



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

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



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

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 <i>Staphylococcus aureus</i> , Methicillin-susceptible <i>Staphylococcus aureus</i> |
| NICU | Neonatal intensive care unit |
| NP | Nasopharyngeal |
| NHSN | National Healthcare Safety Network |
| OrgID* | (NHSN) NHSN 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

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

This section contains

Purpose

Types

Sampling

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 NHSN 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 | <ul style="list-style-type: none"> Date of birth must be \geq 01/01/1890 and \leq current date Date of birth must be \leq event date Date of birth must be \leq admission date Event date must be \geq admission date |
| DROPDOWN MENUS | <ul style="list-style-type: none"> Location of attribution for CLABSI event Pathogen identity |
| EVENTS | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> Format of denominator screen is driven by mapped locations Patient days must be \geq 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

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.

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](#)

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

External Validation

CDC View

Before Audit

Expertise

Secure Data

Facilities

Records

Screening

Site Visits

Validators

80% Rule

Denominator methods

Tools Needed

Discrepancies

Post Visit

Tools

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 NHSN 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.

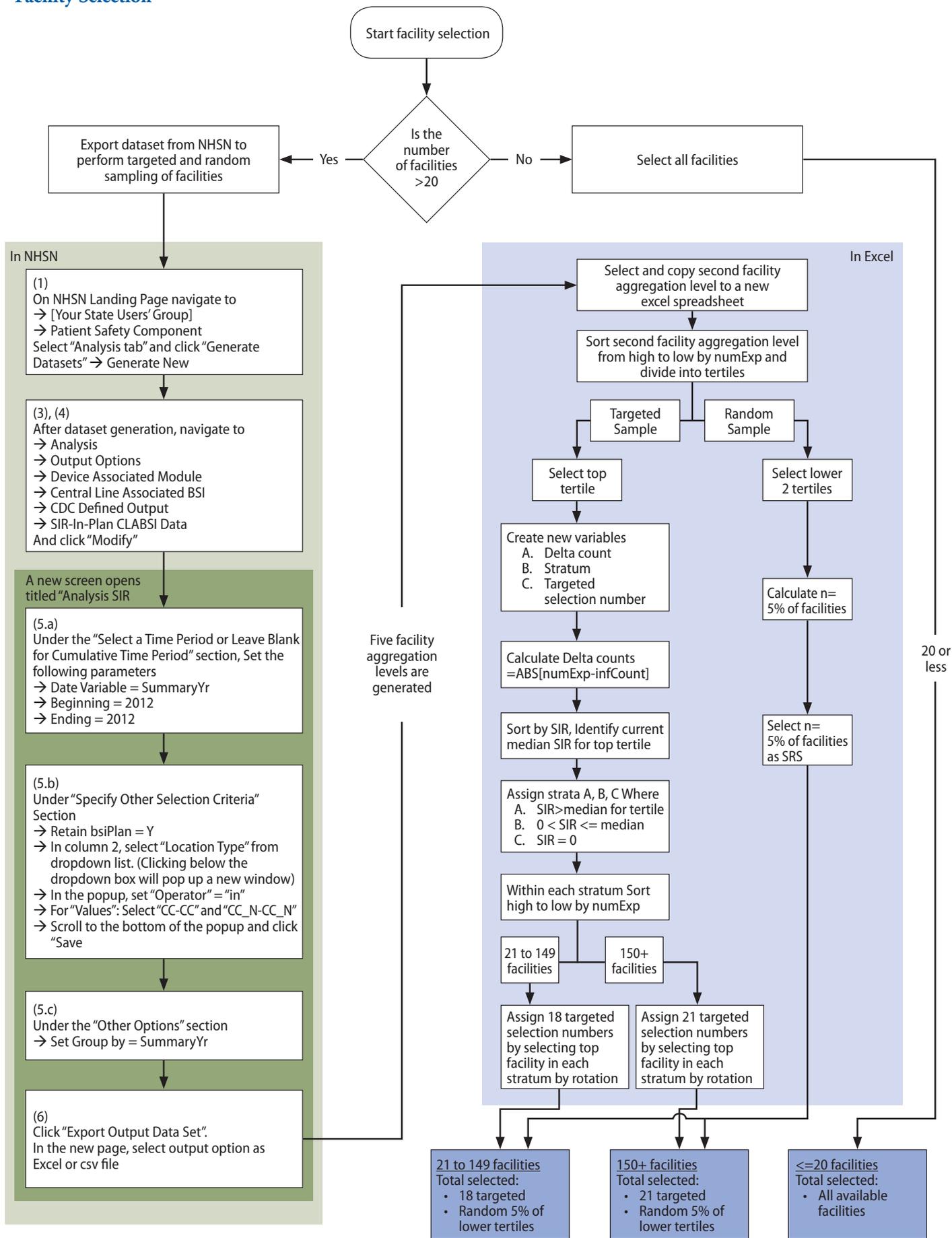
Establish a mechanism for secure data transfer between facilities and the state health department

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

³ National and State Healthcare-associated Infections Standardized Infection Ratio Report (January–December 2010)

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. Antibiofilms 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 different targeted pathogens, consider post-selection adjustment to include a variety of these organisms, in order to evaluate a variety of surveillance skills, as noted below.

| 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

References

1. 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.
2. Levy PS, Lemeshow S. Sampling of Populations: Methods and Applications. Third Edition, 1999. John Wiley & Sons, Inc.
3. McBryde ES, Kelly H, Marshall C, Russo PL, McElwain DLS, Pettitt, AN. Using samples to estimate the sensitivity and specificity of a surveillance process. ICHE 2008; 29(6):559–63.
4. Backman LA, Melchreit R, Rodriguez R. Validation of the surveillance and reporting of central line-associated bloodstream infection data to a state health department. Am J Infect Control 2010; 38:832–8.
5. Maryland Central Line-Associated Blood Stream Infections: Data Quality Review and Chart Audit, June 2010. Maryland Health Care Commission website. Published 2010. Accessed May 19, 2011. http://mhcc.maryland.gov/healthcare_associated_infections/hai/clabsi_final_rpt_20100618.pdf
6. Soe MM, Kainer MA. Sustainable, cost-effective internal data validation of healthcare associated infections surveillance reported to the National Healthcare Safety Network [NHSN]. In: Final Program Fifth Decennial International Conference on Healthcare-Associated Infections 2010; March 18–22, 2010, Atlanta, GA. Abstract 81.
7. Kainer MA, Mitchell J, Frost BA, Soe MM. Validation of central line associated bloodstream infection [CLABSI] data submitted to the National Healthcare Safety Network [NHSN]—a pilot study by the Tennessee Department of Health [TDH]. In: Final Program Fifth Decennial International Conference on Healthcare-Associated Infections 2010; March 18–22, 2010, Atlanta, GA. Abstract 456.
8. New York State Hospital-Acquired Infection Reporting System Pilot Year—2007. New York State Department of Health website. Published June 30, 2008. Accessed May 19, 2011. http://www.health.ny.gov/statistics/facilities/hospital/hospital_acquired_infections/2007/docs/hospital-acquired_infection-full_report.pdf
9. Oh JY, Cunningham MC, Beldavs ZG, Tujo J, Moore SW, Thomas AR, Cieslak PR. Statewide validation of hospital-reported central line-associated bloodstream infections, Oregon—2009. ICHE 2012;33(5):439–445.
10. Magill, SS, Hellinger W, Cohon J, et al. Prevalence of healthcare-associated infections in acute care hospitals in Jacksonville, Florida. ICHE 2012; 33(3):283–91.
11. Malpiedi P, Hota B, Magill S, et al. Interobserver variability in bloodstream infection determinations using National Healthcare Safety Network definitions. In: *Program and Abstracts of Annual Meeting of the Society for Healthcare Epidemiology of America*. Dallas: Society for Healthcare Epidemiology of America, 2011. Abstract 305.
12. Hazamy PA, Van Antwerpen C, Tserenpuntsag B, et al. Determining accuracy of CLABSI data submission for public reporting hospital-acquired infections in NYS 2007–2009. Presented at APIC 2011 Annual Conference and International Meeting, Baltimore MD, 2011.
13. Zarate R, Cummings J, Birnbaum DA. Practical method to validate the accuracy of state-wide hospital infection surveillance. Abstract #842, Fifth Decennial International Conference on Healthcare-Associated Infections, Atlanta, Georgia, March 2010.

Appendix 1 Facility Self-validation Tool for CLABSI Surveillance

(Contributor: Nicola Thompson)

This tool is a self-validation guide for facilities that have entered CLABSI data into NSHN. Following these simple steps will help to identify potential incorrect facility and location descriptions (which affect risk adjustment), and errors in denominator data ascertainment. Completion of this self-validation tool will improve the accuracy, reliability and quality of CLABSI data reported to NHSN.

| Validation component | Items to review | Suggested method |
|--|---|--|
| Annual validation plan (to accompany facility surveillance plan) | <ul style="list-style-type: none"> Number of locations where CLABSI surveillance is planned IT support if electronic reporting will be introduced | On an annual basis, consider plans for CLABSI surveillance and validation, and staffing and training needed for data collection. Include plans for staff training and data quality checks, and consider whether burden of manual data collection is sufficient that establishing and validating electronic denominator reporting is worthwhile. |
| Facility and location information reported to NHSN | <p>Facility level information reported to NHSN</p> <ul style="list-style-type: none"> Medical school affiliation Number of facility beds | <p>On an annual basis, review and confirm the following details reported to the NHSN Patient Safety Component—Annual Facility Survey are correct. Refer to the <i>NHSN documentation for definitions www.cdc.gov/nhsn/PDFs/pscManual/16pscKeyTerms_current.pdf</i>.</p> <p>(Note: in the “Key Terms” document, this information is under “Hospital Type”)</p> <p>In addition, A Table of Instructions for completion of facility surveys will be available in the NHSN Manual, Chapter 3 (Patient Safety Monthly Reporting Plan and Annual Survey), by January 2013.</p> <ol style="list-style-type: none"> Is your facility <u>medical school affiliation</u> correctly reported? <ol style="list-style-type: none"> Is your facility affiliated with a medical school? Yes or No. If yes, what type of affiliation: Major, Graduate or Limited? Make sure you know NHSN definitions for these terms. Is the <u>number of beds set up and staffed</u> for your facility correctly reported? <ol style="list-style-type: none"> Number of ICU beds? Number of Specialty Care Area (SCA) beds? Number of non-ICU, non SCA (Other) beds? |

| Validation component | Items to review | Suggested method |
|-------------------------|--|---|
| CLABSI denominator data | <p>Patient location level information reported to NHSN</p> <ul style="list-style-type: none"> Facility location label and CDC location description The number of beds reported for each location | <p>On an annual basis, review data for each patient location entered into NHSN and confirm the following:</p> <ol style="list-style-type: none"> The CDC location label assigned meets the CDC 80% rule (see Key Terms) for CDC location description (See NHSN Manual, Ch. 15, Location Labels and Descriptions) http://www.cdc.gov/nhsn/PDFs/pscManual/16pscKeyTerms_current.pdf http://www.cdc.gov/nhsn/PDFs/pscManual/15LocationsDescriptions_current.pdf The correct number of beds per location are reported <p>To assure use of up-to-date information on patient demographics by location, work with persons who have objective information such as bed-control or the chief nursing officer.</p> <p>If your facility is using an electronic database to obtain patient days and/or device days, are the data accurate? The NHSN CLABSI protocol states, "When denominator data are available from electronic databases, these sources may be used as long as the counts are not substantially different (+/- 5%) from manually-collected counts." http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf</p> <p>For each location where electronic databases are used to obtain counts of patients days and/or device days, determine if data validation was performed.</p> <p>If yes, validation of electronic data was performed;</p> <ol style="list-style-type: none"> For how many months was the validation performed? What was the % difference in patient days and/or device days between the denominator data counts obtained using manual and electronic database methods? For initial validation, the <u>NHSN manual recommends concurrent counting until 3 consecutive months of data are within 5%</u>. If the counts were <u>not within 5%</u>, continue working with IT staff to improve design of electronic denominator data extraction, while reporting manual counts, until the concurrent counts are within 5% of each other for 3 consecutive months. <p>If electronic database is used and no validation of data obtained from electronic databases has been performed;</p> <ol style="list-style-type: none"> In addition to obtaining denominator data from the electronic database, perform manual data denominator data collection, following the NHSN protocol for each location http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf For each location, compare the denominator data counts obtained using manual and electronic database methods and determine if they are within 5% of each other |

| Validation component | Items to review | Suggested method |
|-----------------------|---|--|
| CLABSI numerator data | <ul style="list-style-type: none"> Complete ascertainment of candidate CLABSIs | <p>a. If the counts are <u>within 5%</u> of each other for 3 consecutive months, the data obtained from the electronic database may be used as NHSN CLABSI denominator data</p> <p>b. If the counts are <u>not within 5%</u> of each other, the data obtained from the electronic database may not be used as denominator data for NHSN; report the manually collected denominator. In conjunction with appropriate facility staff, review data obtained from electronic databases to identify and eliminate sources of errors. Continue with manually-collected counts of denominator data until the counts obtained using each data source are within 5% of each other for 3 consecutive months.</p> <p>If manual data collection is used;</p> <ol style="list-style-type: none"> Assure that staff collecting denominator data know correct NHSN procedures and definitions for this task, and are following the NHSN protocol for each location http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf Conduct periodic spot-checks for denominator accuracy, and share results with staff for recognition of good work or to motivate improvement. |
| | | <p>Keep a record of your surveillance of positive blood cultures and decision making, and review completeness periodically. One suggested method follows:</p> <p>Maintain a line listing of positive blood cultures from patients, especially those assigned to surveillance locations when cultures were drawn, and document that you have reviewed them for possible CLABSI. You may want to record presence or absence of central line, presumed location of attribution for a bloodstream infection, and/or whether an isolate was a contaminant (common commensal unsupported by a second blood culture within 2 days). Periodically (e.g.: annually, or quarterly) assure that all positive blood cultures have been reported to you, for example by requesting a summary report of positive blood cultures and patient locations from the microbiology laboratory. Assure that the report includes assigned patient location at the time of culture collection, not at the time the report was issued. If positive blood cultures have not been reported to infection control, identify causes and remedies for this problem.</p> <p>For any positive blood cultures that meet the definition of LCBI 1, 2, or 3 in a surveillance location, document the LCBI, presence or absence of a central-line, why you consider the blood culture to be either healthcare-associated or POA, primary or secondary, and whether or not the event was reported as a CLABSI to NHSN.</p> |

Appendix 2 Template Denominator Collection Methods Survey for CLABSI Surveillance

(Derived from NM, VA, PA and NY)

Suggestion: Administer the survey in person with the person who is responsible for training and overseeing others doing denominator collection work. Collect contact information for other persons directly responsible for denominator collection in surveillance locations and administer the survey later, by telephone.

Please feel free to copy, paste, and adapt this template to your state's needs

Name of Hospital _____

| | Surveillance location | Name of data collection professional | Work hours/ Preferred time for telephone survey | Phone number(s) | Supervisor |
|------|------------------------------------|--------------------------------------|---|-----------------|------------|
| 1 | | | | | |
| 2 | | | | | |
| Etc. | <i>To be expanded as needed...</i> | | | | |

Denominator Collection Methods Survey

| | | |
|--------------|--------------|-----------------|
| Facility ID: | Interviewer: | Date of Survey: |
|--------------|--------------|-----------------|

Denominator Data Collection Questions

(interview individual directly responsible for collecting central line and patient day data)

| | | |
|---------------------------------|-----------|---------------------------|
| Name of individual interviewed: | Position: | NHSN Location(s) covered: |
|---------------------------------|-----------|---------------------------|

PATIENT DAYS

| | |
|--|-----------|
| 1. How are patient-day data usually collected for this unit? <i>(choose one)</i> | Comments: |
| <input type="checkbox"/> Electronically—collected by electronic medical record <i>(Describe and include name of software utilized)</i> | |
| <input type="checkbox"/> Manually by IP | |
| <input type="checkbox"/> Manually by clerical staff | |
| <input type="checkbox"/> Manually by unit nursing staff | |
| <input type="checkbox"/> Manually by other person <i>(specify role)</i> | |
| <input type="checkbox"/> Other Method <i>(specify)</i> | |

| PATIENT DAYS | |
|--|--|
| 2. Identify the method used to count patient days : (choose one) | Comments |
| <input type="checkbox"/> Count the number of patients currently on the unit | |
| <input type="checkbox"/> Count the total number of patients that were cared for in the unit during that day | |
| <input type="checkbox"/> Count the number of admissions for the day | |
| <input type="checkbox"/> Other (specify) | |
| 2a. Is there a specified time when the count is taken? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2b. When is it done? | |
| 3. What is done if there are missing patient day data? (choose one) | Comments: |
| <input type="checkbox"/> Allow missing information with no adjustments | |
| <input type="checkbox"/> Patient tracking /information system is used to figure out (count) missing patient days | |
| <input type="checkbox"/> Medical records are reviewed to figure out (count) missing patient days | |
| <input type="checkbox"/> Missing patient days are estimated (describe method used): | |
| <input type="checkbox"/> Other (describe): | |
| 4. Which staff member decides which approach is used for missing patient day data? | |

| CENTRAL LINE DAYS (CLD) | |
|--|--|
| 5. How are central-line day data collected for this unit? (choose one) | Comments |
| <input type="checkbox"/> Electronically—collected by electronic medical record (<i>Describe and include name of software utilized. Also briefly describe any validation done by your facility of electronically collected central-line days</i>) | |
| <input type="checkbox"/> Manually by IP | |
| <input type="checkbox"/> Manually by clerical staff | |
| <input type="checkbox"/> Manually by unit nursing staff | |
| <input type="checkbox"/> Manually by other person (<i>specify role</i>) | |
| <input type="checkbox"/> Other Method (<i>specify</i>) | |
| 6. Identify the method used to count central-line days : (choose one) | Comments |
| <input type="checkbox"/> Count the number of patients on the unit with one or more central lines | |
| <input type="checkbox"/> Count the total number of central lines in the unit | |
| <input type="checkbox"/> Count the number of central lines in use | |
| <input type="checkbox"/> Other (<i>specify</i>): | |
| 6a. Is there a specified time when the count is taken? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6b. When is it done? | |
| 7. What is done if there are missing central-line day data? (choose one) | Comments |
| <input type="checkbox"/> SUnit staff rechecks using patient information (<i>e.g.: medical record</i>) | |
| <input type="checkbox"/> IP rechecks using patient information (<i>e.g.: medical record</i>) | |
| <input type="checkbox"/> Missing central-line days are estimated (<i>describe method</i>): | |
| <input type="checkbox"/> Allow missing data with no adjustments | |
| <input type="checkbox"/> Other (<i>describe</i>): | |
| 8. Which staff member decides which approach is used for missing central-line data? | |
| 9. Does your facility keep a line listing of patients with a central line? | |

| CENTRAL LINE DAYS (CLD) | |
|--|--|
| 10. If yes, is it kept by the unit or by infection control? | |
| DAILY COUNTING QUESTIONS | |
| 11. A patient has a radial arterial line and a peripheral IV. How many central line days are counted for this patient? | |
| 12. A patient has a port which has not been not accessed, and a peripheral IV which is in use. How many central line days are counted for this patient? | |
| 13. A patient has a port which was is accessed in the ICU yesterday but is not currently in use, and a peripheral IV which is in use. How many central line days are counted for this patient? | |
| 14. A patient has a temporary central line and a permanent central line. How many central line days are counted for this patient? | |
| 15. A patient has two central lines in use. How many central line days are counted for this patient? | |
| 16. If a central line is removed at 2PM and the line day count is done at 5PM, should the line be counted? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk |
| 17. Are patient days used to estimate central-line days? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk |
| 18. Do daily patient and central-line counts include boarders? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk |
| NICU-Specific Questions (Check here and skip section if no NICU at facility) | |
| 19. How is a neonate's weight categorized when reporting central line (CL) and umbilical line (UL) days? <i>(select one)</i> | <input type="checkbox"/> Birth weight <input type="checkbox"/> Current weight |
| 20. Patients with both a CL and an UL are included in the daily count as: <i>(select one)</i> | <input type="checkbox"/> UL only <input type="checkbox"/> CL only <input type="checkbox"/> 2 separate lines |

| GENERAL | |
|--|---|
| 21. Which best describes your facility's required training for individual(s) who collect central-line days? (select all that apply) | Comments |
| <input type="checkbox"/> Electronic data download (no training needed) | |
| <input type="checkbox"/> No specific training | |
| <input type="checkbox"/> Peer training (person who has counted before explains their approach to counting to new staff) | |
| <input type="checkbox"/> Formal training once | |
| <input type="checkbox"/> Training with annual updates | |
| <input type="checkbox"/> Participation in NHSN online training | |
| <input type="checkbox"/> Other (describe): | |
| 22. Does your facility have a mechanism in place for quality control of central-line days data? | Comments |
| <input type="checkbox"/> (Electronic data) Yes, data submitted electronically is periodically checked using manual methods | |
| <input type="checkbox"/> (Manual data) Yes, manually collected data are periodically counted by more than one staff member | |
| <input type="checkbox"/> Yes, other mechanism (explain) | |
| <input type="checkbox"/> No, not really | |
| 23. Which staff member counts patient days and central line days when the "regular" data collector(s) is/are not working? | |
| 24. What do you do if no one collected information over a weekend/holiday or for another reason? | |
| 25. Which staff member(s) is/are responsible for entering ICU patient days and central line days data into NHSN? | |
| CLABSI (NUMERATOR) REPORTING | |
| 26. Which staff member(s) is/are responsible for entering CLABSIs (numerator events) data into NHSN? | |
| 27. Is entered data checked for errors? | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk |
| 28. If yes, describe method is used to check: | |
| 29. In cases of ambiguity, who makes the final decision regarding the determination of whether an infection is a CLABSI? | |

Appendix 3a External Validation; Targeted Facility Selection

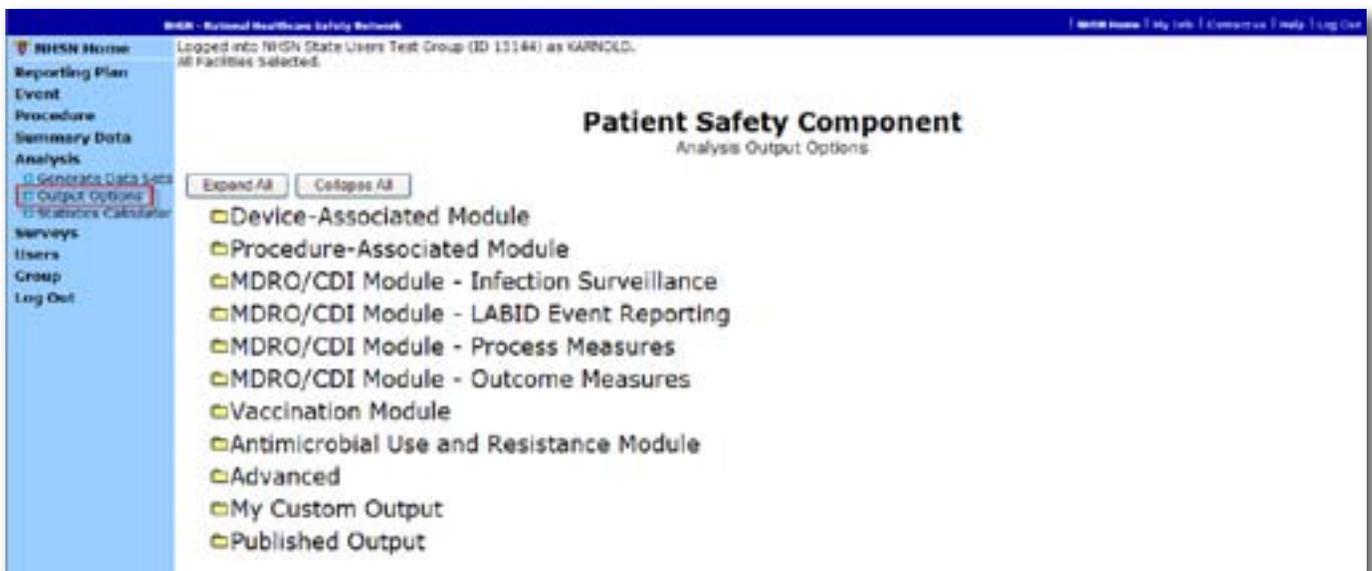
(Contributors Jonathan Edwards, Katie Arnold, Dawn Sievert, Dan Pollock, Paul Malpiedi, Arjun Srinivasan)

Methods:

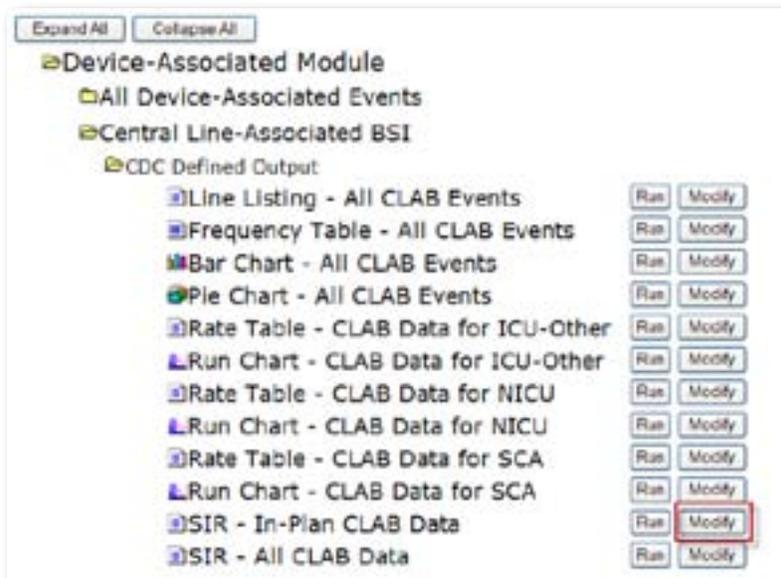
1. Generate new datasets in NHSN to ensure any updates are integrated for analysis. On the NHSN Landing Page, navigate to [YOUR State Users' Group] → Patient Safety Component. Select the “Analysis” tab and click “Generate Datasets”. Click the Generate New button. Allow the dataset generation process to complete; you are able to leave NHSN during the generation process.



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



3. Use the tree view structure to navigate to the SIR report of interest. In this example, we will select the Device Associated Module, → Central Line Associated BSI, → CDC-defined Output, → SIR for In-Plan CLABSI data. This uses data reported to NHSN that has been shared with the group. Click the Modify button to proceed to the modification screen, which you can use to filter and export data from NHSN.



4. A modification screen will open titled "Analysis SIR". On the modification screen, there are two key areas to modify, one that controls the time interval of data that is analyzed and displayed and one that controls the level of aggregation of that data.
 - ◇ Use the "Select a time period" option to limit the time period of data that is included in the report to be exported:

Select a time period or Leave Blank for Cumulative Time Period:

Date Variable Beginning Ending

- ◇ Set Date Variable to SummaryYr, Beginning to 2012 and Ending to 2012:
- ◇ Scroll down to "Specify Other Selection Criteria. Retain bsiPlan = Y. In column 2, select "Location type" from the dropdown list, Click in the space below "Location Type" to pop up new window (shown here in gray):

Specify an operator and value(s) for selection criteria:

| <u>Variable</u> | <u>Operator</u> | <u>Value(s)</u> |
|-----------------|-----------------|-----------------|
| locationType | - | |

Select a time period or Leave Blank for Cumulative Time Period:

| | | | |
|---------------|-----------|--------|-------------------|
| Date Variable | Beginning | Ending | |
| summaryYr | 2012 | 2012 | Clear Time Period |

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

Specify Other Selection Criteria:

[Show Criteria](#) [Column +](#) [Row +](#) [Clear Criteria](#)

| | | | |
|---------|-----|--------------|--|
| bsiPlan | = Y | locationType | |
| | | | |
| | | | |
| | | | |
| | | | |

◇ Set “Operator” = “in” and Value(s) to “CC-CC” and “CC_N-CC_N”. Scroll to the bottom of the pop-up screen and select “Save”:

| variable | Operator | value(s) |
|--------------|----------|--------------------|
| locationType | in | CC-CC CC_N-CC_N |

Save Clear Close

◇ Under the “Other Options” section, use the “Group by” option to view the data at a particular level of aggregation. By default, this is set to SummaryYH, or half-years. Change the Group by option to “SummaryYr”:

Other Options:

Group by: summaryYr

5. After making these modifications, scroll to the bottom of the modification screen. Click the Export Output Data Set button to export the data selected by your modifications to a different file format.



6. Clicking the Export Output Data Set button will take you to the Export Output Options screen. Use the dropdown menu to select the file format to export the data. In this example, we will export to an Excel spreadsheet (*.xls). 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 at on your computer.



7. For Device-Associated Module data, the exported SIR report file will be displayed at several levels, which are color coded and displayed in the screenshot on the next page. They are:
 - ◇ An overall SIR for all data shared with the group
 - ◇ A facility-wide SIR for each individual facility that has joined the group
 - ◇ Within each facility, a location type-specific SIR (either ICU/Other, NICU, or SCA, based on the denominator form type)
 - ◇ Within each facility, a CDC location code-specific SIR (e.g.: – an SIR for all medical ICUs within the facility)
 - ◇ Within each facility, an individual location-specific SIR (example – 5W ICU)

| J# | A | B | C | D | E | F | G | H | I | J | K | L | M | N |
|----|----------|----------|--------|-------|----------|--------------|-----------|-------|--------------|--|----------|--------|---|---|
| | InfCount | numCLDay | numExp | SIR | SIR_gval | SIR5SCI | summaryYr | orgid | locationType | loccdc | location | months | | |
| 1 | 27 | 6491 | 13.203 | 2.045 | 0.0006 | 1.347, 2.975 | 1/1/2012 | | | Overall SIR for all facilities in group combined | | | | |
| 2 | 4 | 1617 | 2.553 | 1.567 | 0.2538 | 0.427, 4.012 | 1/1/2012 | 15164 | | | | | | |
| 3 | 4 | 204 | 0.528 | | | | 1/1/2012 | 15165 | | | | | | |
| 4 | 19 | 4403 | 9.664 | 1.966 | 0.0052 | 1.183, 3.070 | 1/1/2012 | 15634 | | | | | | |
| 5 | 0 | 267 | 0.632 | | | | 1/1/2012 | 15635 | | | | | | |
| 6 | 4 | 1517 | 2.318 | 1.726 | 0.2043 | 0.470, 4.418 | 1/1/2012 | 15164 | ICU-OTHER | | | | | |
| 7 | 0 | 100 | 0.235 | | | | 1/1/2012 | 15164 | NICU | | | | | |
| 8 | 4 | 204 | 0.528 | | | | 1/1/2012 | 15165 | ICU-OTHER | | | | | |
| 9 | 19 | 4403 | 9.664 | 1.966 | 0.0052 | 1.183, 3.070 | 1/1/2012 | 15634 | ICU-OTHER | | | | | |
| 10 | 0 | 267 | 0.632 | | | | 1/1/2012 | 15635 | NICU | | | | | |
| 11 | 3 | 1427 | 2.141 | 1.401 | 0.3614 | 0.289, 4.095 | 1/1/2012 | 15164 | | IN-ACUTE:CC:MS | | | | |
| 12 | 0 | 30 | 0.039 | | | | 1/1/2012 | 15164 | | IN-ACUTE:CC:M_PED | | | | |
| 13 | 0 | 100 | 0.235 | | | | 1/1/2012 | 15164 | | IN-ACUTE:CC:NURS | | | | |
| 14 | 1 | 60 | 0.138 | | | | 1/1/2012 | 15164 | | IN-ACUTE:CC:S | | | | |
| 15 | 4 | 200 | 0.52 | | | | 1/1/2012 | 15165 | | IN-ACUTE:CC:M | | | | |
| 16 | 0 | 4 | 0.008 | | | | 1/1/2012 | 15165 | | IN-ACUTE:CC:MS | | | | |
| 17 | 2 | 927 | 3.059 | 0.654 | 0.4101 | 0.079, 2.362 | 1/1/2012 | 15034 | | IN-ACUTE:CC:CT_PED | | | | |
| 18 | 17 | 3476 | 6.604 | 2.574 | 0.0006 | 1.499, 4.122 | 1/1/2012 | 15034 | | IN-ACUTE:CC:M | | | | |
| 19 | 0 | 145 | 0.344 | | | | 1/1/2012 | 15635 | | IN-ACUTE:CC:NURS | | | | |
| 20 | 0 | 122 | 0.289 | | | | 1/1/2012 | 15635 | | IN-ACUTE:CC_STEP:NURS | | | | |
| 21 | 3 | 1427 | 2.141 | 1.401 | 0.3614 | 0.289, 4.095 | 1/1/2012 | 15104 | ICU-OTHER | | | | | |
| 22 | 0 | 100 | 0.235 | | | | 1/1/2012 | 15104 | NICU | | | | | |
| 23 | 0 | 30 | 0.039 | | | | 1/1/2012 | 15164 | ICU-OTHER | | | | | |
| 24 | 1 | 60 | 0.138 | | | | 1/1/2012 | 15164 | ICU-OTHER | | | | | |
| 25 | 4 | 200 | 0.52 | | | | 1/1/2012 | 15165 | ICU-OTHER | | | | | |
| 26 | 0 | 4 | 0.008 | | | | 1/1/2012 | 15165 | ICU-OTHER | | | | | |
| 27 | 17 | 3476 | 6.604 | 2.574 | 0.0006 | 1.499, 4.122 | 1/1/2012 | 15634 | ICU-OTHER | | | | | |
| 28 | 2 | 927 | 3.059 | 0.654 | 0.4101 | 0.079, 2.362 | 1/1/2012 | 15634 | ICU-OTHER | | | | | |
| 29 | 0 | 145 | 0.344 | | | | 1/1/2012 | 15635 | NICU | | | | | |
| 30 | | | | | | | | | | | | | | |
| 31 | | | | | | | | | | | | | | |
| 32 | | | | | | | | | | | | | | |

Aggregation Levels for SIRs (by group, facilities, location types, location codes, and individual locations)

8. In Excel, select the second aggregation level (Facility-wide SIR for each facility in the group). Copy this information to a second spread sheet. Arrange the facilities in rank order according to the expected/predicted number of CLABSIs [numExp], (high to low)
9. Select the top 33% of facilities by expected/predicted CLABSIs. This “Top Tertile” of facilities, where CLABSIs are most expected, may have the greatest potential for prevention success.
10. Within the top tertile, create new columns for “Deltacount”, defined as the absolute value of the difference between the reported number and expected number of CLABSIs; for “Stratum”, and for “Targeted Selection Number”.
11. Within the top tertile, sort by SIR from highest to lowest, and identify the current median SIR for the top Tertile.
12. Assign stratum A to facilities with SIR above the current median SIR, 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).
13. Re-sort within each stratum A, B, and C, by numExp from highest to lowest.
14. 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. All remaining facilities in the middle and lower tertile (and excluding top tertile) will be subject to random selection under the 5% rule.

Appendix 3b External Validation; 5% Simple Random Sample of Facilities

With simple random sampling (SRS), every possible sample of n elements from a population of size N has the same chance of being chosen. Following are the steps to be taken when selecting a simple random sample of 5% of facilities from the lower two tertiles of facilities ranked by predicted number of CLABSIs.

1. Enumerate and assign sequential numbers to the facilities in the survey population (sampling frame, e.g. lower two tertiles) from 1 to N .
2. Calculate the size of the sample $n = N * 5\%$. Round to the nearest integer.
3. Select n different random numbers between 1 and N (no selected numbers can be greater than N). The selection must be done without replacement; i.e., if a number is the same as any one of the previously selected numbers discard it and continue until n *different* numbers between 1 and N have been chosen. Use either a table of random numbers or a computerized random number generator.
4. Select the facilities corresponding to the numbers generated in step 3.

OR

5. Enumerate facilities in the survey population (sampling frame, e.g. lower two tertiles); total facilities= N .
6. Calculate the size of the desired sample $n = N * 5\%$. Round to the nearest integer.
7. Assign random numbers to each facility in the population using a random number generator. The possibility that the same random number may be assigned to more than one facility is reduced if the range of assigned random numbers is a multiple of N .
8. Select facilities with the lowest assigned random numbers until n facilities have been selected.

Appendix 3c External Validation; Medical Record Selection

Using the blood culture line listing you request from each selected facility, you will select all reported CLABSIs (or up to 20, by random sample), and unreported candidate CLABSIs (up to 40, stratified by adult/pediatric ICUs (75%) vs. NICU (25%, if available), and prioritizing targeted pathogens where reporting errors are considered likely), from the past year of surveillance. Fixing surveillance to a calendar year is helpful for tracking which data are validated, but not essential to the process of quality improvement.

In reality, many hospitals will have far fewer events to sample than the prescribed goals here, but the goal numbers will establish a cap on medical record reviews for larger facilities. Roughly half of the unreported candidate CLABSIs will be eliminated during screening for a central line, and half should have a central line, in which case they may be fully reviewed.

Targeted pathogens include:

- *Candida spp.*, *Torulopsis spp.*
- *Enterococcus spp.*
- *Staphylococcus aureus*, including MSSA and MRSA
- Coagulase-negative staphylococcus
- Common gram-negative organisms (limited to *Klebsiella spp.*, *E. coli spp.*, or *Pseudomonas spp.*)

Following are the steps to be taken when selecting the medical record sample.

1. Assign a random number to each positive blood culture on the line listing. Sort line listing by Medical record number (and admission date if available) to generate recognizable patients and records.
2. Assure line listing is complete (contains all positive blood cultures from all ICU locations throughout the year, including reported CLABSIs)
 - a. If some ICUs are not represented on the blood culture line listing, verify with IP that list is complete and there were no positive blood cultures from that location
 - b. Identify reported CLABSIs on the positive blood culture line listing, and select all (up to maximum 20 by random number) for review. All positive blood cultures assigned to these records will be considered part of stratum 1 (reported CLABSI), whether or not they are part of the actual CLABSI event.
3. Next, limit the list to non-stratum 1 blood cultures. Sort the list by pathogen (Org 1) and identify all “targeted pathogens” listed above and assign these blood cultures to stratum 2. The remaining blood cultures are stratum 3.
4. Sort stratum 2 and 3 blood cultures by facility location and identify two ICU strata (NICU and non-NICU)
5. Select the NICU screening sample, where NICU= Yes and stratum=2 (targeted pathogens); sort by random number and MRN (and admission date if available). Select the first 10 random numbers that identify unique patients/records. If additional NICU records are needed, select NICU records from stratum 3. (Skip this step if there is no NICU, and add the 10 random numbers to the sample below for a total of 40 records).
6. Select the non-NICU screening sample, where NICU = No and stratum = 2 (targeted pathogens); sort by random number and MRN (and admission date if available). Select the first 30 random numbers that identify unique patients/records. If additional records are needed, select non-NICU records from stratum 3.

Your screening sample should include

- All (or up to 20) records with reported CLABSIs
- All (or up to 10) NICU records with unreported candidate CLABSIs in facilities with NICUs
- All (or up to 30) non-NICU ICU records with unreported candidate CLABSIs in facilities with NICUs
- All (or up to 40) non-NICU ICU records with unreported candidate CLABSIs in facilities without NICUs.

Appendix 4 Template Letter Requesting External Validation Site Visit

Please feel free to copy, paste, and adapt this template to your state's needs

Dear [*Name of CEO*]

The [*Name of Health Department*] will be conducting an audit of medical records, and evaluating infection prevention programs in multiple hospitals statewide, focusing on surveillance and prevention of central line-associated bloodstream infections (CLABSI) in intensive care unit (ICU) settings. The purpose of the audit is to assure accountability of all hospitals in complete and accurate reporting of CLABSIs according to National Healthcare Safety Network (NHSN) methods and definitions, and thereby to assure credible reporting and appropriate outcomes under the Centers for Medicare and Medicaid Services (CMS) Inpatient Quality Reporting (IQR) Program.

Participation in the audit is [*select as appropriate, or cite authority*]

- [*obligatory, to assure compliance with state healthcare-associated infection (HAI) reporting legislation and assure that facilities are accurately identifying and reporting healthcare-associated infections*]

OR

- [*voluntary, but should be of value to your program in preparation for CMS validation activities. In addition, the identity of facilities that agree or decline to participate in state HAI validation will be made available to CMS and to the public*].

A site visit has been scheduled for [*Day and Date*] with [*Name of IP*], Infection Preventionist, who has also been asked to work with the microbiology laboratory to prepare a list of positive blood cultures in advance, that qualify as candidate CLABSI events. This list 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 also request CLABSI denominator collection documents for review during our visit, and may require a short meeting with the Director of Nursing to review information about patient care locations and bed-size within your facility.

We will require assistance from medical records to make the selected records available for the audit, including necessary accommodations such as work space and passwords to access appropriate hospital data systems during the site visit. If your Health Information System has initiated or completed conversion to an electronic medical record, we will need the ability to access these records including any diagnostic/laboratory results, and clinical documentation related to these patients during our visit.

The site visit will be scheduled for [*number of days*] and we will plan to bring [*number of reviewers*]. *Note to validators: Several states have recommended planning for 20-30 minutes per medical record review and either staffing or scheduling accordingly*. During this visit, we will be available to describe the process and evaluation tools, as well as answer any questions you may have.

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

Appendix 5 and 5a ICU CLABSI Medical Record Abstraction Tool and Tennessee Checklists for Validation

ICU CLABSI Medical Record Abstraction Tool

A paper-based medical record abstraction tool for 2012 is attached.

In addition, an electronic version using Epi-Info 7 is under development.

Use of this tool will

- Establish a common format database for validation work
- Assure standardized documentation of data used for decision making
- Allow for aggregation, if indicated
- Provide portability with a small thumbprint for onsite use
- Allow for customization by state health departments that wish to add variables

Tennessee Checklists for Validation

Tennessee has developed versioned checklists for NHSN Validation that assure adherence to NHSN Case-Definitions. These are particularly useful to determine whether a potential CLABSI may actually be a secondary bloodstream infection caused by an alternative primary infection site. The Tennessee checklists are updated to new versions as NHSN case-definitions change. These checklists are part of the ICU CLABSI Medical Records Abstraction Tool 2012, and used for distinguishing CLABSI events and alternative primary infections with secondary BSI. When validating 2012 data, be sure to use the correct version of any given checklist. A “how to use the checklists” document and master list of dated versions are available with folders of current and past versions in a downloadable zip file at: <http://health.state.tn.us/ceds/hai/index.htm>

2012 CLABSI Medical Record Abstraction Tool, V(4) 11/16/12

Chart ID/ MRN _____

Note: This tool follows 2012 definitions and methods; do not use for other time periods.

| IDENTIFIERS | | | | |
|---------------|------------------------|--|--|------------------------------------|
| State/Fac ID: | | Date of Audit: | | Reviewer Initials: |
| Patient DOB | Hospital Admission D/T | NICU chart? <input type="checkbox"/> Yes <input type="checkbox"/> No | | If Yes, enter birth weight (grams) |

1. (Table 1) positive blood cultures for this candidate CLABSI event

Document **SELECTED*** blood culture in first row (leave remaining lines blank until step 3) and proceed to step 2.

| | | | Specimen Collection Date/ Time** | Specimen Number | Organisms (up to 3 for each blood culture) |
|--|--|--|----------------------------------|-----------------|--|
| S* (selected), I* (index), P* (pathogen) C* (commensal) MC* (matched commensal), QMC*, qualifying matched commensal | | | | | |
| S | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

*SELECTED blood culture (**S**) is the (one) positive ICU blood culture chosen from the line list that led to this medical record review. Every blood culture should be classified as either: (1) PATHOGEN blood culture (**P**), (as many as indicated) = culture that includes a known pathogen. (2) COMMENSAL blood cultures (**C**), (as many as indicated) = culture growing common commensal(s) ONLY (see #5) and no known pathogens. (3) MATCHED COMMENSALS (**MC**) = at least 2 **C** collected within two days of each other and growing matching organisms. (4) QUALIFYING MATCHED COMMENSALS (**QMC**) = Any **MC** where qualifying symptoms (see #5) occur within 2 days before or after any matching **MC** culture. Only **P** and **QMC** cultures are potential CLABSIs. **INDEX** blood culture (**I**) is the (one) first **P** or **QMC** blood culture from a candidate CLABSI event that may include several positive cultures, and helps to identify infection onset.

**Time of specimen collection required only for Index blood culture

2. Rapid screening questions

a. Was the selected blood culture collected before / during the admission process* to hospital, in the context of no recent hospital discharge*?

- Yes If **Yes, STOP; outcome "a", NOT a candidate ICU CLABSI; Infection present on admission (POA).**
- No or don't know; continue to 2b.

*Note: Patients recently discharged (within 48 hours before admission) may have HAI attributable to recent hospitalization. Also, ER/OR exception: If patient developed infection after CL was placed/accessed in ER/OR during direct admission to ICU, the ICU becomes the location of attribution because ER and OR are non-bedded hospital locations.

b. Was there only one positive blood culture, and the isolated organism was a common commensal* only?

- Yes If **Yes, STOP; outcome "a", NOT a candidate ICU CLABSI; Single common commensal only.**
- No If **No**, continue to 2c

*Common commensals: diphtheroids [*Corynebacterium spp.* not *C. diphtheriae*], *Bacillus spp.* [not *B. anthracis*], *Propionibacterium spp.*, coagulase-negative staphylococci [including *S. epidermidis*], viridans group streptococci, *Aerococcus spp.*, and *Micrococcus spp.*

(See end for expanded list of commensal genus and species).

c. Was the patient in an ICU before the **SELECTED** blood culture was drawn?

- No If **No, STOP; outcome "a", NOT a candidate ICU CLABSI; No eligible ICU admission.**
- Yes If **Yes**, continue to 2d

d. Was a central line (CL) in place during the ICU stay, AND before the **SELECTED** blood culture was drawn?

- No If **No, STOP; outcome "a", NOT a candidate ICU CLABSI; No eligible ICU central line.**
- Yes If **Yes**, proceed to step 3

3. Characterize blood culture "event"*

*A blood culture "event" is often a single or two sets of blood cultures growing the same organism before treatment begins. In complex cases an event may be defined by repeated isolation of the same organism from blood before and/or during treatment of an infection that is difficult to clear. In rare cases, an event may include changing organisms in the setting of continuous symptoms of infection under therapy; e.g., enteric organisms in blood causing unremitting sepsis on therapy, followed by isolation of yeast. If symptoms of infection improve then relapse, this is not a single event.

Are there additional positive blood cultures that are part of the **selected** blood culture event*? (choose one)

- No If No, proceed to step 4
- Yes If Yes,
 - Return to Table 1 and document all positive blood cultures that are part of the same blood culture event;
 - Proceed to step 4

| 4. Index blood culture identification | |
|--|------------------------|
| <p>a. Order the blood cultures in Table 1 by specimen collection date/time and identify the FIRST blood culture.</p> <p>b. Determine whether the FIRST blood culture contains a known pathogen "P" or common commensal(s)* "C" only. Mark specimen 1 as "P" or "C" in Table 1 as appropriate.</p> <ul style="list-style-type: none"> <input type="checkbox"/> If the specimen is a pathogen, it is the INDEX blood culture; skip to step 5. <input type="checkbox"/> If the specimen is a common commensal only, continue to 4c. | |
| <p>*Common commensals: diphtheroids [<i>Corynebacterium spp.</i> not <i>C. diphtheriae</i>], <i>Bacillus spp.</i> [not <i>B. anthracis</i>], <i>Propionibacterium spp.</i>, coagulase-negative staphylococci [including <i>S. epidermidis</i>], viridans group streptococci, <i>Aerococcus spp.</i>, and <i>Micrococcus spp.</i></p> <p>(See end for expanded list of commensal genus and species).</p> | |
| <p>c. Does the NEXT blood culture contain a known pathogen "P" or common commensal(s)* "C" only? Mark specimen as "P" or "C" in Table 1, as appropriate.</p> <ul style="list-style-type: none"> <input type="checkbox"/> If specimen is a pathogen, it is the INDEX blood culture; skip to step 5 <input type="checkbox"/> If the specimen is a common commensal only, proceed to 4d | |
| <p>d. Does a common commensal organism from this specimen match** a common commensal organism from the previous specimen within a two 2 day period?</p> <ul style="list-style-type: none"> <input type="checkbox"/> No If No, repeat process beginning at 4c with each subsequent blood culture(s). If all blood cultures have been evaluated, STOP; outcome "b", UNMATCHED COMMON COMMENSAL. <input type="checkbox"/> Yes If Yes, <ul style="list-style-type: none"> • Mark these cultures as "MC" (matched commensals) in Table 1; • Proceed to 4e | |
| <p>**If one culture is identified to the genus + species level and the other culture only to the genus level, they are assumed to match. "Diphtheroids" are assumed to be <i>Corynebacterium spp.</i></p> | |
| <p>e. For matched commensal cultures, was at least one qualifying symptom of infection*** present within 2 days before or after either of the matched common commensal cultures?</p> <ul style="list-style-type: none"> <input type="checkbox"/> No If No, repeat process beginning at 4c with subsequent blood culture(s) in Table 1. If all blood cultures have been evaluated, STOP; outcome "c", MATCHED COMMON COMMENSALS WITHOUT QUALIFYING SYMPTOMS. <input type="checkbox"/> Yes If Yes, <ul style="list-style-type: none"> • Mark these cultures as "QMC" (qualified matched commensals) in Table 1; • Document patient age, qualifying symptoms and date of symptom onset below; • The first of these QMC cultures is the INDEX blood culture; • Proceed to step 5 | |
| <p>***Qualifying symptoms of common commensal infection [for patient any age: fever (>38°C), chills, hypotension; for child ≤1 year old: fever (>38°C core), hypothermia (<36°C core), apnea, bradycardia]</p> | |
| | Patient age (years): |
| | Qualifying symptom(s): |
| Earliest symptom onset (date and time) within 2 days of either QMC: | |

5. Identify infection onset date/time

a. Mark the **INDEX (I)** blood culture in Table 1, and record specimen collection time.

b. Use the type of **INDEX** blood culture* to determine the infection onset date/time, and record infection onset Date/Time below:

| | |
|----------------------------|--|
| Infection onset Date/Time: | |
|----------------------------|--|

c. Proceed to step 6

*For Index **"P"** (pathogen) cultures, infection onset is blood culture specimen collection date/time.

*For Index **"QMC"** (qualified matched commensal) cultures, infection onset is earlier of Index **QMC** blood culture specimen collection date/time OR (required) earliest symptom onset date and time (see step 4) for Index **QMC** blood culture.

6. Confirm central line presence at infection onset

a. Was a central line* in place at the time of infection onset or during the prior 48 hours?

No **If No, STOP; outcome "d"; INFECTION NOT ATTRIBUTABLE TO CENTRAL LINE**

Yes **If Yes, affirm central line presence during the 48 hour window by checking a box in Table 8a below (ONLY one is necessary), and proceed to step 7**

*A central line terminates at or close to heart or in great vessel (aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic vein, internal jugular vein, subclavian vein, external iliac vein, common iliac vein, femoral vein, or umbilical artery/vein), and is used for infusion, withdrawal of blood, or hemodynamic monitoring. May include introducer or dialysis catheter if placed as above. Does not include ECMO, femoral artery line, or intra-aortic balloon pump.

7. Document location of attribution

a. Was the patient in an ICU* at the time of infection onset or during the prior 48 hours?

Yes **If Yes, affirm ICU location residence during the 48 hour window by checking a box in Table 8b (ONLY one is necessary), and proceed to step 9.**

No **If No, STOP; outcome "e"; LOCATION OF ATTRIBUTION (LOA) WAS NOT ICU;**

- DOCUMENT LOA* _____

*Note ER/OR exception: If patient developed infection after CL was placed/accessed in ER/OR during direct admission to ICU, the ICU becomes the LOA because ER and OR are non-bedded hospital locations.

| Table 8 (a and b). CL PRESENCE and LOA at INFECTION ONSET | |
|--|--|
| <i>a. (affirm one or more)</i> | <i>b. (affirm one or more)</i> |
| <input type="checkbox"/> CL in place at infection onset? | <input type="checkbox"/> ICU residence at infection onset? |
| <input type="checkbox"/> CL in place within 48 hours before infection onset? | <input type="checkbox"/> ICU residence within 48 hours before infection onset? |

9. Possible alternative primary site with secondary bloodstream infection

- a. Is there documentation indicating possible alternative source of infection?
- No **If No, STOP; outcome “g”, ICU CLABSI.**
 - Yes If Yes,
 - use TN checklists to determine whether case meets definition for alternative primary infection
 - attach completed checklist to this form
- b. Does documentation satisfy TN checklist criteria for an alternative primary infection?
- No **If No, STOP; outcome “g”, ICU CLABSI.**
 - Yes **If Yes, If Yes, STOP; outcome “f”, ALTERNATIVE PRIMARY SITE INFECTION WITH SECONDARY BSI.**
 - Document Major site _____
 - Document Specific type of infection _____
 - If there is a (non-blood) organism from the Major site that matches the INDEX blood culture, document match in Table 9.
 - If there is no matching (non-blood) culture evidence for Major site, document logical pathogen for Major site from Index blood culture _____

Table 9: Matching Index blood culture and culture of Major Infection Site

| | Type of culture | Specimen Collection Date | Unique Specimen Number | Organisms (up to 3 for each culture) |
|---------------------|------------------------|---------------------------------|-------------------------------|---|
| Index blood culture | blood | | | |
| Major site | | | | |

Outcome of 2012 CLABSI audit (complete this section when review ends):

- a. Screened out: NOT a candidate ICU CLABSI
 - reason
 - POA;
 - single common commensal only;
 - no eligible ICU admission;
 - no eligible ICU Central Line
- b. Unmatched common commensals
- c. Matched common commensals without qualifying symptoms
- d. Infection not central line attributable
- e. Location of attribution (LOA) was not ICU
 - Document LOA: _____
- f. Alternative primary infection site with secondary BSI (attach completed TN checklist to this form)
 - Major site _____
 - Specific type of infection _____
 - Either: Matching (non-blood) organism from Major site and INDEX blood culture (name of organism) _____,
 - OR
 - Logical pathogen for Major site from Index blood culture _____
- g. ICU CLABSI

Notes/Worksheet:

| Helpful dates, if needed: | | Comments |
|-------------------------------|--|----------|
| Emergency Room Date/Time | | |
| Facility Admission Date/Time | | |
| ICU admission Date/Time | | |
| Line Insertion Date/Time | | |
| Line placement xray Date/Time | | |
| Index blood culture Date/Time | | |
| Infection onset Date/Time | | |

Expanded list of common commensal organisms

| | |
|--------------------------------------|---------------------------------------|
| Aerococcus species | Rhodococcus equi |
| Aerococcus urinae | Rhodococcus species |
| Aerococcus viridans | Staphylococcus auricularis |
| Bacillus cereus | Staphylococcus capitis ss capitis |
| Bacillus species (not B. anthracis) | Staphylococcus capitis ss unspecified |
| Bacillus subtilis | Staphylococcus capitis ss urealyticus |
| Corynebacterium aquaticum | Staphylococcus coagulase negative |
| Corynebacterium bovis | Staphylococcus cohnii |
| Corynebacterium cystitidis | Staphylococcus epidermidis |
| Corynebacterium glutamicum | Staphylococcus gallinarum |
| Corynebacterium group G-2 | Staphylococcus haemolyticus |
| Corynebacterium jeikeium | Staphylococcus hominis |
| Corynebacterium kutscheri | Staphylococcus lentus |
| Corynebacterium matruchotii | Staphylococcus lugdunensis |
| Corynebacterium minutissimum | Staphylococcus saccharolyticus |
| Corynebacterium mycetoides | Staphylococcus saprophyticus |
| Corynebacterium pilosum | Staphylococcus schleiferi |
| Corynebacterium pseudodiphtheriticum | Staphylococcus sciuri |
| Corynebacterium pseudotuberculosis | Staphylococcus simulans |
| Corynebacterium renale | Staphylococcus species |
| Corynebacterium species | Staphylococcus warneri |
| Corynebacterium striatum | Staphylococcus xylosus |
| Corynebacterium ulcerans | Streptococcus anginosus |
| Corynebacterium urealyticum | Streptococcus bovis |
| Corynebacterium xerosis | Streptococcus mitis |
| Diphtheroids | Streptococcus mutans |
| Gram-positive cocci unspecified | Streptococcus salivarius |
| Micrococcus species | Streptococcus viridans species |
| Propionibacterium acnes | |
| Propionibacterium avidum | |
| Propionibacterium granulosum | |
| Propionibacterium lymphophilum | |
| Propionibacterium propionicum | |
| Propionibacterium species | |

**Previously posted list of logical pathogens
has been redacted because it was not intended for surveillance use.
NHSN does not provide a reference list of logical pathogens**

**Previously posted list of logical pathogens
has been redacted because it was not intended for surveillance use.
NHSN does not provide a reference list of logical pathogens**

Appendix 6 Template for CLABSI Audit Discrepancies Report to Facility

Please feel free to copy, paste, and adapt this template to your state's needs

(Adapted from New York State Department of Health)

Note:

First row (dark) = variables as determined by hospital staff (determined by interview).

Second row (light) = corrections required by Health Department

| CLABSI discrepancies | | | Hospital ID: | | | | |
|----------------------------------|---------------------------------|---------------------------------|--------------|-------------------------|------------|----------------------|------------|
| Date _____ | | | Event date | Location of attribution | HAI or POA | Primary or Secondary | CLABSI Y/N |
| Medical Record ID | Positive blood culture organism | LCB1, LCB2, LCB3, or ineligible | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| Add additional rows as necessary | | | | | | | |

Copy 1: to hospital, data to be corrected by _____ [date + 30 days]

Copy 2: to Health Department

Appendix 7 Example Validation Follow-up Letters, With and Without Identified Problems

Please feel free to copy, paste, and adapt this template to your state's needs

(Adapted from New York State Department of Health)

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

Dear [CEO Name],

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

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

We observed the following trends that may contribute to surveillance inaccuracies: [e.g.: Denominator collection methods survey results were suboptimal and documentation of training/validation of electronically uploaded denominator data is recommended before the next audit]. Infection control was not made aware of [X] bloodstream infections identified by the microbiology laboratory, which may have resulted in omissions. Errors in applying NHSN case-definitions were also found, and could be reduced by use of validation checklists. We have provided these checklists to the Infection Prevention and Control Department. Each record requiring corrections was reviewed with [Name of IP] and a list of a data entry edits to be made in NHSN was provided to [her]. All data errors and missed data entry must be edited in NHSN data base within 30 days of this notice.

The Infection Prevention and Control Program continues to count denominator days manually from numerous ICUs, which is relatively labor-intensive for larger hospitals. Working with IT to gather electronic denominator counts will require several months of validation using manual counting and may require iteration until electronic denominator data are correct, but may be worthwhile to explore. Additional IT support to Infection Prevention would be required to make this possible.

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

Dear [CEO name],

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

The purposes of this audit were initially presented to you in the letter of notification. Based upon our review of [X] medical records, no significant compliance issues were detected. During our audit, we identified no unreported infections in the medical records we reviewed. We also reviewed denominator collection methods and the timeliness of reporting and have found it to be acceptable.

There continues to be only one individual, [Name], with access to manage and report in the NHSN data system. In our [specify past years] post-audit letters, we recommended that your facility 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 have discussed infection definitions, reporting and data entry issues or concerns that [*Name of IP*] may have had, in an effort to offer continued support for the [*state*] HAI mandatory reporting. There are some data entry corrections to be made in the NHSN reporting system. A list of each record requiring data edits was reviewed with [*Name of IP*]. The data entry corrections should be completed within 30 days of the audit visit.

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

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

Appendix 8 Facility-Specific CLABSI Validation Summary and Post-Validation Analysis

Please feel free to copy, paste, and adapt this template to your state's needs

Please anonymize and share information with CDC to assist with toolkit improvement.

Part 1. Risk adjustment and Denominator Methods

| | |
|---------------------------------------|-------------------------------------|
| State | |
| Facility ID | |
| Date(s) onsite audit | Data Year Validated |
| | Notes/ problems encountered: |
| Location Mapping | |
| Bed-size | |
| Medical-school affiliation | |
| Manual denominator collection methods | |
| Electronic denominator validation | |

Part 2. Sampling Frame and Sample Selection Report

| | NICU | Non-NICU | NICU | Non-NICU | NICU | Non-NICU |
|--|---|----------|----------------------------------|-------------------|---|----------|
| | Total for facility | | Screening sample (goal up to 60) | | Review sample (goal up to 40) | |
| Records with positive ICU blood cultures | | | | | | |
| Records with reported CLABSI | All reported CLABSI records | | Goal, All Up to 20 combined | | Same as screening sample; goal up to 20 | |
| | | | | | | |
| Records without reported CLABSI | All unreported candidate CLABSI records | | Goal 10 NICU* | Goal 30 non-NICU* | Up to 20 combined NICU and non-NICU, distributed based on central lines | |
| | | | | | | |

*For facilities without a NICU, Goal is 40 non-NICU

Part 3. Discordant cases

For each discordant case, please record case ID, and how the case was resolved. (Identity may be needed for secondary validation during CDC site visit, or developing training cases, but should be redacted before sharing with CDC).

| Discordant Case ID | Discussed with IP and Agreed with IP | Discussed with IP and Agreed with Auditors | Discussed with IP and not resolved locally; referred to CDC |
|-------------------------|--------------------------------------|--|---|
| | | | |
| | | | |
| <i>Expand as needed</i> | | | |
| | | | |
| Total Numbers | | | |

Part 4. Reasons for CLABSI discordance between facility and validators

| | Number of Overcalled CLABSI | Number of Missed CLABSI |
|---|-----------------------------|-------------------------|
| Overlooked positive blood culture | | |
| Wrong location of attribution | | |
| Misclassified secondary BSI as primary | | |
| Misclassified primary BSI as secondary | | |
| Error in identifying pathogen, contaminant, or commensal rules for LCBI | | |
| Other (specify): | | |
| Total | | |

Part 5. Estimate of CLABSI sensitivity, specificity, and concordance at facility

| | Final LABSI yes | Final CLABSI no | Total |
|--------------------------------|-----------------|-----------------|-------|
| Reported CLABSI yes | a | b | |
| Reported CLABSI no | c | d | |
| Total | | | e |
| % Sensitivity $(a/a+c)=$ | | | |
| % Specificity $(d/b+d)=$ | | | |
| % Concordance $(a+d/a+b+c+d)=$ | | | |

Appendix 9 Rate the 2012 CLABSI Validation Guidance and Toolkit

| Name of Tool | Do you like it? (circle one) 1= not at all, 5= very much | Did you find it useful? (circle one) 0= no 1= heavily modified 2= pretty much as is | Comments (please suggest improvements) | Would you like to help us improve it? | If Yes, contact information |
|--|---|---|---|---------------------------------------|-----------------------------|
| Overall Guidance and Toolkit | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 1: Facility Self-validation Tool for CLABSI Surveillance | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 2: Denominator Collection Methods Survey for CLABSI Surveillance | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 3a: Facility Selection Steps in NHSN | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 3b: How to Generate a Simple Random Sample of Facilities | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 3c: Medical Record Selection | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 4: Example Letter Requesting External Validation Site Visit | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 5: ICU CLABSI Medical Record Abstraction Tool | 1 2 3 4 5 | 0 1 2 | | Y N | |

| Name of Tool | Do you like it? <i>(circle one)</i> 1= not at all, 5= very much | Did you find it useful? <i>(circle one)</i> 0= no 1= heavily modified 2= pretty much as is | Comments <i>(please suggest improvements)</i> | Would you like to help us improve it? | If Yes, contact information |
|---|--|--|--|---------------------------------------|-----------------------------|
| Appendix 5a: Tennessee Checklists | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 6: Example Template for Audit Discrepancies Reports to Facilities | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 7: Example Validation Follow-up Letters | 1 2 3 4 5 | 0 1 2 | | Y N | |
| Appendix 8: CLABSI Post-Validation Analysis | 1 2 3 4 5 | 0 1 2 | | Y N | |

Please tell us who you are and provide contact information (optional) _____

Please share results with DHQP; through the NHSN Helpdesk: NHSN@cdc.gov

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