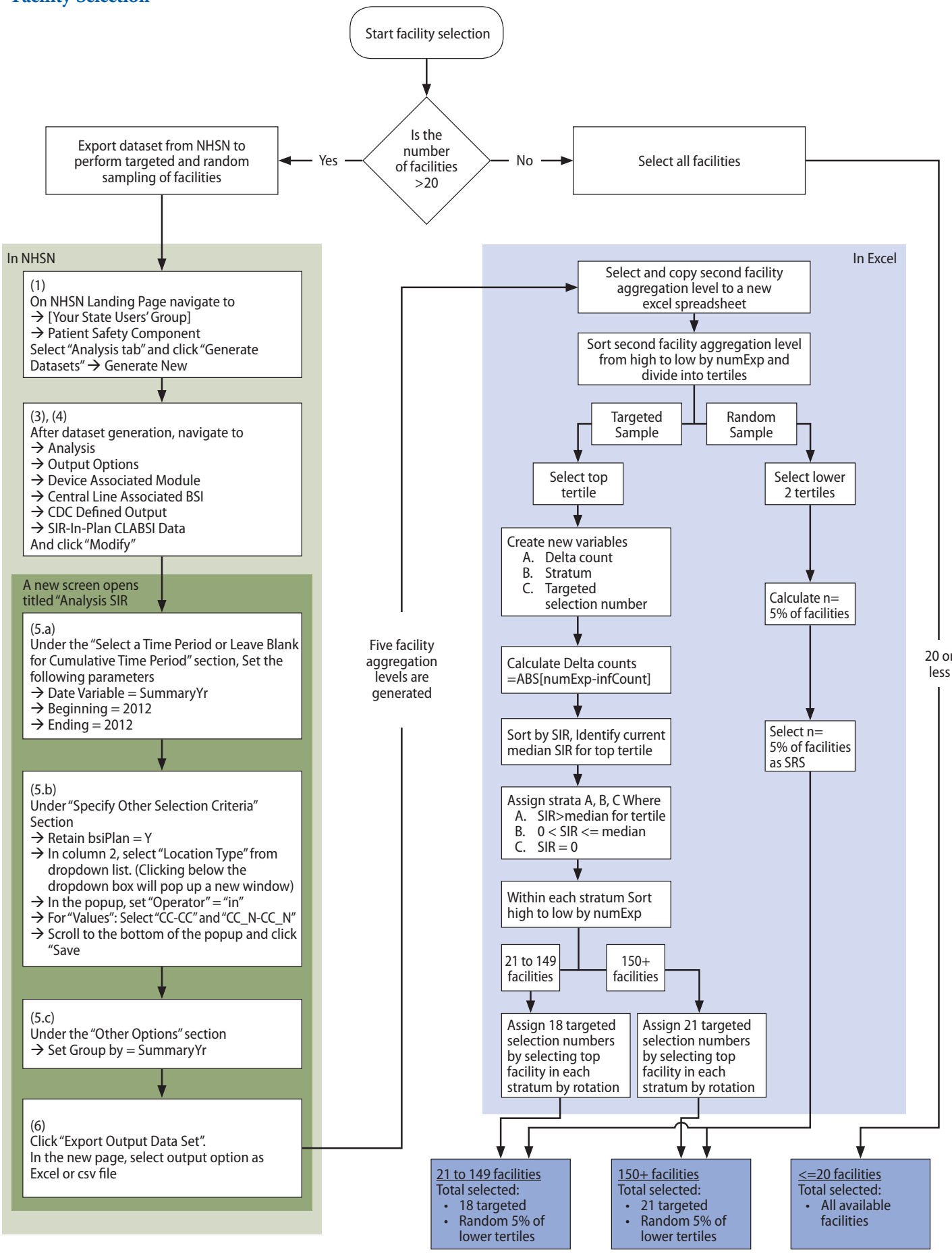
Establish a mechanism for secure data transfer between facilities and the state health department

To build a sampling frame for medical record selection, states will need to request electronic files (spreadsheets) that list positive blood cultures from facilities, including protected health information. Some states have established secure ftp sites for this data transfer. Consider existing systems for secure data transfer used in your state, and how you will secure these data.

Facility selection: The "Targeted Top Tertile Plus 5 Percent" Plan

The following guidance is specific to defining a facility sample for CDC-recommended validation of 2012 ICU CLABSI data. States that wish to add facilities to the CDC-recommended sample (or to expand validation in other ways such as adding HAIs, or CLABSI validation in locations beyond ICUs) are encouraged to do so if they have validation resources that surpass those needed for sampling described here. Under this guidance, the NHSN analysis function is used to download information about facilities participating in the group function, and this information is used to stratify facilities by expected number of CLABSIs. Facilities are either targeted or randomly selected using the algorithm. The final sample of facilities will be limited to those participating in the CMS Inpatient Quality Reporting (IQR) Program; this information is not available by NHSN download. States can identify their IQR participating hospitals by downloading the Hospital Compare database from the CMS website, at http://www.medicare.gov/download/downloaddb.asp. From this website, choose <Hospital Compare> from the "Select a database" dropdown

Facility Selection



box. Participating hospitals are listed by state in the file <Hospital_Data>.

The facility sample

In states with more than 20 eligible facilities, the plan will sample facilities in two ways. First, it targets (prioritizes) facilities with the highest expected numbers of ICU CLABSIs, where validation efforts might make the most impact. Second, a 5% sample of facilities with fewer expected ICU CLABSIs is selected to assure that all facilities are 'at-risk' for an audit, and accountable for good surveillance.

How many facilities?

"Small states" with 20 eligible facilities or fewer will be asked to validate them all. "Medium states" with 21 to 149 eligible facilities will select 18 targeted facilities from the top exposure tertile (facilities with the highest expected number of CLABSIs), plus 5% of remaining (middle and lower tertile) facilities. "Large states" with 150+ eligible facilities will select 21 targeted facilities from the top exposure tertile, plus 5% of remaining facilities. For example, based on the state-specific number of facilities listed in the 2010 SIR Report,[3] the smallest state (DE) would aim to validate all 14 facilities, and the largest state (TX, with 641 facilities) would aim to validate 42 facilities (in total; 21 facilities from the top tertile of 214 facilities with the highest expected number of ICU CLABSIs, and 21 from a 5% sample of the lower two tertiles of 427 facilities), following the algorithm below.

Targeting selected top exposure tertile facilities

States with more than 20 hospitals will begin facility selection by using NHSN analysis to download reported CLABSI data for the year 2012 into an Excel spreadsheet as follows (NHSN screen shots are provided in Appendix 3a):

In NHSN

1. On the NHSN Landing Page, select [your state users' group]. Select the Patient Safety Component from the drop-down list.
2. Generate new datasets in NHSN to ensure that any updates are integrated for analysis.
    a. From the left hand navigation bar, navigate to Analysis → Generate Data Sets. Click the "Generate New" button. Allow the dataset generation process to complete—you are able to leave NHSN during the generation process.
3. After successful dataset generation, navigate to Analysis → Output Options to display the tree view list of all analysis reports available within NHSN's Patient Safety Component analysis tool.
4. Select "Device-Associated Module." Use the tree view structure to navigate past "Central Line-Associated BSI" and "CDC Defined Output," to "SIR-In-Plan CLABSI Data." Click the "Modify" button to proceed to the modification screen, which you will use to filter and export CLABSI data from NHSN.
5. On the modification screen, there are three key areas to modify—one that limits the amount of data that is displayed to the year in question, one that controls the locations to be audited (ICUs), and one that controls the level of aggregation of the data.
    a. Use the "Select a Time Period or Leave Blank for Cumulative Time Period" option to limit the time period of the data that is included in the audit. Under the "Date Variable" drop down box, select "summary Yr"; to validate year 2012, under "Beginning," type [2012]; and under "Ending" type [2012].
    b. Use the "Specify Other Selection Criteria" menu to select the locations included in the audit (All ICUs). Note: The first column already specifies "bsiPlan" = "Y", for in-plan data. Retain this.
        i. Open the drop-down list for the second column by clicking the down arrow. Select "Location Type."
        ii. Click in the box below "Location Type" to open a gray pop-up menu box for Location Type options. You will select the Operator "in" from the Operator drop-down list, and the values "CC-CC" and "CC_N - CC_N" from the Value(s) drop-down lists. These are the options for adult/pediatric ICUs and for neonatal ICUs.
        iii. Scroll to the bottom of the gray pop-up menu box and click "Save."
    c. Under "Other Options", use "Group by" to generate one single SIR for the entire one-year time period selected above, by setting the "Group by" option to be blank or "summaryYr."
6. After making these modifications, scroll to the bottom of the Analysis modification screen.
    a. Click the "Export Output Data Set" button to export the data selected by your modifications to a different file format. Clicking the Export Output Data Set button will take you to the Export Output Options screen.
    b. Use the dropdown menu to select the file

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format to export the data. In this example, we will export to an Excel file. 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.

7. For CLABSI, the exported SIR report file will be displayed at 5 different facility aggregation levels (which are color coded in the example shown in Appendix 3a). The aggregation levels are:
   a. An overall SIR for all data in the report
   b. A facility-wide SIR for each individual facility
   c. Within each facility, a location group-specific SIR based on the denominator form type (either ICU/Other, NICU, or SCA)
   d. Within each facility, a location code type-specific SIR (e.g.: an SIR for all medical ICUs or all surgical ICUs within the facility)
   e. Within each facility, an individual location-specific SIR (eg. 5W ICU).
8. Select the second facility aggregation level (Facility-wide SIR for each individual facility in the group). Copy this information to a new Excel spreadsheet.

In Excel:

9. Arrange the facilities in rank order from highest to lowest according to the number of expected CLABSIs [numExp].
10. Determine the total number of facilities and divide into equal tertiles based on highest, middle, and lowest number of expected CLABSIs. If the number of facilities is not divisible by three, include an extra facility in the upper and middle tertiles (e.g. 10 facilities; top tertile has 4, middle and low tertiles have 3 each. For 11 facilities; top and middle tertiles have 4 each and low tertile has 3). The top tertile will be used to prioritize your targeted facilities.
11. Copy the list of top tertile facilities to another spreadsheet (this is optional if you are comfortable working on the same spreadsheet).
12. Create columns for 3 new variables; "Delta count," "Stratum," and "Targeted Selection Number."
13. Calculate Delta counts for each facility. This variable is defined as the absolute value of the difference between the reported number and expected number of CLABSIs. The formula in Excel is (=ABS[row cell under InfCount]—[row cell under numExp]). Calculate the delta count for each facility (row) in the top tertile.
14. Within the top tertile facilities, sort by SIR from highest to lowest, and identify the current median SIR for the top tertile only.
15. Assign Stratum A to facilities with SIR above the current median SIR for the tertile, Stratum B for remaining facilities with SIR above zero (but not above the median), and Stratum C for facilities with zero reported infections (and SIR of 0).
16. Re-sort within each Stratum A, B, and C, by [numExp] from highest to lowest.
17. Prioritize and assign a sequential targeted selection number to facilities with the highest [numExp] from Stratum A, then B, then C, alternating until no facilities remain or the target number of facilities (18 or 21) is reached.
18. If the top tertile is exhausted, apply the algorithm to the middle tertile to complete the targeted sample.
19. All remaining facilities in the middle and lower tertile (and excluding top tertile) will be subject to selection under the 5% rule.

Random 5% sample of facilities

States with more than 20 hospitals should enumerate the facilities in the lower two tertiles and calculate the number of facilities needed to validate 5% of the lower two tertiles, and use a random number table, or a computer or calculator with a random number generator to select the sample. More information about random sampling is available in Appendix 3b.

Limiting final sample to IQR hospitals

Assure that selected facilities are participating in the Centers for Medicare and Medicaid Services (CMS) Inpatient Quality Reporting (IQR) program. Substitutions should be made for each facility that is removed for this reason, if possible.

Medical Record Selection

Sampling frame for medical record selection within each chosen facility

From each chosen facility, obtain a complete list of positive ICU blood cultures for the year 2012 to select the medical record sample before your site visit. Identify the best way to transfer these data securely between facilities and the health department. Some states have used a secure ftp site. An excel file is recommended for ease of use.

Notify Facilities and Request Positive Blood Culture List

For chosen facilities, contact the IP and discuss the audit process, your current request for a blood culture line listing (with structure described below), and likely scope

of audit (a request for up to 60 specific records to be made available during on-site validation). Ask about the required lead time for the facility to generate the blood culture line listing, and how much lead time the medical records department will need to pull the 60 records after you specify them. Ask how patient medical records can best be accessed and how they are organized; this can impact the time required to abstract the records. Disorganized records on microfilm may be particularly difficult and time-consuming to abstract. Discuss the anticipated number of days you will visit and number of reviewers you plan to bring, based on experience or the guidance to follow.

From each selected facility, you will need a complete list of positive ICU blood cultures for the year with the primary organism ("org1") identified by genus and species, so that you can develop the sampling frame in advance of the planned visit. Antibiograms are not required. Individual positive blood cultures will be distinguished by unique laboratory accession numbers with date of collection. The specimen date for the blood cultures should always be the date of specimen collection, not the date of final result or report. Importantly, the laboratory line listing should come directly from the laboratory information management system (LIMS) and NOT from an infection surveillance software system that may use data from a LIMS but is not the primary source of diagnostic microbiology results.

Every patient with a listed positive blood culture should have been assigned to an ICU location at the time the specimen was collected. The patient location is a required field. If needed, ask the IP to translate specific patient location information on the blood culture line listing to a key of mapped NHSN ICU locations, and assure that all ICU results are included. You will also need to be able to distinguish NICU from adult/pediatric ICU locations on this line listing to stratify the sample.

Validators will need to be able to identify CLABSIs reported to NHSN on the list of positive blood cultures. Although many facilities report HAIs to NHSN using the patient medical record number (MRN), this can vary. For facilities using an alternative standard identifier in NHSN reporting, matching will be based on patient name, gender, date of birth, and approximate date of event. In some situations, more information may be needed from the IP to find CLABSI patients on the line listing. Medical record number and date of birth are required. Patient name and gender are also recommended.

Patients with selected positive blood cultures will need to be linked to medical records for review. The patient medical record number (MRN) will be the primary patient identifier for this purpose, but patient name, date of birth, and admission date may facilitate the medical record review process. If the facility can provide these fields with the line listing, it may be useful at a later phase.

No information about central line status should be requested; validators will screen for this information while reviewing records.

The blood culture line listing should be provided by the facility to the state health department through a secure file transfer (for example, encrypted email, secure FTP site, or encrypted file by courier, or snail mail) sortable and searchable (e.g., .csv, Excel) file, including the following information (* indicates REQUIRED field):

1. *Unique laboratory accession number
2. *Specimen collection date
3. *Organism 1 genus and species identity
4. *Name of ICU location
5. *Medical Record Number (MRN)
6. **First Name (recommended)**
7. **Last Name (recommended)**
8. **Gender (recommended)**
9. *Patient birthdate
10. **Hospital Admission Date (recommended)**

(Facility information: Required in header of line listing, or on first page of line listing)

11. Facility identity (including NHSN facID)
12. Hospital contact
13. Contact phone
14. Contact email
15. Date of report

Example spreadsheet (* indicates required data):

*Laboratory Accession Number	*Specimen collection Date	*Organism 1 Genus and species	*Local Name of ICU	*MRN	First Name	Last Name	Gender	*Patient DOB	Hospital Admission date

Consider a mutually agreeable due date for the blood culture line listing, dates for the medical record request, and proposed date(s) for the onsite audit. For the audit, you may need to request arrangements for computer system access, work space including computer terminals or microfilm readers, system access passwords and (eventually) specific medical records.

Compose a template letter notifying the CEO and copied to IP that provides an overview of the audit process, proposed dates for the audit, and specific data and accommodations needed from hospital staff. Specifically mention infection control, epidemiology, laboratory and medical records for their significant help in this work. (See Appendix 4 for example letter). Explain the purpose of the audit to assure accountability of all hospitals in complete and accurate reporting of CLABSIs according to NHSN methods and definitions, and how validation results will be used and/or reported.

Develop the screening sample of records, using the blood culture line listing and reported CLABSIs

Overview of medical record selection at each facility:

- You will select both reported CLABSIs (up to 20 medical records, by random sample), and unreported candidate CLABSIs (prioritizing targeted pathogens from both NICU and adult/pediatric ICU locations, up to 40 records, using the strategy below). If the sample cannot be completed with targeted pathogens, other organisms should be selected to complete the sample.
- If there is a NICU, 10 of 40 (25%) unreported candidate CLABSIs should be from NICU locations and 30 unreported candidate CLABSIs should be from adult/pediatric ICUs. If there is no NICU, all 40 unreported candidate CLABSI events should be from adult/pediatric ICUs.
- Because you will be working from a blood culture line listing for the whole year, selected events are likely to be distributed throughout the year (not a convenience sample of recent events or one quarter, for example).

Sample structure:

- Total screening sample = (up to) 60 medical records, including
  - ◊ (Up to) 20 reported CLABSIs
  - ◊ (Goal of) 40 non-reported candidate CLABSIs, prioritizing targeted pathogens and stratified by NICU and adult/pediatric ICU locations. Many of these will be eliminated early because they do not have a central line.
- Total review sample = (up to) 40 records, including (up to) 20 reported CLABSIs and 20 candidate CLABSIs that have a central line

Process (see Appendix 3c):

1. From each selected facility, request a securely transmitted line listing of all positive ICU blood cultures, from all ICUs reporting to NHSN, for the entire year, with required additional variables used for medical record identification and matching to NHSN reports (See above for recommended line listing structure).
2. Assure the line listing includes positive blood cultures from all ICU locations required to report CLABSIs to NHSN, using location mapping information in NHSN
3. Assign a random number to each positive blood culture
4. Sort the list of blood cultures by MRN and admission date (if available) to generate clusters of blood cultures associated with recognizable patient records
5. Identify reported CLABSIs on the blood culture line listing
   a. Using the NHSN CLABSI list and available patient information on blood culture line listing, flag and mark blood cultures reported as CLABSIs. Create a new variable, "stratum" and assign these blood cultures and all other blood cultures in the same medical record to stratum 1.
   b. If reported CLABSIs are missing from the blood culture line listing, the list may be flawed (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 ICU CLABSIs for review
   a. Select stratum = 1
   b. Sort by random number, MRN, and hospital admission date (if available)
   c. Select the first 20 random numbers with unique medical records (defined by MRN and admission date) as your sample of reported CLABSI records
7. Identify unreported candidate CLABSI events and stratify by targeted pathogens
   a. Select stratum not equal to 1
   b. Sort non-stratum 1 blood cultures by pathogen (focusing on Organism 1 only)

i. If the organism (Org 1) is a "Targeted Pathogen" (see list), assign the positive blood culture to stratum 2. If the organism (Org 1) is not a "Targeted Pathogen," assign the positive blood culture 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 all 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 cultures by ICU type (NICU vs. adult/pediatric ICU), and create a variable NICU (Yes/No). Assign NICU status to each blood culture 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 (if available)
   c. Select the first 10 random numbers with unique medical records (defined by MRN and admission date) as your sample of NICU records containing candidate CLABSIs involving targeted pathogens.
   d. If 10 NICU medical records with stratum 2 blood cultures are not available, supplement the NICU sample with NICU records with stratum 3 blood cultures (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 (if available)
    c. Select the first 30 random numbers with unique medical records (defined by MRN and admission date) as your sample of adult/pediatric ICU medical records with candidate CLABSIs involving targeted pathogens.
    d. If 30 adult/pediatric ICU medical records with stratum 2 blood cultures are not available, supplement the non-NICU medical record sample with stratum 3 blood cultures (where NICU= No, and stratum = 3); take the initial medical records (lowest random numbers with unique MRNs to total 30 selected medical records from adult/pediatric ICUs.
11. Your final screening sample should contain: (up to) 20 medical records with reported CLABSIs, (up to) 40 medical records divided among NICU (if available) and adult/pediatric ICUs with a preponderance of targeted pathogens.
12. If medical records are not well balanced among <u>different</u> 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.

CLABSI Category		Number of Available Medical Records from Sampling Frame:	Recommended Screening Sample	Recommended Review Sample
Total Candidate and Reported CLABSI records	Total candidate and reported CLABSI records, 'N'	N	'n'=Up to 60	'n'= up to 40
Reported CLABSI	Total records with reported CLABSI, 'Stratum 1'	X	'x'= 20 (logically, all will have central line)	'x'= up to 20
Unreported candidate CLABSIs	Total candidate CLABSI records without reported CLABSI, 'Strata 2 (targeted pathogens* and 3 (non-targeted pathogens), also stratified by NICU vs. adult/pediatric ICU'	Y (Note, Y+X=N)	'y'= 40 (expect 25% from NICU where one exists, largely due to targeted pathogens; expect ~half without central line to be quickly eliminated)	'y'= up to 20 with central lines, largely targeted pathogens, from both NICU and adult/ pediatric ICU locations

*Targeted pathogens: *Candida or Torulopsis spp*. (yeast), *Enterococcus spp*., *Staphylococcus aureus*, including MSSA and MRSA, coagulase-negative staphylococcus, including non-aureus staphylococcus spp., and common gram-negative organisms (*Klebsiella spp*., *E. coli spp*., or *Pseudomonas spp*.).

Why Target 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 restricts the definition of candida pneumonia to immunocompromised patients or those with evidence of lung parenchymal invasion. 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, GI, or IAB with secondary bloodstream infection.
- 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.

Request medical records in advance of the facility site-visit

After creating the sampling frame from the list of positive blood cultures and selecting the medical records to be screened, submit your request to the facility in a secure fashion so they can pull the screening sample (n= up to 60) for your visit.

About Facility Site-visits

Facility site-visits are preferred to other means of auditing medical records, such as requesting copies of paper medical records or remote access to electronic medical records (EMRs). This may be especially important while HAI surveillance programs are development. Compelling reasons include:

- A requirement for credible, transparent validation processes. Conducting validation in plain view provides the opportunity to illustrate objectivity of validation criteria, demonstrate rigor, provide for interaction, and create trust in the fairness of the process. The interaction also provides case-based educational opportunities when errors are found, and the opportunity to learn about barriers to correct reporting. Credibility also requires

that validators be correct, up-to-date, and rigorous in applying NHSN methods and definitions.

- Data elements included in medical records (including EMRs) vary among facilities, and medical records may be incomplete relative to information used during surveillance. If objective elements critical to decision making are missing from a medical record, a site visit allows them to be introduced and considered using alternative mechanisms.
- Infection preventionists may need an external agency to help them defend their correct and consistent application of NHSN definitions for reporting of HAIs from internal challenges in their facilities. A site visit provides the opportunity to explore barriers to correct reporting, to discuss possible solutions, and if necessary, to meet face-to-face with key facility authorities.
- Infection control programs may lack adequate resources or authority to delegate important but routine tasks (such as denominator counting) in order to spend adequate time on prevention activities. A site visit provides an opportunity to observe and explore the functioning of the infection prevention program, to assess weaknesses, and enable useful recommendations to administrators, such as enhancing support from medical records, quality, OR staff, IT, and/or clerical help. Feedback to IP supervisors and hospital administration from an outside agency may be important, whether or not it results in immediate change.
- A site visit assures that facility personnel will set aside time to discuss findings and consider ways to improve the quality and consistency of the surveillance data.
- Validators can sometimes act as consultants or identify a consultant to provide assistance when indicated by high infection rates.

Validator blinding and consultation at the facility site-visit

We recommend sending 2 or more trained auditors to each facility for an on-site visit to conduct validation. This will allow for validator blinding as follows: if each auditor is asked to screen half of the non-reported medical records for presence of a central line, then to combine and mix records that require further review together with half of the reported CLABSI medical records, the two halves can be traded to establish auditor blinding. This also provides for consultation when cases are challenging. Under circumstances where one auditor conducts the site visit, medical records screening and review of all records should be conducted before reported CLABSI status is revealed.

At the Facility Site Visit

Review surveillance location mapping, location bed size, and medical school affiliation

Bring a copy of the facility annual survey with you, 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 (available at http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions_current.pdf). Validators from states that report CLABSIs from ALL inpatient locations may also wish to request a meeting with the chief nursing officer (CNO) or bed control, who would be most familiar with location-specific patient populations and most able to assist with accurate mapping and bed-size criteria in all locations. The key to accurate mapping is adhering to the NHSN definition of "CDC location" and the "80% Rule". A CDC location is "A CDC-defined designation given to a patient care area housing patients who have similar disease conditions or who are receiving care for similar medical or surgical specialties." According to the **"80% Rule,"** if 80% of patients housed in a patient care area are of a certain type (e.g., pediatric patients with orthopedic problems) then that area is mapped to that type of location (in this case, an Inpatient Pediatric Orthopedic Ward).

Review the facility's medical school affiliation. NHSN defines three levels of affiliation with a medical school; **Major:** an important part of the teaching program of the medical school and the majority of medical students rotated through multiple clinical services; **Graduate:** used by the medical school for graduate training programs only (i.e., residency and /or fellowships); and **Limited:** used in the medical school's teaching program only to a limited extent. If there are questions about status, clarify which medical school is affiliated and explore the nature of the relationship.

Use the CDC help desk if questions arise: NHSN@cdc.gov

Review denominator methods and documentation

Manually collected CLABSI denominators

For facilities conducting manual denominator collection, we recommend administering the denominator collection survey found in Appendix 2 to the IP during the site visit (assuming they have responsibility for training and overseeing others in denominator collection), and then collecting contact information during the site visit for other individuals collecting denominators in each of the surveillance locations, in order to administer the denominator collection survey later, by telephone. 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). Contact information should include collector name, contact phone number, work hours, supervisor name, and location(s) covered for each person that normally collects denominator data for each surveillance location.

The denominator data collection survey is best administered by telephone or in person and not in writing to ascertain denominator collectors' fluency with methods and definitions. It is important to directly speak with the person who collects the denominator data for each inpatient location. Results of the survey should be shared in your report to the facility IP to focus training as a component of surveillance evaluation.

While you are visiting, request to see examples of the paperwork showing the denominator collection data, which can provide insight into the reliability and consistency of this task and how any omissions are handled. Consider whether patient days and central-line days data appear to be a true daily count (different ink, different but similar numbers) or suspiciously uniform, as if "filled in" for completeness. Determine for what percent of days data are missing, and what is done for reporting on those days. A form to record your observations by surveillance location is found in Appendix 8.

Electronically collected CLABSI denominators

If the facility uses electronic denominator data collection, obtain documentation of their denominator validation process, including the initial electronic denominator validation process required by NHSN, which specifies that manual and electronic denominator counts should fall within 5% for three consecutive months (See Appendices 1, 2).

If documentation of electronic denominator validation is not available, spot check denominator data in several surveillance locations with the IP to illustrate the process during your visit, and request that the IP determine and report back to you the corresponding electronic count for the day. (Note: totals may not match perfectly due to timing of data collection). Ask the IP to train staff and conduct the required 3-month validation process during the coming year in preparation for a future audit. Explain that electronic denominator counts may be inaccurate initially, and often require iterative programming corrections in consultation with IT support until accuracy is established.

Medical record review for CLABSI numerators

1. Using the list of up to 60 medical records you requested (the screening sample) determine which of the available records contain reported CLABSIs and which contain unreported candidate CLABSIs. Each of two trained validators should take half the records from each stratum. Each validator should screen the candidate CLABSI records first for presence of a central line during the ICU stay, to quickly eliminate ineligible records. The review sample is complete when 20 candidate CLABSI charts with central lines have been identified, along with all reported CLABSIs (up to 20).
2. After removing records without central lines, each validator should mix their (up to 10) reported CLABSI records with their half of the remaining candidate CLABSI (with a central line) records together, and the validators should trade medical records to accomplish validator blinding.
3. Each validator should complete their up to 20 medical record abstractions (to total up to 40 medical records) using the ICU CLABSI Medical Record Abstraction Tool and the Tennessee Checklists, found in Appendix 5. Use NHSN definitions as the gold standard and ask for assistance if there are challenging questions. Record findings on the forms in Appendix 5 (for the state) and Appendix 6 (to be shared with facilities).

Tools to bring along for CLABSI validation site-visit

- Letter of introduction, state ID badge or other authorization, most recent Facility NHSN Annual Survey
- List of surveillance locations
- Screening Sample List of up to 60 requested medical records, with reported CLABSIs marked*
- List of CLABSIs reported to NHSN*
- Copy of Denominator Collection Methods Survey for CLABSI Surveillance (to interview IP) and (using expanded form) to collect contact information for denominator collectors serving each CLABSI surveillance location), Appendix 2
- NHSN Manual
  - ◊ Before visit: Tag/highlight case definitions for CLABSI
  - ◊ Tag/highlight location descriptions for patient location mapping
- Laptop computer with CLABSI medical record abstraction tool in Epi-Info 7 or paper forms
- TN checklists for validation (Appendix 5a) to assess case definitions for primary vs. secondary BSI
- Blank audit discrepancies report (expanded form) to

facilities, (Appendix 6).

- Straight edge (e.g.: ruler) for reading data printouts, stapler, binder clips, pens, highlighters, etc.
- Sticky notes, tape flags

During site visit and after medical record abstraction, meet with IP to discuss discrepancies

If you identify reporting errors, document and review the data with the IP. In some cases, this may not affect the case determination, but may impact reporting quality and risk stratification. For example, a common error in NICU CLABSI surveillance is reporting infant weight at the time of the event rather than birthweight, which is used for risk stratification.

If CLABSI case-determinations are discordant, determine whether reporters or auditors missed any documented information that would affect the correct result. Undocumented information cannot be considered, but you may want to consider documented specimens collected in the ED or as an outpatient that are not available in the medical record, for example. Use NHSN criteria as the gold standard. For difficult cases, seek adjudication from CDC.

Look carefully for systematic reporting errors or misconceptions that could impact reporting beyond the medical records that were reviewed. For example, initial CLABSI reporting problems may concern misconceptions regarding the definition of a central line. Reporters may believe that a dialysis catheter, or a PICC line, or a midline catheter is always a central line. NHSN defines a central line as "an intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring…. Neither the insertion site nor the type of device may be used to determine whether a line qualifies as a central line." If systematic errors are made, the facility should be asked to re-review and correct all numerators or denominators, not just those reviewed by auditors. These errors should be re-assessed during the next audit to assess improvement.

Use errors as learning opportunities for reporters and validators. These discussions may provide insight into how robust the facility's surveillance processes and competencies are, and areas where additional training may be useful to all reporters. Leave a copy of expected changes to NHSN data with IP, and agree to a deadline for changes to be made (see Appendix 6). Communicate with IP and administration about your findings, ideally in person before leaving (in general terms) and later (including survey results and in greater detail) by letter.

Find ways to commend them for excellent processes, and/or progress, to suggest improvements to minimally acceptable processes, or require a process improvement plan if serious deficiencies are found. IPs are sometimes worried that an unfavorable report may lead to sanctions or dismissal by their supervisors; if the IP is trying hard to report correctly, emphasize this in your communication to hospital leadership and consider whether additional time and experience, or additional resources are what is most needed. Dismissal of a good IP will not correct poor performance and may exacerbate reporting problems.

Post-visit

Administer the denominator data collection survey in Appendix 2 for each surveillance location (manual data collection); score and share results with IP.

Check back to assure that facilities with electronic denominator collection are working toward validation if they have not yet done so.

Compile your validation findings using Appendix 8 into a report. Send a letter to administration and infection prevention program, thanking them and documenting results, necessary corrections, and recommendations. When appropriate, identify systematic strengths as well as problems with surveillance, data collection, and reporting, and potential underlying reasons. Identify resource and support issues that should be addressed in a letter to administration (Appendix 7).

If you have required the facility 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.

Complete Facility-specific Validation Report for CDC (Appendix 8) using your completed forms from Appendix 5.

Consider which facilities are performing well and where you will next focus more support for prevention.

Tools for External Validation of CLABSI

- Medical Record Abstraction Tool (Appendix 5)
- TN Checklists for alternative primary infections (Appendix 5a)
- Appendices 1–8

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