National Healthcare Safety Network (NHSN) External Validation Guidance and Toolkit 2015, for Validation of

- 2015 Central Line-Associated Bloodstream Infection (CLABSI) in ICUs
- 2015 Catheter-Associated Urinary Tract Infection (CAUTI) in ICUs
- Surgical Site Infection (SSI) following 2015 Abdominal Hysterectomy (HYST) Procedure
- Surgical Site Infection (SSI) following 2015 Colon (COLO) Procedure
- 2015 Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia LabID Event
- 2015 *Clostridium difficile* Infection (CDI) LabID Event

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- 2015 *Clostridium difficile* (CDI) LabID Event

About the 2015 NHSN External Validation Guidance and Toolkit

The 2015 NHSN External Validation Guidance and Toolkit provides guidance for NHSN data validation. Like 2014, CDC provides guidance and tools for validation of six healthcare-associated infection (HAI) metrics: ICU CLABSI, ICU Catheter-Associated Urinary Tract Infection (CAUTI), selected Surgical Site Infections (following colon (COLO) and abdominal hysterectomy (HYST) procedures), Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia LabID Event and *Clostridium difficile* infection (CDI) LabID Event for 2015 HAI validation. The guidance and tools for CLABSI and CAUTI were designed to work in settings including and beyond acute care hospitals; validation of CLABSI is appropriate for long-term acute care hospitals (LTACs, termed long-term care hospitals by the Centers for Medicare and Medicaid Services, CMS), and validation of CAUTI is appropriate for LTACs and inpatient rehabilitation facilities (IRFs).

The purpose of validation is to assure high-quality surveillance data through accountability and by identifying, understanding, and correcting reporting problems. The focus of this document is external validation of facility-reported NHSN surveillance data conducted by state health departments or other oversight agencies. A separate guidance for facilities that seek to conduct internal validation (quality assurance) of their own NHSN data is also available at http://www.cdc.gov/nhsn/validation/index.html.

This document proposes standard methods for state health departments and other oversight agencies to conduct external validation of reported 2015 HAI data. Developing a standard approach to HAI data validation is important to assure nationwide data quality and to enhance fairness under current and planned reimbursement programs that use NHSN data. States may vary in their regulatory authorities and capacities for NHSN data validation but can best assure equivalent high data quality by striving to follow these standards. NHSN-specified external validation standards are intended to assure concordance of reported surveillance outcomes with those expected under NHSN surveillance definitions and methods, as determined and documented by trained auditors. Recommended sample sizes attempt to balance feasibility with adequate precision for HAI metrics at the facility level. Survey tools are provided to assess reporter knowledge and facility practices required to conduct adequate surveillance.

For 2015 data audits, the specified approach to facility and medical records sampling will be targeted external validation. Targeted validation provides an efficient approach to identify and correct likely reporting errors and their underlying processes in facilities with high volume of exposure to HAI risk, and thus to use limited validation resources as effectively as possible. Accuracy measures (e.g., sensitivity and specificity) derived from a targeted sample are likely to be reduced relative to a more representative sample. Although it may be a simpler and more efficient approach to begin the external validation process, targeted sampling has an important limitation in that representative information is not generated in this way. Future guidance is likely to focus on sampling methods that generate quantifiable representative information regarding NHSN data quality.

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

Acknowledgements and Thanks

Many aspects of this document were adapted from states conducting validation. In addition, many experts from state and local health departments and healthcare facilities collaborated to develop, review, and contribute to this document. The contributions of these individuals are gratefully acknowledged. However, 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 received the endorsement of any individuals or organizations outside of CDC.

Abbreviations, Terms, and Acronyms Used in this Document

ABUTI*	(NHSN) Asymptomatic bacteremic urinary tract infection. This type of UTI may or may not be catheter-associated (CAUTI).
ADT	Admissions/discharges/transfers (A core facility data system)
BABY LOCATIONS*	(NHSN) Patient care locations housing a high proportion of infants aged <1 year, i.e. newborn nurseries, neonatal ICUs, and LDRP locations
BSI	Bloodstream infection
CAUTI*	(NHSN) Catheter-associated urinary tract infection. A primary UTI where an indwelling urinary catheter was in place for >2 calendar days when all elements of the UTI criteria were first present together AND indwelling urinary catheter was in place on the date of event or the day before.
CCN	CMS Certification Number, i.e., a facility identifier
CDC	Centers for Disease Control and Prevention
CDI	*Clostridium difficile* Infection
CEO	Chief executive officer
CL	Central line
CLABSI*	(NHSN) Central line-associated bloodstream infection. A primary laboratory-confirmed bloodstream infection (LCBI) where a central line was in place for >2 calendar days when all elements of the LCBI criteria were first present together AND central line was in place on the date of event or the day before.
CMS	Centers for Medicare & Medicaid Services
C-SUITE	Office for senior executives such as Chief Executive Officer (CEO) or Chief Medical Officer (CMO) of a healthcare facility
DELTA COUNT*	(NHSN, as used in this guidance) The absolute difference between the number of expected events and observed events
DI SSI*	(NHSN) Deep incisional surgical site infection
DOB	Date of birth
DOH	Department of health
ED	Emergency department
EMR	Electronic medical record
EPISODE OF CARE	All medical services provided to a patient within a specific time period within a facility. For surveillance of HAIs, this term is used to indicate a single inpatient admission, and includes the ED visit leading to admission
EXTERNAL VALIDATION	Survey and record review process by external agency to assure quality of NHSN surveillance and reporting
FacWideIN*	(NHSN) Facility-Wide Inpatient, a type of surveillance used for LabID Event reporting
FOLEY CATHETER	Indwelling urethral (urinary) catheter
GI*	(NHSN) Gastrointestinal system healthcare-associated infection
HAI*	NHSN) Healthcare-associated infection: An infection is considered an HAI if all elements of a CDC/NHSN site-specific infection criterion were not present during the POA time period but were all present on or after the 3rd calendar day of admission to the facility (the day of hospital admission is calendar day 1). All elements used to meet the CDC/NHSN site-specific infection criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between any two adjacent elements. The definition of a gap day is a calendar day during which no infection criterion elements are present.
IAB*	(NHSN) Intra-abdominal healthcare-associated infection; a subset of GI*
ICU	Intensive care unit

INDWELLING URINARY CATHETER*	(NHSN) Drainage tube inserted through the urethra to the urinary bladder, left in place, and connected to a drainage bag. Also called a Foley catheter. May be used for drainage and/or irrigation. Excludes condom catheters, straight in-and-out catheters, nephrostomy tubes, and suprapubic catheters.
INPATIENT SURGERY*	(NHSN) Surgery in a patient whose date of admission is different from date of discharge
INTERNAL VALIDATION	Active efforts by a reporting facility to assure completeness and accuracy of NHSN data
IP	Infection preventionist
IT	Information technology
LabID Event*	(NHSN) A measure developed for infection surveillance using laboratory results data without the requirement for extensive clinical documentation and intended for easy electronic reporting
LCBI 1,2,3*	(NHSN) laboratory-confirmed bloodstream infection criteria
LDRP	Labor, Delivery, Recovery, and Post-partum, a type of NHSN location in an acute care facility
LOS	Length of stay (days)
MEDICAL RECORD	A record systematically documenting a single patient's medical history and care across time within a healthcare provider's jurisdiction. For the purpose of sampling, a medical record (which over time could include many healthcare encounters) refers to a single facility inpatient admission.
MRN	Medical record number
MRSA, MSSA	Methicillin-resistant *Staphylococcus aureus*, Methicillin-susceptible *Staphylococcus aureus*
NICU	Neonatal intensive care unit
NP	Nasopharyngeal
NHSN	National Healthcare Safety Network
OBSERVATION LOCATION	A bedded patient care location designated for patients under observation, a form of outpatient status. The purpose of observation is to allow the physician time to make a decision about whether the patient should be admitted, and then rapidly move the patient to the most appropriate setting, i.e., admit to inpatient status or to send home.
OBSERVATION PATIENT	Status for patients who are undergoing short-term treatment, assessment, and reassessment while a decision is made regarding the need for admission to the hospital. Observation patients may occupy beds in observation locations or inpatient locations.
OrgID*	(NHSN) NSHN facility identifier
O/S SSI*	(NHSN) Organ/space surgical site infection
OUTI*	(NHSN) Other UTI
PATIENT DAYS*	(NHSN) The number of patients (inpatients and observation patients) housed in a facility inpatient location during the designated counting time each day, and summed for a monthly denominator report for device-associated infections (CLABSI, CAUTI, VAE), and for LabID Events.
PDS	Post-discharge surveillance
POA*	(NHSN July 2013) Present on admission. An infection is POA if all elements of the site-specific infection criterion are present during the two calendar days before the day of admission, the day of admission, and /or the day after admission, and documented in the medical record by a healthcare provider. POA infections should not be reported as HAIs, however POA is not used for SSI, VAE, or LabID Events.
PRIMARY*	(NHSN) Originating source of infection (See SECONDARY)
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

SECONDARY* INFECTION	(NHSN) Site affected by infection by dissemination from an alternative originating source (see PRIMARY)
SIR*	(NHSN) Standardized infection ratio
SI SSI*	(NHSN) Superficial incisional surgical site infection
SSI*	(NHSN) Surgical site infection
SUTI*	(NHSN) Symptomatic UTI
TARGETED SAMPLE	In this document, a purposive sample taken to target facilities at higher risk for HAI or medical records at higher risk for misclassification of HAI status (See also, purposive sample)
URINARY CATHETER*	(NHSN) See indwelling urinary (urethral) catheter.
UTI	Urinary tract infection
TERTILE	Lowest, middle, or highest one-third of a group
VAE*	(NHSN) Ventilator-associated event. An objective surveillance algorithm that can identify a broad range of conditions and complications (including but not limited to pneumonia) occurring in mechanically-ventilated adult patients, detailed in NHSN Manual Chapter 10.
VALIDATION	Assurance that reported NHSN surveillance data meet their pre-determined specifications and quality attributes as intended

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

Chapter 1: Overview and 2015 Validation Standards

Validation can be defined as confirming or assuring that data meet pre-determined specifications and quality attributes. NHSN validation should assure high quality of three domains in reporting healthcare-associated infections (HAIs): denominators, numerators, and risk adjustment variables.

Why Validate?

NHSN was launched as a voluntary, confidential HAI reporting system for hospitals conducting surveillance, benchmarking, and quality improvement for HAIs. Since 2006, NHSN data have also been used by state and federal agencies for public reporting purposes and increasingly are used to incentivize quality improvement through payment mechanisms. These new uses have heightened the importance of the completeness and accuracy of the data. Hospital boards, administrators, and clinical leadership need to trust their own facility's data to assess performance, manage change in their facilities, and to know that other facilities are held to the same high standards when reporting. Consumers seeking to make informed decisions about their healthcare 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 information 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 introduce opportunities for variation. This complex landscape will continue to change over time as NHSN methods evolve, use of electronic medical records increases, and reporting requirements expand.

In the context of powerful 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 and disease prevention. In the absence of meaningful external validation, healthcare facilities may fail to identify or report HAIs. This would not require overt gaming because variation in effort, resources, and practices between facilities can result in surveillance bias ("the harder you look the more you find") and in assessment bias ("we tend to see what we want to see"). For example, approaches to surveillance that create barriers to reporting, such as requiring the agreement of multiple reporters or permission from authorities before reporting can lead to lower measures of disease rates without improving patient safety.[1,2] To provide for fair comparisons 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 accounting for HAIs. Accurate, high quality NHSN data are important to infection prevention programs for setting priorities and measuring the impact of prevention efforts. Further, public health agencies at the local, state and federal levels need these data to identify HAI problems and to measure prevention program success. Each of these data users also has a role and a stake in assuring quality of NSHN data.

External Validation

External validation is a survey and audit process conducted by an agency outside the reporting facility (e.g. state health department), in which a facility's surveillance determinations and methods are investigated by one or more trained validators who work for the external agency, to evaluate surveillance program quality (e.g. knowledge and practices), and completeness and accuracy of reporting. Findings from external validation can be used to correct reporter misconceptions about NHSN definitions, criteria, and data requirements. As a result, external validation can help assure adherence to NHSN's specifications for HAI reporting by identifying and correcting shortcomings that would be difficult to address through internal validation alone. Data correction and completion should be required of reporters, and helping reporters understand what led to the errors enhances the likelihood of better reporting in the future. Common errors and challenging cases should be documented to derive information for teaching and to improve future reporting.

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 or review every patient record in search of candidate HAIs. Sampling is a practical necessity, and sampling methods should strike a balance between resource availability and programmatic objectives.

2015 Validation Guidance

For 2015 data validation, this guidance document specifies an algorithm for targeted sampling that provides for efficient investigation of potential surveillance and reporting problems in highly exposed facilities and medical records, where HAIs are most expected. Exposure risk derives from increased device days, surgical procedures, or specified positive laboratory test results, and targeting is driven by either high or low event reporting. In targeted samples, the ability to produce generalizable information about the population as a whole is constrained. A favorable outcome under targeted sampling suggests that success would be even more likely in a probability sample representing the entire population at risk. Because all facilities should be held accountable for accurate reporting, and smaller facilities that are unlikely to be targeted given low exposure risk may actually derive great benefits from validation, a 5% random sample of additional facilities should also be drawn after the targeted facility sample has been selected. States should not be constrained by the algorithm, and should seek adequate reporter training and internal quality assurance of all reporting facilities in their jurisdiction, even those that are not audited.

Chapter 2: Guidance for Conducting 2015 NHSN Validation

A targeted validation approach is recommended to use resources as efficiently as possible to identify reporting errors, particularly errors caused by correctable systematic surveillance problems or misconceptions. The recommended sample sizes and enriched sampling frames provide a reasonable chance to identify reporting errors if they exist. The scope of external validation includes six metrics: ICU CLABSI, ICU CAUTI, COLO SSI, HYST SSI, MRSA Bacteremia LabID Event and CDI LabID Event which are consistent with CMS Inpatient Quality Reporting Program requirements.

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

When selecting which HAIs to validate, oversight agencies may choose to use experience and/or data analysis to prioritize choices. For example, if validation of ICU CLABSI was completed as recommended in the 2014 Validation Guidance and Toolkit, agencies may seek to focus on other HAIs for 2015. Those with high rates of a particular HAI may wish to focus validation on this problem to assist facilities with prevention.

Facilities that will not be targeted for external validation audits using this suggested sampling method should still be held accountable for high quality surveillance and reporting programs and for conducting internal validation activities. Requesting evidence of up-to-date NHSN reporter training (such as a 2015 certificate of successful completion produced by each of NHSN's multimedia training modules from all facilities) is one way to assure appropriate reporter training without a site visit. Some may wish to administer surveillance process surveys or request documentation of internal validation activities by facilities.

For audited facilities, recommended external validation for 2015 includes assessment of numerators, denominators, and risk-adjustment variables, with medical records audit focused on outcomes (numerators). Numerator quality can be assured by a) adequate reporter knowledge (as demonstrated by completed certificates for 2015 online multimedia assessments), b) good surveillance practices (assessed by survey), and c) evidence of correct reporting (by an audit of medical records showing concordance of validator outcomes with events reported to NHSN). Denominators can be assessed by a) review of denominator data records, b) denominator collection practices surveys, and c) (for COLO and HYST procedures) comparison of crude monthly procedure counts in NHSN with ICD-10-PCScodes generated by the facility. Risk adjustment variables and documentation of internal validation work conducted by facilities should also be reviewed.

This external validation guidance and toolkit, informed by state and facility experience and the need for standardized validation methods, recommends on-site medical record reviews by trained validators using a medical record abstraction tool that follows 2015 NHSN methods and definitions, with CDC serving as adjudicator of discordant outcomes when necessary. On-site validation provides optimal opportunity for validators to gain full access to any documented information used by reporters when

conducting surveillance, and to strengthen relationships with reporting facilities through transparency. Use of electronic medical records systems that are made available at a distance to validators is a feasible, though perhaps a sub-optimal alternative way to audit medical records. This approach may require technical expertise and iterative work with facilities to assure validator access to all relevant documentation. In addition, without site visits the opportunities for interaction, education, and understanding of the overall HAI surveillance program are likely to be reduced. Remote review of copied medical records is discouraged for external validation program methodology, as potentially lacking complete data access and the interactivity that facilitates program capacity building. Ideally, validators will be either employed or contracted by agencies that have oversight responsibilities for patient safety and public health in the audited healthcare facilities, and across the continuum of healthcare.

CDC-Recommended Validation Elements and Preferred Approach

Validation Element	**Off-site**	**On- or Off-site**	**On-site**
Validator training and assessment	X		
NHSN Data analysis for completeness, timeliness, and quality	X		
Facility selection, request for line listings (CLABSI, CAUTI, MRSA bacteremia, and CDI), and monthly surgical procedure counts (COLO, HYST)	X		
HAI Sampling Frame Development	X		
Medical Record Selection, NHSN data download, and arrangements for audit	X		
Facility surveillance Practices Surveys (Appendix 2)		X	
Review of facility mapping, bed size			X
Medical Record Reviews (Appendix 3)			X
Post-review conference with IP re: surveillance practices and medical records audit discrepancies			X
Administration of additional denominator counting surveys, as needed		X	
Review of facility results, strengths, and weaknesses		X	
Follow-up corrections and report to IP and administration	X		

Chapter 3: Preparation for External Validation

1. Assure or update validator expertise in 2015 definitions

For CLABSI, be aware that important changes in NHSN require surveillance for, and reporting of, Mucosal Barrier Injury-Laboratory Confirmed Bloodstream Infection (MBI-LCBI) events introduced at the beginning of 2015. Additionally, the definition of neutropenia in the MBI-LCBI criteria was expanded in 2015. These additions and definitions can affect case-ascertainment and classification for CLABSI events. Validators MUST be familiar with these to correctly audit NHSN cases. The Medical Records Abstraction Tools are also designed to support these changes. Additional instructions for location mapping may affect location of attribution and risk adjustment for device-associated events, and should be part of the audit and survey process.

For SSI, be aware that important changes in definitions include the addition of: height and weight; diabetes status; incisional closure type (primary vs. non-primary); and a modified definition of procedure duration. The SSI definition changes can affect reporting of procedures (denominators) and SSI case-ascertainment (numerators). Validators need to be familiar with these changes to correctly audit procedures and SSIs in NHSN.

Surveillance and validation require rigorous adherence to standard NHSN protocols, surveillance methods, and NSHN definitions as written. Persons conducting audits must be trained in NHSN specifications, remain up-to-date when changes are made, and commit to using appropriate NHSN methods and definitions to validate HAI data reported to the system. In addition to reporter training resources, validator training resources are available on the NHSN website and will be expanded in the future (http://www.cdc.gov/nhsn/validation/2015/index.html). The following trainings are available on the training website. They are listed in order of recommendation for validators:

Type of NHSN Training	Recommended Validator Standard	Symbol Key for Online NHSN Training Types (Examples as below)
Interactive Online Multimedia Instruction Modules	Assure that all 2015 validators successfully complete these courses for any NHSN component they will validate, and provide copies of the certificates of completion	Self-paced, interactive trainings used to gain in-depth knowledge of NHSN HAI definitions
Slide sets	Highly recommended: Slide presentations include case-studies to help validators implement the basic content presented in HAI training webinars	Presentations and case studies used to walk through difficult cases to learn to apply the NHSN HAI definitions accurately
Webinars & Podcasts	Basic prerequisite for prospective validators; Basic training in HAI surveillance	Webinars and podcasts used to provide basic information on NHSN HAI definitions and surveillance protocols

Other opportunities for training include:

- CDC-sponsored trainings.
- NHSN blast emails, external partner calls, the quarterly NHSN newsletter, and the NHSN Manual, updated prior to each January with any changes to methods and definitions.

Even after training, willingness to seek help when needed from NHSN on definitions and criteria is important when cases are challenging. If facilities and auditors cannot agree on case-status using documented information and the NHSN case-definition as a gold standard, the case should be referred to CDC for adjudication. Forms for tracking cases that result in discrepancies and that require adjudication are found in Appendices 4.1 and 4.3.

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

2. Select facilities

For 2015, as in 2014, CDC recommends targeted validation in order to investigate and correct potential deficiencies in an efficient manner, given the assumption of limited resources for validation. This approach also provides maximum opportunity to work with reporters to improve reporting.

The exercise for facility selection can also be used as a means of developing situational awareness about exposure risk and performance of facilities. This information may be useful for targeting prevention programs.

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

To build a sampling frame for medical record selection, electronic files (spreadsheets) are required from laboratories that list positive blood cultures, positive quantitative urine cultures, and positive CDI toxin tests, with test dates, patient locations, identified pathogens and patient information to identify medical records for review. In addition, assistance may be needed from hospital medical records departments to identify hospital re-admissions within the surveillance window (3 months for COLO and HYST) of audited surgical procedures. Some agencies have established secure FTP sites for transfer of these sensitive data. Consider existing systems for secure data transfer and how to secure these data in both directions--to send line listings to characterize the sampling frame and to respond with the sample of medical records to be reviewed.

4. For each selected facility, know which HAIs you will be validating, based on information derived from the algorithms in Chapter 4, and your individual priorities and goals.

Before the validation process, for each selected facility and HAI to be validated, record the total number of HAI events reported by the facility for 2015 using Appendix 4.3, “Numerator Validation.”

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

For CLABSI, CAUTI, MRSA Bacteremia LabID Event and CDI LabID Event, sampling frames derive from positive laboratory (blood culture, urine culture, and CDI toxin-positive specimen) line-listings in surveillance locations. Hospitals should be encouraged to develop capacity to generate these lists electronically, because recurring need for this capability is expected, and creation of manual line-listings would present an excessive burden.

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

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

For SSI, sampling frames derive from procedures in NHSN. **However, to assure that the NHSN procedure sampling frame is complete, a monthly tally from the facility for COLO procedures and HYST procedures performed, based on ICD-10 procedure/CPT codes in discharge data should be used.** This data request may be made along with the line listing requests and the procedure numbers entered in Appendix 4.3, "Denominator Validation COLO" and "Denominator Validation HYST." If these numbers are reasonably close to the number of procedures listed in NHSN, the procedure denominator data are presumed to be relatively complete.

Structure of laboratory line listings

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

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

CLABSI in ICU

From each selected facility, obtain a complete list of positive ICU blood cultures collected in 2015 to select the medical record sample before the site visit. A spreadsheet file (e.g. Excel) is recommended for ease of use.

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

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Blood Organism 1 Genus and Species	*Specific ICU Location	*Gender	*Date of Birth	First Name	Last Name

- For positive ICU blood cultures, the medical record number, admission date, laboratory specimen number, the date of specimen collection (not date of report), the resulting first organism ("Org 1") genus and species, specific ICU location, gender, and date of birth are required. Additional patient identifiers such as patient name may be helpful. If needed, ask the IP to translate specific patient location information on the laboratory line listings to mapped NHSN ICU locations, and assure that results for all ICUs are included. Be sure it is possible to distinguish NICU from adult/pediatric ICU locations on this line listing to stratify the CLABSI sample. No information about central line use should be requested; validators will screen for this information while reviewing records.
- Using the line listing, sort by MRN and facility admission date (which together characterize unique eligible admissions/episodes of care with possible ICU CLABSI), then enumerate the eligible episodes of care using the spreadsheet. Enter the number of unique episodes of care eligible for CLABSI review for the year in Appendix 4.3, "Numerator Validation, Sampling Frame Information."

CAUTI in ICU

From each selected facility, obtain a complete list of positive ICU urine cultures collected in 2015 to select the medical record sample before the site visit. A spreadsheet file (e.g., Excel) is recommended for ease of use. Limit positive ICU urine cultures to those with no more than 2 identified pathogens and at least 10^5 CFU/ml organisms.

Template positive ICU urine culture line listing (* indicates required data; †second organism information is conditionally required):

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Urine Organism 1 Genus and species	*Urine Colony Count 1 (CFU/ml)	†Urine Organism 2 Genus and Species	†Urine Colony Count 2 (CFU/ml)	Continued…

…continued	*Specific ICU Location	*Gender	*Date of Birth	First Name	Last Name

- For positive ICU urine cultures, the medical record number, facility admission date, laboratory specimen number, specimen collection date, identity of organisms (up to two) and colony counts (CFU/ml), specific ICU location, gender, and date of birth are needed. Additional patient identifiers such as patient name may be helpful. If needed, ask the IP to translate specific patient location information on the laboratory line listings to mapped NHSN ICU locations, and assure that results for all ICUs are included. Urine specimens with mixed flora, more than two organisms, or fewer than 10^5 CFU/ml organisms will be rejected. No information about indwelling urinary (Foley) catheter status should be requested; validators will screen for this information while reviewing records.

- Using the line listing, sort by MRN and facility admission date (which together characterize the eligible admissions/episodes of care with possible ICU CAUTI), then enumerate unique eligible episodes of care using the spreadsheet. Enter the number of episodes of care eligible for CAUTI review for the year in Appendix 4.3, "Numerator Validation, Sampling Frame Information."

COLO Procedures

- For each selected facility, use NHSN to determine the number of reported COLO procedures conducted in 2015. Enter the number of NHSN-reported COLO procedures in Appendix 4.3, "Numerator Validation, Sampling Frame Information."
- Use NHSN to determine the monthly number of reported COLO procedures conducted in 2015. Record the results in Appendix 4.3, "Denominator Validation COLO." (These monthly data will be compared to the facility report generated below to assure that the procedure denominator is complete).
- Provide the list of ICD-10 procedure codes for NHSN COLO procedures and ask the facility to provide a monthly count of COLO procedures conducted in 2015, derived from hospital discharge data. Record the results in Appendix 4.3, "Denominator Validation COLO," juxtaposed by month with the number of COLO procedures entered into NHSN for each month as determined above.

HYST Procedures

- For each selected facility, use NHSN to determine the number of reported HYST procedures conducted in 2015. Enter the number of NHSN-reported HYST procedures in Appendix 4.3, "Numerator Validation, Sampling Frame Information."
- Use NHSN to determine the monthly number of reported HYST procedures conducted in 2015. Record the results in Appendix 4.3, "Denominator Validation HYST." (These monthly data will be compared to the facility report generated below to assure that the procedure denominator is complete).
- Provide the list of ICD-10- procedure codes for NHSN HYST procedures and ask the facility to provide a monthly count of HYST procedures conducted in 2015, derived from hospital discharge data. Record the results in Appendix 4.3, "Denominator Validation HYST," juxtaposed by month with the number of HYST procedures entered into NHSN for each month as determined above.

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

From each selected facility, obtain a complete list of blood cultures positive for methicillin-resistant *Staphylococcus aureus* (MRSA: includes *S. aureus* cultured from any specimen that tests oxacillin-, cefoxitin-, or methicillin-resistant by standard susceptibility testing methods or by a laboratory test that is FDA-approved for MRSA detection). Include those collected in 2015 for inpatient location/ED/ 24 hour observation unit facility-wide, to select the patient admissions/episodes of care for which review is planned. A spreadsheet format is recommended for ease of use. These laboratory line lists should include patient location at the time of specimen collection.

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

*Medical Record Number	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Blood Organism Genus and Species (Documenting *S. aureus* or MRSA)	*Documentation of Methicillin-Resistance (susceptibility test result or MRSA)	Continued…

…continued	*Specific Mapped NHSN Location at Specimen Collection	*Gender	*Date of Birth	First Name	Last Name

- For positive MRSA bacteremia LabID Event (facility-wide, inpatient), the medical record number, facility admission date, laboratory specimen number, specimen collection date, documentation that specimen source was blood, genus and species, methicillin susceptibility information (organism ID may be shortened to MRSA, covering genus, species, and methicillin susceptibility requirements), specific inpatient or emergency department (ED) location/ 24 hour observation location, gender, and date of birth are required. Additional patient identifiers such as patient name may be helpful.
- Using the line listing, sort by MRN and facility admission date (which together characterize the eligible admissions/episodes of care with possible MRSA bacteremia LabID Event), then "count" the number of unique eligible episodes of care using the spreadsheet. Enter the number of episodes of care eligible for MRSA bacteremia LabID Event review for the year in Appendix 4.3, "Numerator Validation, Sampling Frame Information."

CDI LabID Event, facility-wide, inpatient (FacWideIN)

To create a sampling sample, obtain from each selected facility, a complete list of final *Clostridium difficile* toxin-positive laboratory results collected in 2015 for inpatients facility-wide [excluding NICU, skilled care nursery, babies in labor/delivery/recovery/post-partum (LDRP) locations, or well-baby nurseries]/ ED/ 24 hour observation units. Laboratories may conduct one- two- or three-step testing for toxigenic *C. difficile* on unformed stool specimens; regardless of the testing approach, only final positive results indicating the presence of toxin-producing *C. difficile* should be included.

A spreadsheet format is recommended for ease of use. These laboratory line lists should include patient location at the time of specimen collection.

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

*MRN	*Facility Admission Date	*Laboratory Stool Specimen Number	*Specimen Collection Date	*Result of Final CDI Toxin Test (assure test is toxin-positive for CDI)	* Specific Mapped NHSN Location at Specimen Collection	Continued…

…continued	*Gender	*Date of Birth	First Name	Last Name

- For positive CDI LabID Event (facility-wide, inpatient), the medical record number, facility admission date, stool specimen number, specimen collection date, result of final CDI toxin test, specific inpatient (or ED/ 24 hour observation) location, gender, and date of birth are required. Additional patient identifiers such as patient name may be helpful.
- Using the line listing, sort by MRN and facility admission date (which together characterize unique eligible admissions/episodes of care with possible CDI LabID Event), then enumerate the eligible episodes of care using the spreadsheet. Enter the number of episodes of care eligible for CDI LabID Event review for the year in Appendix 4.3, "Numerator Validation, Sampling Frame Information."

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

The request may include:

a) 2 separate positive blood culture line listings (positive ICU blood cultures for CLABSI validation and positive MRSA bacteremia for LabID event validation in facility-wide inpatients/ ED/ 24 hour observations.)
b) Positive ICU urine cultures for CAUTI validation
c) CDI toxin-positive specimens for LabID Event validation in facility-wide inpatients/ ED/ 24 hour observations.
d) Monthly totals for COLO and HYST procedures from medical records-based monthly ICD-10-PCS procedure totals

For chosen facilities, contact the IP and discuss the audit process, including the likely scope of the audit and how the audit sample will be drawn from eligible medical records. Discuss the current request for blood culture, urine culture, and *C. difficile* toxin-positive line listings for appropriate patient populations (with structures described above). If all six HAIs will be validated, up to 60 specific medical records will be requested each for ICU CLABSI and ICU CAUTI, up to 60 medical records each for COLO and HYST procedures with any subsequent admissions within 3 months following the procedure, and for LabID Event, access to either a) ADT data and complete inpatient and outpatient laboratory records for 60 specified episodes of care each for MRSA bacteremia and CDI LabID Event auditing OR b) corresponding medical records that include these elements during on-site validation. Ask about the lead-time for the facility to generate the required line listings and how much lead-time the medical records department will need to arrange for medical record access. Ask how patient medical records can best be accessed onsite and how they are organized; this can affect the time required to abstract the records. Disorganized records on microfilm may be particularly difficult and time-consuming to abstract. Discuss the anticipated number of days and reviewers needed to complete the audit, based on experience or the guidance to follow. Request documentation that the facility's NHSN reporters have completed training on 2015 NHSN reporting methods and definitions. In addition, a monthly breakdown of how many COLO and HYST procedures were conducted using ICD-10-PCS coded data should be requested if these will be validated.

Consider a mutually agreeable due date for the laboratory line listings, dates for the medical record request, and proposed date(s) for the onsite audit. For the audit, request arrangements for medical

records access including e.g., workspace, computer systems, terminals and passwords, microfilm readers, and (eventually) specific medical records.

The laboratory line listings should be provided by the facility through a secure file transfer (for example, encrypted email, secure FTP site, or encrypted file by courier, or snail mail) as a sortable and searchable (e.g., .csv, Excel) file, and should include facility information (identity and NHSN facID), hospital contact name, hospital contact phone, hospital contact email, date of report, and timeframe of laboratory results.

Compose a letter notifying the facility CEO and copied to the IP that provides an overview of your authority to conduct validation (if applicable) or requesting voluntary access to medical records for the audit process, the purpose of the audit, proposed dates for the audit, and specific data and accommodations needed from hospital staff (see Appendix 1.2 for an example letter). Explain the purpose of the audit (i.e., to assure accountability of all hospitals in complete and accurate reporting of HAIs according to NHSN methods and definitions) and how validation results will be used and/or reported.

7. Select medical records (to be discussed in the next chapter)

8. Download ("freeze") the facility's reported data from NHSN before disclosing which medical records were selected for the audit.

Do this after selecting the medical records sample to minimize downloads, using NHSN analysis. We suggest using CDC-defined output with the modifications below for freezing and exporting reported 2015 NHSN data.

NOTE: All output options should be exported using the "Export Output Dataset" option at the bottom of the modification screen within NHSN. For more information about how to make modifications to these output options, please see the Analysis Quick Reference Guide library at: http://www.cdc.gov/nhsn/PS-Analysis-resources/reference-guides.html.

Output Option: Line Listing – All CLAB Events
Found within: Device-associated Module > Central Line Associated BSI
Purpose: Obtain a line listing of all CLABSI events in ICU and NICU locations
Suggested Modifications:

- Change the output title to "<Facility ID > Freeze Data <Freeze Date> ICU CLABSI, 2015"
- Specify time period as: **specDateYr** 2015 to 2015
- Specify other selection criteria: **locationType** IN ('CC – CC' , 'CC_N – CC_N')
- Indicate "Sort" variables (optional)

Output Option: Line Listing – All CAU Events
Found within: Device-associated Module > Urinary Catheter-Associated UTI
Purpose: Obtain a line listing of all CAUTI events in ICU locations
Suggested Modifications:

- Change the output title to "<Facility ID > Freeze Data <Freeze Date> ICU CAUTI, 2015"
- Specify time period as: **specDateYr** 2015 to 2015
- Specify other selection criteria: **locationType** IN ('CC – CC')

- Indicate "Sort" variables (optional)

Output Option: Line Listing – All Procedures
Found within: Advanced > Procedure-level Data
Purpose: Obtain a line listing of all COLO and HYST procedures, with associated surgical risk-adjustment variables
Suggested Modifications:

- Change the output title to "<Facility ID > Freeze Data <Freeze Date> COLO procedures (or HYST procedures), 2015"
- Specify time period as: **procDateYr** 2015 to 2015
- Specify other selection criteria: **procCode = COLO (or procCode=HYST)**
- Indicate "Select Available Variables" including (optional) procID, procCode, dob, patID, gender, procDate, modelRiskAll, asa, anesthesia, scope, emergency, trauma, ageAtProc, swClass, procDurationHr, procDurationMin

Output Option: Line Listing – All SSI Events
Found within: Procedure-associated Module > SSI
Purpose: Obtain a line listing of all COLO (or HYST) SSI events
Suggested Modifications:

- Change the output title to "<Facility ID > Freeze Data <Freeze Date> <procedure> SSI, 2015"
- Specify time period as: **specDateYr** 2015 to 2015
- Specify other selection criteria: **procCode = COLO** (or **procCode=HYST**)
- Indicate "Sort" variables (optional)

Output Option: Line Listing **for All CDIF LabID Events**
Found within: MDRO/CDI Module – LABID Event Reporting > **All C. difficile LabID Events**
Purpose: Obtain a line listing of all **C. difficile LabID Events**
Suggested Modifications:

- Change the output title to "<Facility ID > Freeze Data <Freeze Date> **CDIF LabID Events, FacWideIN, 2015"**
- Specify time period as: **specDateYr** 2015 to 2015
- Specify other selection criteria: "**cdif" =Y,**
- Indicate "Sort" variables (optional)

Output Option: Line Listing **for All MRSA LabID Events**
Found within: MDRO/CDI Module – LABID Event Reporting > **All MRSA LabID Events**
Purpose: Obtain a line listing of all **All MRSA Blood LabID Events FacWideIN**
Suggested Modifications:

- Change the output title to "<Facility ID > Freeze Data <Freeze Date> **MRSA Blood LabID Events FacWideIN, 2015"**
- Specify time period as: **specDateYr** 2015 to 2015
- Specify other selection criteria: **"mrsa"=Y, "SpecimenSource"= (BLDSPC)**
- Indicate "Sort" variables (optional)

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

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

Chapter 4: Targeted Sampling of Facilities and Medical Records

Targeted Facility Sampling Overview (see detailed algorithm in Appendix 1.1)

Validators are encouraged to complete the facility ranking algorithms in Appendix 1.1 for the six HAI types. If CLABSI and CAUTI will be validated in facility types other than acute care hospitals, separate rankings should be completed for acute care hospitals, long-term acute care hospitals (LTACs), and inpatient rehabilitation facilities (IRFs). This will provide a system for assigning relative priority to each facility for each HAI. Even for those not planning to conduct validation, this ranking activity provides awareness of which facilities are highly exposed to HAI risk and those reporting high or low event outcomes. Additional analyses to evaluate data completeness, timeliness, and quality also are encouraged. In particular, targeted sampling of hospitals performing the surgical procedures to be audited and of the surgical procedures themselves requires that risk-adjustment variables (e.g., ASA score, anesthesia, procedure duration) are complete. Analysis to assure completeness of these variables is recommended before facilities are ranked for SSI validation.

Ultimately, validation resources must be weighed and decisions made as to which HAIs will be validated based on past validation work, need for information on data quality and training needs, unrealized disease prevention, and perceived utility for prevention activities. The facility rankings should help with logistical planning when these considerations are weighed.

- The recommended approach to facility selection for 2015 is targeted (as was recommended for 2014 validation) to prioritize validation of facilities where HAIs are most expected. A recommended minimum number of facilities should be validated (with a recommended minimum number of medical records) for each selected HAI:
    - Smaller states/jurisdictions with 20 or fewer facilities should validate them all
    - Medium states with 21 to 149 facilities should select at least 18 targeted facilities plus a 5% random sample of remaining facilities
    - Larger states with 150 or more facilities should select at least 21 targeted facilities plus a 5% random sample of remaining facilities

Ranking Algorithm

- For each HAI, sort facilities based on predicted/expected number of events.
- After sorting, the top tertile (33%) of facilities will undergo further targeting and prioritization, based on performance, using the facility SIR relative to the median SIR for the top tertile group of facilities. Detailed guidance for this process is found in Appendix 1.1.
- If the minimum number of targeted facilities is not reached within the top tertile alone, the process should be repeated by targeting the second tertile, and (if necessary) the third.
- If additional facilities are needed to achieve the recommended minimum number, facilities without a calculated SIR may be considered for validation based on the “delta count”, defined as the absolute difference between expected and observed NHSN Events reported to NHSN.
- For each HAI, all unselected facilities from all 3 tertiles will be subject to a 5% random sample in order to assure accountability for facilities that are not highly exposed.
- If you choose to validate multiple HAIs at your facilities then you will need to evaluate the facilities to be chosen based on where they rank after you’ve completed the ranking algorithm for each HAI individually.

Targeted Medical Record Sampling Overview (see detailed algorithms in Appendix 1.3)

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

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

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

Sample structure

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

Line listings required from facility

To identify unreported "candidate" CLABSI, CAUTI, MRSA bacteremia LabID Events and CDI LabID Events, a sampling frame of medical records and/or positive laboratory tests is needed, and will require assistance from the facility being validated before the audit (see table below and specific instructions for medical records selection in Appendix 1.3: Step-by-Step Targeted Medical Record Selection). For COLO

and HYST SSIs the required sampling frame is derived from COLO and HYST procedures already entered and available in NHSN, however completeness of surgical risk-adjustment variables should be assured before sampling is conducted, because these variables are used for targeting.

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

HAI Event to be Validated	Request to Facility for Line Listing (detailed in Chapter 3)	Line Listing Will Define the Following Sampling Frame Elements
ICU CLABSI	Line listing of positive ICU and NICU blood cultures, with patient ID and admission date	Episodes of care (identified by patient ID and unique admission date) with one or more positive ICU blood culture(s) (include NICUs)
ICU CAUTI	Line listing of positive ICU (non-NICU) urine cultures[a] with patient ID and admission date	Episodes of care (identified by patient ID and unique admission date) with one or more positive ICU urine culture(s)[a] (exclude NICUs)
MRSA bacteremia LabID Event	Inpatient[b] blood cultures positive for MRSA	Episodes of care with one or more inpatient[b] blood cultures positive for MRSA
CDI LabID Event	Inpatient[b] stools[c] toxin-positive for *C. difficile*, excluding those from baby locations[d]	Episodes of care with one or more inpatient[b] stools[c] toxin-positive for *C. difficile*, excluding those from baby locations[d]

[a]Positive ICU urine cultures with no more than 2 identified pathogens and at least 10^5 CFU/ml organisms
[b]For LabID Event, emergency department (ED) and 24 hour observation location specimens are considered facwideIN. Specimens collected from other affiliated outpatient locations on the day of admission are considered inpatient specimens.
[c]Surveillance guidance for laboratories recommends that *C. difficile* toxin testing be done only on unformed stool specimens, and formed stool should be rejected
[d]Baby locations include those with 80% or more infants (≤1 year); typically NICU, newborn nursery, and special care nursery. Babies in LDRP locations should also be excluded.

Chapter 5: Activities During and After the Facility Site Visit

Suggested Tools to bring along for validation site-visits

- Letter of introduction, state ID badge or other authorization
- 2015 NHSN Manual
  - Before visit: Tag/highlight case definitions
  - Tag/highlight location descriptions for patient location mapping
- Information about the facility:
  - Facility's most recent NHSN Annual Survey
  - List of surveillance locations with demographics
  - List of medical records requested for screening
  - Confidential list of HAIs reported by facility to NHSN (assure that validators are blinded until after review is completed).
- Copies of Methods Surveys (Appendix 2) and form to collect contact information (Appendix 2.3)
- Multiple copies of blank medical record abstraction tools (Appendix 3)
- Copies of 2015 Tennessee checklists (available at http://health.state.tn.us/ceds/hai/)
- Blank audit discrepancies reports (Appendix 4.1)
- External Validation Documentation Form (Appendix 4.3)
- Miscellaneous tools: Straight edge (e.g.: ruler) for reading data printouts, stapler, binder clips, pens, highlighters, sticky notes, tape flags

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

Request documentation of current NHSN reporter training

NHSN reporters should have documentation of successful completion of the online, self-paced multimedia training modules for HAIs they oversee. This is an opportunity to establish or reinforce state expectations for this annual update. Consider recording the results in Appendix 4.3, custom field.

Review risk adjustment variables:

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

Bring a copy of the facility NHSN Annual Survey, and review the ICU location mapping and bed size information with the IP, along with an up-to-date list of CDC locations and descriptions (see http://www.cdc.gov/nhsn/forms/instr/57_103-TOI.pdf and http://www.cdc.gov/nhsn/PDFs/pscManual/validation/pcsManual-2015-valid.pdf). If there is insufficient time to complete this onsite, consider arranging a conference call to review location mapping when data are readily accessible.

Review NHSN definitions for teaching hospital types (under Key Terms, http://www.cdc.gov/nhsn/PDFs/pscManual/validation/pcsManual-2015-valid.pdf), and assure that facility teaching hospital status is accurate in the NHSN Annual Survey.

For COLO and HYST, many risk adjustment variables can be validated as part of the medical record review process. The medical record abstraction forms for COLO and HYST include fields for ASA score, patient age, and other risk adjustment variables, as well as SSI outcome. Validation of risk adjustment variables is recommended to assure that sampling has appropriately targeted high-risk procedures.

Review denominator methods and documentation

CLABSI and CAUTI denominator counting methods

Surveillance and denominator data collection surveys found in Appendices 2.1 and 2.4 may be administered to the IP contact before or during the site visit; however it may be impractical to interview multiple denominator data collectors during the site visit. In this case, collecting contact information during the site visit may be advisable for subsequent administration of surveys by telephone (Appendix 2.3). This allows time at the facility to be used efficiently and accommodates interviews with individuals who may work at other times (e.g. the night shift).

In many facilities, the same person will collect denominator data for device-associated infections (including CLABSI and CAUTI) concurrently. Because of this, the denominator counting survey for CLABSI and CAUTI in Appendix 2.4 may be administered for each metric separately or for both combined. Knowledge of definitions and counting methods is important even in facilities where denominators are reported electronically in order that spot-checks can be conducted periodically. A form for facilities to document required internal validation of electronic denominator counting is provided in Appendix 2.2.

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

CLABSI and CAUTI denominator records

While visiting, request original records of denominator data collection paperwork, which can provide insight into the frequency, reliability, and consistency of this task and how omissions are handled (NHSN provided guidance for missing device-associated denominator data in September 2013 http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf). Consider whether patient days and central-line days data appear as anticipated when manually counted each day: different ink, different but similar numbers. Determine for what percent of days data are missing and what was done for reporting on those days. Findings should be documented in Appendix 4.3.

Electronically collected CLABSI and CAUTI denominators

Unexamined electronic denominator counting may be a source of error in HAI reporting.[5,6] If the facility uses electronic denominator data collection, obtain documentation of their denominator validation process and any periodic spot checks. NHSN specifies that electronic denominator counts should fall within 5% of manual counts for three consecutive months before electronic counts can be used (See Appendix 2.2).

If documentation of electronic denominator validation is not available, the facility should resume manual counting (and assure staff training), to re-validate electronic counts, and to retain evidence of valid electronic counting (within 5% for 3 months). Facilities should conduct periodic spot checks even after formal validation to prevent lost information due to changing medical records systems or other

disruptions. Accurate electronic denominator reporting may require iterative programming corrections in consultation with IT support until accuracy is established.[7,8]

Completeness and accuracy of SSI (COLO and HYST) denominators

Evaluate the information in Appendix 4.3, "Denominator Validation COLO" and "Denominator Validation HYST" (this information was gathered during preparation for the facility site visit). If there appear to be large differences in the number of procedures identified by these two data sources, discuss this with the IP. Consider matching a subset of records between the two systems and examining un-matched records to explore potential reasons for this discrepancy. In particular beginning in 2013, all procedures meeting the NHSN procedure definition should be entered, regardless of pre-existing infection / wound class or incision closure method. If the two systems generate roughly similar data, the NHSN procedure denominator should be considered complete.

Electronically collected MRSA bacteremia and CDI facility-wide inpatient (FacWideIN) denominators

"FacWideIN" surveillance data includes all patient days counted at the same time each day for all inpatient locations, including any patients housed for the day in inpatient locations, whether or not the facility considers them "admitted patients" or "observation" patients, but excluding any patients housed for the day in outpatient "observation" locations. This information is often collected electronically. Because the task of validating "FacWideIN" patient days and admissions is daunting, denominator data validation can be accomplished using manual counting of patient days and admissions in three specified location types for one month each: one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location (if available), and one or more wards where "observation" patients are frequently located. Manual counts should be within 5% of the referent (usual) electronic counts, or an evaluation of why they differ should be conducted. One consideration is the facility's ability to capture "observation" patients within inpatient locations electronically. Electronic ADT data often are found to be more accurate than electronic billing data in this regard. Note that patient counts should differ for MRSA bacteremia LabID Event and CDI LabID Event denominators because CDI denominators exclude infants (< 1 year old). This internal validation process can be conducted by facilities when requested or required.

Structured Medical Records Review

Validator blinding and consultation at the facility site-visit

Validator blinding as to HAI status is required and is normally accomplished by mixing and reviewing the selected medical records before determining which have been reported to NHSN with HAIs.

Medical records should be reviewed in a blinded manner using 2015 Medical Records Abstraction Tool processes (Appendix 3). These tools include algorithms and logic designed to establish presence or absence of required criteria for case definitions and to provide support to avoid common errors.

For CLABSI validation, when consideration is given to an alternative primary site infection leading to secondary bloodstream infection, use of an appropriate Tennessee checklist (available at http://health.state.tn.us/ceds/hai/) is highly recommended. These checklists provide a structure to record required elements from the NHSN Manual's Chapter 17 criteria. The Tennessee checklists are also useful for surgical site infection (SSI) validation when documenting organ/space SSIs. The

checklists exist for multiple infection types (derived from the NHSN manual Chapter 17), and in multiple dated versions. Be sure the selected version is for 2015 definitions.

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

Discussion of audit results with IP

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

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

Use errors as learning opportunities for reporters and validators. These discussions may provide insight into the soundness of the facility's surveillance processes and competencies, and topics where additional training may be useful. Leave a copy of expected changes to NHSN data with the IP and agree to a deadline for changes to be made (see Appendix 4.1). An exit interview with a facility C-suite administrator (e.g., CEO or CMO) would rarely be needed, unless a process improvement plan is indicated.

Post-visit

Denominator data collection surveys (Appendix 2.4) may be completed after the visit.

Document validation findings (e.g., using Appendix 4.3) to create a facility summary report.

A follow-up letter to the IP and facility C-suite administrator will close the communication loop and provide valuable feedback. Send a letter thanking them, recognizing all participants in the audit, and documenting results, necessary corrections, and recommendations. When appropriate, identify systematic strengths as well as problems with resources and support for surveillance, data collection, and reporting (Appendix 4.2).

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

References

Cited References:

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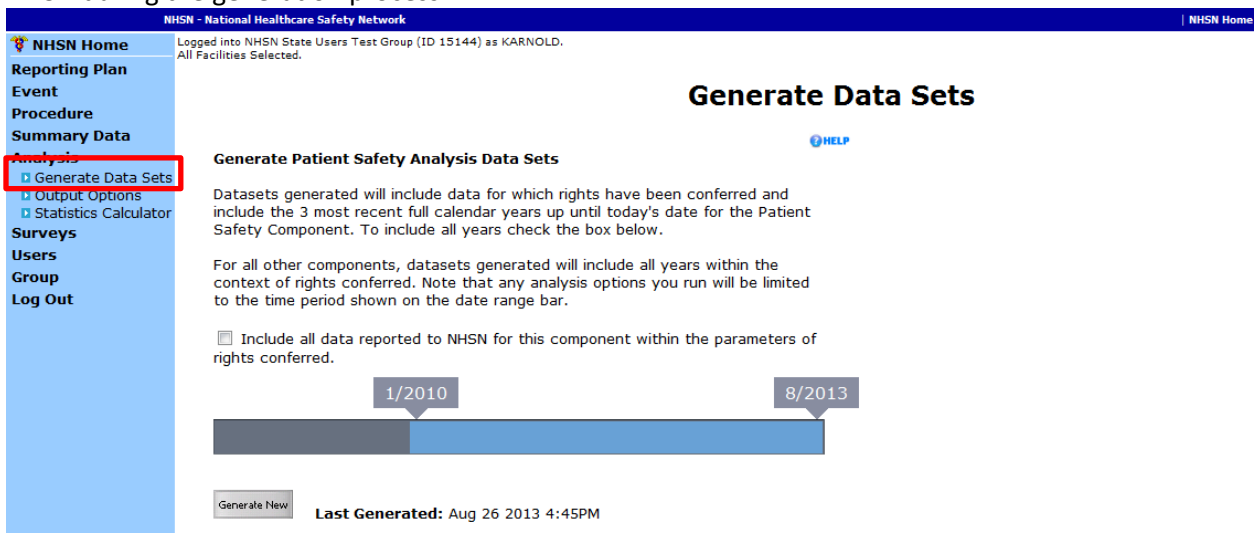
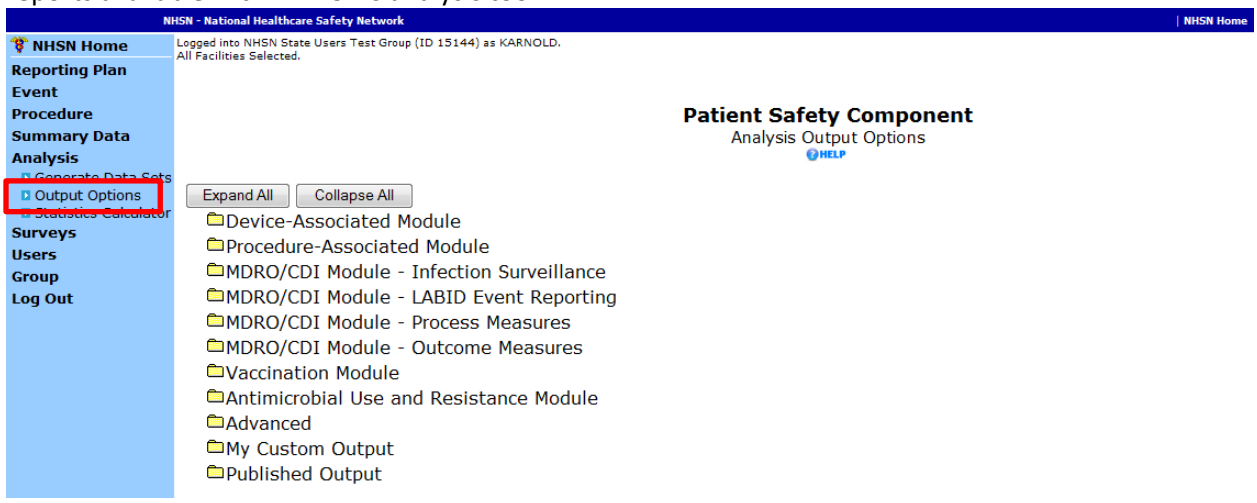
Appendix 1: Preparation Tools for External Validation

Appendix 1.1: Step-by-Step Targeted Facility Ranking

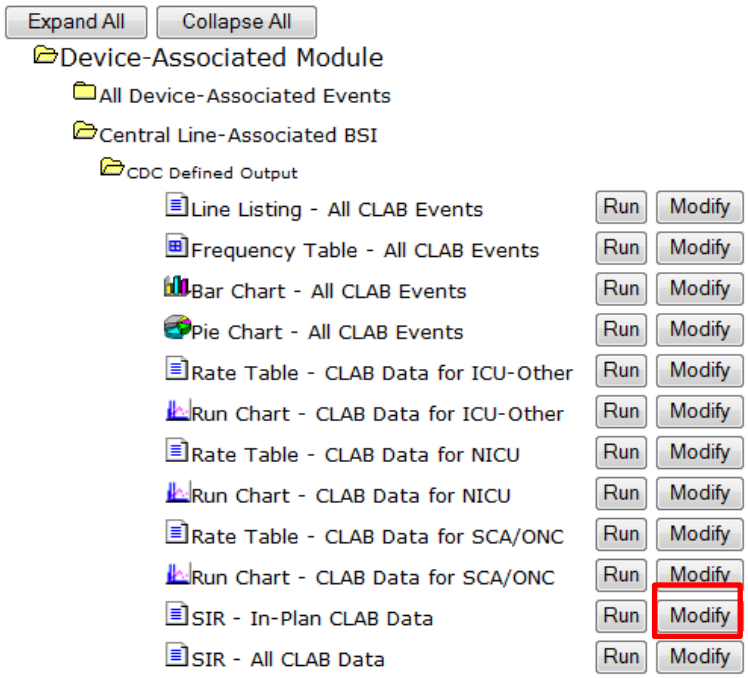
1. Generate new datasets in NHSN to ensure any data updates are included for analysis. On the NHSN Landing Page, navigate to Patient Safety Component -->[YOUR State Users' Group]. Select the "Analysis" tab and click "Generate Datasets." Click the Generate New button. Allow the dataset generation process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



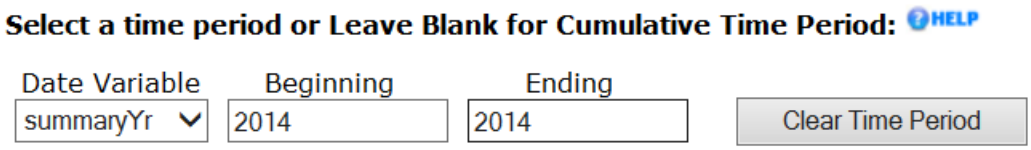
2. After successful dataset generation, navigate to Analysis→Output Options to display the tree view list of all analysis reports available within NHSN's analysis tool.



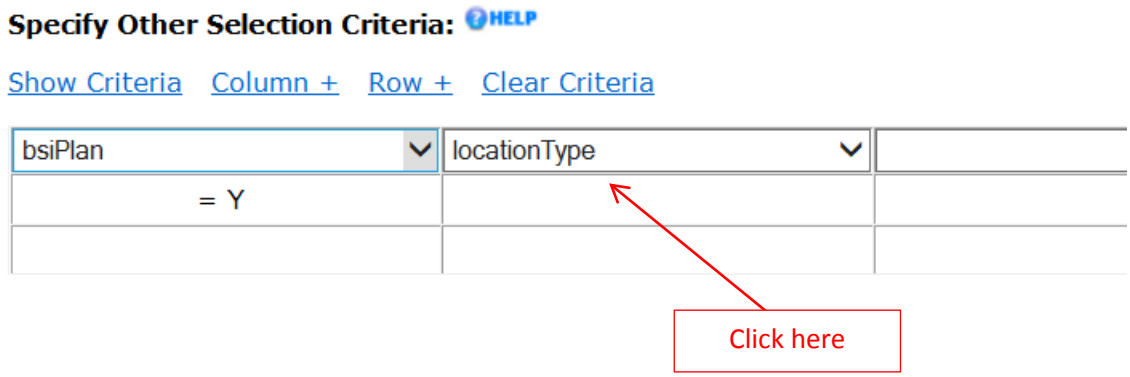
3. Use the tree view structure to navigate to the SIR report of interest. In this example (targeting for ICU CLABSI validation), we will select the Device Associated Module, -> Central Line-Associated BSI, -> CDC Defined Output, -> SIR for In-Plan CLABSI data. This uses data reported to NHSN that has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



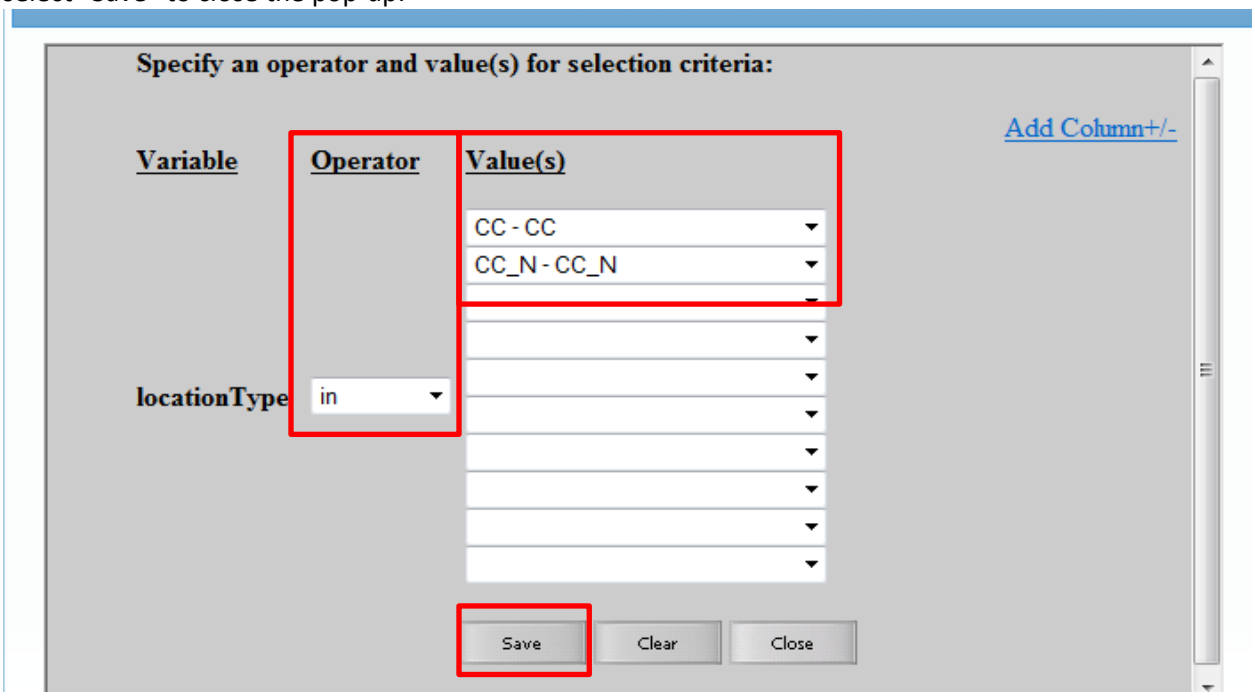
4. A modification screen will open titled "Analysis SIR." On the modification screen, there are two key areas to modify, one that controls the time interval of data that are analyzed and displayed and one that controls the level of aggregation of that data.
   a. Use the "Select a time period" option to limit the time period of data that is included in the report to be exported. Set "Date Variable" to SummaryYr, "Beginning" to 2015 and "Ending" to 2015:



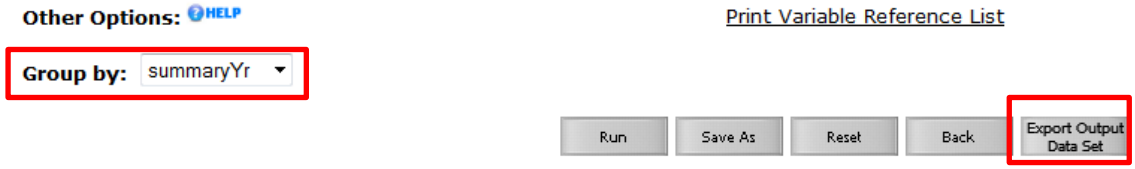
   b. Scroll down to "Specify Other Selection Criteria." Retain bsiPlan = Y. In column 2, select "Location type" from the dropdown list, Click in the space below "location Type."



c. Doing this will pop up a new window (shown below in gray). Set "Operator" = "in" and Value(s) to "CC-CC" and "CC_N-CC_N" to specify all ICU locations, adult and neonatal. Scroll to the bottom of the pop-up screen and select "Save" to close the pop-up:

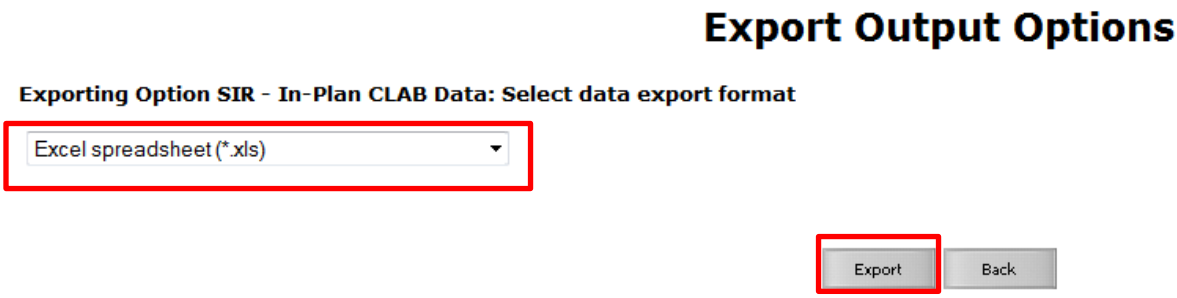


d. Under the "Other Options" section, use the "Group by" option to view the data at a particular level of aggregation. By default, this is set to SummaryYH, (half-years). Change the Group by option to "SummaryYr".



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 on your computer.



For CLABSI data, the exported SIR report file will be displayed at multiple levels of aggregation, which are outlined and displayed in the screenshot to follow.

8. In Excel, select the aggregation level that provides a facility-specific SIR for all ICUs (shown below in black). This level of aggregation will allow you to explore the level of exposure risk for ICU CLABSIs and measured performance at each facility. Select these rows and copy this information to a new spreadsheet. (Also, insert a row above your data

and copy the header row so you can identify the variables on the new page). Arrange the facilities in rank order according to "exposure;" the expected/predicted number of CLABSIs [numExp], (high to low), and create three new columns titled "Delta count", "Stratum", and "Targeted Selection Number".

9. Use Excel to calculate the Delta count for each facility/row. The formula in Excel is (=ABS[row cell under InfCount]—[row cell under numExp]). (You will use Delta count only if an SIR is not calculated by NHSN).

10. Select the top tertile (33%) of facilities by predicted number of ICU CLABSIs. This "Top Tertile" of facilities where ICU CLABSIs are most expected, may have the greatest potential for surveillance and prevention impact.

11. Within the top tertile, sort by SIR from highest to lowest, and identify the current median SIR for the top Tertile. (Recall that median is the "middle" value for the group). To sort just the top tertile, highlight the entire row for each facility in the top tertile, and click "Data, "Sort"; Column "Sort by" (select SIR),"Sort On" (values), and "Order" (highest to lowest).

12. Within the top tertile, assign stratum A to facilities with SIR above the current median SIR, stratum B for remaining facilities with SIR less than or equal to the median and above zero, and stratum C for facilities with SIR = zero (but not missing). Note that some facilities will not have a calculated SIR; do not include these in the strata (see step 15 below).

13. Re-sort <u>within each stratum</u> A, B, and C, by numExp from highest to lowest. To sort just one stratum at a time, highlight the entire row for each facility in the first stratum, and click "Data," "Sort;" Column "Sort by" (select numExp),"Sort On" (values), and "Order" (highest to lowest). Repeat this process for the next two strata, one-by-one.

14. Assign sequential Targeted Selection Numbers to facilities, by selecting the highest available numExp from each stratum alternating A, B, and C. For example, facility #1 will be the facility with the highest numExp from stratum A, facility#2 the facility with the highest numExp from stratum B, and #3 the facility with the highest numExp from stratum C. Return to stratum A and assign#4) to the next facility in stratum A, assign #5 to the next facility in stratum B, and facilty #6 will be the next facility in stratum C. Continue alternating strata until no facilities remain or the target number of facilities (18 or 21) is reached. If additional facilities are needed, repeat this process (steps 11-14) using the second and then third tertile based on exposure.

15. Once all hospitals with an assigned SIR have been prioritized, evaluate facilities with fewer expected events. In hospitals where NHSN does not calculate an SIR (because the predicted number of infections is less than one), a different method rather than the above method of stratifying by SIR should be used. This is because the value of a calculated SIR is exceedingly imprecise when the expected number of infections is less than one, and a single infection can result in a very high SIR. If additional facilities are needed to complete the targeted number, prioritize them based on the highest and descending delta count (only for facilities without a calculated SIR).

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

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

File Home Insert Page Layout Formulas Data Review View

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	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	infCount	numCLDays	numExp	SIR	SIR_pval	SIR95CI	summaryYr	locationtype	loccdc	orgid	location	months			
2	6	2366	4.076	1.472	0.2269	0.540, 3.204	1/1/2014	*SIR for all ICUs in all facilities in group*							
3	5	2344	4.012	1.246	0.3735	0.405, 2.908	1/1/2014	ICU-OTHER	*SIR for all adult/pediatric ICUs in all facilities in group*						
4	1	22	0.065				1/1/2014	NICU	*SIR for all neonatal ICUs in all facilities in group*						
5	0	10	0.02				1/1/2014		IN:ACUTE:CC:C						
6	4	1195	2.271	1.761	0.1948	0.480, 4.510	1/1/2014		IN:ACUTE:CC:M						
7	0	1123	1.685	0	0.1854	, 2.189	1/1/2014		IN:ACUTE:CC:MS	*SIRs for each ICU location type in all*					
8	1	22	0.065				1/1/2014		IN:ACUTE:CC:NURS	*facilities in the group*					
9	1	16	0.037				1/1/2014		IN:ACUTE:CC:S						
10	3	414	0.664				1/1/2014			10000					
11	2	1942	3.394	0.589	0.3409	0.071, 2.129	1/1/2014			15164	***THIS IS THE LEVEL TO EVALUATE***				
12	1	10	0.019				1/1/2014			17775	***Facility-specific SIRs combing all ICU location types***				
13	3	394	0.605				1/1/2014	ICU-OTHER		10000					
14	0	20	0.059				1/1/2014	NICU		10000					
15	1	1940	3.388	0.295	0.1482	0.007, 1.645	1/1/2014	ICU-OTHER		15164	*Facility and ICU location type-specific SIRs*				
16	1	2	0.006				1/1/2014	NICU		15164					
17	1	10	0.019				1/1/2014	ICU-OTHER		17775					
18	0	10	0.02				1/1/2014		IN:ACUTE:CC:C	10000					
19	2	10	0.019				1/1/2014		IN:ACUTE:CC:M	10000					
20	0	368	0.552				1/1/2014		IN:ACUTE:CC:MS	10000					
21	0	20	0.059				1/1/2014		IN:ACUTE:CC:NURS	10000	*Facility and specific ICU location SIRs*				
22	1	6	0.014				1/1/2014		IN:ACUTE:CC:S	10000					
23	1	1175	2.233	0.448	0.3466	0.011, 2.495	1/1/2014		IN:ACUTE:CC:M	15164					
24	0	755	1.133	0	0.3221	, 3.256	1/1/2014		IN:ACUTE:CC:MS	15164					
25	1	2	0.006				1/1/2014		IN:ACUTE:CC:NURS	15164					
26	0	10	0.023				1/1/2014		IN:ACUTE:CC:S	15164					
27	1	10	0.019				1/1/2014		IN:ACUTE:CC:M	17775					
28	0	368	0.552				1/1/2014	ICU-OTHER	IN:ACUTE:CC:MS	10000	3 MS	1			
29	0	10	0.02				1/1/2014	ICU-OTHER	IN:ACUTE:CC:C	10000	5W	1			
30	2	10	0.019				1/1/2014	ICU-OTHER	IN:ACUTE:CC:M	10000	NEWAUN	1			
31	0							ICU	IN:ACUTE:CC:NURS	10000	NICU 3	1			
32	1							CU-OTHER	IN:ACUTE:CC:S	10000	SICU	1			
33	1							ICU	IN:ACUTE:CC:NURS	15164	10323-5	1			
34	0							CU-OTHER	IN:ACUTE:CC:MS	15164	2T - MSICU	3			
35	0							CU-OTHER	IN:ACUTE:CC:S	15164	3N - SICU	1			

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

Targeted Facility Ranking for ICU CAUTI:

Note: See "Step-by-Step Targeted Facility Ranking Method, using ICU CLABSI" as an example; a similar process will be used for ranking of facilities for ICU CAUTI, with the following exceptions:

Follow parts 1 and 2, as shown above.

In part 3, select the Device Associated Module, -> Urinary Catheter-Associated UTI, -> CDC-defined Output, ->SIR—In-Plan CAUTI Data. Select the modify button to proceed to the modification screen as before.

Follow part 4a, as shown above.

In part 4b, scroll down to "Specify Other Selection Criteria. Retain utiPlan=Y. In column 2, select location Type and click in the space below to pop up the new selection window. Set "Operator" to "=" and Value(s) to "CC-CC". (Omit "CC_N-CC_N", because you do not want to include NICU locations in the exposure calculations for CAUTI). Scroll to the bottom of the gray pop-up and select "SAVE".

The selection box should resemble the screen shot below.

Specify Other Selection Criteria: HELP

Show Criteria Column + Row + Clear Criteria

utiPlan	locationType	
= Y	= CC	

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

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

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

Targeted Facility Ranking for COLO:

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

Note: See "Step-by-Step Targeted Facility Ranking Method, using ICU CLABSI" as an example; a similar process will be used for ranking of facilities for COLO validation, with the following exceptions:

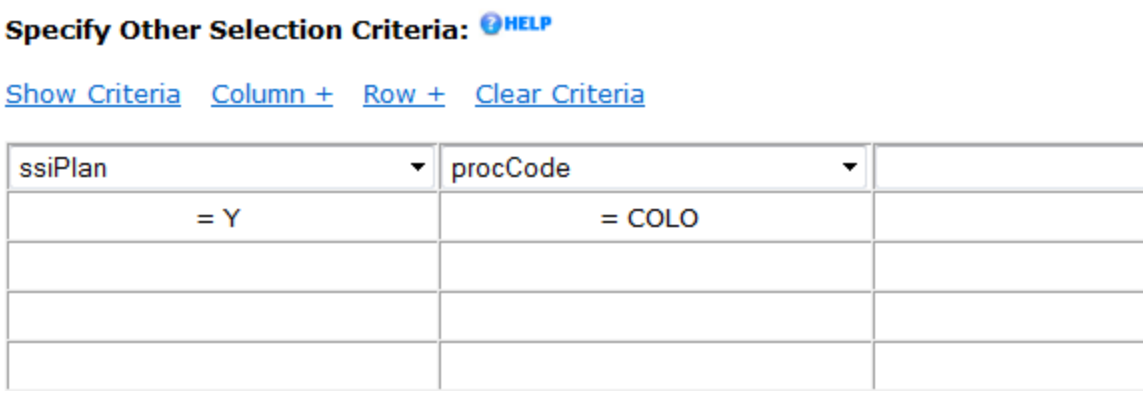
Follow parts 1 and 2, as shown above.

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

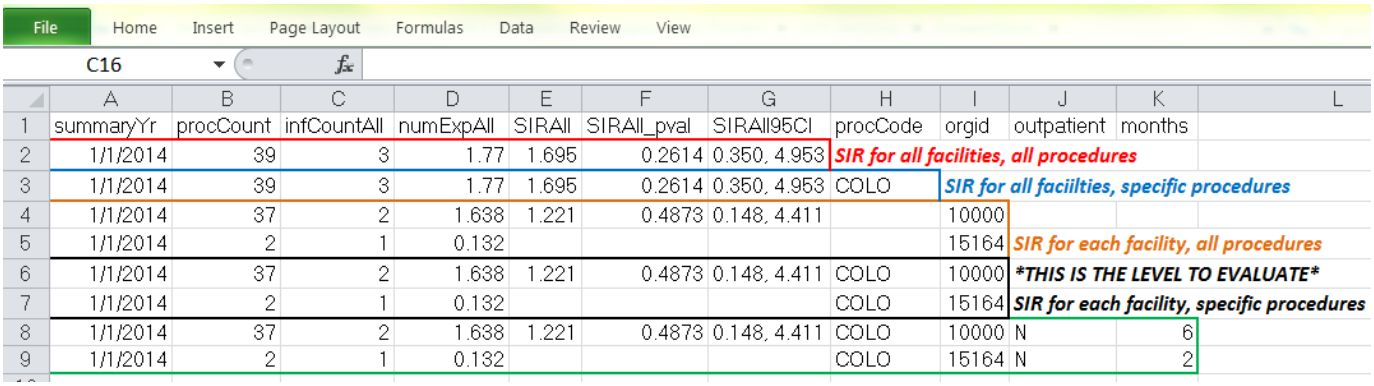
Follow part 4a, as shown above.

In part 4b, scroll down to "Specify Other Selection Criteria. Retain ssiPlan = Y. In column 2, select procCODE and click in the space below to pop up the new selection window. Set "Operator" to "=" and Value(s) to "COLO." Select "SAVE."

The selection box should resemble the screen shot below:



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



	A	B	C	D	E	F	G	H	I	J	K	L
1	summaryYr	procCount	infCountAll	numExpAll	SIRAll	SIRAll_pval	SIRAll95CI	procCode	orgid	outpatient	months	
2	1/1/2014	39	3	1.77	1.695	0.2614	0.350, 4.953					
3	1/1/2014	39	3	1.77	1.695	0.2614	0.350, 4.953	COLO				
4	1/1/2014	37	2	1.638	1.221	0.4873	0.148, 4.411		10000			
5	1/1/2014	2	1	0.132					15164			
6	1/1/2014	37	2	1.638	1.221	0.4873	0.148, 4.411	COLO	10000			
7	1/1/2014	2	1	0.132				COLO	15164			
8	1/1/2014	37	2	1.638	1.221	0.4873	0.148, 4.411	COLO	10000	N	6	
9	1/1/2014	2	1	0.132				COLO	15164	N	2	

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

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

Targeted Facility Ranking for HYST:

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

Note: See "Step-by-Step Targeted Facility Ranking Method, using ICU CLABSI" as an example; a similar process will be used for ranking of facilities for HYST validation, with the following exceptions:

Follow parts 1 and 2, as shown above.

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

Follow part 4a, as shown above.

In part 4b, scroll down to "Specify Other Selection Criteria. Retain ssiPlan = Y. In column 2, select procCODE and click in the space below to pop up the new selection window. Set "Operator" to "=" and Value(s) to "HYST." Select "SAVE."

The selection box should resemble the screen shot below.

Specify Other Selection Criteria: HELP

Show Criteria Column + Row + Clear Criteria

ssiPlan	procCode	
= Y	= HYST	

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

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

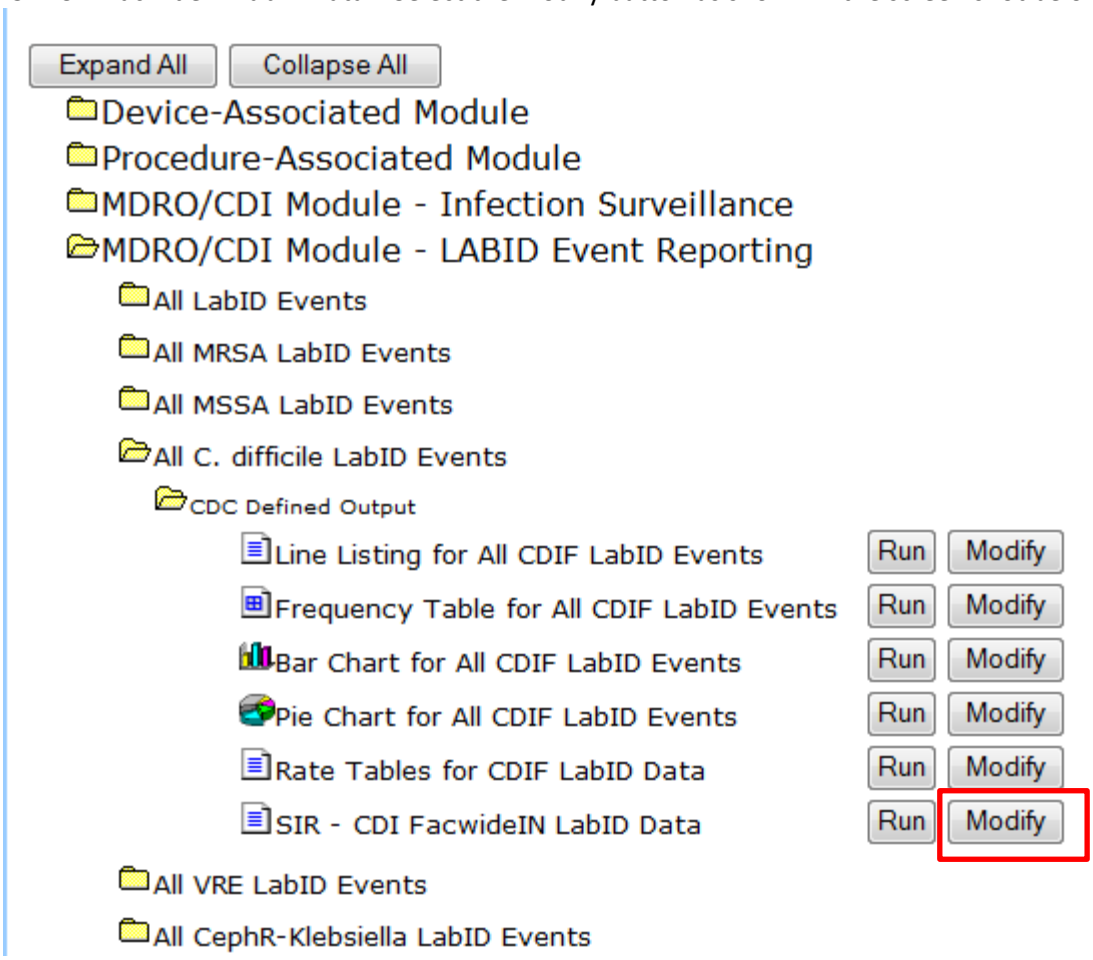
Complete steps 9-16 to assign a sequential Targeted Selection Number for HYST SSI to facilities and to draw a 5% random sample as before.

Targeted Facility Ranking for CDI LabID Event:

Note: See "Step-by-Step Targeted Facility Ranking Method, using ICU CLABSI" as an example; a similar process will be used for ranking of facilities for CDI LabID Event, with the following exceptions:

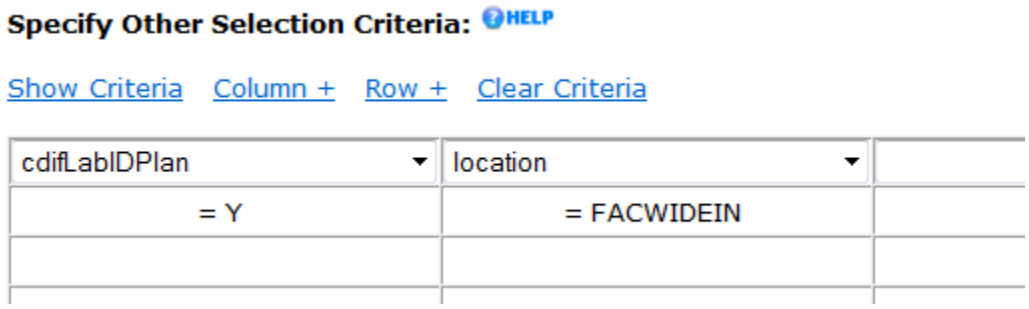
Follow parts 1 and 2, as shown above.

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



Follow part 4a, as was shown for ICU CLABSI.

In part 4b, modify the selection criteria grid to analyze only IN-PLAN, FacWideIN data. Click the first box in the top row, and select the variable "cdifLabIDPlan"; click on the empty cell directly below this variable, to open a gray pop-up box, and type "Y" in "Value(s)" cell. Click SAVE. Next, click in the second box in the top row, and select the variable "location"; click on the empty cell directly below this variable to open another gray pop-up box. Select location = FACWIDEIN, and SAVE. See screen shot below.



Follow steps 4d, 5 and 6, as shown for ICU CLABSI.

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

File Home Insert Page Layout Formulas Data Review View

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

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

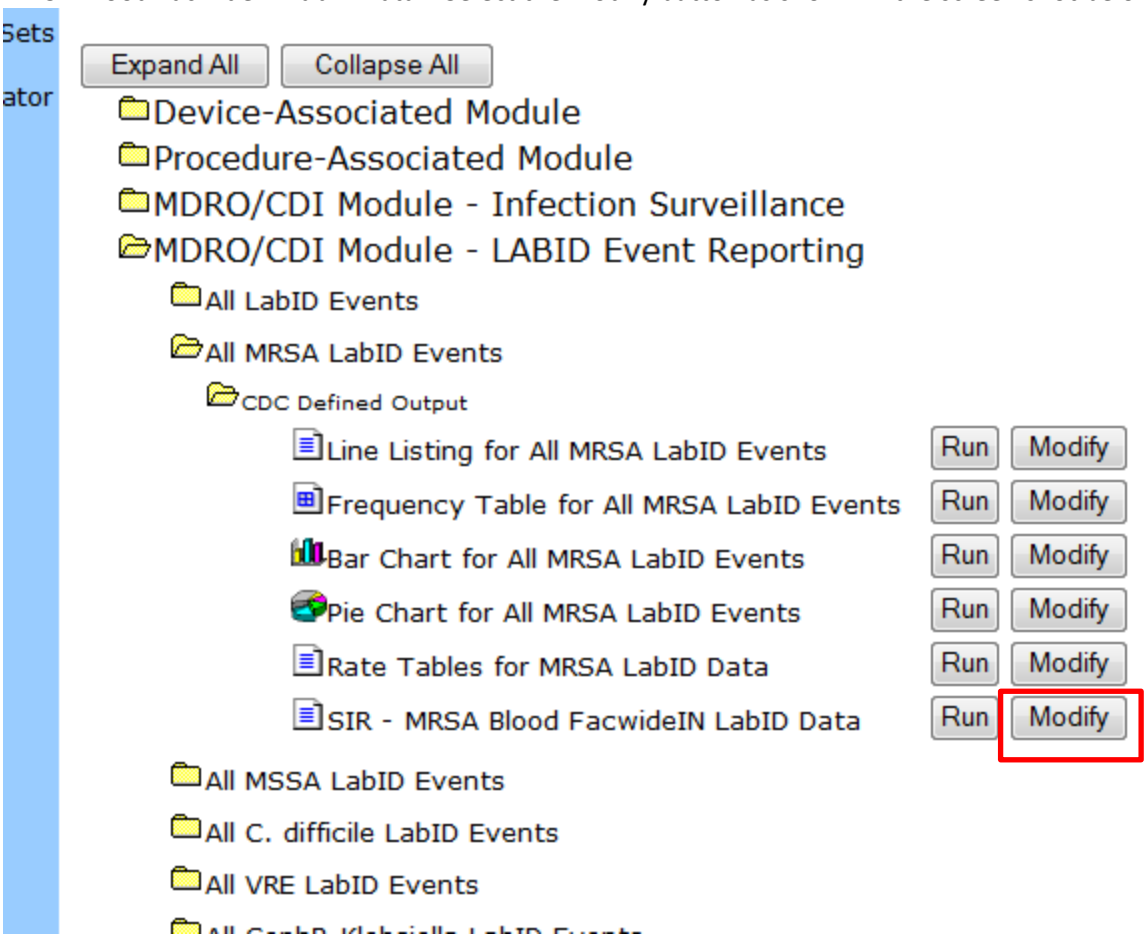
Complete steps 9-16 to assign a sequential Targeted Selection Number for LabID Events to facilities and to draw a 5% random sample as before.

Targeted Facility Ranking for MRSA Bacteremia LabID Event:

Note: See "Step-by-Step Targeted Facility Ranking Method, using ICU CLABSI" as an example; a similar process will be used for ranking of facilities for MRSA Bacteremia LabID Event, with the following exceptions:

Follow parts 1 and 2, as shown above.

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



Follow part 4a, as shown for ICU CLABSI above.

In part 4b, modify the selection criteria grid to analyze only IN-PLAN data. Click the first box in the top row, and select the variable "mrsaLabIDBldPlan"; click on the empty cell directly below this variable, to open a gray pop-up box, and type "Y" in "Value(s)" cell. Click SAVE.

NOTE: facilities that are conducting IN-PLAN MRSA all specimen surveillance are ALSO conducting IN-PLAN MRSA Bacteremia surveillance as a subset. NHSN includes these facilities under "mrsaLabIDBldPlan'=Y. Any surveillance that is not IN-PLAN will be excluded. Next, click in the second box in the top row, and select the variable "location"; click on the empty cell directly below this variable to open another gray pop-up box. Select location = FACWIDEIN, and SAVE. See screen shot below.

Specify Other Selection Criteria: HELP

Show Criteria Column + Row + Clear Criteria

mrsaLabIDBldPlan	location	
= Y	= FACWIDEIN	

Follow steps 4d, 5 and 6, as shown for ICU CLABSI above.

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

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

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

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

Please customize this template to meet your state's needs

Dear [*Name of CEO*]

Cc*: [Name of IP]*

The [*Health Department*] will conduct an audit of surveillance practices and reporting of healthcare-associated infections in [multiple/all] hospitals statewide, focusing on 6 different metrics for 2015 data. These include the metrics designated by the CMS Inpatient Quality Reporting Program: central line-associated bloodstream infections (CLABSI) and catheter-associated urinary tract infections (CAUTI) in ICUs, surgical site infections (SSI) following colon (COLO) and abdominal hysterectomy (HYST) procedures, and proxy measures for MRSA bacteremia (MRSA bacteremia LabID Event) and *Clostridium difficile* infection (CDI LabID Event). [Modify metrics as indicated] Participation in the audit is

[select as appropriate]

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

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

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

Requested Line Listings

1) A complete list of positive ICU blood cultures for 2015, with additional variables based on the template below. NICUs should be included.

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

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Blood Organism 1 Genus and Species	*Specific ICU patient Location	*Gender	*Date of Birth	First Name	Last Name

2) A complete list of positive ICU urine cultures for 2015, with additional variables based on the template below. NICUs should not be included. If possible, limit positive ICU urine cultures to those with no more than 2 identified pathogens and at least 10^3 CFU/ml organisms.

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

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Urine Organism 1 Genus and Species	*Urine Colony Count 1 (CFU/ml)	†Urine Organism 2 Genus and Species	†Urine Colony Count 2 (CFU/ml)	*Specific ICU Location	*Gender	*Date of Birth	First Name	Last Name

3) A complete list of blood cultures positive for methicillin-resistant *Staphylococcus aureus* (MRSA), among inpatients facility wide for 2015, with additional variables based on the template below.

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

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Blood Organism Genus and Species (documenting *S. aureus* or MRSA)	*Documentation of Methicillin-Resistance (susceptibility test result or MRSA)	*Specific Mapped NHSN Location	*Gender	*Date of Birth	First Name	Last Name

4) A complete list of toxin-positive *Clostridium difficile* stool specimens among inpatients facility-wide for 2015, with additional variables based on the template below. Please include only final results for toxin testing that is conducted following multiple steps.

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

*MRN	*Facility Admission Date	*Laboratory Specimen Number	*Specimen Collection Date	*Result of CDI Toxin Test	* Specific Mapped NHSN Location	*Gender	*Date of Birth	First Name	Last Name

The line listings will be due by [*day and date in advance of site visit]* so that we may select medical records for review from among candidate records. We will then communicate our selected records to infection prevention so that they can be made available for the audit.

5) In addition, we request a monthly count of selected 2015 inpatient surgical procedures performed in your facility based on the following ICD-9-CM/ICD-10-PCS procedure codes:

Procedure Class	COLO Procedures	HYST Procedures
ICD-9-CM/ ICD-10-PCSProcedure Codes:		
2015 Month	**Number of Procedures**	**Number of Procedures**
January		
February		
March		
April		
May		
June		
July		
August		
September		
October		
November		
December		

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

If your healthcare facility has initiated or completed conversion to an electronic medical record system, we will need a means of accessing these records during our visit, including any diagnostic/laboratory results, clinical documentation and ICD-9-CM codes related to these patients.

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

HAI Program Director /Regional Representative

cc: IP name

enc.

Appendix 1.3: Step-by-Step Targeted Medical Record Selection

ICU CLABSI Targeted Medical Record Selection Process

(Note: this is the same process recommended for 2013 ICU CLABSI validation)

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 Chapter 3 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 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 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
    c. Select the first 20 random numbers with unique episodes of care (defined by MRN and admission date) as the sample of reported CLABSI records
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 below), 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 most staphylococcus spp. other than *S. aureus*, MRSA, MSSA)
            5. *Klebsiella spp*., *E. coli*, or *Pseudomonas spp*. (common gram negatives)
8. Among unreported candidate CLABSI events, use location information to identify NICU vs. adult/pediatric ICU records (If facility has no NICU, skip to step 10 below, and select 10 additional medical records from adult/pediatric ICUs for screening sample.).
    a. Re-sort blood 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

c. Select the first 10 random numbers with unique episodes of care (defined by MRN and admission date) as the sample of NICU records containing candidate CLABSIs.
d. If 10 NICU medical records with stratum 2 blood 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
    c. Select the first 30 random numbers with unique episodes of care (defined by MRN and admission date) as the sample of adult/pediatric ICU medical records with candidate CLABSIs.
    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. The final screening sample should contain: (up to) 20 medical records with reported CLABSIs, (up to) 40 medical records divided among NICU (if available) and adult/pediatric ICUs.
12. If medical records are not well balanced among different targeted pathogens, consider post-selection adjustment to include a variety of these organisms, in order to evaluate a variety of surveillance skills, as noted below.

Before requesting medical records for the audit, download ("freeze") the facility's reported data from NHSN

Why Target CLABSI Pathogens?

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

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

- **Facilities need to know how to correctly report single and confirmed isolates of common commensal organisms like coagulase-negative staphylococcus, and should be able to recognize synonyms (e.g. *Staphylococcus epidermidis)*, used by the microbiology laboratory.**

ICU CAUTI Medical Record Selection Process

1. From each selected facility, request a securely transmitted line listing of all positive ICU urine 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 Chapter 3 for recommended line listing structure).
2. Assure the line listing includes appropriate positive urine cultures from all ICU locations required to report CAUTIs to NHSN, using location mapping information in NHSN
3. Assign a random number to each positive urine culture
4. Sort the list of urine cultures by MRN and admission date to generate clusters of urine cultures associated with recognizable episodes of care
5. Identify reported CAUTIs on the urine culture line listing
    a. Using the NHSN CAUTI list and available patient information on urine culture line listing, flag and mark urine cultures reported as CAUTIs. Create a new variable, "stratum," and assign these urine cultures and all other urine cultures in the same medical record to stratum 1.
    b. If reported CAUTIs are missing from the urine culture line listing, the list may be incomplete. Investigate and correct this problem. Add omitted CAUTI records to the medical record review list.
6. Select simple random sample of (up to) 20 reported ICU CAUTIs for review
    a. Select stratum = 1
    b. Sort by random number, MRN, and hospital admission date
    c. Select the first 20 random numbers with unique patient episodes of care (defined by MRN and admission date) as the sample of reported CAUTI records
7. Identify unreported candidate CAUTI events
    a. Select stratum not equal to 1
8. Select the screening sample
    a. Sort by random number, MRN, and admission date (if available)
    b. Select the first 40 random numbers with unique medical records (defined by MRN and admission date)
9. The final screening sample should contain: (up to) 20 medical records with reported CAUTIs, and (up to) 40 medical records without reported CAUTIs from adult/pediatric ICUs.

Before requesting medical records for the audit, download ("freeze") the facility's reported data from NHSN

COLO Procedure Targeted Medical Record Selection Process

1. Using NHSN, download a line listing of all COLO procedures for 2015, following these steps:
    a. Log In to NHSN for the facility being validated and the Patient Safety Module.
    b. From the left hand Nav Bar, Click "Analysis" then "Output Options."
    c. Select the folder titled "Advanced," then "Procedure-level Data," then "CDC Defined Output."
    d. Select the "Modify" button for "Line Listing – All Procedures."
    e. Under Modify Attributes of the Output, change the Output Name to "Line Listing – COLO Procedures 2015," and the Output Title to "Line Listing for COLO Procedures 2015."
    f. Option: Under "Select output format" retain "Output Format" as HTML (this will allow you to download and manipulate the file in Excel), and consider whether you want to check the box for "Use Variable Labels." This option will make the variable names longer (and more explicit), but is often not necessary if you know the variable names.
    g. Under "Select a time period or Leave Blank…etc" for "Date Variable," select ProcDateYr, for "Beginning" enter 2015, and for "Ending" enter 2015.
    h. Under "Specify Other Selection Criteria" do the following:
        i. Column 1, row 1: select "procCode"
        ii. Column 1, click row 2 to pop-up a gray dialog box, where Variable= "procCode", Operator= "=" and Value(s) = "COLO-Colon surgery"
        iii. Click Save
        iv. Column 2, row 1: select "outpatient"
        v. Column 2, click row 2 to pop-up a gray dialog box, where Variable= "outpatient", Operator= "=" and Value(s) = "N-No"
        vi. Click Save
        vii. Column 3, row 1: select "ageAtProc"
        viii. Column 3, click row 2 to pop-up a gray dialog box, where Variable= "ageAtProc", Operator= ">=" and Value(s) = "18"
        ix. Click Save
    i. Under "Modify Variables to Display by Clicking" select "Modify List"; retain the default Selected Variables: orgID, patID, dob, gender, procID, procDate, and procCode. Add variables by double clicking from the left hand list: ProcDateYr, outpatient, ageAtProc (to assure that you have selected 2015 inpatient adult COLO procedures), anesthesia, asa, procDurationHr, procDurationMin, Scope, medAff, numBeds, swClass, and modelRiskAll (variable that will be used to select procedures at higher risk to result in SSI). Click Save.
    j. Under "Specify Sort Variables by Clicking" select "Modify List"; remove procCode from the right hand list by double clicking (all procedures will be COLO). Add procID by double clicking the variable in the left hand box; it will move to the right hand box. Click Save.
    k. Select Run. You should see a line listing sorted by procID from lowest to highest. Click the box "Save As" to save your Template. The template will save under the name you specify, e.g., "Line Listing for COLO Procedures 2015."
    l. Select Export Output DataSet. Under Export Output Options, select Excel Spreadsheet (*.xls). Select Export. An Excel file will be produced titled "LineListing_COLOProcedures2015."
2. Next, you will identify any of these procedures that have been reported to NHSN with an SSI. For this step, return to NHSN Analysis Output Options. This time, select the folders titled "Procedure-Associated Module," "SSI," and "CDC Defined Output."
    a. Select the "Modify" button for "Line Listing – All SSI Events"
    b. Under "Modify Attributes of the Output" change the Output Name to "Line Listing – COLO SSI Events 2015," and the Output Title to "Line Listing for COLO Surgical Site Infection Events 2015."
    c. Optional: decide if you want to use Variable Labels.
    d. Under "Select a time period or Leave Blank…etc" for "Date Variable," select ProcDateYr, for "Beginning" enter 2015, and for "Ending" enter 2015.
    e. Under "Specify Other Selection Criteria" do the following:
        i. Column 1, row 1: select "procCode"

ii. Column 1, click row 2 to pop-up a gray dialog box, where Variable= “procCode,” Operator= “=” and Value(s) = “COLO-Colon surgery”
iii. Click Save
iv. Column 2, row 1: select “outpatient”
v. Column 2, click row 2 to pop-up a gray dialog box, where Variable= “outpatient”, Operator= “=” and Value(s) = “N-No”
vi. Click Save

f. Under “Modify Variables to Display by Clicking” select “Modify List”; retain the default Selected Variables: orgID, patID, dob, gender, admitDate (this is date of admission for the procedure), eventID, eventDate, eventType, spcEvent, and procDate and procCode. Remove the remaining variables by double clicking.
g. Under “Specify Sort Variables by Clicking” select “Modify List”; select linkedproc. This is the same variable as procID in the procedures file. NOTE: if you do not find a linked procedure, this SSI has probably been entered off-plan. You can use the other variable (procDate, patID, etc.) to investigate this.

3. Returning to the procedures file; mark any procedure that has been reported with an SSI as a reported case. All others are considered Candidate SSIs. Select the 40 candidate SSIs with the highest SSI risk (“modelRiskAll”) for review.

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

HYST Procedure Targeted Medical Record Selection Process

1. Using NHSN, download a line listing of all HYST procedures for 2015, following the steps outlined above for COLO.
   a. If you have saved your template for downloading the line list of COLO procedures, you can make a few small modifications to download the HYST procedures rather than starting over (where you have entered “COLO” replace it with “HYST).
2. (As for COLO above), using NHSN, download a line listing of all HYST SSIs for 2015, following the steps outlines above, and replacing “COLO” with “HYST.”
3. (As for COLOs above) return to the HYST procedures file; mark any HYST procedure that has been reported with an SSI as a reported case. All others are considered candidate SSIs. Select the 40 candidate SSIs with the highest SSI risk (“modelRiskAll”) for review.

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

Strategy for Selection of MRSA Bacteremia LabID Events for Validation

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

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

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

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

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

Appendix 1.4: Sample Letter Requesting Availability of Medical Records for Audit

Please customize this template to meet your state's needs

Dear [*Name of IP*]

As we discussed in our letter of [date], the [*Name of Health Department]* plans to audit surveillance practices and reporting of healthcare-associated infections for 2015 in multiple hospitals including your own. Thank you for your recent assistance in procuring the required line listings for medical record selection.

In the list below, we have identified the [XXX] medical records we would like to review during the audit, scheduled for [date(s)]. We appreciate your assistance in assuring that our team of [X] reviewers will have access to adequate working space, any necessary system passwords, and to these records when we visit. If your healthcare facility has initiated or completed conversion to an electronic medical record system, we will need a means of accessing these records including any diagnostic/laboratory results, clinical documentation, and ICD-9-CM codes related to these patients during our visit.

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

Appendix 2: Surveillance Surveys

(Designed for External Validation of Surveillance Processes)

Appendix 2.1: CLABSI/CAUTI Surveillance Coordinator Survey

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

Instructions: Administer this survey to the person who oversees NSHN surveillance and denominator counting		
1. Which best describes your facility's training for CLABSI and CAUTI Denominator counters? *(select all that apply)*		
	No specific training is provided or required	
	Peer training (person who previously counted) trains new staff	
	Training is provided by IP	
	Training by NHSN (e.g. online training) is required	
	Annual training updates are required / provided	
	Other (describe):	
2. Do you conduct periodic spot-checks or otherwise validate CLABSI and CAUTI denominator counts? *(select all that apply)*		
	Not at this time	
	Yes, when we have a new denominator counter	
	Yes, when I have concerns	
	Yes, routinely	
3. Which best describes your own training for 2015 NHSN surveillance? *(select all that apply)*		
	No specific training for 2015	Select Training Modules Taken
	CDC-sponsored 2015 training webinar (live or on-line)	☐CLABSI ☐ CAUTI ☐SSI ☐LabID Event
	CDC-sponsored 2015 on-line case-studies	☐CLABSI ☐ CAUTI ☐SSI ☐LabID Event
	CDC-sponsored 2015 online self-paced interactive multimedia instruction trainings	☐CLABSI ☐ CAUTI ☐SSI ☐LabID Event
	State-sponsored 2015 NHSN training event(s)	☐CLABSI ☐ CAUTI ☐SSI ☐LabID Event
	Other (describe):	
4. Which staff member(s) is/are responsible for entering CLABSI (numerator events) data into NHSN?		☐ IP ☐ Clerical support ☐ Other
5. Which staff member(s) is/are responsible for entering CAUTI (numerator events) data into NHSN?		☐ IP ☐ Clerical support ☐ Other
6. Is entered data checked for errors or validated by analysis?		☐ Yes ☐ No ☐ Unk
a. If yes, describe what is done:		

7. How many persons typically review a medical record before an event is reported to NHSN?	☐ One reviewer typically decides, with internal (e.g. second reviewer) adjudication when needed ☐ Two or more persons typically review and agree before reporting ☐ One reviewer typically decides, with external (e.g. CDC) adjudication when needed ☐ Approval is required (e.g. from physician or administrator) before events are reported ☐ Other (explain):
8. Is there ever pressure (e.g.; from administrators or physicians) to not report a CLABSI, CAUTI (or other NHSN) event?	☐ Yes ☐ No ☐ Unsure Comment:
9. In cases of ambiguity, who makes the final decision regarding the determination of whether an infection should be reported?	

Appendix 2.2: Documentation of Electronic CLABSI/CAUTI Denominator Validation

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

Instructions: NHSN requires that the monthly electronic denominator count falls within a 5% tolerance interval of the monthly manual denominator count for 3 months before reporting electronic denominator counts for CLABSI/CAUTI. *If there is no electronic denominator counting at this facility, skip this survey.*
If electronic device denominator counting is used for reporting at this facility, document the NHSN-required validation results below:

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

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

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

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

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

Appendix 2.3: Contact Information for Manual CLABSI / CAUTI Denominator Counters

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

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

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

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

Appendix 2.4: CLABSI and CAUTI Denominator Counting Survey (with Key)

Instructions: Administer in person or by telephone, directly to individuals responsible for denominator counting. This form is color-coded so that it can be divided into a CLABSI denominator collection form (pink and orange) and a CAUTI denominator collection form (yellow and orange) in facilities where these tasks are performed by different persons. Orange indicates questions applicable to both CLABSI and CAUTI denominator collection.

Facility OrgID:	Name/ID of individual interviewed:	Position: ☐ IP ☐ Clerical ☐ Nursing ☐ Other (explain)	Interviewer initials:	Date of survey:

(*circle*): CLABSI, CAUTI, BOTH	NHSN location(s) covered:

PATIENT DAYS *(for both CLABSI and CAUTI denominator counters)*			***Answer Key:***
1. How are patient days usually collected? *(choose one)*			
	Electronically (*document the software system utilized and skip to Q8*):		
	Manually		
	Some units electronic and some units manual		
	Comment:		
2. Is there a specified time when the denominator count is taken?		☐ Yes ☐ No	*The answer should be Yes*
3. When is it done?			*Counts should be done at a specific time daily, preferably at nearly the same time throughout the facility to avoid errors when patients transfer*
4. Describe the method used to count **patient days**:			*(from NHSN) "To calculate patient days, <u>for each day of the month at the same time each day, record the number of patients</u>. At the end of the month, sum the daily counts and enter the total into NHSN. "*
	Count the number of <u>patients</u> assigned to a unit bed <u>at the time counts are conducted</u>		
	Other *(specify)*		

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

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

11. Identify the method used to count **central line days**: (*choose one*)		*A daily count of <u>the number of patients with a central line</u> in the patient care location during a time period, which is summed for the monthly total*
	Count the number of patients with at least one central line at the time surveillance rounds are conducted	
	Count the number of central lines that are in place at the time surveillance rounds are conducted	
	Count the number of central lines that are in use at the time surveillance rounds are conducted	
	Other (specify):	

12. When reporting monthly patient day total, what is done if there are missing central line day data? *(choose one)*		*NHSN issued specific guidance on imputing values for missing data in September 2013 (http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf)*
	Report sum of available daily counts with no adjustment for missing data	
	Estimate or re-create missing data using existing information (e.g.: medical records), then sum	
	Impute missing values using recent CDC/NHSN guidance for missing denominator data	

13. A patient has a radial arterial line and a peripheral IV. How many central line days are counted for this patient on this day?	*Zero. The radial arterial line and peripheral IV are not central lines.*
14. A patient has a temporary central line and a permanent central line that are both in use. How many central line days are counted for this patient on this day?	*One. Although the patient has two central lines, a device day is defined as the number of patients who have the device, not the number of devices.*
15. The patient above with the temporary central line and the permanent central line is on an oncology ward. Should you report one temporary line day, one permanent line day, or both a temporary and a permanent line day?	*When a patient in an oncology location has both temporary and permanent lines, the line day is reported as a temporary line day. This information is detailed in the NHSN Manual, Instructions for Form 57.117l)*
16. A patient has a long-term port-a-cath that has not been accessed during this hospital stay, and a peripheral IV that is in use. How many central line days are counted for this patient on this day?	*Zero. The port-a-cath was not inserted during this visit and thus is not counted until accessed. The peripheral IV is not a central line. If the port-a-cath was inserted during this admission it would be counted each day thereafter, whether in use or not*
17. A port-a-cath was inserted during this admission for planned chemotherapy. It is not in use. How many central line days are counted for this patient on this day?	*One. If a central line was inserted during this admission it would be counted each day that it remains in place, whether in use or not*

18. A patient has a long-term central line that was accessed for a blood draw in the ICU yesterday but is not currently in use, and a peripheral IV that is in use. How many central line days are counted for this patient on this day?		*One. The port-a-cath was accessed during this stay and subsequently the line will be counted for each daily count until discharge, unless removed.*
19. A patient has a long-term central line that was accessed once for a blood draw in the ED during evaluation leading to admission, but the line is not currently in use. How many central line days are counted for this patient on this day?		*Zero. Brief access in an outpatient location does not count toward line-days during an admission. If the line had been accessed after admission or remained in use after admission following first access in the ED, it would be considered accessed for the purpose of counting line-days.*
20. If a central line is removed at 2PM and replaced at 8PM. The central line day count is done at 5PM, should the line be counted?	☐ Yes ☐ No ☐ Unk	*No. Central line must be in place at time of count*

NICU-Specific Central Line Questions (*Optional: Check here and skip section if NICU questions do not apply to your job*) ☐)		
21. When reporting central line (CL) days, in neonates, which neonatal weight is used for reporting? *(select one)*	☐ Birth weight ☐ Current weight	*Birth weight*
22. Neonates with both a CL and an umbilical catheter (UC) are included in the daily count as: *(select one)*	☐ UC only ☐ CL only ☐ 2 separate lines	*CL only. No separate reporting of UCs; UCs are considered CLs, and reporting is for one or more CL, stratified by birth weight.*

Indwelling Urinary Catheter Days *(for indwelling urinary catheter counters only)*		
23. How are **indwelling urinary catheter-days** collected for the units you oversee? (choose one)		
	Electronically (specify *software system utilized and skip to Q26*):	
	Manually	
	Some units electronic and some units manual	
	Comment:	
24. Identify the method used to count indwelling urinary catheter **days**: (*choose one*)		*7-2: Indwelling urinary catheter (AKA Foley catheter): A drainage tube that is inserted into the bladder through the urethra, left in place, and connected to a drainage bag, including urinary catheters that are used for intermittent or continuous irrigation, but excluding suprapubic, condom, or straight in-and-out catheters.*
	Count the number of patients on the unit with a urine collection bag	
	Count the number of patients on the unit with a Foley catheter or condom catheter	
	Count the number of patients on the unit with a Foley catheter, condom catheter, or suprapubic catheter	
	Count the number of patients on the unit with a Foley catheter or indwelling urethral three-way (infusion) catheter used for bladder washes	
	Other (specify):	
25. When reporting monthly patient day total, what is done if there are missing **catheter day** data? *(choose one)*		*NHSN issued specific guidance on imputing values for missing data in September 2013 (http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf)*
	Report the sum of available daily counts with no adjustment for missing data	
	Estimate or re-create missing data using patient information (e.g.: medical record), then sum	
	Impute missing values using recent CDC/NHSN guidance for missing denominator data	
26. A patient has a draining ureteral stent and a Foley catheter; each one connected to a collection bag. How many urinary catheter days are counted for this patient on this day?		*One. Ureteral stents are not counted because they are not urethral catheters*
27. A patient has a three-way indwelling urinary catheter used for irrigation after surgery to prevent blood in the bladder from clotting, and to provide for urinary drainage. How many urinary catheter days are counted for this patient on this day?		*One. Catheters to be counted include indwelling urethral catheters used for intermittent or continuous irrigation, as well as those used for drainage.*
28. A patient on the unit has a supra-pubic urinary catheter. How many urinary catheter days are counted for this patient on this day?		*Zero. Supra-pubic catheters are not urethral catheters because they enter the bladder through the abdominal wall.*
29. A patient's indwelling urinary catheter is removed at noon and replaced at 5PM. Daily indwelling urinary catheter counts take place at 2PM. How many urinary catheter days are reported for this patient on this day?		*None. There was no indwelling urinary catheter at the time of the daily denominator count. NOTE: However, If this patient develops a bloodstream infection attributable to a urinary tract infection, this day will count as one of two required catheter days to establish CLABSI criteria, because the catheter need only be in place for part of the two days to meet this criterion.*

Appendix 2.5: Surgical Procedure and SSI Surveillance Methods Survey (with Key)

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

Procedure (Denominator) Data		
1) Does your facility normally upload surgical procedure data electronically to NHSN, or is procedure data entered manually? *(choose one):*	☐ Electronic (skip to Q3) ☐ Manual ☐ Other (comment):_____	
2) If manual, who has primary responsibility for surgical procedure data entry to NHSN? *(choose one):*	☐ IP ☐ Clerical/support staff ☐ Clerical/support staff with IP oversight ☐ Other _____	*If IP is responsible for entering denominator data and unable to fully meet other responsibilities, please recommend clerical support for this task*
3) What source(s) of information does your facility NORMALLY use to identify COLO and/or HYST procedures? *(choose all that apply):*	☐ The complete OR records/reports system ☐ Selected flagged/filtered OR records/reports ☐ CPT codes assigned by surgeons ☐ ICD-9-CM procedure codes assigned by coders after discharge ☐ Vendor system using OR records (specify) _____ ☐ Vendor system using ICD-9-CM procedure codes assigned after discharge (specify) _____ ☐ Vendor system using both OR records and ICD-9-CM procedure codes assigned after discharge (specify) _____ ☐ Other _____	*Discussion for Q 3 and 4: Medical records coder opinion is regarded as technical gold standard for identifying NHSN procedures, but may be questioned if other sources are inconsistent, and is often not as timely as OR systems. Presence of designated ICD-9-CM procedure code is considered a requirement of NHSN procedure.* *Planned OR schedules are often inaccurate due to inability to predict procedures. OR records systems may be imprecise (e.g., may record XLAP rather than specifying that XLAP led to COLO, APPY, or SB). OR notes may be coded inaccurately; e.g.; surgeon may call procedure VHYS based on route of extraction whereas coder may classify as HYST based on route of detachment.*
4) How do you assure COLO and/or HYST procedure reporting is complete?	☐ No systematic way ☐ Extra scrutiny to XLAPs ☐ Cross-reference data sources (explain):_____ ☐ Other _____	*Cross-referencing of sources (e.g.: OR records plus ICD-9-CM procedure codes assigned after discharge) is probably the best way to assure complete denominator. In general, XLAPs should be scrutinized by IPs conducting surveillance for COLO and HYST.*

5) Under what circumstances do you remove COLO and/or HYST procedures from NHSN? *(choose all that apply):*	□ COLO or HYST ICD-9-CM procedure code was not assigned for the procedure □ COLO or HYST ICD-9-CM procedure code was assigned, but IP believes coder assigned COLO or HYST code in error □ Incision not primarily closed in OR □ Patient did not stay overnight □ Infection was present at the time of surgery (wound class = CO or D) □ ASA score was high □ Other _____	*Although questioning of ICD-9-CM procedure codes is acceptable, removal of procedures with designated ICD-9-CM procedure code is only acceptable if procedure does not meet other aspects of NHSN procedure definition. Therefore it would be appropriate to remove procedure if there is 1) no appropriate ICD-9-CM procedure code, 2) no primary closure (note: new definition of primary closure for 2015), 3) not an inpatient (no overnight stay), 4) no incision/scope (Correct answers 1,3,4)*
6) If the OR record does not match the listed ICD-9-CM procedure codes, what should you do?	_____	*For validation purposes, NHSN recommends that IPs should bring coding mismatches to coders for review, and should not over-ride coders' decisions.*
7) Which of the following are consistent with the definition of primary closure for 2015 (clarified as of April 1)? *(check ALL that apply)*	☐ Complete closure of skin with suture ☐ Partial closure of skin with staples ☐ Closure of skin except for wick/drain through incision ☐ Closed fascia with incision loosely closed at the skin level ☐ Closed fascia, with skin layer left open	*All but the last option are considered primary closure in 2015.*
8) Does your facility conduct NHSN analysis to look at longitudinal trends for COLO or HYST SSIs and procedures?		*This is recommended practice for facility use of NHSN data*
9) What would you do if your procedure denominator this month was dramatically higher from one month to the next?		*Recommended: investigate this aggregate data by exploring the data at a patient/procedure level to identify the reason.*

Surgical site Infection (Numerator) Data Collection Questions		
Instructions: Interview individual(s) directly responsible for identifying and reporting SSI data		Date of survey:
Name/ID of individual interviewed:	Position	(*circle*): COLO, HYST, BOTH

<u>Numerator (SSI Event) Data:</u>

10) If a patient with an SSI is admitted to your facility but the surgical procedure was performed in another hospital ("hospital A"), what do you do? *(choose all that apply)*	☐ Report the SSI to NHSN ☐ Report the SSI to "hospital A" ☐ Report the SSI to the health department ☐ No external reporting Comment: _____	*Best practice is to report to "hospital A" and (if required by the state) to health department. Hospital A should report to NHSN.*
11) If you do not report the SSI to "hospital A", why not? *(choose all that apply)*	☐ HIPAA concerns ☐ Not a priority for IP program ☐ Logistically difficult (which hospital, who to contact) ☐ Not required Comments: _____	*If facility cites HIPAA concerns, consider sharing Appendix 7, or CSTE position statement 13-ID-09, which contains information from the Office of Civil Rights assuring that sharing SSI information with the originating facility does not violate HIPAA.*
12) If you are contacted by the IP from another hospital regarding a patient with an SSI who underwent a procedure in your facility, what do you do? (*choose all that apply*)	☐ Ask the IP for help completing the NHSN report ☐ Document in your tracking records ☐ Report the SSI to NHSN ☐ Ask the IP to report the SSI to NHSN ☐ No internal reporting or documentation Comment: _____	*The other IP can best document the depth of infection, but cannot report the event to NHSN because it has to be linked. Suggest asking the other IP to help complete the NHSN report form, include a note or a copy in the patient record, and report to NHSN.*

13) What methods are routinely and systematically used to identify possible SSI? (*Check all that apply)*	Reports/Rounds: ☐ Emergency department line lists with diagnoses ☐ Admissions line lists with diagnoses ☐ Surgical ward rounds ☐ Positive laboratory cultures from inpatients ☐ Positive laboratory cultures from ED ☐ Pharmacy reports (antibiotic starts or continuations) ☐ Other _____ Surgical service information: ☐ Inpatient returns to surgery ☐ Surgical service readmissions ADT/Medical Records Data Mining: ☐ Readmissions within one month of discharge ☐ Extended LOS ☐ Discharge diagnostic coding ☐ Other _____	
14) How does your facility conduct post-discharge surveillance for SSIs? *(check all that apply*)	☐ IP does not have a formal post-discharge surveillance plan ☐ IP conducts patient survey by mail ☐ IP conducts patient survey by telephone ☐ IP provides line list of patients to surgeon for response ☐ Surgeon indicates SSIs identified at surgical follow-up ☐ Surgeon surveys patient by mail ☐ Surgeon surveys patient by telephone ☐ IP reviews surgical clinic / wound clinic information ☐ IP reviews surgical patient records 30-60 days after procedures Other/ Comment: _____	
15) During one trip to the operating room, both a COLO procedure and a HYST procedure are done. A deep-incisional SSI develops. To which procedure should you attribute the SSI?	☐ COLO ☐ HYST ☐ Both ☐ Whichever is higher on the procedure hierarchy ☐ Neither	*Two answers are correct (a and d): The procedure which is higher on the 2015 procedure hierarchy (this would be COLO), because you cannot determine which procedure led to the SSI*

16) During one trip to the operating room, both a COLO procedure and a HYST procedure are done. The patient later meets criteria for a GI-IAB with peritonitis (an organ-space SSI). To which procedure should you attribute the SSI?	☐ COLO ☐ HYST ☐ Both ☐ Whichever is higher on the procedure hierarchy ☐ Neither	*Two answers are correct(a and d): The procedure which is higher on the 2015 procedure hierarchy (this would be COLO) because you cannot determine which procedure led to the SSI*
17) During one trip to the operating room, both a COLO procedure and a HYST procedure are done. An abscess of the vaginal cuff (organ-space SSI) develops. To which procedure should you attribute the SSI?	☐ COLO ☐ HYST ☐ Both ☐ Whichever is higher on the procedure hierarchy ☐ Neither	*The vaginal cuff is the operative site of the HYST, and the hierarchy is not needed; this SSI is attributable to the HYST (answer b).*
18) During one trip to the operating room, both a SB procedure and a HYST procedure are done. An abscess of the small-bowel anastomosis site (organ-space SSI) develops. To which procedure should you attribute the SSI?	☐ SB ☐ HYST ☐ Both ☐ Whichever is higher on the procedure hierarchy ☐ Neither	*The SSI is localized to the operative site of the SB, and the hierarchy is not needed; this SSI is attributable to the SB (answer a). SB is higher on the hierarchy, but the hierarchy is only used when attribution cannot be determined by localized infection.*

Appendix 2.6: LabID Event Surveillance Methods Survey (with Key)

OrgID / Name of Hospital _____

LabID Event Surveillance Methods Survey *Instructions: Administer this survey to the person who oversees NHSN LabID Event reporting*				
Denominator Data Collection Questions				
Name of individual interviewed:	Position:	☐ FacWideIN MRSA bacteremia ☐ FacWideIN CDI	Interviewer initials:	Date of survey:
1) For FacWideIN reporting, denominator data are entered into NHSN once a month at the facility-wide level			☐ True ☐ False	T
2) For CDI reporting, the denominator should include all completed CDI toxin tests			☐ True ☐ False	F (denominator = admissions and patient days)
3) Patient days include only admitted patients on inpatient wards; observation patients located on inpatient wards are excluded			☐ True ☐ False	F (all patients housed in inpatient locations)
4) For CDI reporting pediatric locations should be excluded from FacWideIN reporting			☐ True ☐ False	F (NICU and well-baby locations and babies on LDRP are excluded for CDI)
5) For MRSA bacteremia reporting baby locations (NICU, newborn nursery, etc) should be excluded from the denominator			☐ True ☐ False	F (no location exclusions for MRSA)
Numerator Data Collection Questions				
Name of individual interviewed:	Position:	☐ FacWideIN MRSA bacteremia ☐ FacWideIN CDI	Interviewer initials:	Date of survey:
6) For FacWideIN reporting, one monthly numerator for Events is reported at the facility-wide level			☐ True ☐ False	F (events are reported by location)
7) For CDI reporting, the numerator should include toxin-positive CDI results conducted on formed stool specimens			☐ True ☐ False	F (laboratories should only process and report results for unformed stools)
8) A second event is always reported if >14 days have passed from the most recent positive MRSA bacteremia or toxin-positive CDI test result			☐ True ☐ False	T
9) A second event is only reported if >14 days have passed from the most recently reported labID event			☐ True ☐ False	F (If the patient changes location, a second event is reported even within 14 days of prior event)
10) A second event is only reported if the patient changes location OR >14 days have passed since the most recent positive MRSA bacteremia or toxin-positive CDI test in the same location			☐ True ☐ False	T
11) Only reportable CDI LabID Events should be entered into NHSN			☐ True ☐ False	T
Policy Question				
12) Does your facility laboratory limit CDI testing and reporting to unformed stool specimens only, or does the laboratory process all stool specimens for CDI if ordered?			☐ Unformed stool specimens only ☐ All stool specimens	Recommended policy is to only process unformed stool specimens for CDI

Appendix 2.7: Template for Internal Validation of LabID Event Denominator (FacWideIN)

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

Electronically collected MRSA bacteremia and CDI FacWideIN denominators

"FacWideIN" includes all patient days counted at the same time each day for all inpatient locations, including any patients located for the day in inpatient locations, whether or not the facility considers them admitted patients or observation patients, but excluding any patients located for the day in outpatient observation locations. This information is typically collected electronically. Because the task of validating electronic patient days and admissions facility-wide is daunting, denominator validation can be accomplished using manual counting of patient days and admissions in three specified location types for three months each: one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location (if available), and one or more inpatient wards where observation patients are frequently located. Electronic counts should be within 5% of manual counts or an evaluation of why they differ should be conducted.

MRSA Bacteremia LabID Event Denominator Validation							
Location of Validation*	Month of Validation *(specify)*	Admissions			Patient Days		
		Usual Count	5% Tolerance interval†	Manual Count	Usual Count	5% Tolerance interval†	Manual Count
	1						
	2						
	3						
	1						
	2						
	3						
	1						
	2						
	3						

*Select one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location if available, and one or more inpatient ward location where observation patients are frequently located and conduct manual (patient level) validation of admissions and patients days for three months, according to NHSN definitions (http://www.cdc.gov/nhsn/PDFs/pscManual/validation/pcsManual-2015-valid.pdf, and http://www.cdc.gov/nhsn/forms/instr/57_127.pdf).
Remember that for MRSA bacteremia **both mothers and babies** are counted in LDRP locations.

†Equation for 5% tolerance interval is: Usual Count ± (Usual Count * 0.05).
Example calculations where Usual Count = 164 and Manual Count = 178:
Eligible 5% tolerance interval = [164±(164*0.05)]=155.8 to 172.2
Manual Count 178 falls outside the tolerance interval, suggesting that Usual Count is inaccurate and should be investigated.

CDI LabID Event Denominator Validation							
Location of Validation*	Month of Validation *(specify)*	Admissions			Patient Days		
		Usual Count	5% Tolerance interval†	Manual Count	Usual Count	5% Tolerance interval†	Manual Count
	1						
	2						
	3						
	1						
	2						
	3						
	1						
	2						
	3						

*Select one ICU, one Labor/Delivery/Recovery/Post-Partum (LDRP) location if available, and one or more inpatient ward location where observation patients are frequently located and conduct manual (patient level) validation of admissions and patients days for three months, according to NHSN definitions (http://www.cdc.gov/nhsn/PDFs/pscManual/validation/pcsManual-2015-valid.pdf, and http://www.cdc.gov/nhsn/forms/instr/57_127.pdf).
Remember that for CDI**, only mothers (and not babies**) are counted in LDRP locations.

†Equation for 5% tolerance interval is: Usual Count ± (Usual Count * 0.05).
Example calculations where Usual Count = 164 and Manual Count = 178:
Eligible 5% tolerance interval = [164±(164*0.05)]=155.8 to 172.2
Manual Count 178 falls outside the tolerance interval, suggesting that Usual Count is inaccurate and should be investigated.

Appendix 3: Medical Record Abstraction Tools

Note: Criteria, logic, and order of questions in the Medical Records Abstraction Tools should NOT be modified by state health departments; they have been designed and piloted to facilitate correct auditing using NHSN definitions. Please bring any problems to the attention of NHSN.

2015 CLABSI Medical Record Abstraction Tool

Part A: Determination of CLABSI

1. IDENTIFIERS AND ABSTRACTED DATA:

Use Tables on page 1 to document information as needed to answer questions beginning on page 2.

State	Facility (NHSN) orgID	(*circle*): ACH / LTACH / CancerH / Other	Date of Audit ___/___/____
Patient ID	Patient DOB ___/___/____	Reviewer Initials	
Review Start Time:	End Time:	Time spent reviewing this record (minutes):	
FACILITY Admission Date: ___/___/____	FACILITY Discharge Date: ___/___/____		

Positive Blood Cultures /Repeat Infection Timeframe:

Pre-screening Question: Were any positive blood cultures drawn on or after facility day 3 or was the DOE the day of transfer or discharge, or the next day?

- ☐ If Yes, continue
- ☐ If No, (all positive blood cultures were drawn before facility day 3) there was no HAI/CLABSI Event. STOP, record outcome (a) No candidate VL CLABSI

a. *Document ALL positive blood cultures sequentially below in Table 1a..Then using information from "Table 1b. Locations" below, indicate which were "Validation Location (VL) blood cultures", defined as those collected during VL stays, or on day of or day after VL discharge. Note: These VL blood cultures are eligible for possible VL CLABSI. (Non VL blood cultures may also be important to establish BSI repeat infection timeframe and other location of attribution.). Complete Table 1c. which documents presence placed/accessed.*

b. *For each organism, indicate whether it is a pathogen (P) or common commensal (cc); the list of common commensals is available in LCBI Criteria. Note:* ***Common commensals should only be evaluated as matched pairs/multiples if they were drawn on same/consecutive days; otherwise they are considered contaminants.***

The matching common commensals represent a single element; therefore, the collection date of the **first** common determine the Date of Event. If signs/symptoms occur within the 3 days prior to date of element, the first sign/symp RIT dates.

c. *Using clinical information (which can include signs/symptoms, and test results), divide listed blood cultures into distinct "RITs" and assign na RIT Number. Repeatedly positive blood cultures during previous BSIRIT (regardless of possible change in organism) are considered a single Infection Event.*

Note:

Infection Window Period (IWP): The NHSN Infection Window Period is defined as the 7-days during which all site-specific infection criteria must be met. It includes the day the first positive diagnostic test that is used as an element of the site-specific infection criterion, was obtained, the 3 calendar days before and the 3 calendar days after.

The RIT is a 14-day timeframe during which no new infections of the same type are reported. The date of event is Day 1 of the 14-day RIT. If criteria for the same type of infection are met within the 14 day RIT, a new event is not identified or reported. Additional pathogens recovered during the RIT from the same type of infection are added to the event.

Table 1a. List of positive blood cultures

Positive BC	Date BC Collection	Validation Location BC?	Optional: CL on this date or day before?	Organism genus/species	P or CC*	Infection DOE #	RIT Dates and RIT number
1	___/___/___	Y/N	Y/N			1	___/___/___
2	___/___/___	Y/N	Y/N				___/___/___
3	___/___/___	Y/N	Y/N				___/___/___
4	___/___/___	Y/N	Y/N				___/___/___
5	___/___/___	Y/N	Y/N				___/___/___
6	___/___/___	Y/N	Y/N				___/___/___
7	___/___/___	Y/N	Y/N				___/___/___
8	___/___/___	Y/N	Y/N				___/___/___
9	___/___/___	Y/N	Y/N				___/___/___
10	___/___/___	Y/N	Y/N				___/___/___

**BC=blood culture, P=pathogen, CC=common commensal, RIT= Repeat Infection Timeframe, DOE=Date of Event. Add rows if needed.*

Table 1b. Locations:

Document all facility locations and dates sequentially for this episode of care below, and indicate locations being validated for CLABSI by circling Yes or No (VL=validation location).

Facility Location Order	Physically Admit/ Transfer IN	Discharge/ Transfer OUT	Location Name (include ED)	Pt in VL?
1	___/___/___	___/___/___		Y/N
2	___/___/___	___/___/___		Y/N
3	___/___/___	___/___/___		Y/N
4	___/___/___	___/___/___		Y/N
5	___/___/___	___/___/___		Y/N
6	___/___/___	___/___/___		Y/N
7	___/___/___	___/___/___		Y/N
8	___/___/___	___/___/___		Y/N

Add rows if needed

Table 1c. Central Lines*:

Document time periods below with ANY central line in place for at least part of a day, following placement or access (do not document individual lines removed and replaced on same/ consecutive days) (CL=central line)

**Central line: IV catheter ending at/near heart or in great vessel (aorta, PA, SVC, IVC, brachiocephalic, internal jugular, subclavian, external iliac, common iliac, or femoral vein; umbilical artery/vein), placed or accessed and used for infusion, blood draw, or hemodynamic monitoring (NHSN Manual 4-2)*

CL placed or accessed	CL removed without replacement	Locations housed with CL
___/___/___	___/___/___	
___/___/___	___/___/___	
___/___/___	___/___/___	

Add rows if needed

2. SCREENING QUESTIONS *(may be answered in any order)*

S1. Were any positive blood cultures taken during ANY validation location stay, the day of, or day after VL discharge?

Select one:
- ☐ Yes -> Proceed
- ☐ No -> STOP, record outcome (a) No candidate VL CLABSI

S2. Was CL in place** for >2 calendar days AND in place during a VL stay for any period of time?

Select one:
- ☐ Yes -> Proceed
- ☐ No -> STOP, record outcome (a) No candidate VL CLABSI

If yes to both screening questions: there is a candidate VL CLABSI.

***In place: day of CL placement is considered CL day 1, unless patient admitted to facility with CL in place, where first central line access is CL Day 1.*

3. LABORATORY CONFIRMED BLOODSTREAM INFECTION (LCBI) CRITERIA

a. Evaluate all positive blood cultures in order as potential Laboratory Confirmed Bloodstream Infection (LCBI), using table columns below to ***determine if there was a LCBI, and which type (LCBI 1, LCBI 2 or LCBI 3) was met, if any.*** *All elements listed in a column are required to meet the LCBI definition.*

b. If an LCBI definition is met, determine whether the LCBI also meets the corresponding definition of mucosal-barrier injury (MBI-LCBI), which is a subset of LCBI. Each positive blood culture reviewed should result in a reported outcome on page 4.

c. ONLY IF Infection Event is related to infection at another primary site, document the alternative primary site and specific type of infection on page 4, ***attach completed 2015 Tennessee checklist for alternative primary site****, and cite evidence (e.g.; required cultures, test results, logical and DOE dates) documenting that alternative primary site infection definition was met within a timeframe that does not exceed 1 calendar day between adjacent required elements, and that there was evidence of infection at the specific site at the time of positive blood culture collection and documentation of the secondary BSI attribution period.* ***Correct assignment also requires review of 2015 NHSN Manual Ch. 4, Appendix 1 "Secondary Bloodstream Infection Guide", pp. 4-16 to 4-19, with documentation on page 4.***

LCBI type:	LCBI 1 (any age)	LCBI 2 (any age)	LCBI 3 (age ≤1 year only)
Organism(s) in blood element	☐ Recognized pathogen (P) cultured from one or more blood cultures	☐ Matching common commensal* (CC) cultured from two or more blood cultures drawn on separate occasions on same or consecutive days (this is one element and can bridge to other elements either forward or backward).	☐ Matching common commensal* (CC) cultured from two or more blood cultures drawn on separate occasions on same or consecutive days (this is one element and can bridge to other elements either forward or backward).
Other site exclusion	☐ Organism cultured from blood is not related to an infection at another site. ➢ *If alternative primary site is likely, completed 2015 Tennessee checklist is required, with review of NHSN Manual Appendix 1 (pp 4-22 through 4-27).* *Type of alternative primary site infection, date of alternative primary event, and Appendix 1 criterion should be recorded under outcomes on p 4.*	☐ Organism cultured from blood is not related to an infection at another site. ➢ *If alternative primary site is likely, completed 2015 Tennessee checklist is required, with review of NHSN Manual Appendix 1 (pp 4-22 through 4-27).* *Type of alternative primary site infection, date of alternative primary event, and Appendix 1 criterion should be recorded under outcomes on p 4.*	☐ Organism cultured from blood is not related to an infection at another site. ➢ *If alternative primary site is likely, completed 2015 Tennessee checklist is required, with review of NHSN Manual Appendix 1 (pp 4-22 through 4-27).* *Type of alternative primary site infection, date of alternative primary event, and Appendix 1 criterion should be recorded under outcomes on p 4.*
Age and Symptoms/ Signs element	(Any Age) (Any symptom or No Symptoms/Signs)	(Any Age) ☐ At least ONE of: ○ Fever >38.0°C ○ Chills, or ○ Hypotension	(Infant ≤1 year of age) ☐ At least ONE of: ○ Fever >38.0°C ○ Hypothermia <36.0° ○ Apnea, or ○ Bradycardia
Timeframe	(NA)	☐ All LCBI 2 elements must occur within the Infection Window Period, the seven-day time period which includes the date the positive blood culture was collected, the 3 calendar days before and the 3 calendar days after.	☐ All LCBI 3 elements must occur within a the Infection Window Period, the seven-day time period which includes the date the positive blood culture was collected, the 3 calendar days before and the 3 calendar days after.

**Common commensal: 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 complete list of CCs at http://www.cdc.gov/nhsn/XLS/master-organism-Com-Commensals-Lists.xls*

For any event meeting LCBI criteria above, determine whether event is an MBI-LCBI using criteria below.

Patient meets at least one of the following:

☐ Allogeneic hematopoietic stem cell transplant recipient within the past year with one of the following documented during the same hospitalization as positive blood culture:

- Grade III or IV gastrointestinal graft vs. host disease (GI-GVHD) and/or
- ≥1 liter diarrhea in a 24-hour period (or ≥20 mL/kg in a 24-hour period for patients <18 years of age) with onset on or within 7 calendar days before the date the positive blood culture was collected

OR

☐ Is neutropenic, defined as at least 2 separate days with values of absolute neutrophil count (ANC) or total white blood cell (WBC) count <500 cells/mm^3 within a 7-day time period which includes the date the positive blood culture was collected (Day 1), the 3 calendar days before, and the 3 calendar days after.

--AND— *(select appropriate LCBI column)*

MBI	☐ Organism is one of the following intestinal organisms and no other organism is isolated: *Bacteroides spp.,* *Candida spp.,* *Clostridium spp.,* *Enterococcus spp.,* *Fusobacterium spp.,* *Peptostreptococcus spp.,* *Prevotella spp.,*	☐ Organism is viridans group streptococcus with no other organisms isolated	☐ Organism is viridans group streptococcus with no other organisms isolated

	Veillonella spp., Enterobacteriaceae*,		

*Partial list of MBI-LCBI eligible *Enterobacteraciae* genera:
Citrobacter, Enterobacter, Escherichia, Klebsiella, Proteus, Providencia, Salmonella, Serratia, Shigella, Yersinia

4. Did Infection Episode Qualify as LCBI Event? *(begin loop)*

☐ No	*If LCBI definition was NOT met, record outcome ([b] No LCBI, and reason (e.g. unmatched common commensal or asymptomatic matched commensals or alternative primary site infection with secondary BSI), and continue to next Infection Event.* *If no more positive blood cultures, STOP*
☐ Yes	*If Yes LCBI, document type of LCBI and Date of Event below* *Note: there may be more than one LCBI during an episode of care.*

	Type of LCBI (*circle one*):						Date of LCBI Event (*date FIRST of required elements was met*):
First LCBI	LCBI 1	MBI LCBI 1	LCBI 2	MBI LCBI 2	LCBI 3	MBI LCBI 3	
Second LCBI	LCBI 1	MBI LCBI 1	LCBI 2	MBI LCBI 2	LCBI 3	MBI LCBI 3	
Third LCBI	LCBI 1	MBI LCBI 1	LCBI 2	MBI LCBI 2	LCBI 3	MBI LCBI 3	

Add rows if needed

5. Was LCBI Healthcare-Associated, Present on Admission, or Neither?

a. Date of Event of LCBI met during the time period of 2 days before facility admission to the day after facility admission (POA)? *(Select Yes or No):*

(Note: Acceptable documentation for POA includes self-reported symptoms by the patient. Criteria documented by a healthcare professional [e.g., nursing home documented fever or stated patient was febrile prior to arrival at the hospital] is also acceptable. Physician diagnosis of LCBI without criteria documentation cannot be accepted.

☐ Yes	*If Yes, LCBI was POA; document (c) POA LCBI type and evaluate next positive blood culture outside of the event LCBI RIT.* *If no more blood cultures, STOP*
☐ No	*If no, proceed to b.*

b. Was the Date of Event on or after the facility Day 3? *(Select Yes or No):*

☐ Yes	*If Yes, the LCBI was HAI; proceed to 6.*
☐ No	*If No, LCBI was not HAI; document (d) non-HAI LCBI type and evaluate next positive blood culture .* *If no more blood cultures, STOP*

6. Was this HAI-LCBI a CLABSI?

a. Was a central line that had been in place for >2 calendar days present or removed on the date of LCBI event or the day before LCBI event? *(Select Yes or No):*

**Note: If the patient was admitted to a facility with central line in place, day of first line access is considered line Day 1.*

☐ Yes	*If yes, HAI-LCBI is CLABSI; proceed to 7.*
☐ No	*If no, document e) HAI-LCBI not CLABSI and evaluate next positive blood culture .* *If no more blood cultures, STOP*

7. WAS VALIDATION LOCATION (VL) the Location of Attribution (LOA)?

a. Was patient in a VL on date of LCBI Event* or day before Event? *(Select Yes or No):*

☐ Yes	*If yes, proceed to b.*
☐ No	*If no, document (f) CLABSI not attributable to VL and evaluate next positive blood culture outside the previous LCBI RIT.* *If no more blood cultures, STOP*

**Date of LCBI Event is date when first of required LBCI elements occurred.*

b. Was patient transferred to VL from another bedded inpatient location, on date of LCBI Event or day before Event? *(Select Yes or No):*

☐ Yes	*If yes, location of attribution was the transferring location. Proceed to c.*
☐ No	*If no, location of attribution was location at time of infection; STOP record outcome (g) VL CLABSI*

c. Was the transferring location a validation location (VL)? *(Select Yes or No):*

☐ Yes	*If yes, location of attribution (transferring location) WAS a validation location; STOP record outcome (g) VL CLABSI*
☐ No	*If no, location of attribution (transferring location) was NOT a validation location; record outcome (f) CLABSI not VL attributable*

Positive Blood Culture Number	Outcome (a-g)	Detail for outcomes (b) through (g) (See key below)	Date of Primary Event/ Secondary BSI Attribution Period
1			
2			
3			
4			
5			

(a) No candidate validation location (VL) CLABSI
(b) No LCBI
Reason, *Select one*):

- ☐ Contaminant (unmatched cc)
- ☐ Matching ccs with no symptoms
- ☐ Alternative primary source of BSI (complete box):

-Primary source of BSI _____
-Date of alternative primary event _____
-Attach TN checklist with elements abstracted
-Circle correct NHSN Manual Appendix 1 criterion:

1. Blood/site-specific cxs match for ≥1 organism
2. Blood/site-specific cxs do NOT match but blood cx/site-specific cx are each elements of separate site-specific infection criteria
3. No site-specific cx taken but blood cx is logical pathogen for site and site-specific criteria are met
4. Negative site-specific cx with positive blood cx that fulfills element of site-specific infection criteria

(c) POA LCBI
Type of LCBI, *Select one:* *LCBI1* *MBI-LCBI1* *LCBI2* *MBI-LCBI2* *LCBI3* *MBI-LCBI3*
(d) non-HAI LCBI
Type of LCBI, *Select one*: *LCBI1* *MBI-LCBI1* *LCBI2* *MBI-LCBI2* *LCBI3* *MBI-LCBI3*
(e) HAI-LCBI not CLABSI
Type of LCBI, Select one: *LCBI1* *MBI-LCBI1* *LCBI2* *MBI-LCBI2* *LCBI3* *MBI-LCBI3*
(f) CLABSI not VL attributable
Type of LCBI, Select one: *LCBI1* *MBI-LCBI1* *LCBI2* *MBI-LCBI2* *LCBI3* *MBI-LCBI3*
(g) VL CLABSI;
Type of LCBI, Select one: *LCBI1* *MBI-LCBI1* *LCBI2* *MBI-LCBI2* *LCBI3* *MBI-LCBI3*
Date of VL CLABSI_____
Location of attribution_____

Note: Each infection episode should have an assigned outcome a-g. There may be multiple LCBIs, or multiple CLABSIs during a single episode of care.

This tool requires that the episode of care be reviewed only until the first validation location CLABSI is found (option g above), or the end of the medical record is reached.

Don't forget to record the abstraction end time on page 1

2015 CAUTI Medical Record Abstraction tool

1. IDENTIFIERS AND ABSTRACTED DATA :
Fill in demographic (white) section and then complete the Section 2, screening questions. Fill in Tables 2a, 2b, 2c, and 3 to document information as needed to answer questions

State	Facility (NHSN) orgID	(*circle*): ACH / LTACH / CancerH / IRF / Other		Date of Audit ___/___/___
HICNO:	Patient ID	Patient DOB ___/___/___		Reviewer Initials

Review Start Time:	End Time:	Time spent reviewing this record (minutes):
FACILITY Admission Date ___/___/___	FACILITY Discharge Date ___/___/___	

2. SCREENING QUESTIONS (may be answered in any order)

S1. Were any positive* urine cultures collected on or after facility day 3 (Day of physical admission to an inpatient location is Facility Day 1)?	Select one: □ Yes -> Proceed □ No? -> STOP (a) **Not a candidate VL CAUTI**	*Note: The complete list of UTI pathogens and common commensals are provided on the supporting documents sublink of NHSN website (http://www.cdc.gov/nhsn/acute-care-hospital/cauti/index.html)*
S2. Were any positive urine cultures* taken during ANY validation location (VL) stay, the day of, or day after VL discharge?	Select one: □ Yes -> Proceed □ No? -> STOP (a) **Not a candidate VL CAUTI**	
S3. Was a Foley catheter in place for >2 calendar days AND in place during a VL stay for any period of time?	Select one: □ Yes -> Proceed □ No? -> STOP (a) **Not a candidate VL CAUTI**	
If yes to all 3 screening questions: there is a candidate VL CAUTI. • *Enter all qualifying positive urine cultures collected in any location in Table 1 (?)the Positive Urine Cultures, and indicate those collected in a validation location (VL).* • *Document presence of Foley catheter (Table 2b on page 2), and OTHER supportive evidence, (Positive Blood Cultures Tables or Symptoms Tables) as needed to evaluate each infection episode sequentially for a UTI. You will use these data to determine if the UTI was HAI, whether HAI-UTI was a CAUTI, and whether the CAUTI was attributable to a validation location. NHSN UTI Definitions are found below in Part 3.*		

Laboratory Cultures

*Positive urine culture = at least 10^5 CFU/ml of 2 or fewer organisms, one of which must be a bacterium with at least 10^5 CFU/ml. DO NOT LIST cultures with more than 2 species or those classified as "mixed" flora; these cannot be used to meet UTI criteria. Exclude urine cultures that are positive only for yeast, mold, dimorphic fungi, or parasites. Note: 10^5 =100,000

Document ALL positive urine cultures* sequentially below and using information from "Locations" below (Table 2b), indicate which were "VL urine cultures", defined as those collected during VL stays, or on day of or day after VL discharge. Note: These VL urine cultures should be evaluated for possible VL CAUTI. (Non VL urine cultures may also be important to establish prior onset of UTI Repeat Infection Timeframe (RIT) and another location of attribution.)

Columns 3, 4, and 7 (in red) are optional, but some validators may prefer to use these columns to organize their investigation

Table 1. Positive Urine Cultures

Candidate UTI	Date UC Collection	VL UC?	Foley on this date or day before?	CFU/ml ($\geq 10^5$)	Organism genus/species (maximum 2)	Matched uropathogen in blood Within UTI IWP?**
1	___/___/___	Y/N	Y/N			Y/N or NA (sx)
2	___/___/___	Y/N	Y/N			Y/N or NA (sx)
3	___/___/___	Y/N	Y/N			Y/N or NA (sx)
4	___/___/___	Y/N	Y/N			Y/N or NA (sx)
5	___/___/___	Y/N	Y/N			Y/N or NA (sx)
6	___/___/___	Y/N	Y/N			Y/N or NA (sx)

Add rows if needed

***If colony counts are high (CFU/ml $\geq 10^5$), circle Y or N and document matching organism(s) isolated from blood in "positive blood cultures" Table 2d below; if patient with UTI symptoms ("sx") in UTI Infection Window Period (IWP) circle NA.*

Table 2a. Locations

Document all facility locations and dates for this episode of care chronologically below, and indicate locations being validated for CAUTI by circling Yes or No (VL=validation location).

Facility Location Order	Admit/Transfer IN	Discharge/ Transfer OUT	Location Name (include ED)	Validation Location (VL)?
1	___/___/___	___/___/___		Y/N
2	___/___/___	___/___/___		Y/N
3	___/___/___	___/___/___		Y/N
4	___/___/___	___/___/___		Y/N
5	___/___/___	___/___/___		Y/N
6	___/___/___	___/___/___		Y/N

Add rows if needed

Table 2b. Foley Catheters

Document time periods with ANY Foley catheter in place for at least part of each day below (do NOT document individual catheters removed and replaced on same/ consecutive days).

Foley placed or in place	Foley removed without replacement	Locations with Foley	Foley in validation location
__/___/___	__/___/___		Y/N
__/___/___	__/___/___		Y/N
__/___/___	__/___/___		Y/N
__/___/___	__/___/___		Y/N
__/___/___	__/___/___		Y/N
__/___/___	__/___/___		Y/N

Table 2c. Positive Blood Cultures

IF urine culture above contains ≥10^5 CFU/ml and patient is ASYMPTOMATIC, document any positive blood culture(s). This information is needed to document ABUTI, and requires a matching organism in blood (or ≥two common commensal organisms in blood). At least one of the blood organisms must have been collected within the UTI IWP. If no positive blood cultures, indicate below.

□ No positive blood culture(s) OR

Candidate UTI (from Table above)	Blood culture collection date	Matching organism(s)	Matching common commensal(s)
1	__/___/___		
2	__/___/___		
3	__/___/___		
4	__/___/___		
5	__/___/___		
6	__/___/___		

3. **Symptoms*** (Check one or more as required, or note date)

* Symptoms required to meet UTI definition, within the IWP.

No UTI sx	Candidate UTI	Apnea	Bradycardia	CVA pain	Dysuria	Fever	Frequency	Hypothermia	Lethargy	SP Tenderness	Urgency	Vomiting
	1											
	2											
	3											
	4											

Add rows if needed

4. URINARY TRACT INFECTION (UTI) CRITERIA

Starting with Candidate UTI #1 , determine which type of UTI criteria [ABUTI, SUTI1a, SUTI1b, SUTI2] were met (if any). Required elements for UTI are highlighted in color. ***All elements listed in a column are required within the infection window time frame.***

UTI type:	*SUTI1a (Symptomatic, any age)*	*SUTI1b (Symptomatic, any age)*	*SUTI2 (Symptomatic, infants only)*		*ABUTI (Asymptomatic, any age)*
urine culture element	☐ *≥ 10^5 CFU/ml urine (2 or fewer microorganisms, at least one of which is a bacterium of ≥105 C)*	☐ *≥10^5 CFU/ml urine (2 or fewer microorganisms, at least one of which is a bacterium of ≥105 CFU/ml))*	☐ *≥ 10^5 CFU/ml urine (2 or fewer microorganisms, at least one of which is a bacterium of ≥105 CFU/ml))*	☐	☐ *≥ 10^5 CFU/ml urine (2 or fewer microorganisms) at least one of which is a bacterium of ≥105 CFU/ml)*
		o		o	
Blood culture(s) element					☐ *Matching organisms/matching common commensals*
Age, Appropriate symptoms (= no other recognized cause) and Foley catheter status element*	*(Any age, Foley present)* ☐ *At least ONE of:* o *Fever >38.0°C* o *Suprapubic tenderness** o *CVA pain or tenderness** *AND* ☐ *Foley for >2 days and in place when last required element documented*	☐ *Patient has/had an indwelling urinary catheter but it has/had not been in place >2 calendar days on the date of event†* *OR* ☐ *Patient did not have a urinary catheter in place on the date of event nor the day before the date of event* ☐ *At least ONE of: fever (>38°C) in a patient that is ≤ 65 years of age* • *suprapubic tenderness** • *costovertebral angle pain or tenderness** • *urinary frequency ** • *urinary urgency** • *dysuria**	*(With or without a Foley)* ☐ *Age ≤1 year AND* ☐ *At least ONE of:* o *Fever >38.0°C* o *Hypothermia <36.0°C* o *Apnea** o *Bradycardia** o *Dysuria** o *Lethargy** o *Vomiting** *(Foley optional)*	(	*(With or without a Foley) (Any age)* ☐ *No listed symptoms allowed within time frame (Foley optional)* *Note: Patients > 65 years of age with a non-catheter-associated ABUTI may have a fever and still meet the ABUTI criterion)*
	--OR--	***--OR--***			
	☐	*(Any age, Foley recently removed)* ☐ *At least ONE of:* o *fever (>38°C) in a patient that is ≤ 65 years of age* o *Urgency**			

		o *Frequency** o *Dysuria** o *Suprapubic tenderness** o *CVA pain or tenderness** *AND* ☐ *Foley for >2 days removed day before date of event*			

5. Did candidate UTI qualify as a UTI event, using criteria shown on page 3? (begin loop)				
☐Yes	*If Yes, document type of UTI and Date of Event, RIT # and RIT dates below, and then proceed to 6.* *Note: there may be more than one UTI during an episode of care if outside the repeat infection timeframe.*			
☐ No	*If no UTI definition was met, record outcome (b) no UTI and reason (e.g. asymptomatic with no matching pathogen in blood,). Loop to next positive urine culture Episode.* *If no more positive urine cultures, STOP.*			
	Type of UTI	Date of UTI (date FIRST required element was met)	UTI RIT #	UTI RIT dates
First candidate UTI		___/___/___		___/___/___ to ___/___/___
Second candidate UTI		___/___/___		___/___/___ to ___/___/___
Third candidate UTI		___/___/___		___/___/___ to ___/___/___
Add rows if needed				
Note: *The UTI RIT is a 14-day timeframe during which no new UTIs are reported. The UTI RIT applies to both POA and HAI determinations. The date of UTI event is Day 1 of the 14-day RIT. If date of event for UTI occurs within a previous 14 day UTI RIT, no new UTI is identified nor reported. Additional positive urine cultures during the UTI are added to the event.* *UTI Infection Window Period (IWP): The NHSN UTI Infection Window Period is defined as the 7-days during which all UTI criteria must be met. It includes the day the positive urine culture, was obtained, the 3 calendar days before and the 3 calendar days after.*				

6. Was UTI Healthcare-Associated (HAI), Present on Admission (POA), or Neither?	
a. Did the date of event of UTI occur during the time period of 2 days before admission to the day after admission (i.e., POA)? (Select one):	
Note: *Date of Event: The Date of Event is the date the first element used to meet an NHSN UTI criterion occurs for the first time within the seven-day infection window period. Acceptable documentation includes patient-reported signs or symptoms documented in the chart by a healthcare professional (e.g., patients states measured fever > 38.0° C or 100.4° F, nursing home documents fever prior to arrival to the hospital, patient complains of dysuria).*	
☐ Yes	If Yes, this UTI was POA; document outcome (c) POA UTI and an RIT is set. Evaluate next positive urine culture collected outside the RIT.. If no more urine cultures, STOP
☐ No	If no, UTI was a HAI. Proceed to 7.

7. Was this HAI-UTI a CAUTI?	
a. Was a Foley catheter in place for > 2 days on the date of event AND was either present for any portion of the calendar day on the date of event, OR removed the day before the date of event?	
Note: If the patient was admitted to a facility/ED with a Foley in place, date of admission to inpatient location is considered to be device day 1	
☐ Yes	If yes, HAI-UTI is CAUTI; proceed to 8.
☐ No	If no, HAI-UTI was not CAUTI; document outcome (d) HAI-UTI not CAUTI and a UTI RIT is set. Evaluate next positive urine culture outside the UTI RIT. If no more urine cultures, STOP.
8. Was VALIDATION LOCATION (VL) the Location of Attribution (LOA)	
a. Was patient in a VL on the date of UTI Event* or day before UTI event? (Select Yes or No)	
☐ Yes	If Yes, proceed to b.
☐ No	If No, CAUTI was not attributable to VL; document outcome (e) CAUTI not VL attributable and a UTI RIT is set. Evaluate next positive urine culture outside the UTI RIT . If no more urine cultures, STOP
*Date of UTI Event is date when first of required UTI elements occurred during the UTI IWP.	
b. Was patient transferred to VL from another institution or bedded inpatient location, on date of UTI Event or day before UTI Event? (Select Yes or No):	
☐ Yes	If yes, location of attribution was the transferring location**; Proceed to c.
☐ No	If no, location of attribution was location at time of UTI Event; STOP, record outcome (f) VL CAUTI
c. Was the transferring location** a validation location (VL)? (Select one):	
☐ Yes	If yes, location of attribution (transferring location) WAS a validation location; STOP, record outcome (f) VL CAUTI
☐ No	If no, location of attribution (transferring location) was NOT a validation location; record outcome (e) CAUTI not VL attributable and a UTI RIT is set. Evaluate next positive urine culture outside the UTI RIT. If no more urine cultures, STOP
**If patient is transferred more than once on the day of /day before the UTI Event, the FIRST transferring location from that time period is location of attribution.	

Outcome of 2015 CAUTI audit:

Candidate UTI*	Outcome (a-g)	Detail for outcomes (b) through (g) (See key to right)
1		
2		
3		

(a) Not a candidate VL CAUTI
(b) No UTI; reason:
- ☐ Asymptomatic but no matching blood pathogen

(c) POA UTI (not HAI)
(d) HAI-UTI not CAUTI
- ☐ Type of UTI _____
- ☐ Date of Event _____

4			(e) CAUTI not VL attributable ☐ Type of UTI _____ ☐ Date of Event _____ ☐ Location of Attribution _____ (f) VL CAUTI ☐ Type of UTI_____ ☐ Date of Event _____ ☐ Validation location of attribution _____
5			

Note:
*Report only those candidate UTIs which are outside previous UTI RITs
- There may be multiple UTIs or multiple CAUTIs during a single episode of care.

This tool requires that the episode of care be reviewed only until the first Validation Location (VL) CAUTI is found (outcome g above), or all positive urine cultures have been reviewed.

2015 COLO Procedure/SSI Medical Record Abstraction Tool

For use in acute care hospital SSI validation following inpatient COLO procedures performed during Q1-Q4, 2015

1. Patient and Medical Record IDENTIFIERS

State	Facility OrgID	Date of Audit	Reviewer Initials
HICNO:	Patient ID	Patient DOB ___/___/____	Gender: F M

Facility Admission Date 1 (for index COLO Procedure)	Facility Discharge Date 1

Review Start Time:		End Time:		Time spent reviewing record (minutes):	

COLO Procedure Date: ___/___/2015

(USE THIS TOOL ONLY FOR COLOs PERFORMED IN 2015)

- *Describe in words all procedure(s) performed during index COLO surgery (e.g. colon resection, colostomy formation, appendectomy)*:

- *Circle ICD-9-CM COLO procedure code(s) for index COLO:*

17.31-17.36, 17.39, 45.03, 45.26, 45.41, 45.49, 45.52, 45.71-45.76, 45.79, 45.81-45.83, 45.92-45.95, 46.03, 46.04, 46.10, 46.11, 46.13, 46.14, 46.43, 46.52, 46.75, 46.76, 46.94

Note to validators: For Q1-Q3 2015, the presence of one or more of the above ICD-9-CM codes is a required element of a COLO procedure. IPs are advised not to over-ride medical records coding decisions, but may discuss errors with coders.

(Criteria for Q4 2015 will include ICD-10-PCS codes). Link to SSI section for ICD-10-PCS and CPT codes can be found in the "Supporting materials" section of the link below: http://www.cdc.gov/nhsn/acute-care-hospital/ssi/index.html

- "ModelRiskAll" Score (derived from NHSN line list):

Record later admission dates below only if they occur within 30 days of COLO Procedure (Procedure date = day 1 of 30).

Facility Admission Date 2: ___/___/____	Facility Discharge Date 2: ___/___/____
Facility Admission Date 3: ___/___/____	Facility Discharge Date 3: ___/___/____

2. NHSN Operative Procedure Criteria

▪ Did COLO operative procedure meet NHSN definition for inpatient procedure? (NHSN Manual 9-9 and 9-10)*	☐ COLO procedure performed on NHSN inpatient during trip to hospital inpatient O.R./equivalent where ≥1 incision was made through skin/mucous membrane (including laparoscopic approach), or during reoperation via an incision that was left open during a prior procedure. (*Note incisional closure is NO longer an element of the NHSN Operative Procedure definition, but is addressed under risk-adjustment*)
☐ No	If No, STOP, record (a) Not a candidate COLO SSI; did not meet NHSN Operative Procedure definition
☐ Yes	If Yes, proceed to 3.

**Notes to validator:*

- *Do not report procedure if ASA score=6*
- *"NHSN Inpatient" requires that admission date is different from discharge date*
- *"Inpatient procedure" requires use of inpatient O.R./equivalent. "O.R. equivalent" may include C-section room, interventional radiology room, or cardiac catheterization lab meeting FGI or AIA criteria; see Manual 9-3 for details.*

- *Regardless of wound class at the time of procedure or closure method (primary vs non-primary) all inpatient NHSN COLO procedures should be reported to the NHSN denominator, and all infections meeting COLO SSI criteria during the surveillance window should be reported.*

3. Document COLO Procedure Risk-Adjustment Variables in Medical Record at Time of Procedure for Comparison to NHSN	
Type of closure: *Definitions: Primary Closure: "defined as closure of the skin level during the original surgery, regardless of the presence of wires, wicks, drains, or other devices or objects extruding through the incision. This category includes surgeries where the skin is closed by some means. Thus, if any portion of the incision is closed at the skin level, by any manner, a designation of primary closure should be assigned to the surgery. "(See NHSN Manual Ch 9-10 for detail*).	Primary Other than primary
Diabetes: *Definition: The NHSN SSI surveillance definition of diabetes indicates that the patient has a diagnosis of diabetes requiring management with insulin or a non-insulin anti-diabetic agent. This includes patients with "insulin resistance" who are on management with anti-diabetic agents. This also includes patients with a diagnosis of diabetes who are noncompliant with their diabetes medications. The discharge ICD-9-CM codes in the 250 to 250.93 range are also acceptable for use to answer YES to the diabetes field question.* *. ICD-10 CM Codes that may be used to answer the question about diabetes beginning with procedures with dates of surgery on October 1, 2015 or later, can be found under Supporting Materials at this site: http://www.cdc.gov/nhsn/acute-care-hospital/ssi/index.html* *The NHSN definition excludes patients with no diagnosis of diabetes. The definition excludes patients who receive insulin for perioperative control of hyperglycemia but have no diagnosis of diabetes.* *Note: gestational diabetes is a type of diabetes.*	Yes No
ASA score *(circle one)*:	1 2 3 4 5 (*Do not report if ASA=6*)
General anesthesia *(Select one)*:	Yes No
Scope (*includes robotic*) *(Select one)*:	Yes No
Emergency? (non-elective and unscheduled) *(Select one)*:	Yes No
Trauma? (blunt or penetrating injury) *(Select one)*:	Yes No
Gender *(Select one)*:	M F
Age (years):	
Height:	___feet/___inches **OR** ___ meters
Weight:	____pounds **OR** ____kilograms
Wound class *(Select one)*:	C CC CO D
Was there evidence of infection in the surgical area at the time of the index procedure*-	Yes No

COLO procedure duration*:	Procedure date:	Procedure start time (mil***):	Procedure finish* date:	Procedure finish* time (mil):
Index procedure				
2nd Procedure within 24 hours**				

Procedure duration (derived from above information): _____hours and _____minutes

**Procedure finish time is when all instruments and sponge counts are completed and verified, post-op x-rays in OR are done, all dressings and drains are secured, and physicians/surgeons have completed all procedure-related activities on the patient.*

***If pt goes to OR again and another procedure is performed through the same incision within 24 hours of the original procedure finish time and during the same admission, count as only one procedure combining the durations for both procedures and using the higher of the wound class and ASA scores.*

**** minutes in length*	
4. Document Subsequent Surgery /Invasive Procedure During SSI Surveillance Window	
▪ Was a subsequent surgery performed through the primary incision beyond 24 hours after the original procedure finish time but within the 30-day surveillance window following the original procedure, OR was the surgical organ/space otherwise entered or manipulated invasively (e.g., to drain a hematoma) at any time during the 30-day surveillance window [Date of procedure=Day 1]?	
☐ No	If no, skip to 5.
☐ Yes	If yes, d*ocument additional procedure(s) and dates for consideration and proceed to 5.*
Invasive procedure 1:	Date 1:
Invasive procedure 2:	Date 2:
Document any evidence of infection during invasive procedures above:	
5. Document surgical infection during surveillance window period	
▪ Was there any documentation of surgical infection within the surveillance window, including while hospitalized or post-discharge, e.g. communication from patient or other hospital, visits to the ED or clinic? (NOTE: Reporting an SSI to the surgical facility IP is required when SSI is detected at a different facility).	
☐ No	*If No, proceed to 7.*
☐ Yes	*If Yes, abstract information regarding infection status in the space below, and proceed to 6.*
6. Document SSI Definition Criteria	
▪ *Using the NHSN SSI Definitions criteria (see following), document which depth of infection criteria were met and the date of infection (date when the last element used to meet NHSN infection criterion occurred). Note: Available criteria for SSI may progress (e.g. superficial to deep); review the entire infection event and record the* ***DEEPEST*** *level of SSI during the surveillance window. Use the open space in 5 above, and the checklist that follows to document information for decision making. Enter outcome of audit in part 7 below, and for SSIs, continue to part 7B for attribution assignment.*	

2015 HYST Procedure/SSI Medical Record Abstraction Tool

For use in acute care hospital SSI validation following inpatient HYST procedures performed during Q1-Q3, 2015

1. Patient and Medical Record IDENTIFIERS

State	Facility OrgID	Date of Audit	Reviewer Initials
HICNO	Patient ID	Patient DOB	Gender F M

Facility Admission Date 1 (for index HYST procedure):	Facility Discharge Date 1:

Review Start Time:		End Time:		Time spent reviewing this record (minutes):	

HYST Procedure Date: ___/___/2015

(USE THIS TOOL ONLY FOR HYSTs PERFORMED IN 2015)

- *Circle ICD-9-CM procedure code(s) for index HYST: 68.31, 68.39, 68.41, 68.49, 68.61, 68.69*

Note to validators: For Q1-Q3 2015, the presence of one or more of the above ICD-9-CM codes is a required element of a COLO procedure. IPs are advised not to over-ride medical records coding decisions, but may discuss errors with coders.

(Criteria for Q4 2015 will include ICD-10-PCS codes).Link to SSI section for ICD-10-PCS and CPT codes can be found in the "Supporting materials" section of the link below: http://www.cdc.gov/nhsn/acute-care-hospital/ssi/index.html

Describe in words all procedure(s) during index HYST surgery (e.g. hysterectomy, bilateral salpingoophorectomy (BSO), cesarean section, appendectomy)

"ModelRiskAll" Score (derived from NHSN line list):

Record later admission dates below only if they occur within 30 days of HYST Procedure (Procedure date = day 1 of 30).

Facility Admission Date 2:___/___/____	Facility Discharge Date 2:___/___/____
Facility Admission Date 3:___/___/____	Facility Discharge Date 3:___/___/____

2. NHSN Operative Procedure Criteria

▪ Did HYST operative procedure meet NHSN definition for inpatient procedure? (NHSN Manual 9-9 and 9-10)*	☐ HYST procedure performed on NHSN inpatient during trip to hospital inpatient O.R./equivalent where ≥1 incision was made through skin/mucous membrane (including laparoscopic approach), or during reoperation via an incision that was left open during a prior procedure. (*Note incisional closure is NO longer an element of the NHSN Operative Procedure definition, but is addressed under risk-adjustment*)

☐ No	If No, STOP, record (a) Not a candidate HSYT SSI; did not meet NHSN Operative Procedure definition
☐ Yes	If Yes, proceed to 3.

**Notes to validator:*

- *Do not report procedure if ASA score=6*
- *"NHSN Inpatient" requires overnight stay ("admission date is different from discharge date"); "Inpatient procedure" requires use of inpatient O.R./equivalent. "O.R. equivalent" may include C-section room, interventional radiology room, or cardiac catheterization lab meeting FGI or AIA criteria; see Manual 9-2 for details.*

- *Regardless of wound class at the time of procedure or closure method (primary vs non-primary) all inpatient NHSN HSYT procedures should be reported to the NHSN denominator, and all infections meeting HYST SSI criteria during the surveillance window should be reported.*

3. Document HYST Procedure Risk-Adjustment Variables in Medical Record for Comparison to NHSN	
Type of closure: *Definitions: Primary Closure: "defined as closure of the skin level during the original surgery, regardless of the presence of wires, wicks, drains, or other devices or objects extruding through the incision. This category includes surgeries where the skin is closed by some means. Thus, if any portion of the incision is closed at the skin level, by any manner, a designation of primary closure should be assigned to the surgery. "(See NHSN Manual Ch 9-10 for detail*).	Primary Other than Primary
Diabetes: *Definition: The NHSN SSI surveillance definition of diabetes indicates that the patient has a diagnosis of diabetes requiring management with insulin or a non-insulin anti-diabetic agent. This includes patients with "insulin resistance" who are on management with anti-diabetic agents. This also includes patients with a diagnosis of diabetes who are noncompliant with their diabetes medications. The discharge ICD-9-CM codes in the 250 to 250.93 range are also acceptable for use to answer YES to the diabetes field question. ICD-10 CM Codes that may be used to answer the question about diabetes beginning with events with dates of surgery on October 1, 2015 or later, can be found under Supporting Materials at this site: http://www.cdc.gov/nhsn/acute-care-hospital/ssi/index.html* *The NHSN definition excludes patients with no diagnosis of diabetes. The definition excludes patients who receive insulin for perioperative control of hyperglycemia but have no diagnosis of diabetes.* *Note: gestational diabetes is a type of diabetes.*	Yes No
ASA score *(circle one)*:	1 2 3 4 5 (*Do not report if ASA=6*)
General anesthesia (Select one):	Yes No
Scope (Select one):	Yes No
Emergency? (non-elective, unscheduled) *(Select one)*:	Yes No
Trauma? (blunt or penetrating injury) *(Select one)*:	Yes No
Gender *(Select one)*:	F
Patient Age (years):	
Height:	___feet/___inches **OR** ___ meters
Weight:	____pounds **OR** ____kilograms
Wound class *(Select one)*:	C CC CO D
Was there evidence of infection in the surgical area at the time of the index procedure*	Yes No

HYST procedure duration*:	Procedure date:	Procedure start time (mil):	Procedure finish* date:	Procedure finish* time (mil):
Index procedure				
2nd Procedure within 24 hours**				
Procedure duration (derived from above information): _____hours and _____minutes				

**Procedure finish time is when all instruments and sponge counts are completed and verified, post-op x-rays in OR are done, all dressings and drains are secured, and physicians/surgeons have completed all procedure-related activities on the patient.*

***If pt goes to OR again and another procedure is performed through the same incision within 24 hours of the original procedure finish time and during the same admission, count as only one procedure combining the durations for both procedures and using the higher of the wound class and ASA scores.*

4. Document Subsequent Surgery /Invasive Procedure During (HYST) SSI Surveillance Window	
▪ Was a subsequent surgery performed through the primary incision beyond 24 hours after the original procedure finish time but within the 30-day surveillance window following the original procedure, OR was the surgical organ/space otherwise entered or manipulated invasively (e.g., to drain a hematoma) at any time during the 30-day surveillance window [Date of procedure is Day 1]?	
☐ No	*If No, skip to 5.*
☐ Yes	If yes, *document additional procedure(s) and dates for consideration and proceed to 5.*
Invasive procedure 1:	Date:
Invasive procedure 2:	Date:
Document any evidence of infection during invasive procedures above:	

5. Additional /Post-Discharge Infection Surveillance	
▪ Was there any documentation of surgical infection within the surveillance window, including while hospitalized or post-discharge (e.g. communication from patient or other hospital, visits to the ED or clinic)? (NOTE: Reporting of SSI to the surgical facility IP is required when SSI is detected at a different facility).	
☐ No	*If No, proceed to 7.*
☐ Yes	*If Yes, abstract information regarding infection status in the space below, and proceed to 6.*

6. Document SSI Definition Criteria
Using the NHSN SSI Definitions criteria (See following), document which depth of infection criteria were met and the date of infection (date when the last element used to meet NHSN infection criterion occurred). Note: Available criteria for SSI may progress (e.g. superficial to deep); review the entire infection event and record the ***DEEPEST*** *level of SSI during the surveillance window. Use the open space in 5 above, and the checklist that follows to document information and decision-making. Enter infection status in part 7 below, and for SSIs, continue to part 7B for attribution assignment.*

6 (continued): NHSN SSI Definitions: Use checklist to establish elements met:		
Superficial Incisional HYST SSI	Deep incisional HYST SSI	Organ/Space HYST SSI
☐ Occurs within 30 days or end of surveillance window (whichever comes first)	☐ Occurs within 30 days (HYST) or end of surveillance window (whichever comes first)	☐ Occurs within 30 days (HYST) or end of surveillance window (whichever comes first)
AND	AND	AND
☐ Involves only skin and subcutaneous tissue of the incision	☐ Involves deep soft tissues (e.g., fascia and muscle layers) of the incision	☐ Involves any body part opened or manipulated during surgery except skin incision, fascia or muscle.
AND	AND	AND
☐ at least one of the boxes:	☐ at least one of the boxes:	☐ at least one of the boxes:
○ Purulent drainage from superficial incision	○ Purulence from deep incision	○ Purulence from a drain placed into the organ/space

○ Organisms isolated from Aseptically-obtained culture of fluid or tissue superficial incision		○ Organisms isolated from Aseptically-obtained culture of fluid or tissue organ/space
○ Attending physician* deliberately opened superficial incision AND ○ Culture-positive or not-cultured AND ○ At least one of: o pain or tenderness o localized swelling o redness o heat	○ Spontaneous dehiscence or surgeon deliberately opened deep incision AND ○ Deep incision is culture-positive or not-cultured AND ○ At least one of: o fever (>38.0°C) o localized pain or tenderness	
○ Diagnosis of superficial incisional SSI by attending physician*	○ Abscess or other evidence of infection involving the deep incision that is found on (at least one of) o Direct examination o During invasive procedure o Histopathologic examination o Imaging test	○ Abscess or other evidence of infection involving the organ/space that is found on (at least one of) o Direct examination o During invasive procedure o Histopathologic examination o Imaging test
**Note: the term attending physician for the purposes of application of the NHSN SSI criteria may be interpreted to mean the surgeon(s), infectious disease, other physician on the case, emergency physician or physician's designees (nurse practitioner or physician's assistant).*		
		AND ☐ Meets at least one criterion for a specific organ/space infection site; particularly (for HYST) IAB, OREP, or VCUF. **Document using Tennessee Checklist.**
Reporting Notes		
➢ *Do not report stitch abscess, localized stab wound, pin site infection, or cellulitis alone*	➢ *The depth of SSI (SI, DI, or O/S) reported should reflect the deepest tissue layer involved during the surveillance window.*	➢ *If a patient has O/S infection during the primary operative procedure subsequent continuation meeting NHSN SSI criteria is considered an O/S SSI.*

7. Outcome of 2014 HYST SSI audit *7(A): Select (a), (b), or (c); If (b) is selected, define depth and date of infection, then proceed to 7(B)*:		
☐ (a) Not a candidate HYST SSI: Did not meet NHSN Operative Procedure definition		
☐ (b) SSI: *(select deepest level during surveillance window)*	☐ (b1) Superficial incisional SSI ☐ (b2) Deep incisional SSI ☐ (b3) Organ/Space SSI (Specify site) _____	Date of SSI *(date SSI was first met at any depth):*
☐ (c) No SSI		

7(B): Attribution of HYST SSI to Procedure	
▪ Was the SSI attributable to the HYST, or was the SSI attributable to another invasive concurrent NHSN Operative Procedure or to invasive manipulation of the HYST operative site after the HYST procedure? *(Select one):*	
☐ HYST SSI	*Note to validator: In the context of serial invasive manipulations (including surgery) affecting the same operative site, an SSI is attributed to the most recent intervention. In the context of multiple concurrent NHSN Operative Procedures through the same incision, superficial and deep incisional infections are attributable to the procedure highest on the surgical hierarchy*, because there is no way to distinguish which of the NHSN Operative Procedures led to the infection. For organ/space SSIs, the specific location of infection should be examined for attribution; e.g., in the event of concurrent COLO and HYST, a vaginal cuff infection should be attributed to the HYST. E.g.; in the event of concurrent HYST and SPLE, abscess of the bed of the spleen should be attributed to the SPLE. E.g.; in the event of concurrent HYST and COLO, deep pelvic abscess would be attributed to the HYST, whereas the hierarchy would assign peritonitis to the COLO. (*See hierarchy below)*
☐ SSI not attributable to HYST; SSI attributable to (specify): _____	

***2014 Surgical Hierarchy for Abdominal Operations, from NHSN Manual Ch 9, Table 5.**

Priority	Code	Abdominal Operations
1	LTP	Liver transplant
2	COLO	Colon surgery
3	BILI	Bile duct, liver, or pancreatic surgery
4	SB	Small bowel surgery
5	REC	Rectal surgery
6	KTP	Kidney transplant
7	GAST	Gastric surgery
8	AAA	Abdominal aortic aneurysm repair
9	HYST	Abdominal hysterectomy
10	CSEC	Cesarean section
11	XLAP	Exploratory laparotomy
12	APPY	Appendix surgery
13	HER	Herniorrhaphy
14	NEPH	Kidney surgery
15	VHYS	Vaginal hysterectomy

16	SPLE	Spleen surgery
17	CHOL	Gall bladder surgery
18	OVRY	Ovarian surgery

8. (For health department use) If SSI was missed by facility, what was the reason?	
☐ Surveillance missed ☐ Misinterpreted criteria ☐ Incorrect use of infection at another site ☐ MD ruled out an SSI ☐ Other _____	Provide detail:

Don't forget to record the abstraction end time on page 1

2015 MRSA Bacteremia LabID Event (FacWideIN) Validation Tool

For validation of MRSA bacteremia (only) LabID Event reporting in acute care hospitals conducting LabID Event surveillance for either MRSA bacteremia or all MRSA clinical specimens (EXCLUDES SCREENING CULTURES for colonization). Note: Based on CDC sampling guidance, this tool will be used in two ways; [Sample A] to validate reportability of the FIRST inpatient MRSA culture for a patient and episode of care, and [Sample B] to validate reportability of a subsequent SELECTED (non-first) MRSA culture for a patient and episode of care. Sample A evaluates the facility's ability to link early inpatient MRSA cultures to recent episodes of care and affiliated ED/outpatient specimens on the date of admission. Sample B evaluates the facility's ability to correctly classify duplicate vs. reportable events.

Facility LabID Event Surveillance Method (NHSN monthly reporting plan)		☐ MRSA Bacteremia only (note: *omit Table 2, column G below*) ☐ MRSA All specimens (note: *include Table 2, column G below*)	
Sample ***Select one:***	☐ Sample A: validating "first" inpatient MRSA culture	Date of "first" inpatient MRSA culture	
	☐ Sample B: validating SELECTED (non-first) inpatient MRSA culture	Date of SELECTED (non-first) inpatient lab culture	

Instructions:

For Sample A: Begin with the "first" inpatient MRSA bacteremia. Through additional investigation determine whether a prior MRSA-positive blood specimen was collected from this patient in ED or other facility-affiliated outpatient location on the NHSN inpatient admission date. If such a specimen is identified, enter it in Table 2, row S1. Then enter the "first" inpatient specimen in row S2. If no ED or facility-affiliated outpatient specimen is identified, enter the "first" inpatient MRSA Culture in Table 2, row M1. Note that If a specimen was collected in ED or affiliated outpatient location on calendar day of admission, reporters are allowed to assign the specimen to the location of inpatient admission.

Through additional investigation, determine if this patient had a prior inpatient stay within the 14 days prior to specimen collection, and whether any MRSA Culture specimens were reported or collected within that timeframe for the patient and same location. Working across the row, determine if the chosen ("first") inpatient MRSA Culture on the laboratory line list was reportable to NHSN.*

For Sample B: Begin with the SELECTED (non-first) inpatient MRSA culture. Using the Sample B sorted list, identify the most recent specimen collected from the same patient in the same location prior to this selected specimen. If prior specimens from the same patient were found, enter theses specimens starting in Table 2, row S1. If no prior specimen was collected from the same location, enter the SELECTED (non-first) inpatient MRSA Culture in Table 2, row S1. Working across the row, determine if the SELECTED (non-first) inpatient MRSA Culture on the laboratory line list was reportable to NHSN.*

Patient and Medical Record IDENTIFIERS

NHSN orgID#:		Date of Audit:		Reviewer Initials:
Review Start Time:		End Time:	Time spent reviewing this record (minutes):	
Patient ID	Patient DOB	NHSN Inpatient Admission Date (Date when placed in inpatient location as "observation" or "admitted" patient):		Facility Location 1 (Specific first inpatient bedded location name; not ED):
HICNO	Gender F M			

Table 1: Patient care locations and transfer dates: *If validating for Sample B, enter dates and locations from ADT data* ***up to the date of SELECTED specimen****. (Note: SKIP step below for Sample A validation)*

Date transfer to Location 2		Facility Location 2		Date transfer to Location 4		Facility Location 4	
Date transfer to Location 3		Facility Location 3		Date transfer to Location 5		Facility Location 5	

Table 2: Positive MRSA Blood Cultures

A	**B**	**C**	**D**		**E**			**F**		**G (*Complete only if all specimen surveillance*)**		**H**	
Lab list #	Date of specimen collection	Location of specimen collection*	Number of days since last positive MRSA Culture		Was last positive MRSA Culture from same NHSN location?			Was this a "duplicate specimen", i.e.; ≤14 days since last positive MRSA Culture AND patient in same location (could include a previous episode of care)		Was this MRSA blood culture the first MRSA culture of any type for this month?		Reportable to NHSN**?	
S1	__/__/__		____ days	☐ no prior	☐ No	☐ Yes	☐ no prior	☐ No	☐ Yes	☐ No	☐ Yes	☐ No	☐ Yes
S2	__/__/__		____ days		☐ No	☐ Yes		☐ No	☐ Yes	☐ No	☐ Yes	☐ No	☐ Yes
S3	__/__/__		____ days		☐ No	☐ Yes		☐ No	☐ Yes	☐ No	☐ Yes	☐ No	☐ Yes

*Reportable to NHSN if:

- Facility conducting MRSA all specimen surveillance, AND MRSA blood culture was first positive MRSA culture of any type for the month (Table 2, Column G = yes).
- No prior MRSA bacteremia from the patient in the same location
- More than 14 days since last MRSA bacteremia from the patient in the same location

2015 CDI LabID Event (FacWideIN) Validation Tool

For use in acute care hospitals (ACH). Note: This tool will be used in two ways; [Sample A] to validate reportability of the FIRST inpatient CDI toxin-positive specimen for a patient and episode of care, and [Sample B] to validate reportability of a subsequent SELECTED (non-first) CDI toxin-positive specimen for a patient and episode of care. Sample A evaluates the facility's ability to link inpatient specimens to recent episodes of care and affiliated ED/outpatient specimens on the date of admission, which could render the first inpatient specimen non-reportable; Sample B evaluates the facility's ability to correctly classify duplicate vs. reportable events.

Patient and Medical Record IDENTIFIERS		
NHSN orgID#:	Date of Audit:	Reviewer Initials:
Review Start Time:	End Time:	Time spent reviewing this record (minutes):

Patient DOB	Patient ID	HICNO	NHSN Inpatient Admission Date (Date when placed in inpatient location as observation or admitted patient):	Facility Location 1 (Specific first inpatient bedded location name; not ED):

***Select one*:**	☐ Sample A: validating chosen "first" inpatient CDI toxin-positive specimen	Date of chosen "first" inpatient CDI toxin-positive specimen:
	☐ Sample B: validating SELECTED (non-first) inpatient CDI toxin-positive specimen	Date of SELECTED (non-first) inpatient CDI toxin-positive specimen:

Note: SKIP step below for Sample A validation only. If validating for Sample B, enter dates and locations from ADT data up to the date of SELECTED specimen.

Date transfer to Location 2		Facility Location 2		Date transfer to Location 6		Facility Location 6	
Date transfer to Location 3		Facility Location 3		Date transfer to Location 7		Facility Location 7	
Date transfer to Location 4		Facility Location 4		Date transfer to Location 8		Facility Location 8	
Date transfer to Location 5		Facility Location 5		Date transfer to Location 9		Facility Location 9	

Instructions:

For Sample A: Begin with the chosen ("first") inpatient CDI toxin-positive specimen*. Through additional investigation determine whether a prior specimen was collected from this patient in ED or other facility-affiliated outpatient location on the NHSN inpatient admission date. If such a specimen is identified, enter it in row C1. Then enter the chosen ("first") inpatient specimen in row C2. If no ED or facility-affiliated outpatient specimen is identified, enter the chosen ("first ") inpatient CDI* toxin-positive specimen *in row C1. Note that If a specimen was collected in ED or affiliated outpatient location on calendar day of admission, reporters are allowed to assign the specimen to the location of inpatient admission.*

Through additional investigation, determine if this patient had a prior inpatient stay within the prior 14 days, and whether any CDI toxin-positive *specimens were reported or collected within that timeframe for the patient and same location. Working across the row, determine if the chosen ("first") inpatient CDI* toxin-positive specimen *on the laboratory line list was reportable† to NHSN.*

For Sample B: Begin with the SELECTED (non-first) inpatient CDI toxin-positive specimen*. Using the Sample B sorted list, identify the most recent specimen collected from the same patient in the same location prior to this selected specimen. If a prior specimen from the same the patient and location is found, enter this specimen in row C1; the SELECTED (non-first) inpatient CDI* toxin-positive specimen *will then be in C2. If no prior specimen was collected from the same location, enter the SELECTED (non-first) inpatient CDI toxin assay in row C1. Working across the row, determine if the SELECTED (non-first) inpatient CDI* toxin-positive specimen *on the laboratory line list was reportable† to NHSN.*

A	**B**	**C**	**D**		**E**			**F**		**G**	
Lab list #	Date of specimen collection	Location of specimen collection*	Number of days since last CDI toxin-positive result		Was last positive CDI toxin-positive specimen from same NHSN location?			Was this a "duplicate specimen", i.e.; ≤14 days since last positive CDI toxin-positive specimen AND patient in same location (could include a previous episode of care)		Reportable to NHSN†	
C1	__/__/__		____ days	☐ no prior	☐ No	☐ Yes	☐ no prior	☐ No	☐ Yes	☐ No	☐ Yes
C2	__/__/__		____ days		☐ No	☐ Yes		☐ No	☐ Yes	☐ No	☐ Yes
C3	__/__/__		____ days		☐ No	☐ Yes		☐ No	☐ Yes	☐ No	☐ Yes

*If specimen collected in ED or affiliated outpatient location on calendar day of admission, reporters are allowed to assign specimen entered in NHSN to the location of inpatient admission, to establish community-association.

†Reportable to NHSN if:

- No prior positive CDI toxin-positive specimen from the patient in the same location –OR--
- More than 14 days since last CDI toxin-positive specimen from the patient in the same location

Appendix 4: Documentation of External Validation Results

Appendix 4.1: (Optional) Templates for Audit Discrepancies Discussion with Facilities

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

(Instructions: For each HAI Event with discordant outcome between reporters and validators, record the following [first row-enter hospital report; second row-enter recommended changes]. Use the Comment area to document reasons for error, e.g.: overlooked candidate culture; confusion re common commensals; did not meet alternative primary definition, not an uropathogen, etc. Many states have examined this type of data to identify common errors and direct future education and training. Keep a copy for your records and leave a copy with the facility). H=hospital; V=validator

Central line-associated Bloodstream Infection (CLABSI) Discrepancies

Pt. ID		Positive blood culture event: first culture date	Select One:			If LCBI, Event date	If LCBI, MBI* LCBI?				
			Not candidate CLABSI	Alternative primary (specify)	LCBI1, LCBI2, LCBI3*		MBI Yes or MBI No	POA, HAI or neither	Central line >2d?	Location of attribution	ICU CLABSI Y/N
	H										
	V										
Comment:											
	H										
	V										
Comment:											
	H										
	V										
Comment:											
	H										
	V										
Comment:											
	H										
	V										
Comment:											
****LCBI 1, 2, 3 (NHSN): types of laboratory- confirmed bloodstream infection. MBI-LCBI (NHSN) mucosal barrier injury LCBI. See definitions in NHSN Manual Chapter 4.***											

Catheter-asssociated Urinary Tract Infection (CAUTI) Discrepancies

Pt. ID		Positive urine culture event: first culture date	Select One:			If UTI, Event date				
			Not candidate CAUTI	SUTI 1a, SUTI 2a, SUTI 3, SUTI 4, ABUTI*	Did not meet UTI criteria (specify below)		POA, HAI or neither	Urethral catheter >2d?	Location of attribution	ICU CAUTI Y/N
	H									
	V									
Comment:										
	H									
	V									
Comment:										
	H									
	V									
Comment:										
	H									
	V									
Comment:										
	H									
	V									
Comment:										
	H									
	V									
Comment:										

SUTI 1a, 2a, 3, 4 (NHSN): types of symptomatic urinary tract infection. ABUTI (NHSN): asymptomatic urinary tract infection. See definitions NHSN Manual Chapter 7.

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

Pt. ID		Procedure Date:	Surveillance window closed Date:	Select One:			If SSI, Event date		Optional Validation of SSI Risk Factors			
				NHSN procedure Y/N	No SSI	SI SSI DI SSI O/S SSI* (specify)		Attributable to COLO? Y/N	ASA†	Age	SW class‡	Duration of procedure
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												

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

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

Pt. ID		Procedure Date:	Surveillance window closed Date:	Select One:			If SSI, Event date		Optional Validation of SSI Risk Factors			
				NHSN procedure Y/N	No SSI	SI SSI DI SSI O/S SSI* (specify)		Attributable to HYST? Y/N	ASA†	Age	SW class‡	Duration of procedure
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												
	H											
	V											
Comment:												

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

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

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

Clostridium difficile Infection (CDI) LabID Event Discrepancies

Pt. ID		Admission Date	Date of first reportable LabID Event during this inpatient stay	NHSN location of LabID Event	CDI toxin-positive result from date of admission specimen? Y/N	Prior CDI toxin-positive result from same location within prior 14 days? Y/N	Other reason for error
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							
	H						
	V						
Comment:							

Appendix 4.2: Example Validation Follow-up Letters, With and Without Identified Problems

(Courtesy of New York State Department of Health)

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

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

Dear CEO Name,

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

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

We observed the following trends that may contribute to surveillance inaccuracies: [e.g.: Of the X colon procedure records reviewed as entered in the NHSN database, X were not NHSN colon procedures. The reporting of non-colon procedures is an infection control program surveillance system issue. In addition, infection control was not made aware of X bloodstream infections identified by the microbiology laboratory, which may have resulted in omissions.] We reviewed the reporting requirements with [Name of IP] and [she] will be reporting the missing SSIs and deleting the non-NHSN colon and HYST procedures. Each record requiring corrections was reviewed with [Name of IP] and a list of a data entry edits to be made in NHSN was provided to [her]. All data errors and missed data entry must be edited in NHSN data base within 30 days of this notice.

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

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

Given the issue identified with colon procedure reporting, we request your hospital review all 2015 inpatient colon procedures entered in NHSN to validate they are NHSN colon procedures. A follow- up communication as to your findings and action plans to eliminate reporting non-NHSN colon procedures should be sent to my attention <u>no later than [Date].</u> Your response can be faxed or electronically sent to me. If you need any additional information or have any further questions regarding this site visit please contact me directly at [phone, fax, email].

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

Dear CEO name,

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

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

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

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

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

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

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

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

Appendix 4.3: External Validation Data Form

State Health Department Validation Record

*required **conditionally required

Facility Validation Overview

*Facility ID:

*Facility Type: ☐ Acute care hospital ☐ Long term acute care hospital (LTAC/LTCH)
☐ Oncology hospital ☐ Inpatient rehabilitation facility (IRF)

*Sampling version: ☐ CDC Version 1 (Targeted Sampling)

*Data for year: ☐ 2015

*HAI validated at this facility, and reason:

☐ CLABSI (ICU, includes NICUs if applicable)

☐ CAUTI (ICU, excludes NICUs)

☐ COLO (DI/OS SSI)

☐ HYST (DI/OS SSI)

☐ MRSA bacteremia LabID event

☐ CDI LabID event

Reason:

☐ All facilities are validated ☐ Targeted facility ☐ 5% random sample facility

Numerator Validation

*Sampling information for numerator audit at this facility

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

[a]DI/OS - deep incisional or organ/space SSI
[b]Inpatient includes specimens collected on day of admission from ED or other outpatient location

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

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

State Health Department Validation Record

Numerator Validation (continued)

*Facility audit results, numerators

**CLABSI in ICU (including NICU):

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

**CAUTI in ICU (excluding NICU):

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

**DI/OS COLO SSI:

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

**DI/OS HYST SSI:

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

**MRSA bacteremia LabID event:

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

**CDI LabID event:

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

State Health Department Validation Record

Denominator Validation: CLABSI

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

☐ Manual counting ☐ Electronic counting ☐ Both manual and electronic counting

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

Note: Validation of manual denominator data counting requires either:

- *Method A – Concurrent dual counting (with more experienced counter as reference) for ≥ three months OR*
- *Method B – Concurrent patient level data (reference) and standard counting for ≥ three months*

Validation of electronic denominator data counting requires:

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

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

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

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

Denominator Validation: CAUTI

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

☐ Manual counting ☐ Electronic counting ☐ Both manual and electronic counting

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

Note: Validation of manual denominator data counting requires either:

- *Method A – Concurrent dual counting (with more experienced counter as reference) for ≥ three months OR*
- *Method B – Concurrent patient level data (reference) and standard counting for ≥ three months*

Validation of electronic denominator data counting requires:

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

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

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

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

State Health Department Validation Record

Denominator Validation: COLO

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

Month	Number of COLO procedures entered into NHSN by facility before validation	Number of ICD-9 procedure codes for COLO identified from hospital discharge billing

Denominator Validation: HYST

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

Month	Number of HYST procedures entered into NHSN by facility before validation	Number of ICD-9 procedure codes for HYST identified from hospital discharge billing

Denominator Validation: MRSA bacteremia LabID event & CDI LabID event

NHSN inpatient location validation

**Do any inpatient locations require mapping or re-mapping within NHSN? ☐ Yes ☐ No

**If yes, indicate which locations need to be mapped/re-mapped and recommendations:

Location	Current CDC location code designation	Current bed count	Recommended CDC location code designation	Recommended bed count

**How does this facility obtain inpatient admissions data?

☐ Electronic from billing ☐ Electronic from vendor system ☐ Electronic from ADT

☐ Other (specify): _____

**How does this facility obtain inpatient patient days data?

☐ Electronic from billing ☐ Electronic from vendor system ☐ Electronic from ADT

☐ Other (specify): _____

State Health Department Validation Record

Denominator Validation: MRSA bacteremia LabID event & CDI LabID event (continued)

**Has this facility completed any internal validation of LabID event denominator data counting?

☐ Yes ☐ No

Note: Validation of denominator data counting requires concurrent patient level denominator counting (reference) vs. standard electronic data for three specified location types [one ICU, one LDRP if available, and one or more wards where observation patients are frequently housed] for ≥1 month; validated data should fall within 5% of the reference standard (see validation Guidance and Toolkit Appendix 1).

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

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

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

[c]Excludes 'baby locations'

Risk Adjustment Variable Validation

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

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

Number of locations incorrectly mapped as ICUs (includes NICUs): _____

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

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

**Teaching hospital affiliation (ICU CLABSI, ICU CAUTI, MRSA bacteremia LabID event, CDI LabID event)

Facility teaching hospital affiliation reported on 2015 NHSN annual facility survey:

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

Is facility teaching hospital affiliation correct? ☐ Yes ☐ No

**ASA score (COLO, HYST)

Number (% of audited) correct for COLO: _____

Number (% of audited) correct for HYST: _____

State Health Department Validation Record

Risk Adjustment Variable Validation (continued)

**Patient age (COLO, HYST)

Number (% of audited) correct for COLO: _____

Number (% of audited) correct for HYST: _____

**Facility bed size (all inpatient locations, including 'baby locations') (MRSA bacteremia LabID event, CDI LabID event)

Facility bed size reported on 2015 NHSN annual facility survey: _____

Validated bed size: _____

Custom Fields

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

Comments

Appendix 5: Facility/Provider to Facility/Provider Communications under HIPAA: Questions and Answers

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

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

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

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

Question One

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

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

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

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

Answer One

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

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

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

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

Question Two

Under HIPAA, is a health care facility permitted to share PHI with another health care facility that previously treated or housed a patient, without that patient's authorization, for purposes of notifying this source facility of a potential complication of care related to the health care provided at the source facility so as to monitor and improve care and prevent future complications?

- A hospital identifies a surgical site infection (SSI) that is probably attributable to an ambulatory surgical care facility and/or surgeon that performed the surgery within the past 12 months. The hospital seeks to notify the ambulatory surgical care facility about the SSI, or in a given situation, notify the surgeon directly.
- A patient is admitted to Hospital B with a surgical site infection (SSI) after an operation at another hospital (Hospital A), where the patient had been operated on and then discharged without signs or symptoms of infection. Because of federal requirements (e.g., the Centers for Medicare and Medicaid

Services' Inpatient Quality Reporting program requirements) or state law or policy, both hospitals are committed to reporting all SSIs following the type of operation performed on the patient. Hospital B seeks to report the SSI to Hospital A, where the SSI is presumed to have originated, so that Hospital A can fully account for SSIs attributable to its care.

Answer Two

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

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

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