

*MHCC 11-016*  
*HEALTHCARE-ASSOCIATED INFECTIONS (HAI) DATA*  
*QUALITY REVIEW & CHART AUDIT*  
*EDUCATIONAL WEBINAR SFY 2012 & SFY 2013*

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# Presentation Overview

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- Brief background of HAI data quality review and chart audit for Maryland
- Report the statewide findings for the Central Line Associated Blood Stream Infections (CLABSI) data quality review & chart audits during state fiscal year (SFY) 2012 & SFY 2013
- Review pertinent surveillance criteria that affected the quality of the data
- Identify common factors that influenced the over or under reporting of CLABSI events
- Brief review of NHSN guidelines

# Contract Overview

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- Purpose
  - ▣ To review the completeness & accuracy of Healthcare-Associated Infection (HAI) data collected from non-federally owned Maryland hospitals via the National Healthcare Safety Network (NHSN) of the Centers for Disease Control & Prevention (CDC).
  
- Duration
  - ▣ Five (5) years
  - ▣ 1 August 2011 to 31 July 2016 Contract Cycles
  - ▣ SFY2012 to SFY2017

# HAI 5-Year Audit Plan

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- SFY2012 – CLABSI data review is from July 1, 2010 to June 30, 2011.
- SFY 2013 - CLABSI & SSI data review is from July 1, 2011 to June 30, 2012.
- SFY2014-2016
  - ▣ CLABSI
  - ▣ Surgical Site Infections (SSI)
  - ▣ Multiple Drug Resistant Organisms (MDRO)
  - ▣ *Clostridium difficile*-Associated Disease (CDAD)

# Goal of Validation Process

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- Ensure the accuracy of HAI data reported to NHSN by non-federally funded hospitals in Maryland
- Identify areas & opportunities to improve the education & training of infection prevention (IP) staff performing the surveillance

# MHCC and NHSN Guidelines for Reporting

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- The Maryland mandate for reporting CLABSI to NHSN is limited to CLABSI events occurring in intensive care unit (ICU) adult & neonatal patients while they reside in the ICU location.
- In NHSN, 48 hour transfer rule must be applied.
- In NHSN, dates for both hospital admission & discharge & ICU admission & discharge must be applied.

# Validation Process Key Points

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- All HAI surveillance criteria must be supported by the documentation in the patient's medical record.
- Clinical opinions that are not supported by documented surveillance criteria cannot be applied to the determination of an HAI.
- Validation is based upon the NHSN surveillance criteria in effect at the time of the Event & not the NHSN surveillance criteria in effect on the date of the chart review or subsequent findings.
  - Example: 2013 NHSN criteria cannot be used to validate CLABSI surveillance definitions for HAI events that occurred during the audit validation period of July 1, 2011 to June 30, 2012.

# More Validation Process Key Points

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- Surveillance criteria is designed to look at a population at risk – the ICU patient.
- Identifies the patients at risk.
- Ensures that NHSN HAI surveillance criteria are consistently applied across all Maryland facilities.
- Ensures the national & statewide comparability of data among patients in the same type of ICUs (as defined by NHSN).

# Positive Blood Cultures & Validation Process

- The specimen date for the blood cultures **should always be** the date of specimen collection, **not** the date of final result or report.
- For purposes of validation sampling, a targeted pathogen approach can provide an opportunity to assess a facility's competency in correctly using different components of the NHSN CLABSI definition.

Source: 2012 NHSN CLABSI Validation Toolkit

# Sampling Strategies

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- **SFY 2012** sampling criteria was applied to all Maryland non-federally funded hospitals & all ICUs - both adult & neonatal.
- **SFY 2013** was a focused audit which concentrated on ICUs likely to have higher numbers of patients at risk for CLABSI & ICU classifications that were comparable.

# CLABSI SFY 2012 Validation

# Validation Plan SFY 2012

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- Sample size was limited to 200 cases.
- Sampling plan included all 94 ICU's in 45 hospitals.
  - ▣ Chart audit covered 91 of the 94 ICU's
  - ▣ 3 ICUs reported no CLABSI's & no positive blood cultures

# Sampling Strategy SFY 2012

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- 190 cases were picked using the following criteria:
  - ▣ From each ICU with at least one (1) reported case of CLABSI
    - 1 CLABSI & 1 positive blood culture
  - ▣ For ICU's with no reported CLABSI cases
    - 2 positive blood cultures from different patients
- The remaining 10 cases were randomly sampled among the lowest-reporting ICU's
- All sampling was random

# Positive Blood Culture Findings

	#	% of Positive Blood Culture Sample	% of CLABSI Risk
<b>Positive Blood Culture Sample</b>	<b>128</b>		
<b>Meeting CLABSI Risk</b>	<b>68</b>	<b>53%</b>	
Positive on Admission to Hospital	40	31%	
No Central Line	28	22%	
<b>Meeting CLABSI Risk</b>	<b>60</b>	<b>47%</b>	
Under-Reported CLABSI	10	8%	17%
1 Skin Commensal	22	17%	37%
CLABSI Prior to ICU Admission	4	3%	7%
CLABSI Post ICU Discharge	4	3%	7%
Secondary Bacteremia	20	16%	33%

# Data Analysis SFY 2012

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	Definitions/Formula	All Positive Blood Cultures (1)	Patients with CLABSI Risk (2)	ICU Patients With HAI BSI (3)
a	True Positive CLABSI	71	71	71
b	False Positive CLABSI	1	1	1
c	False Negative CLABSI	10	10	10
d	True Negative CLABSI	118	50	21
Total Sample		200	132	103
Sensitivity	$a/(a+c)$	88%	88%	88%
Specificity	$d/(b+d)$	99%	98%	95%
Positive Predictive Value	$a/(a+b)$	99%	99%	99%
Negative Predictive Value	$d/(c+d)$	92%	83%	68%
Concordance	$(a+d)/(a+b+c+d)$	95%	92%	89%
Prevalence	$(a+c)/(a+b+c+d)$	41%	61%	79%
Extent under-reported	$c/(a+c)$	12%	12%	12%
Extent over-reported	$b/(a+c)$	1%	1%	1%
Notes:				
(1) Positive blood cultures sample.				
(2) Positive on admission blood cultures & patients without central lines removed from the sample.				
(3) CLABSIs prior to ICU admission & after ICU discharge also removed from the sample.				

# Under-Reported Cases SFY 2012

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Type of ICU	Explanation	Organism Causing CLABSI
NICU	Hospital reported a Ventilator Associated Pneumonia (VAP) but patient had been off of the ventilator for more than 48 hours before the blood cultures were drawn and became positive	Staphylococcus coagulase negative
MS<15	The hospital questioned whether the criterion for hypotension was met. Blood pressure readings were clearly hypotensive in a patient with a history of hypertension. Case met CLABSI criteria.	Staphylococcal species
NICU	Hospital reported a primary BSI not a CLABSI.	<i>Staphylococcus epidermidis</i>
MICU	Criteria met for reporting a CLABSI. Although a physician's note is not a requirement for the hospital to report a CLABSI, this case was confirmed by an Infectious Disease note in the chart.	<i>Staphylococcus epidermidis</i>
MS<15	Criteria met for reporting a CLABSI; confirmed by an Infectious Disease note in the chart.	<i>Staphylococcus epidermidis</i>
CVU	Case met CLABSI criteria and it was coded by the hospital as a central line infection. Although not a reporting requirement, this case was also confirmed with a physician note.	<i>Staphylococcus epidermidis</i>

# Under-Reported Cases SFY 2012

Type of ICU	Explanation	Organism Causing CLABSI
MS<15	Hospital thought they had reported a CLABSI but it could not be confirmed in the MHCC database.	<i>Candida glabrata</i>
NICU	The hospital Director of Neonatology thought this was a case of neonatal sepsis. Blood cultures were drawn and negative on birth, an umbilical vein catheter was placed, and the baby was intubated. On day 2, the baby was extubated. On day 4, the baby got progressively sicker, was re-intubated, and blood cultures were drawn. The organism was identified on day 6, then they changed the line and the antibiotics and the baby got better. The case was sent to CDC NHSN and CDC agreed it should have been reported as a CLABSI.	<i>Klebsiella pneumoniae</i> ESBL
MS<15	Hospital thought they had reported a CLABSI but it could not be confirmed in MHCC database.	<i>Serratia marsescens</i>
CSU	Central Line not identified as a central line by the hospital. The line was a sheathed venous femoral line.	<i>Staphylococcus aureus</i>

# Data Issues SFY2012

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## Overall:

- Hospitals could not easily access sections of the patients' medical record to validate the data.

## Laboratory specific:

- Laboratories throughout the state do not have a consistent nomenclature for the reporting of organisms recovered from positive blood cultures.
- Some report a skin commensal as a contaminant when this decision to declare the organism as a contaminant has not been made in the context of clinical manifestations.

# CLABSI SFY 2013 Validation

# CLABSI SFY 2013 Validation

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- Sample initially included 207 cases, 1 of which was a reported CLABSI that could not be validated due to unavailable information
- Goal of sample was to look for opportunities to improve quality of reported data & related educational needs

# Focused Sample for CLABSI SFY 2013

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- Concentrated on specific types of ICUs
  - ▣ Neonatal ICUs
  - ▣ Medical-Surgical ICUs >15 beds
  - ▣ Medical Teaching Hospital Surgical ICUs
  - ▣ Cardiothoracic Surgical ICUs
  - ▣ Medical-Surgical ICUs  $\leq 15$  Beds unless
    - Average length of stay < 2 days
    - Device Utilization Ratio  $\leq 0.20$
    - No reports of CLABSI
    - No positive blood cultures during ICU stay

# Maryland Hospital ICU Classifications

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<b>ICU NHSN Classifications</b>	<b>Number</b>
Burn	1
Medical Major Teaching	4
Medical all others	1
Medical Cardiac	8
Med-Surg Major Teaching	3
Med-Surg $\leq$ 15 beds	24
Med-Surg $>$ 15 beds	14
Neurologic	2
Neurosurgical	1
Pediatric Med-Surg	4
Surgical	6
Cardiothoracic	7
Trauma	3
Neonatal	16
<b>Total</b>	<b>94</b>

# Focused Sample for CLABSI SFY 2013

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Per CDC NHSN Validation Guidelines, sample targeted specific pathogens & commensal organisms.

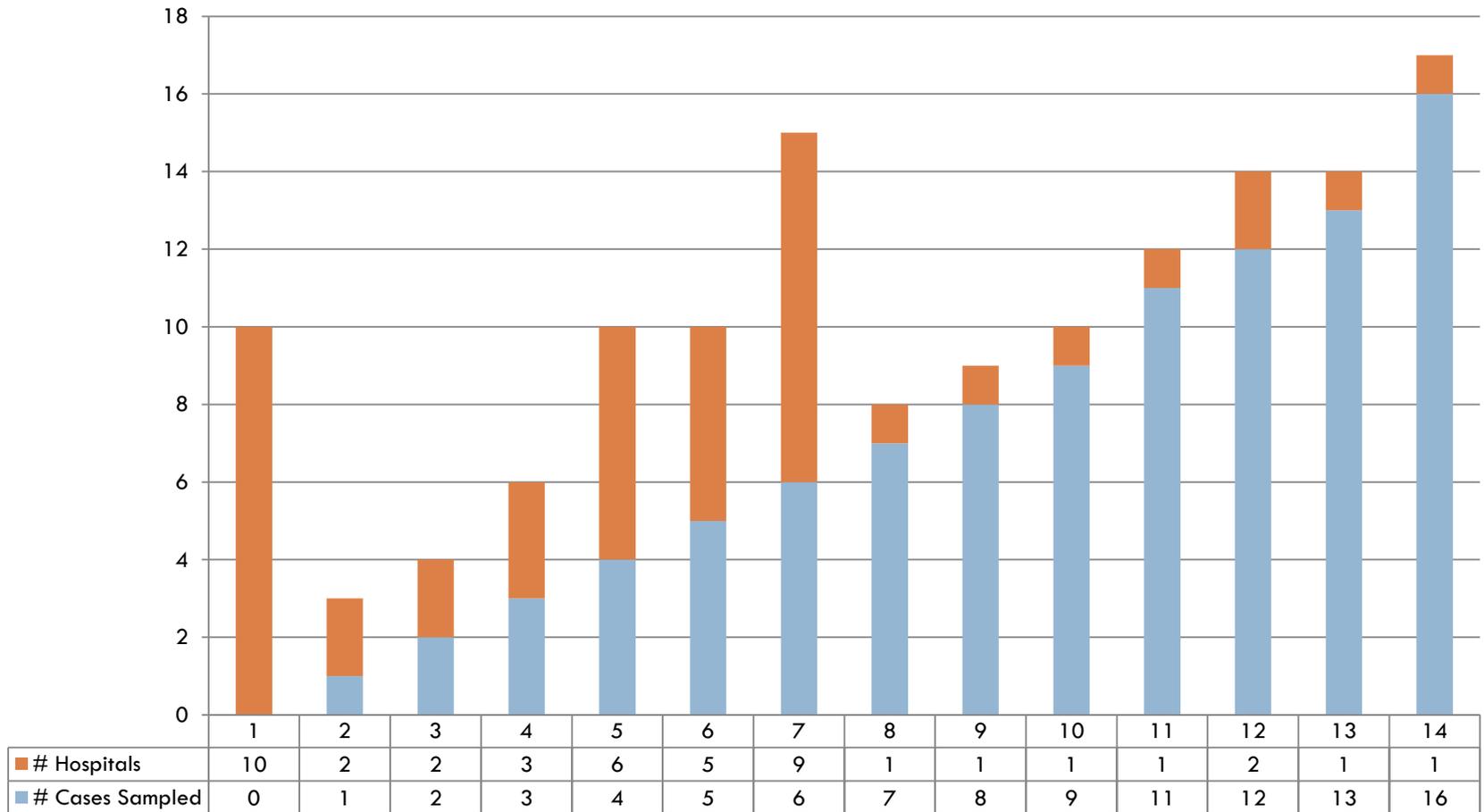
- Anaerobic organisms reported as pathogen for CLABSI.
- Commensal organisms identified on the NHSN 2011 commensal organism list.

# Data Sources for Sampling SFY2013

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- Reports of CLABSI to NHSN
- Hospital-supplied discharge administrative data inclusive of diagnoses & procedures for each admission in the period (used for reference)
- Hospital reports from labs of positive & negative blood cultures including ICU & hospital admission & discharge dates (used for sample selection)

# SFY 2013 Sample Among 45 Hospitals



# Validation Approach SFY 2013

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- Auditors were informed of cases that were reported as CLABSIs to NHSN
- On-site inspection of records
- On-site discussion of findings with hospital IP staff
- Post on-site audit QA review of documents submitted by auditor to support audit findings & decisions
- Post on-site audit discussions between AGS project director, 2<sup>nd</sup> auditor & hospital IP staff where questions were raised by the project director or the hospital IP staff
- Questions submitted to CDC for guidance

# Guidelines for CDC Resolution of Findings

- All documentation for surveillance criteria had to be supported by the patient's medical record.
- If hospital had previously sought guidance from the CDC all emails sent & received by the hospital & the CDC were included in the AGS query to the CDC.
- For some cases, multiple emails were exchanged between CDC & AGS before a final decision or guidance was provided by CDC.

# Cases Sent to CDC for Guidance

Hospitals					Cases Audited	Cases Sent to CDC	
Total	Included in Sample	% Sampled	Cases Sent by AGS to CDC for Guidance	% of Hospitals Sampled	Total	#	% Total Cases Audited
<b>45</b>	<b>35</b>	<b>78%</b>	<b>4</b>	<b>11%</b>	<b>206</b>	<b>12</b>	<b>6%</b>
<b>CLABSI Findings After CDC Guidance</b>							
<b>Over-Reported</b>		<b>Under-Reported</b>			<b>Confirmation of Hospital's Determination</b>		
#	% Total Cases Sent to CDC	#	% Total Cases Sent to CDC	#	% Total Cases Sent to CDC		
<b>4</b>	<b>33%</b>	<b>7</b>	<b>58%</b>	<b>1</b>	<b>8%</b>		

# Recommendations for Hospitals when Querying CDC for a Decision

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- Queries should include
  - ▣ The specific date (including the year) of event related information – otherwise, CDC may believe the information sought pertains to a prospective event or a different time period
  - ▣ Complete information regarding all criterion elements of surveillance definitions
  - ▣ All relevant facts of the case in the context of all potentially pertinent surveillance definitions for proper HAI versus BSI determination
- What to do when CDC responds with “if so, then” instructions

# Summary Findings SFY 2013

		Reported to NHSN		Totals
		CLABSI	No	
<b>Audited Positive Blood Cultures</b>	<b>True CLABSI</b>	68 (a) 33%	19 (c) 9%	88 (a+c) 43%
	<b>No CLABSI</b>	11 (b) 5%	108 (d) 52%	118 (b+d) 57%
	<b>Totals</b>	79 (a+b) 38%	127 (c+d) 62%	206 (a+b+c+d) 100%

# Statistical Measures SFY2013

		95% Conf. Level		
		Results	Low	
<b>Sensitivity</b>	78%	67%	86%	$a/(a + c)$
<b>Specificity</b>	91%	84%	95%	$d/(b+d)$
<b>Positive Predictive Value</b>	86%	76%	93%	$a/(a+b)$
<b>Negative Predictive Value</b>	85%	77%	90%	$d/c+d)$
<b>Concordance</b>	85%	79%	90%	$(a+d)/(a+b+c+d)$
<b>Sample Prevalence</b>	42%	36%	50%	$(a+c)/(a+b+c+d)$
<b>Extent Under-reported</b>	22%	14%	33%	$c/(a+c)$
<b>Extent Over-reported</b>	13%	6%	21%	$b/(a+c)$

# Focused Sample Results SFY 2013

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<b>Sensitivity</b>	About 3 of every 4 CLABSIs were correctly reported
<b>Specificity</b>	About 9 of every 10 non CLABSIs were correctly not reported
<b>Positive Predictive Value</b>	About 6 of every 7 cases entered into NHSN were CLABSIs
<b>Negative Predictive Value</b>	About 6 of every 7 cases were correctly not reported
<b>Concordance</b>	About 6 of every 7 cases were correctly handled
<b>Sample Prevalence</b>	About 3 of 7 sampled cases contained CLABSIs
<b>Extent Under-reported</b>	CLABSIs were under-reported 1 out of 5 times
<b>Extent Over-reported</b>	CLABSIs were over-reported 1 out of 8 times

# Accuracy of Reporting CLABSIs SFY2013

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- CLABSIs were accurately reported in 176 or 85% of the 206 cases in the focused sample (i.e., the concordance).
- The other 30 or 15% of the 206 cases (close to 1 in every 7) were discrepant between the auditor's decision and the hospital's findings.

# Reasons for No CLABSI Findings SFY 2013

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<b>Positive Blood Cultures Not CLABSI</b>	<b>Total Cases</b>	<b>% of Total</b>
Secondary bacteremia	48	44%
No Central Line	40	37%
Prior to ICU admission	10	9%
Only 1 skin commensal organism	3	3%
Not in ICU	2	2%
Positive blood culture > 48 hours post ICU discharge	2	2%
Blood culture positive for 2 different skin commensals	1	1%
1st positive blood culture prior to central line insertion	1	1%
Central line discontinued prior to blood culture draw	1	1%
<b>Total</b>	<b>108</b>	<b>100%</b>

# Reasons for Over-Reports SFY2013

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<b>Over-Reported CLABSIs</b>	<b>Total Cases</b>	<b>% of Total</b>
Streptococcal skin commensals	4	36%
Anaerobic infection from another site	3	27%
Related to pneumonia	1	9%
Related to prior to admission infection	1	9%
Related to meningitis	1	9%
Fever prior to insertion of Central Line	1	9%
<b>Total</b>	<b>11</b>	<b>100%</b>

# Reasons for Under-Reports SFY2013

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<b>Under-Reported CLABSIs</b>	<b>Total Cases</b>	<b>% of Total</b>
Staphylococcal Commensals	9	47%
Streptococcal Commensals	2	11%
Evaluated as pneumonia	2	11%
Evaluated as gastrointestinal tract infection (GIT)	2	11%
Evaluated as Intraabdominal abscess (IAB)	1	5%
Evaluated as upper respiratory tract (UR)	1	5%
Evaluated as other urinary tract infection (OUTI)	1	5%
Evaluated as a peripheral line skin infection	1	5%
<b>Total</b>	<b>19</b>	<b>100%</b>

# Factors Influencing Outcomes

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- CLABSI surveillance criteria for skin commensals
- Insufficient documentation in the patient's medical record that supports the surveillance definition
- Not completely evaluating an HAI surveillance definition to determine if the blood culture is a BSI or secondary BSI
- Not correlating clinical conditions to surveillance criteria when the surveillance criteria are met

# Insufficient Medical Record Documentation

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- Number one cause of clinical definitions for HAI & surveillance criteria not matching is the lack of supporting HAI surveillance criteria being recorded in the patient's medical record.
- Physician diagnosis alone without supporting HAI surveillance documentation in the medical record cannot be applied.
- Diagnosis of pneumonia with secondary BSI most common mismatch.

# Incomplete Evaluation of HAI Surveillance Criteria

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- Tends to occur when blood culture is positive for an “uncommon” or “unfamiliar” or “newly renamed” or “reclassified” microorganism.
  - ▣ Example: Prevotella used to be called Bacteroides.
- Determine logical primary source of HAI & if medical record documents the surveillance criteria.
- Matching positive site culture may not be required to meet the primary site definition.

# Neonatal HAI CLABSI Surveillance & Skin Commensals

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- Not correlating clinical conditions to surveillance criteria when there is a match
  - ▣ Example: Break-through apnea at time of blood culture positivity
    - Increased oxygen requirements or need for intubation
    - Sharp drop in respirations while on caffeine citrate therapy

# Quick Review of NHSN Guidelines

# CDC NHSN CLABSI Surveillance Methodology

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## Surveillance Methodology

CLABSI Surveillance requires:

- Active
- Patient-Based
- Prospective
- Priority-directed surveillance that will yield risk-adjusted incidence rates

Source : Presentation by Katherine Allen-Bridson, RN, BSN, CIC, Nurse Consultant, CDC dated July 14, 2011 - "CLABSI Reporting through NHSN: Tips, Tricks, & Best Practices ..."

# CLABSI Definition

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## Central Line-associated Bloodstream Infection (CLABSI)

- CLABSI = Primary BSI that develops in a patient that had a central line within the 48 hours prior to the infection onset.

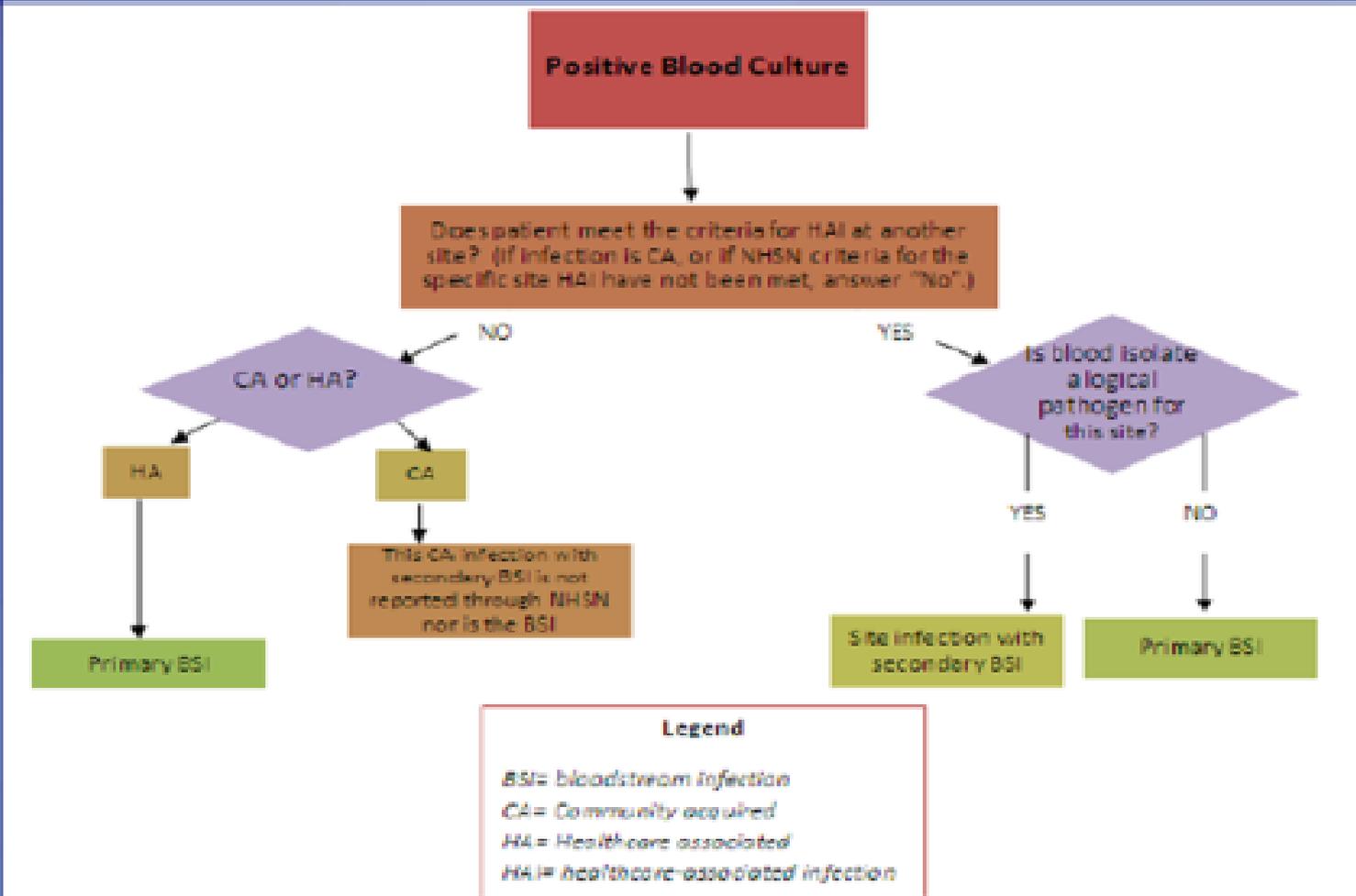
Primary bloodstream infections (BSI) are laboratory-confirmed bloodstream infections (LCBI) that are not secondary to an HAI meeting CDC/NHSN criteria at another body site (see criteria in [Chapter 17](#) or a community-associated infection.) Report BSIs that are central line associated (i.e., a central line or umbilical catheter was in place at the time of, or within 48 hours before, onset of the event).

**NOTE:** There is no minimum time period that the central line must be in place in order for the BSI to be considered central line-associated.

Source : Presentation by Katherine Allen-Bridson, RN, BSN, CIC, Nurse Consultant, CDC dated July 14, 2011 - "CLABSI Reporting through NHSN: Tips, Tricks, & Best Practices ..."

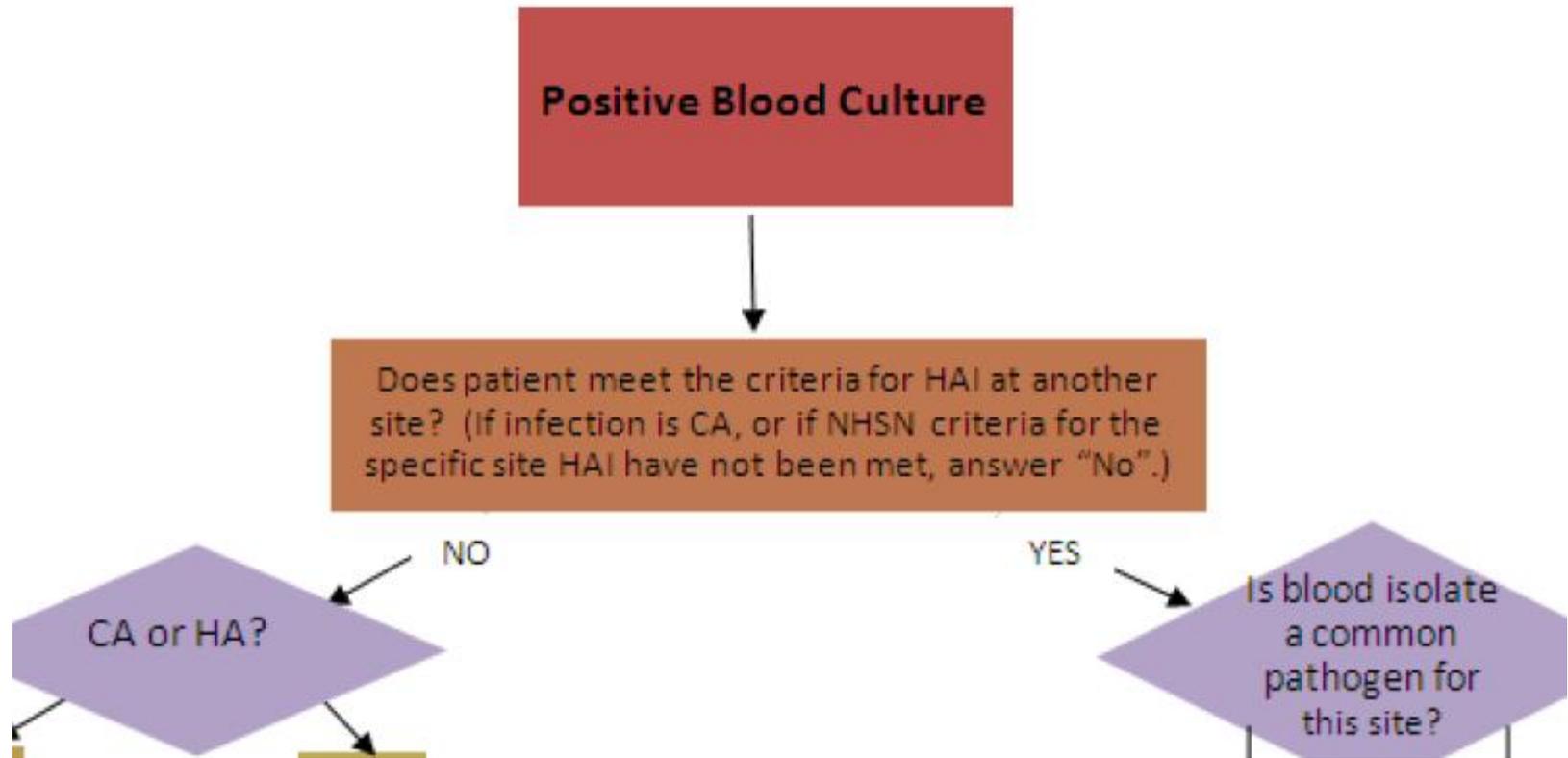
# Algorithm for secondary BSI

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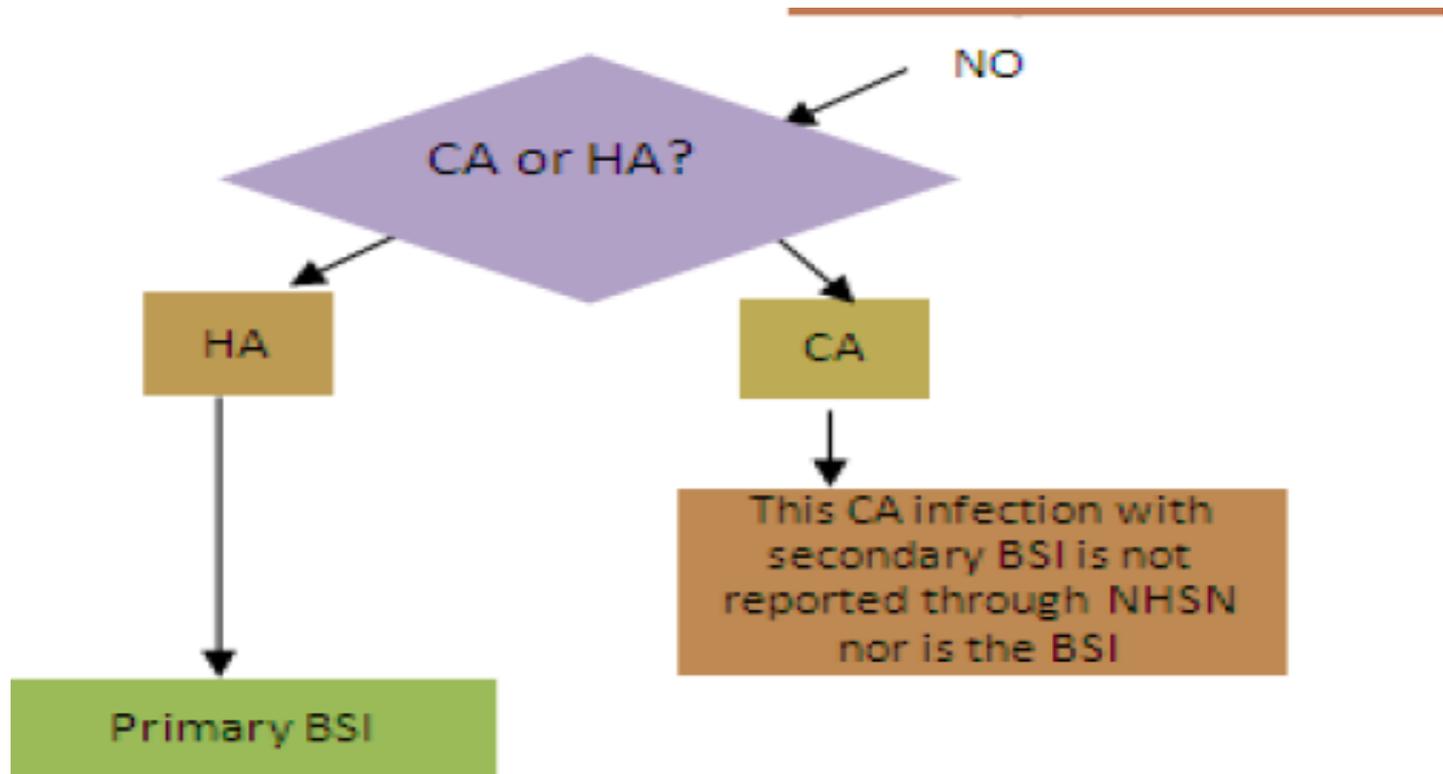
# Algorithm for Secondary BSI

45



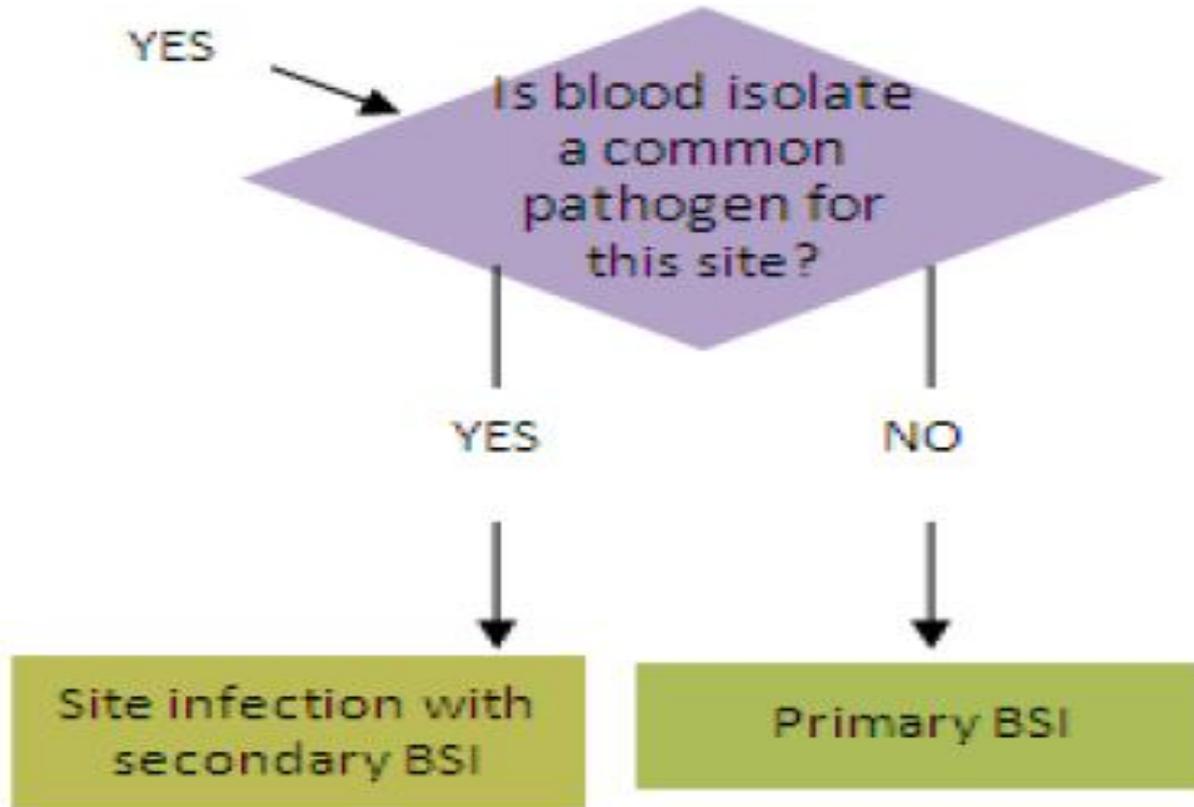
# Algorithm for Secondary BSI

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# Algorithm for Secondary BSI

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# Primary vs. Secondary BSI

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## **“Not Related to an Infection at Another Site” a.k.a. Secondary BSI**

- A culture-confirmed BSI associated with a documented HAI at another site.
- Primary infection must meet one of the CDC/NHSN definitions (Chapter 17)
- BSI and other site must be related with
  - Same organism matching genus and species
  - If no culture of primary site, then BSI organism must be logical for the primary site (flowchart next slide)

Source : Presentation by Katherine Allen-Bridson, RN, BSN, CIC, Nurse Consultant, CDC dated July 14, 2011 - “CLABSI Reporting through NHSN: Tips, Tricks, & Best Practices ...”

# Culture Techniques for Anaerobes

- Anaerobic organisms identified as the causative organism of a BSI were cultured using blood culture media specific for anaerobes.
- If a culture from a site other than blood is not obtained using special anaerobic culture media, it is unlikely that an anaerobic organism will be recovered or identified.

# Evaluating Skin Commensals

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## Criterion for blood culture positivity for CLABSI

- “2 or more blood cultures drawn on separate occasions”
  - ▣ Means that blood from at least 2 blood draws were collected within 2 days of each other (e.g., blood draws on Monday & Tuesday or Monday & Wednesday would be acceptable for blood cultures drawn on separate occasions.
  - ▣ 2 calendar days not within a 48 hour interval (changes in 2013 to “... does not exceed a gap of 1 calendar day...”)

# NHSN Recommendation for Blood Culture Specimen Collection

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- “Ideally, blood specimens for culture should be obtained from 2 to 4 blood draws from separate venipuncture sites (e.g., right & left antecubital veins), not through a vascular catheter. These blood draws should be performed simultaneously or over a short period of time (i.e., within a few hours).”

# Summary

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- Surveillance & clinical definitions do not always match & that is OK.
- NHSN definitions must be followed consistently within & across facilities to ensure usefulness.
- NHSN is continually addressing issues of inter-rater reliability & clinical acceptance of data.
- Denominator accuracy is as important as numerator accuracy; continually review these data for quality.

# Next Steps

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- CLABSI denominator survey in summer 2013
- Expansion of FAQs to improve application of HAI surveillance definitions & new 2013 CLABSI reporting criteria
- Changes in audit reconciliation process

# Audit Reconciliation Changes

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- At the time of exit briefing, the auditor will review findings & request the hospital IP to sign off indicating his/her agreement, disagreement (including the specific reason), or unsure (including the specific reason)
  - Any cases designated as “disagreement” or “unsure” will under QC
  - Follow-up communications will be held with the hospital
- Hospitals will be asked to supply any CDC communications regarding a case to the auditor at the time of the on-site visit
- All communications between AGS and CDC regarding specific cases will be copied to the hospital
- AGS will prepare a structured format for hospitals to use when supplying additional information to support resolution of findings