Using NHSN Data Validation for Improved CLABSI Surveillance and Prevention

100-Hospital Validation Project Summary, 2011
(Updated to Reflect 2013 NHSN Changes)

HAI Liaison Program
Healthcare-Associated Infections Program
Center for Health Care Quality
California Department of Public Health
Today’s Presentation

1. Describe the attributes of quality HAI surveillance
2. Identify best practices for CLABSI case-finding
3. Review NHSN CLABSI surveillance protocols and definitions, targeting key issues identified during validations
4. Demonstrate CLABSI data validation process and forms for internal use by hospitals
What is Surveillance?

- **System** that starts and ends with communication and action
- **Information** loop or cycle

![Diagram of the information loop or cycle]

Collection → Collation and recording (reporting) → Analysis and interpretation → Dissemination and data use → Collection
Endpoint of HAI Surveillance?

- Data that demonstrate **HAI Prevention**

Example: CLABSI, 2009-2011
Quality Surveillance for Healthcare-Acquired Infections (HAI)

Requires

- Consistency
- Coordination
- Confidence
- Compassion
**Consistency**

Complete case-finding requires a consistent, complete evaluation of a minimum set of clinical data*

<table>
<thead>
<tr>
<th>To identify CLABSI</th>
<th>Always Step 1</th>
<th>Step 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Review every positive blood culture</td>
<td>Review for presence of central line</td>
</tr>
</tbody>
</table>

*NHSN protocols currently silent on expectations; revisions proposed*
Coordination

- IP can’t perform CLABSI surveillance alone
- CLABSI surveillance needs to be a shared responsibility across hospital units (e.g. for central line days) and services (e.g. microbiology lab data)
- The more connection of relevant clinical data points, the better the surveillance (e.g. positive blood culture, presence of central line, confirmation of symptoms)
Confidence

- Know the CLABSI definition AND other HAI surveillance definitions
- Apply definitions with confidence the same way every time
- Seek assistance for ambiguity*

*Contact NHSN@cdc.gov or your CDPH Liaison IP
Compassion

- Patients want to feel safe
- Patient advocates want to be assured that providers are doing everything possible to prevent CLABSI
- Identifying every CLABSI is necessary to understand what your patients are experiencing
- No one should get a CLABSI
Compassion

Embrace the Cultural Change

Old: “Many infections are inevitable but some may be preventable”

New: “Each infection is potentially preventable unless shown otherwise”

Most HAIs are Preventable - Believe it!

Adopt facility goal of “HAI Elimination”
Objectives of HAI Data Validation, 2011

HAI Program Liaison IPs performed onsite data validation in 100 volunteer hospitals to

- Gain a better understanding of how NHSN surveillance protocols were understood and being applied
- Provide immediate one-on-one education and coaching to volunteer hospitals
- Develop targeted education and training to all CA hospitals based on common errors, identified gaps, misinterpretations

What this validation process was NOT:

- A research study
- Formal evaluation of HAI reporting implementation
Validation Process

• Performed onsite review at each hospital 1 to 2½ days
  ▫ Team of 2 Liaison IPs (1 IP for smaller hospitals)

• Started with lab line lists for 3 months; required access to medical records

• Assessed completeness and accuracy of reporting for
  ▫ CLABSI
  ▫ CDI (LabID)
  ▫ MRSA BSI (LabID)
  ▫ VRE BSI (LabID)

• Interviewed 2 key hospital staff members (20-30 min each)
  ▫ Denominator data collection processes
  ▫ Hospital location mapping

• Used a standardized set of forms to capture data
Presentation of CLABSI Validation Findings

- **Sensitivity**
  - Proportion of CLABSI reported by hospitals among all patients with CLABSI
  - High sensitivity indicates CLABSI were identified and reported

- **Specificity**
  - Proportion of CLABSI not reported by hospitals among patients without CLABSI
  - High specificity indicates accuracy of “ruling out” CLABSI

- **Positive Predicted Value**
  - Proportion of CLABSI reported by hospitals that actually were CLABSI
  - High PPV indicates accuracy in applying CLABSI surveillance definition

<table>
<thead>
<tr>
<th>Validation Review (Considered “Gold Standard” or truth)</th>
<th>CLABSI</th>
<th>Not CLABSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identified and Reported by Hospital</td>
<td>CLABSI</td>
<td>True positives</td>
</tr>
<tr>
<td></td>
<td>Not CLABSI</td>
<td>False negatives</td>
</tr>
</tbody>
</table>

Positive Predictive Value (PPV) = \( \frac{\text{True positives}}{\text{True positives} + \text{False positives}} \) \times 100

Sensitivity = \( \frac{\text{True positives}}{\text{True positives} + \text{False negatives}} \) \times 100

Specificity = \( \frac{\text{True negatives}}{\text{True negatives} + \text{False positives}} \) \times 100
Quick Review of NHSN CLABSI Protocol
“Rules”

For CLABSI surveillance, criteria are:

- Presence of central line currently or within previous 48 hours
- One or more positive blood cultures (depending on organism), and
- Clinical review to determine:
  - If infection present on admission (not a CLABSI)
  - If BSI secondary to infection at another site (not a CLABSI)
  - If lab findings represent contamination during blood draw (not a CLABSI)
  - If patient symptomatic when 2 positive blood cultures of common commensal bacteria (CLABSI)
CLABSI Validation Findings

Positive blood cultures, inpatients, 3 mo: 13,259
Positive blood culture “events” reviewed: 4,099 97 hospitals
CLABSI reported: 135 52 hospitals
Reported in error: 23 19 hospitals
CLABSI not identified, not reported: 68 42 hospitals

<table>
<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Predictive Value (PPV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>62.0%</td>
<td>99.4%</td>
<td>82.3%</td>
</tr>
</tbody>
</table>

*Of note:*
55 hospitals had identified and reported ALL CLABSI; none were missed
4 hospitals reported CLABSI in error and also missed CLABSI
16 of the hospitals that missed CLABSI had reported 0 CLABSI
**CLABSI Reported in Error**

<table>
<thead>
<tr>
<th>Reason should not have been reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>23 of 168 reported “CLABSI” did not meet NHSN criteria</td>
</tr>
<tr>
<td>Secondary to another site of infection - 14</td>
</tr>
<tr>
<td>Contaminant - 6</td>
</tr>
<tr>
<td>CLABSI present on admission - 3</td>
</tr>
</tbody>
</table>
# CLABSI Missed, Should Have Been Reported

<table>
<thead>
<tr>
<th>Reason Missed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>68 additional CLABSI identified during validation</strong></td>
</tr>
<tr>
<td>Had been ruled as secondary to another infection - 12</td>
</tr>
<tr>
<td>Had been ruled a contaminant – 6</td>
</tr>
<tr>
<td>Had been ruled as present on admission - 4</td>
</tr>
<tr>
<td>Disagreement with NHSN definition – 4</td>
</tr>
<tr>
<td>Had been ruled as a continuation of previous BSI – 2</td>
</tr>
<tr>
<td>Other (reason observed only once) – 5</td>
</tr>
<tr>
<td>Missed* – 35</td>
</tr>
</tbody>
</table>

* Cases missed most often due to
  1. inconsistencies between the final retrospective laboratory line lists reviewed during validation and the lists or systems that had been used for IP surveillance
  2. Positive blood culture not reviewed (whatever the reason)

* Specific details not captured on validation forms

Agreement could not be reached for only 8 unreported CLABSI
Assessing Accuracy of Reported Data

<table>
<thead>
<tr>
<th>No. reported CLABSI reviewed</th>
<th>Accurate on all fields reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>88</td>
<td>81%</td>
</tr>
</tbody>
</table>

Inaccurately reported fields:
- Location attribution: 7
- Onset date: 9
- Admission date: 2
- Pathogen: 7
Accuracy of Hospital Unit “Location Mapping”

By Hospital (96)
- All locations correct 49%
- One or more locations incorrect 51%

Locations (972)
- Correct 87%
- Incorrect 13%

Correct
- 845
Incorrect
- 127
Improving CLABSI Surveillance
Improving CLABSI Case-finding

• Review every positive blood culture from inpatients
  - Make sure you are receiving all final blood culture results
  - Many of the missed CLABSI had simply been MISSED

• First screen: Determine if patient had central line during hospitalization
  - Develop your own method based on available information systems

• Perform internal Validation (minimum once/year)
  - Ask to have retrospective line list of all positive blood culture results produced directly form your hospital’s laboratory information system (LIS)
  - Compare to positive blood culture list used for routine CLABSI surveillance
Know the CLABSI Surveillance Definition ( )

- **Criterion 1:** Single blood culture if a pathogen, which means any organism other than a common commensal
  - No other symptoms are needed to confirm CLABSI
  - Presence of central line & BSI not related to infection at another site

- **Criterion 2:** 2 positive blood cultures with same common commensal organism plus 1 of 3 symptoms --- fever, chills, or hypotension
  - Cultures can be drawn up to 2 days apart
  - Considered 2 separate blood draws if from
    - 2 peripheral sites
    - 1 peripheral and 1 central line port
    - 2 different ports from the same central line
    - 2 different central lines
  - Same even if 1 at genus level (e.g. coag negative staph) and the other at species level (e.g. Staph epi)
Know the CLABSI Surveillance Definition

• New in 2013
  • All elements used to meet the infection criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between elements.
  • Date of event is the date when the last element used to meet the lab confirmed BSI (LCBI) criterion occurred.
  • Central line or Umbilical catheter in place for >2 calendar days. Day of device placement is day 1.
### NHSN List of Common Commensal Organisms

#### Common Commensals

<table>
<thead>
<tr>
<th>Organism and NHSN Code</th>
<th>SNOMED Concept Code</th>
<th>SNOMED Fully Specified Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actinomyces propionicus - PRPRO</td>
<td>427413007</td>
<td>Propionibacterium propionicum (organism)</td>
</tr>
<tr>
<td>Aerococcus christensenii - AECH</td>
<td>409818008</td>
<td>Aerococcus christensenii (organism)</td>
</tr>
<tr>
<td>Aerococcus Genus - AEGU</td>
<td>9008009</td>
<td>Genus Aerococcus (organism)</td>
</tr>
<tr>
<td>Aerococcus sanguincola - AESG</td>
<td>131205009</td>
<td>Aerococcus sanguincola (organism)</td>
</tr>
<tr>
<td>Aerococcus sanguinicola - AESGN</td>
<td>42722006</td>
<td>Aerococcus sanguinicola (organism)</td>
</tr>
<tr>
<td>Aerococcus spp. - AESP</td>
<td>131206005</td>
<td>Aerococcus species (organism)</td>
</tr>
<tr>
<td>Aerococcus urinae - AEUR</td>
<td>243230001</td>
<td>Aerococcus urinae (organism)</td>
</tr>
<tr>
<td>Aerococcus urinaeaequi - AEURQ</td>
<td>43097003</td>
<td>Aerococcus urinaeaequi (organism)</td>
</tr>
<tr>
<td>Aerococcus urinaehominis - AEURH</td>
<td>409819000</td>
<td>Aerococcus urinaehominis (organism)</td>
</tr>
<tr>
<td>Aerococcus viridans - AEVI</td>
<td>78803006</td>
<td>Aerococcus viridans (organism)</td>
</tr>
<tr>
<td>Arachnia propionica - PRPRO</td>
<td>427413007</td>
<td>Propionibacterium propionicum (organism)</td>
</tr>
<tr>
<td>Arthrobacter variabilis - CORVAR</td>
<td>11575001</td>
<td>Corynebacterium variabile (organism)</td>
</tr>
<tr>
<td>Bacillus aerolus - BAEOL</td>
<td>428272006</td>
<td>Bacillus aerolus (organism)</td>
</tr>
<tr>
<td>Bacillus aerius - BAERI</td>
<td>446489005</td>
<td>Bacillus aerius (organism)</td>
</tr>
<tr>
<td>Bacillus agaradhaerus - BAGAR</td>
<td>429112003</td>
<td>Bacillus agaradhaerus (organism)</td>
</tr>
<tr>
<td>Bacillus alcalophilus - BALCA</td>
<td>90547001</td>
<td>Bacillus alcalophilus (organism)</td>
</tr>
<tr>
<td>Bacillus algicola - BALGI</td>
<td>428273005</td>
<td>Bacillus algicola (organism)</td>
</tr>
<tr>
<td>Bacillus amyoliquefaciens - BAMYL</td>
<td>82289003</td>
<td>Bacillus amyoliquefaciens (organism)</td>
</tr>
</tbody>
</table>

From NHSN website Feb 2013

Simplified View of CLABSI Definition

**LCBI 1**
Patient of any age
- has a recognized pathogen cultured from one or more blood cultures
  - And
- Organism cultured from blood is not related to an infection at another site

**LCBI 2**
Patient of any age
- has a common commensal cultured from 2 or more blood cultures drawn on separate occasions
  - And
- Has at least one of the following signs or symptoms:
  - Fever (>38°C), chills, or hypotension
    - And
- Signs & symptoms and (+) lab results are not related to an infection at another site.

**LCBI 3**
Patient <1 year of age
- has commensals cultured from 2 or more blood cultures drawn on separate occasions
  - And
- At least one of the following signs or symptoms:
  - Fever (>38°C core), hypothermia (<36°C core), apnea, or bradycardia
    - And
- Signs and symptoms and (+) lab results are not related to an infection at another site.

All elements used to meet the infection criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between elements.

Note: Patient <1 year old can meet ANY criteria

Updated to reflect 2013 NHSN changes
Mucosal Barrier Injury Laboratory-Confirmed Bloodstream Infection (MBI-LCBI)

- New in 2013 related to immunosuppressed patients
- MCI-LCBI 1
  - Allogeneic hematopoietic stem cell transplant recipient – and specific organisms isolated
  - And Additional criterion – see protocol
- MCI-CLBI 2
  - Viridans group streptococci – no other organisms
  - And Additional criterion – see protocol
- MCI-LCBI 3
  - Patients <1 year of age
  - Viridans group strep with no other organisms
  - And Additional criterion – see protocol

Updated Feb 2013

See: NHSN Patient Safety Manual, Device-Associated Module, CLABSI, Chapter 4, pp6-7 for more details on this definition
NHSN Surveillance Infection Definitions

- There are 53 NHSN-defined infections in 14 categories
- Each infection has a surveillance definition
- Many infections can result in BSI
- Access definitions via the NHSN website; most up-to-date

NHSN Patient Safety Manual, Chapter 17, pp 4-49
Updated to reflect 2013 NHSN changes
Primary BSI (CLABSI) or Secondary BSI?

- Rule out a CLABSI if patient has a bloodstream infection (BSI) and another site is suspected as being the primary site of infection
  - Review medical record for other primary sites of infection, especially for patients with complex co-morbidities

- IMPORTANT: To classify a BSI as secondary to another site, you must ensure the primary site of infection meets the NHSN surveillance definition
  - If does not meet the NHSN definition, you consider the BSI as the primary infection and report as CLABSI

NHSN Patient Safety Manual, NHSN Surveillance Definitions, chapter 17
CLABSI or Secondary BSI (continued)

• Secondary BSIs are not reported as separate events in NHSN
  - When entering Events into NHSN (e.g. SSI, CAUTI, PNEU, etc), there is a data field to indicate the infection resulted in a secondary BSI

• For many surveillance definitions, a positive blood culture is included in the criteria and can help define the infection *(see next slide)*
15 HAI surveillance definitions include “Positive Blood Culture” in their criteria

- ABUTI - asymptomatic bacteremic UTI
- BONE - osteomyelitis
- BURN - burn infection
- DECU - decubitus ulcer infection
- ENDO - endocarditis
- GIT - other GI tract infection
- IAB - intraabdominal infection
- MED - mediastinitis
- MEN - meningitis
- OREP - other infection of genital tract
- PNU 2, PNU 3 - pneumonia
- SA - spinal abscess w/o meningitis
- ST - soft tissue infection
- UMB - omphalitis
- UR - upper respiratory tract infection
Using Lab Findings to Determine CLABSI or Secondary BSI

1. If the primary infection site is cultured, the secondary BSI must yield a culture of the same organism as that of the primary site

*Example A:* Patient has central line. *S. aureus* isolated from both urine and blood cultures. Clinically meets criteria for symptomatic UTI.

Report as SUTI with a secondary BSI

*Example B:* Patient has central line. *E. coli* isolated from urine. Blood culture with *S. aureus.* Clinically meets criteria for a symptomatic UTI.

Report both a SUTI and CLABSI
Using Lab Findings to Determine CLABSI or Secondary BSI (continued)

2. If the primary infection site is **NOT cultured**, the secondary BSI must be a pathogen appropriate for the primary site

   *Example C:* Patient with central line has a post-surgical abscess detected by CT scan. No culture of abscess performed. Has blood culture positive for *E. coli*.
   
   Report as SSI-GIT with secondary BSI

   *Example D:* Patient with a central line has acute onset diarrhea and fever. Stool culture not performed. 2 blood cultures positive for coagulase negative staphylococcus.

   Report as CLABSI
Common Infections with Secondary BSI

- During the 2011 data validation reviews, many complex cases were reviewed to confirm or rule-out CLABSI
- Commonly observed infections with secondary BSI were
  - UTI, symptomatic (SUTI)
  - UTI, asymptomatic with bacteremia (ABUTI)
  - Pneumonia meeting criteria 2 or 3 (PNEU 2, 3)
  - GI tract infection (GIT)
  - Intra-abdominal infection (IAB)
  - Osteomyelitis (BONE)
  - Endocarditis (ENDO)
  - Deep Incisional and Organ/space SSI
Positive blood culture is in the ABUTI definition and is required to meet the definition.

NHSN has no definition for asymptomatic UTI without BSI.
Example: SUTI

Can have secondary BSI to SUTI, but positive blood culture not in SUTI definition.

Meaning, BSI is not needed or used to define SUTI.
Example: Pneumonia

Laboratory defined pneumonia (PNU2)

Pneumonia in immunocompromised patient (PNU...
Example: **GIT**, GI Tract, Infection

**GIT-Gastrointestinal tract (esophagus, stomach, small and large bowel, and rectum) excluding gastroenteritis and appendicitis**

Gastrointestinal tract infections, excluding gastroenteritis and appendicitis, must meet at least 1 of the following criteria:

1. Patient has an abscess or other evidence of infection seen during a surgical operation or histopathologic examination.
2. Patient has at least 2 of the following signs or symptoms with no other recognized cause and compatible with infection of the organ or tissue involved: fever (>38°C), nausea, vomiting, abdominal pain, or tenderness
   
   and
   
   at least 1 of the following:
   
   a. organisms cultured from drainage or tissue obtained during a surgical operation or endoscopy or from a surgically placed drain
   b. organisms seen on Gram’s or KOH stain or multinucleated giant cells seen on microscopic examination of drainage or tissue obtained during a surgical operation or endoscopy or from a surgically placed drain
   c. organisms cultured from blood
   d. evidence of pathologic findings on radiographic examination
   e. evidence of pathologic findings on endoscopic examination (eg, *Candida* esophagitis or proctitis).
Example: **IAB - Intraabdominal Infection**

**IAB - Intraabdominal, not specified elsewhere including gallbladder, bile ducts, liver (excluding viral hepatitis), spleen, pancreas, peritoneum, subphrenic or subdiaphragmatic space, or other intraabdominal tissue or area not specified elsewhere**

Intraabdominal infections must meet at least 1 of the following criteria:

- 1. Patient has organisms cultured from purulent material from intraabdominal space obtained during a surgical operation or needle aspiration.
- 2. Patient has abscess or other evidence of intraabdominal infection seen during a surgical operation or histopathologic examination.
- 3. Patient has at least 2 of the following signs or symptoms with no other recognized cause: □fever (> 38°C), □nausea, □vomiting, □abdominal pain, or □jaundice and at least 1 of the following:
  - □organisms cultured from drainage from surgically placed drain (eg. closed suction drainage system. open drain. T-tube drain)
  - □organisms seen on Gram’s stain of drainage or tissue obtained during surgical operation or needle aspiration
  - □**organisms cultured from blood and radiographic evidence of infection** (eg. Abnormal findings on ultrasound, CT scan. MRI, or radiolabel scans [gallium. technetium, etc] or on abdominal x-ray).

**Reporting instruction**
- Do **not** report pancreatitis (an inflammatory syndrome characterized by abdominal pain, nausea, and vomiting associated with high serum levels of pancreatic enzymes) unless it is determined to be infectious in origin.
Example: **BONE Osteomyelitis**

**BJ—BONE AND JOINT INFECTION**

**BONE-Osteomyelitis**

Osteomyelitis must meet at least 1 of the following criteria:

1. Patient has organisms cultured from bone.
2. Patient has evidence of osteomyelitis on direct examination of the bone during a surgical operation or histopathologic examination.
3. Patient has at least 2 of the following signs or symptoms with no other recognized cause: fever (>38°C), localized swelling, tenderness, heat, or drainage at suspected site of bone infection
   
   and
   
   at least 1 of the following:

   a. organisms cultured from blood
   b. positive blood antigen test (eg, *H influenzae*, *S pneumoniae*)
Data Correction

• Remember, if you note any errors or omissions, you can always go back and edit NHSN records to correct your data.

• If you find errors that require you to make numerous changes to your data after it has been entered into NHSN, record the date when changes were made.

• Keep records of clinical or systems issues that may change your blood culture data to help understand variation over time.

Examples include:

  • Focused education for phlebotomy / blood specimen collection processes
  • Reducing blood specimens drawn from central lines
  • Introduction of 3rd party HAI surveillance software
  • Changes in laboratory practices or lab systems
Remember that the “power of surveillance is in sharing findings with those who need to know and who can act on the findings to improve patient safety”

“Recommended Practices for Surveillance”
AJIC Am J Infect Control 2007; 35:427-40
Report and Use CLABSI Data

- Use NHSN analysis features to review and interpret your data
- Plan for distribution of findings, reporting to healthcare providers most able to impact patient care
- Report in a manner to demonstrate prevention progress or spark need for improvement
  - Use visual displays of data
    - charts, graphs, tables

See Analysis Guidance series at www.cdph.ca.gov/HAI
Steps for Advancing CLABSI Prevention Using Your NHSN Data

- Think beyond public reporting and hospital-to-hospital comparisons
- Focus on CLABSI prevention progress within your hospital units over time (requires you to find all CLABSI that occur)
- Set CLABSI prevention goals and targets
- Remember the 4 C’s of surveillance data quality
  - Consistency, coordination, confidence, compassion
  - Establish systems’ approaches for identifying CLABSI and capturing accurate line days and patient days

Don’t go it alone anymore!
CLABSI Data Validation Process and Forms
CLABSI Validation - Form A
Summary of Positive Blood Culture Laboratory Data

Instructions: To begin validation of CLABSI, ask your laboratory to produce a line list directly from the laboratory information system for a 3-month time period to include:

- Positive blood cultures from inpatients for each of 3 months

Reports should include date of admission to the hospital if possible.
Ask to have printed twice: sorted by date and then sorted by patient name or medical record number.

Months selected for validation:
- Jan
- Feb
- Mar
- Apr
- May
- Jun
- Jul
- Aug
- Sep
- Oct
- Nov
- Dec

Laboratory information system (LIS): ____________ e.g. Meditech, Sunquest, Cerner

IMPORTANT: For validation, do not produce this positive blood culture line list from a surveillance software system (e.g. Medminder, TheraDoc, AICÉ, etc) or infection control integration software programs. Get directly from LIS.

STEP 1: From positive blood cultures from Inpatients only, indicate total each MONTH:

- Month _____ # _____  
- Month _____ # _____  
- Month _____ # _____

STEP 2: Determine number of months to include in CLABSI validation.

<table>
<thead>
<tr>
<th>If total inpatient positive blood cultures in 3 mo. is</th>
<th>Perform review for</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 60</td>
<td>all 3 months</td>
</tr>
<tr>
<td>&gt;60 and &lt;120</td>
<td>2 months</td>
</tr>
<tr>
<td>≥120</td>
<td>1 month</td>
</tr>
</tbody>
</table>

Select the month with the greatest #, then a 2nd month that makes a 2-month total closest to 60.

In general, starting with 60 positive blood cultures results in approximately 40-55 infectious event “clusters” and will result in in-depth chart review of 10-15 records. The remaining generally require only cursory review to identify or rule out CLABSI (often accomplished using data available through EMR systems). The likelihood of identifying CLABSI is based on your underlying rate and the number of positive blood cultures you include in your validation.

STEP 3: Check the boxes next to months (above) you are including in the CLABSI validation review.

- # Positive blood cultures from Inpatients during months ✓’d to include in review_____
- # Separate BSI Events* __________ [INCLUDE IN CLABSI REVIEW]

*Event = “Cluster” of positive blood cultures near same date for same patient counts as 1 event; single positive blood cultures also count as 1 event.

STEP 4: On your lab line list, number each BSI event.

STEP 5: For each numbered BSI event, enter the corresponding culture date (1st positive) and admission date in table on Form 4. Follow instructions on Form 4 to complete review.

OPTIONAL STEP: For most comprehensive review, review positive blood cultures from ED patients for recent hospital discharge (and presence of central line in previous 48 hours)

- # _______ [INCLUDE IN CLABSI REVIEW AS POSSIBLE] Add recent discharges to table on Form
CLABSI Validation – Form B
BSI Events Table

Instructions:
1. Fill in first specimen date for each BSI event in table below. Numbers should correspond to laboratory line list (see Form A).
2. Use Analysis to produce CLABSI line list for the 1, 2, or 3-month review period. Also print NHSN Event record for each reported CLABSI.
3. For each numbered BSI event, answer Q1 by referring to your NHSN line list. For cases reported to NHSN, record NHSN Event #. If CLABSI on your NHSN list but were not on lab line list, add to the bottom of the table.
4. For each BSI event, review patient’s medical record to verify your decision to report or not report to NHSN. Carefully follow NHSN protocols and surveillance definitions; refer to them often.
   - For each CLABSI Reported to NHSN, complete a Form C, CLABSI Validation Review. Record info on table in 1 of 2 columns as shown.
   - For each BSI event NOT reported to NHSN, indicate reason why in the appropriate column. Use Form D as worksheet if needed. If BSI event should have been reported as a CLABSI but was not, record as missed. Indicate a reason the case may have been missed.
5. Complete Form E, CLABSI Validation Findings.

When review complete, make all needed corrections to your data in NHSN!

BSI Events Table.

<table>
<thead>
<tr>
<th>Lab list #</th>
<th>First positive blood culture of each BSI Event (Specimen date</th>
<th>Admission date</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td><strong>/</strong>/11</td>
<td><strong>/</strong>/11</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Q1. Was Event reported to NHSN as a CLABSI?
   - YES: Perform medical record review, complete Form 5, then fill in 1 of columns below.
   - NO: Not a CLABSI Reported in error Why?
   * Data fields correctly reported to NHSN?
   √ if NO, List

If YES to Q1

<table>
<thead>
<tr>
<th>NO central line or no line in previous 48 hours</th>
<th>Present on admission and not discharged in previous 48 hours</th>
<th>Contaminant i.e. Common skin commensals Single + bld cx ≥ 2 + bld cx but no S/S</th>
<th>Secondary BSI Primary site of infection</th>
<th>MISSED CLABSI Should have been reported</th>
</tr>
</thead>
</table>

If NO to Q1

Perform medical review. Use BSI review work sheet if helpful. Stop as soon as you can complete one of the columns below.

Column totals: __________

9.13.12 Form B - CLABSI
CLABSI Validation – Form C

☐ Confirm Accuracy of Reported CLABSI  ☐ OR- ☐ Record CLABSI that was Missed

Instructions: Complete for each reported CLABSI from Form B. Check box (☐) if data field correct as reported to NHSN or fill-in correct information. -OR- use form to collect data for Missed CLABSI by filling-in all fields.

| Lab Line List# | 1st positive blood culture | Date of Event (onset): |
|---------------|---------------------------|_______________________|
|               | / / /11                   | ___/___/___           |
|               |                           | __/___/11             |

Patient ID:

Gender:  F  M  Other
Date of Birth:  / / /

Event Type: BSI

MDRO Infection Surveillance: ☐ “Yes, this infection’s pathogen & location are not in-plan for Infection Surveillance in the MDRO/CDI Module”
☐ “No, this infection’s pathogen & location are not in-plan for Infection Surveillance in the MDRO/CDI Module”

Date Admitted to Facility:  / / /11

Location Attribution:

Risk Factors

☐ Mark Relevant Location
☐ If ICU/Other locations
☐ Central line:  Yes  No
☐ If Specialty Care Area,
☐ Permanent central line:  Yes  No
☐ Temporary central line:  Yes  No
☐ If NICU,
☐ Non-umbilical central line:  Yes  No
☐ Umbilical catheter:  Yes  No
☐ Birth weight (grams):

Location of Device Insertion:

Reason Reported in Error:

Medical record review revealed NOT a CLABSI

Event Details

Specific Event: Laboratory-confirmed BSI

Criteria:

Signs & Symptoms  NOTE: S/S needed only if common skin commensal
Any patient
☐ Fever  ≤1 year old
☐ Chills
☐ Hypotension

Laboratory

☐ Recognized pathogen from one or more blood cultures
☐ Common skin commensal from ≥2 blood cultures

Died:  Yes  No
If Died, BSI Contributed to Death:  Yes  No

Pathogen/s:  ☐ Reported Correctly  If VRE or MRSA, reported also as LabID?  ☐ Yes  ☐ No

9.13.12  Form C - CLABSI
CLABSI Validation – Form D
Chart Review Work Sheet

Instructions: Use for notes when reviewing BSI Events (from Form B) to either rule out or confirm CLABSI. Record final determination by checking appropriate boxes. Transfer findings to BSI Events table, Form B.

☐ 1. BSI event from patient with no central line present or during previous 48 hours.

☐ 2. BSI associated with Infection that was PRESENT ON ADMISSION from patient not recently discharged from hospital in the previous 48 hours.

☐ 3. Positive blood culture was determined to be a CONTAMINANT, i.e. common commensal organism(s) from
   ☐ only one positive culture within a 2 day period
   ☐ 2 cultures on separate occasions, but patient with no signs/symptoms of infection

4. Infection was a BSI SECONDARY TO ANOTHER SITE OF INFECTION.
   ☐ UTI
   ☐ PNEU
   ☐ Central nervous system
   ☐ EENT or URI
   ☐ GI
   ☐ Skin/ Soft tissue
   ☐ SSI
   ☐ Bone/ Joint
   ☐ Cardiovascular
   ☐ LRI
   ☐ Reproductive tract
   ☐ Systemic

Refer to NHSN Infection definitions to be sure criteria for primary infection site have been met!

☐ 5. Infection met NHSN surveillance criteria for CLABSI, and should have been reported to NHSN.
   Complete Form 5, CLABSI Review Form.

MEDICAL RECORD REVIEW: Lab Line List# ___ 1st positive blood culture of Event ___/___/11

| Hospital Admission Date ___/___/___ | HOSPITALIZATION |
| Discharge Date ___/___/___ | Reason for Admission |
| Date of 1st +blood Culture ___/___/___ | Admitted from Home SNF Dialysis |
| Date admitted to location: ___/___/___ | Discharge disposition |
| Date of initial central line insertion ___/___/___ | Hospital location at time of 1st positive culture: |
| Line type: ___________________________ | If on unit < 48 hrs, previous location __________________ |
| Date of 2nd central line insertion ___/___/___ | CENTRAL LINE HISTORY |
| Line type: _________________________ | Location of Line Insertion ___________________ |
| Date of 3rd central line insertion ___/___/___ | Insertion site ___________________ Removal __________________ |
| Line type: _________________________ | Location of Line Insertion ___________________ |
| _________________________ | Insertion site ___________________ Removal __________________ |

CLINICAL NOTES

____________________________________________________________________________________

____________________________________________________________________________________

9.13.12

Form D CLABSI
Validation results can be displayed using 2x2 tables and the accuracy and completeness of HAI surveillance and reporting can be calculated. Quantitative findings of data validation include sensitivity, specificity, and positive predictive value (defined below).

<table>
<thead>
<tr>
<th>Validation Review (Considered “Gold Standard” or truth)</th>
<th>CLABSIs</th>
<th>Not CLABSIs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identified and Reported by Hospital</td>
<td>CLABSI</td>
<td>True positives</td>
</tr>
<tr>
<td>Not CLABSI</td>
<td>False negatives</td>
<td>True negatives</td>
</tr>
</tbody>
</table>

**Sensitivity**
- Answers question “How likely are all true infections found?”
- For CLABSI surveillance, sensitivity is defined as the proportion of CLABSI identified and reported from the total of all patients who had a CLABSI.
- If sensitivity is high, it means CLABSI are being identified during surveillance. If sensitivity is low, it means CLABSI are being missed and the hospital’s CLABSI rate could be higher than what is being reported.
- Measures completeness and implies effective surveillance methods for case-finding.

**Specificity**
- Answers question “How likely are patients without an infection accurately identified as not having an infection?”
- For CLABSI surveillance, specificity is defined as the proportion of CLABSI not reported from the total of all patients who did not have a CLABSI.
- If specificity is high, it means CLABSI are being ruled out appropriately among patients with positive blood cultures. If specificity is low it means that CLABSI are being reported that are not really CLABSI. The hospital’s CLABSI rate may actually be lower than what is being reported.

**Positive Predictive Value (PPV)**
- Also called the precision rate.
- For CLABSI surveillance, PPV is the proportion of CLABSI reported that met the case definition.
- If PPV is high, it means the identified and reported CLABSI really are CLABSI. If PPV is low, it means CLABSI being reported do not meet the case definition.
- Measures accuracy in applying surveillance definitions and following protocols.
**Example**

<table>
<thead>
<tr>
<th>Positive blood cultures events reviewed for validation = 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identified and Reported by Hospital</td>
</tr>
<tr>
<td>CLABSI 5</td>
</tr>
<tr>
<td>Not CLABSI 95</td>
</tr>
<tr>
<td>CLABSI</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>2 Missed</td>
</tr>
<tr>
<td><strong>Positive Predictive Value (PPV)</strong> = 80%</td>
</tr>
<tr>
<td>4 True positives  + 1 False pos. X 100</td>
</tr>
</tbody>
</table>

**Sensitivity** = \( \frac{4 \text{ True positives}}{4 \text{ True pos.} + 2 \text{ False neg.}} \times 100\% = 67\% \)

**Specificity** = \( \frac{93 \text{ True negatives}}{93 \text{ True neg.} + 1 \text{ False pos.}} \times 100\% = 99\% \)

**Interpretation:**

For the 100 blood culture events reviewed for CLABSI, the validation reviewers found 5 disparities compared to the hospital surveillance report.

The hospital had identified and reported 5 CLABSI. The validation reviewers determined only 4 should have been reported; 1 did not meet the surveillance criteria.

The calculated **positive predictive value (PPV)** reveals that what routine hospital surveillance identifies as CLABSI meets the CLABSI surveillance criteria only 80% of the time.

For the other 95 positive blood culture events reviewed in which routine hospital surveillance identified no CLABSI, the validation reviewers identified 2 additional CLABSI.

The calculated **sensitivity** reveals routine hospital surveillance is identifying only 67% of the CLABSI occurring (1/3 are being missed).

The calculated **specificity** reveals hospital routine surveillance accurately “rules out” CLABSI 99% of the time.
# Data Validation for CLABSI

Hospital: ____________________________

Surveillance time period: _______________________

## From BSI Events Table, Form 4

<table>
<thead>
<tr>
<th>Validation Review</th>
<th>CLABSI</th>
<th>Not CLABSI</th>
</tr>
</thead>
<tbody>
<tr>
<td># positive blood culture events reviewed = ______</td>
<td>A</td>
<td>B Report in Error</td>
</tr>
<tr>
<td>Identified and Reported by Hospital</td>
<td>CLABSI _____</td>
<td>Not CLABSI _____</td>
</tr>
<tr>
<td>Form B, total Q1 = Yes</td>
<td>A</td>
<td>C Missed</td>
</tr>
<tr>
<td>Form B, total Q1 = No</td>
<td>D</td>
<td></td>
</tr>
</tbody>
</table>

### Sensitivity = \( \frac{A}{A + C} \times 100 = \) __________

### Specificity = \( \frac{D}{D + B} \times 100 = \) __________

### Positive Predictive Value = \( \frac{A}{A + B} \times 100 = \) __________
Infection Definitions Worksheets

Instructions:
1) Use when reviewing positive blood cultures for determining and documenting whether a positive blood culture is a primary BSI (CLABSIs), secondary BSI to another site of infection, or a contaminant.
2) Use for surgical site infection (SSI) surveillance.
3) DO NOT use for LabID CDI or MRSA-VRE BSI surveillance. Use LabID methods in the MDRO/CDI Module protocol.
4) Refer to often when performing surveillance. Make notes on individual infection pages as you are reviewing medical records.

2 Urinary tract infections
SUTI Symptomatic urinary tract infection
• Catheter in place at time of specimen-2
• Catheter recently removed, past 48h-3
• NOT catheter-associated - 4
• In infants and babies ≤1 year old - 5

6 ABUTI Asymptomatic UTI with Bacteremia

7 Surgical site infections
SIP Superficial incisional primary SSI
SIS Superficial incisional secondary SSI
DIP Deep incisional primary SSI
DIS Deep incisional secondary SSI
SSI-xxx Organ/space specific types
• BONE - 11
• JNT - 11
• BRST - 25
• LUNG - 21
• CARD - 15
• MED - 15
• DISC - 11
• MEN - 13
• EAR - 17
• ORAL - 17
• EMET - 22
• OREP - 22
• ENDO - 14
• SA - 13
• EYE - 16
• SINU - 18
• GIT - 19
• UR - 18
• IAB - 20
• VASC - 14
• IC - 12
• VCUF - 22

8 Bloodstream infection
LCBI Lab-confirmed BSI

9 Pneumonia
PNU1 Clinically defined pneumonia
PNU2 Pneumonia with specific lab findings
PNU3 Pneumonia in immunocompromised

10 PNU1 Alternate clinical definition, ≤1yo

11 Bone and joint infections
BONE Osteomyelitis
JNT Joint or bursa
DISC Disc space

12 Central nervous system infections
IC Intracranial infection
MEN Meningitis or ventriculitis
SA Spinal abscess without meningitis

14 Cardiovascular system infections
VASC Arterial or venous infection
ENDO Endocarditis
CARD Myocarditis or pericarditis
MED Mediastinitis

16 Eye, ear, nose, throat, mouth, and URI infections
CONJ Conjunctivitis
EYE Eye, other than conjunctivitis
EAR Ear, mastoid
ORAL Oral cavity (mouth, tongue, or gums)
SINU Sinusitis
UR Upper respiratory tract, pharyngitis

19 Gastrointestinal system infection
GE Gastroenteritis
GIT Gastrointestinal (GI) Tract
HEP Hepatitis
IAB Intra-abdominal not specified elsewhere
NEC Necrotizing enterocolitis

21 Lower respiratory tract infection, other than Pneu
BRON Bronchitis, tracheobronchitis, tracheitis, without evidence of pneu
LUNG Other infections of lower resp tract

22 Reproductive tract infections
EMET Endometritis
EPIS Episiotomy
VCUF Vaginal cuff
OREP Other infections of male or female reproductive tract

23 Skin and soft tissue infection
SKIN Skin
ST Soft tissue
DECU Decubitus ulcer
BURN Burn
BRST Breast abscess or mastitis
UMB Omphalitis
PUST Pustulosis
CIRC Newborn circumcision

26 Systemic Infection
DI Disseminated infection

Refer to CDC/NHSN for official version of definitions
GASTROINTESTINAL SYSTEM INFECTIONS

GE - Gastroenteritis

Gastroenteritis must meet at least 1 of the following criteria:

☐ 1. Patient has an acute onset of diarrhea (liquid stools for more than 12 hours) with or without vomiting or fever (>38°C) and no likely noninfectious cause (eg, diagnostic tests therapeutic regimen other than antimicrobial agents. Acute exacerbation of a chronic condition. or psychologic stress).

☐ 2. Patient has at least 2 of the following signs or symptoms with no other recognized cause: □ nausea, □ vomiting, □ abdominal pain, □ fever (>38°C), or □ headache and at least 1 of the following:
   a. □ an enteric pathogen is cultured from stool or rectal swab
   b. □ an enteric pathogen is detected by routine or electron microscopy
   c. □ an enteric pathogen is detected by antigen or antibody assay on blood or feces
   d. □ evidence of an enteric pathogen is detected by cytopathic changes in tissue culture (toxin assay)
   e. □ diagnostic single antibody titer (IgM) or 4-fold increase in paired sera (IgG) for pathogen.

GIT - Gastrointestinal tract (esophagus, stomach, small and large bowel, and rectum) excluding gastroenteritis and appendicitis

Gastrointestinal tract infections, excluding gastroenteritis and appendicitis, must meet at least 1 of the following criteria:

☐ 1. Patient has an abscess or other evidence of infection seen during a surgical operation or histopathologic examination.

☐ 2. Patient has at least 2 of the following signs or symptoms with no other recognized cause and compatible with infection of the organ or tissue involved: □ fever (>38°C), □ nausea, □ vomiting, □ abdominal pain, or □ tenderness and at least 1 of the following:
   a. □ organisms cultured from drainage or tissue obtained during a surgical operation or endoscopy or from a surgically placed drain
   b. □ organisms seen on Gram's or KOH stain or multinucleated giant cells seen on microscopic examination of drainage or tissue obtained during a surgical operation or endoscopy or from a surgically placed drain
   c. □ organisms cultured from blood
   d. □ evidence of pathologic findings on radiographic examination
   e. □ evidence of pathologic findings on endoscopic examination (eg. Candida esophagitis or procti)

HEP - Hepatitis

Hepatitis must meet the following criterion:

☐ Patient has at least 2 of the following signs or symptoms with no other recognized cause: □ fever (>38°C), □ anorexia, □ nausea, □ vomiting, □ abdominal pain, □ jaundice, or □ history of transfusion within the previous 3 months and at least 1 of the following:
   a. □ positive antigen or antibody test for hepatitis A, hepatitis B, hepatitis C or delta hepatitis
   b. □ abnormal liver function tests (eg. elevated ALT/AST, bilirubin)
   c. □ cytomegalovirus (CMV) detected in urine or oropharyngeal secretions.

Reporting instructions

- Do not report hepatitis or jaundice of noninfectious origin (alpha-I antitrypsin deficiency. etc).
- Do not report hepatitis or jaundice that results from exposure to hepatotoxins (alcoholic or acetaminophen-induced hepatitis. etc).
- Do not report hepatitis or jaundice that results from biliary obstruction (cholecystitis).
The Healthcare Associated Infections (HAI) Program is one of three programs in the Center for Health Care Quality of the California Department of Public Health. The Program is responsible for the surveillance, reporting, and prevention of infections in California's general acute care hospitals as mandated by Senate Bills 739, 1056, and 156. The Program was authorized in December 2009.

HAIs are the most common complication of hospital care and are listed among the top ten leading causes of death in the United States. It is estimated that each year there are more than 1.7 million infections, 99,000 deaths, and $3.1 billion dollars in excess healthcare costs in acute care hospitals alone. Based on this data it is estimated that approximately 200,000 infections occur in California each year with an annual cost of about $600 million - $1.6 billion. The vision of the HAI Program is to eliminate HAIs for California patients.
Questions?

Email
InfectionControl@cdph.ca.gov

or
Your designated HAI Liaison IP
FirstName.LastName@cdph.ca.gov

Lynn.Janssen@cdph.ca.gov