**Texas Device Associated HAI Validation Protocol, 2016**

1. **Assure or update Auditor expertise in the applicable NHSN definitions**

Surveillance and validation require rigorous adherence to standard NHSN protocols, surveillance methods, and NHSN 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, Auditor training resources are available on the NHSN website and will be expanded in the future. The following trainings are available on the NHSN training website. They are listed in order of recommendation for Auditors:

|  |  |  |
| --- | --- | --- |
| **Type of NHSN Training** | **Recommended Auditor Standard** | **Symbol Key for Online NHSN Training Types (Examples as below)** |
| Interactive  Online Multimedia Instruction Modules | Assure that all Auditors 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 | Slide presentations include case-studies to help Auditors 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 Auditors; 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/APIC/TSICP-sponsored trainings.
* NHSN blast emails, external partner calls, the quarterly NHSN newsletter, and the NHSN Manual, updated annually with any changes to methods and definitions.

1. **Select facilities**

CDC recommends targeted validation in order to investigate and correct potential deficiencies in an efficient manner. For each HAI type to be audited (CLABSI, CAUTI), twenty-one facilities will be chosen via targeted selection plus 5% of the remaining facilities will be randomly selected.

For example, if Texas has 400 facilities reporting CLABSIs, and CAUTIs then 21 + ((400-21)\*0.05) = 39.95 or 40 facilities will be selected for each of the HAI types for a total of up to 80 facilities for audit.

**Pilot Facility Selection Process:**

Due to limited resources, a pilot may be conducted to determine best practices and time/resources required to conduct HAI auditing using the NHSN protocol. Therefore, during the pilot, only 9 targeted facilities and approximately 3 (1%) randomly selected facilities will be audited. Afterwards, the pilot selection process will be evaluated to determine feasibility given the number of auditors and other resources available at that time.

**Detailed Facility Selection Process**

1. In Excel, select the aggregation level that provides a facility-specific SIR overall for CLABSI and CAUTI. Select these rows and copy this information to a new spreadsheet. Be sure to include the header row so you can identify the variables on the new page. Arrange the facilities in rank order according to the expected/predicted number of HAIs [numExp], (high to low). Then create three new columns titled “Delta count,” “Stratum,” and “Targeted Selection Number.”
2. 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 to select hospitals with no SIR calculated).
3. Select the top tertile (33%) of facilities by predicted number of infections. To do this, sort table by predicted number of infections (highest to lowest). Divide the total number of facilities by 3. Select that number of facilities from the top of the table. For example, if we have 300 facilities, the top tertile will include the top 100 facilities with the highest predicted number of infections. This “Top Tertile” of facilities where HAIs are most expected, may have the greatest potential for surveillance and prevention impact.
4. Within the top tertile, re-sort by SIR from highest to lowest, and calculate the median SIR for the top Tertile. This can be calculated by entering the following formula into an empty cell in Excel (=MEDIAN([cell range]).
5. Within the top tertile,
   1. Assign stratum A to facilities with SIR above the current median SIR,
   2. Stratum B for remaining facilities with SIR less than or equal to the median and above zero
   3. 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 8 below).
6. Re-sort within each stratum A, B, and C, by numExp from highest to lowest. To do this, sort by numExp from highest to lowest. Then sort stratum alphabetically from A to Z.
7. Assign sequential Targeted Selection Numbers to facilities, by selecting the highest available numExp from each stratum alternating A, B, and C. For example, facility #1 will be the facility with the highest numExp from stratum A, facility #2 the facility with the highest numExp from stratum B, and #3 the facility with the highest numExp from stratum C. Return to stratum A and assign #4) to the next facility in stratum A, assign #5 to the next facility in stratum B, and facility #6 will be the next facility in stratum C. Continue alternating strata until no facilities remain or the target number of facilities is reached.
8. After the targeted selection is complete, select the random sample (either 1% or 5% depending on pilot or full validation) from the remaining facilities from ALL tertiles.

**In the event that a facility that was selected for audit for the same HAI type is selected again in the subsequent audit time period:**

1. If a specified number of discrepancies or more were found in the previous audit, then facility will be re-audited. The purpose of this is to ensure that the facility corrects any surveillance mistakes that were previously identified.
2. If no discrepancies were identified in the previous audit, then the facility will not be re-audited and the next facility in line (in the same strata or randomly chosen) will be selected.

**PLEASE NOTE: This will be re-evaluated at the end of each audit time period to determine the appropriate discrepancy threshold for facility re-audit.**

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

For chosen facilities,

1. DSHS/Auditor to contact the IP and discuss the audit process including:
   1. Explain the new process – how it is different from the past
   2. The likely scope of the audit
   3. How the audit sample will be drawn from eligible medical records
   4. Discuss the current request for positive culture line listings
      1. Up to 60 specific medical records will be requested for CAUTI and CLABSI.
         1. 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.
         2. 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.
   5. Discuss the anticipated number of days and reviewers needed to complete the audit, based on experience or the guidance to follow.
   6. 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.
      1. For the audit, request arrangements for medical records access including EMR navigator, appropriately sized workspace, computer systems, terminals and passwords, and specific medical records.

*NOTE: The laboratory line listings should be provided by the facility through a secure file transfer (for example, encrypted email, secure FTP site) 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.*

1. DSHS Compose a letter notifying the facility IP of the audit:
   1. Provide an overview of your authority to conduct validation (if applicable)
   2. 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)
   3. Date of the audit
   4. Specify data and accommodations needed from hospital staff
   5. Explain how validation results will be used and/or reported.
2. **Request selected medical records in advance of the facility site-visit**

**Positive Blood/Urine Culture Line listings required from facility**

To identify unreported “candidate” CLABSI/CAUTI, a sample of medical records from patients with positive blood and/or urine cultures is needed, and will require assistance from the facility being validated before the audit.

From each selected facility, obtain a complete list of positive ICU blood and/or urine cultures collected for the audit time frame 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/urine culture line listing to be provided by the facility to DSHS (\* indicates required data):**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| \*MRN | \*Gender | \*Date of Birth | \*Admission Date | \*ICU or NICU | \* ICU Name | ICU Type (i.e. Medical, Surgical, Burn, etc) | Laboratory Specimen Number | \*Specimen Collection Date | \*Blood Organism 1 Genus and Species |

**ICU CLABSI/CAUTI Targeted Medical Record Selection Process**

(Up to) 60 medical records each for ICU CLABSI, ICU CAUTI including

* (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.
* (Goal of) 40 non-reported candidate HAIs. For ICU CLABSIs, these will be stratified by NICU and adult/pediatric ICU locations. For CLABSI and CAUTI, many of these will be eliminated early because they do not have a device (central line or urinary catheter).

\*Note: For CLABSI and CAUTI, ensure that all medical records reviewed are from ICU and current reporting year only\*

1. From each selected facility, request a securely transmitted line listing of all positive ICU cultures, from all ICUs reporting to NHSN, for the validation time period.
2. Assign a random number to each positive culture
3. Sort the list of cultures by MRN and admission date to generate clusters of cultures associated with recognizable patient records
   1. Highlight duplicate MRNs.
4. Identify reported CLABSI/CAUTIs on the positive culture line listing
   1. Using the NHSN CLABSI/CAUTI list and available patient information on positive culture line listing, flag and mark cultures reported as HAIs. Create a new variable, “stratum” and assign these positive cultures and all other positive cultures in the same medical record to stratum 1.
   2. If reported CLABSIs/CAUTIs are missing from the positive culture line listing, the list may be incomplete. Investigate and correct this problem. Add omitted HAI records to the medical record review list.
5. Select simple random sample of (up to) 20 reported ICU HAIs for review
   1. Select stratum = 1
   2. Sort by random number, MRN, and hospital admission date
   3. Select the first 20 random numbers with unique episodes of care (defined by MRN and admission date) as the sample of reported records
6. If applicable, select the NICU screening sample for CLABSIs (NICU CAUTIs are not reportable)
   1. Select NICU= Yes
   2. Sort by random number, MRN, and admission date
   3. 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.
7. Select the ICU screening sample
   1. Select NICU = No
   2. Sort by random number, MRN, and admission date
   3. Select the first 30-40 random numbers with unique episodes of care (defined by MRN and admission date) as the sample of adult/pediatric ICU medical records with candidate HAIs.
8. The final screening sample should contain: (up to) 20 medical records with reported HAIs, (up to) 40 medical records divided among NICU (if applicable) and adult/pediatric ICUs.

**\*Note:** The final list of MRNs for review should not contain culture information. This is to help to convey to the facility that the entire patient’s medical record will be reviewed during the audit.

1. **DSHS Send Validation Survey and Select Site Visit Date**
2. Once medical records are selected, DSHS will securely email the facility designated Audit Liaison, Facility Administrator and HAI contacts with a line list of the medical records that will be reviewed on the day of the audit. Facility is responsible for compiling the medical records for review (EMR or paper-based) and having them ready to review at the visit. The facility is strongly encouraged to provide an EMR navigator to help the auditor abstract data.
3. DSHS to send the Validation Survey (to be completed and returned to the auditor one week prior to site visit).
4. Auditor to send a list of possible audit dates for the facility to choose from. Be sure to specify a deadline for audit date selection.
5. Once audit date has been agreed upon, DSHS to notify CEO/Administrator of date selected for Audit (cc IP).
   1. Describe purpose of visit and audit process
   2. Date/time of visit
   3. Auditor’s credentials
   4. How long the audit should last
6. Notify Regulatory, Regional HAI Epidemiologist and Regional Health Departments of date/time of site visit. One representative from local/regional health departments will be able to attend the audit, as long as it is approved by the facility being audited.
7. **Review Validation Survey Results**

Prior to the site visit, the HAI survey should be completed by the facility and reviewed by auditor for the following:

**Manually collected denominators:**

* Frequency, reliability, and consistency of denominator collection - this should be consistent with the following guidance from NHSN:
  + For each day of the month, at the same time each day, record the number of patients on the selected unit who have 1 (or more) central lines or urinary catheters. Only record 1 central line day for a patient that has more than 1 central line in place.
    - If the patient has only a tunneled or implanted central line, begin recording days on the date the central line was inserted or the first day the line was accessed if the patient was admitted to the facility with the line in place and continue until the line is physically removed or the patient is discharged. “Access” is defined as line placement, infusion or withdrawal through the line.
* Determine for what percent of days data are missing and what was done for reporting on those days. Review NHSN Guidance for missing denominator data (<http://www.cdc.gov/nhsn/PDFs/NHSNMissingDenomData_Sep2013.pdf>) if facility is not following the NHSN protocol.

**Electronically collected denominators:**

* If the facility uses electronic denominator data collection, obtain documented explanation 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.
* 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.

ALL Surveys should be reviewed for general adherences to proper infection prevention and surveillance practices:

For example:

* Who is responsible for final determination of HAI? If not an IP, then how are they trained in the use of NHSN surveillance definitions?
* How are errors in data handled? Are corrections made in NHSN when they are identified?

1. **Conduct Site Visit**

**Suggested Tools for validation site-visits**

* Sign In Sheet
* Letter of introduction, state ID badge or other authorization
* NHSN HAI Protocol for applicable validation time period
* Information about the facility:
  1. Facility’s most recent NHSN Annual Survey
  2. Audit Survey
  3. List of surveillance locations
* List of medical records for review
* A separate list of reported HAIs (Should contain date of event, patient DOB and admit date to determine which events were correctly reported after the validation process is completed)
* Multiple copies of blank medical record abstraction tools
* Optional: Laptop with internet access (for logging into TxHSN) – confirm if hospital will provide internet access

**Structured Medical Records Review**

Auditor should conduct blind medical record reviews, where possible. Auditor should not know which medical records correspond to a reported HAI event upon initial review. After medical record review is completed, comparison to the NHSN reported HAIs will determine whether there were any discrepancies identified during the audit.

Any discrepancies between the NHSN-reported events and the Auditor’s findings should be discussed with the IP staff. Any disagreements should be referred to NHSN for final determination by emailing [NHSN@cdc.gov](mailto:NHSN@cdc.gov) and cc’ing the facility IP. This correspondence should be saved and attached to the facility record in TxHSN.

Any HAIs identified by the Auditor but not reported, should be entered into NHSN by the facility. Review the NHSN reported events list to determine if any HAIs were reported but not identified during the validation. If any are found, discuss with IP. Events that should not have been reported to NHSN should be deleted in NHSN. Any events that require a response from NHSN will need to be changed after a response has been received.

**Discussion of audit results with facility staff: Debriefing/Exit Interview**

Whether or not reporting errors are identified, review the data with the IP and other facility staff (as needed/requested) 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.

Use errors as learning opportunities for reporters and Auditors. 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.

1. **Post-visit Summary Report Email**

A Summary Report will be created by DSHS/Auditor and sent to all contacts and others as requested. Additionally, regional public health departments may also be notified. The email will:

1. Document results, necessary corrections, and recommendations.
2. When appropriate, identify systematic strengths as well as problems with resources and support for surveillance, data collection, and reporting