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Association for Professionals in Infection Control and Epidemiology

The Identification and Mitigation of False-Positive CLABSIs

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Speaker Financial Disclosures

Disclosure of Relevant Financial Relationships:

I have the following financial relationships to disclose:

Employee of: Magnolia Medical Technologies

The First Person in the World Saved by Antibiotics

In March, 1942 Mrs. Anne Miller of New Haven, Connecticut, was near death.

The Start of Resistance

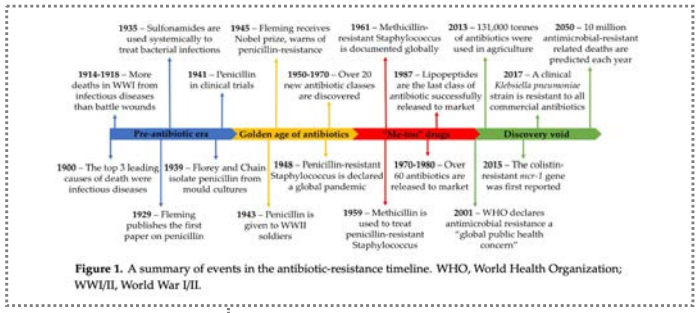


Figure 1. A summary of events in the antibiotic-resistance timeline. WHO, World Health Organization; WWI/II, World War I/II.

This pattern of resistance, first emerging in hospitals and then spreading to the community, is now a well-established pattern that recurs with each new wave of antimicrobial resistance

1942

Penicillin-resistant staphylococci were recognized, first in hospitals and subsequently in the community.

1944

94% of staph isolates were **susceptible** to penicillin by 1950 half were **resistant**

1945

Fleming received the Nobel prize and warned of antibiotic resistance, predicting that high public demand would create an era of abuse

1960

80% of both community- and hospital-acquired staphylococcal isolates were resistant to penicillin.

Lobanovska,, Yale J Biol Med. 2017 Mar; 90(1): 135–145.Published online 2017 Mar 29
J Antimicrob Agents 2000 Nov16 Suppl 1:53-10; doi: 10.1016/s0924-8579(00)00299-5.Antibiotic resistance staphylococci
WHO A summary of events in the antibiotic-resistance timelinez

The Criticality of Antibiotics

Issues with antibiotics

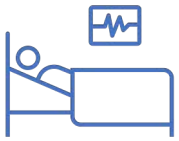
- No new class of antibiotics has been developed since 1980's
- Antibiotic resistance and our high-risk patients critically dependent on antibiotics

Organ transplant

>33,000 organ transplants were completed in 2016/US

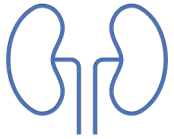
Chemotherapy

>650,000 people receive outpatient chemotherapy each year/US



Chronically ill

~30,000,000 with diabetes



Renal patients

>500,000 received dialysis in 2016/US

Richard Baltz, Pewtrusts.org lead developer of Daptomycin
Llor, Carl, Ther Adv Drug Saf , Dec; 5(6):229-241;2013
Milken Institute School of Public Health; Antibiotic Resistance Action Network
CDC AR Threat Report CDC; 2019

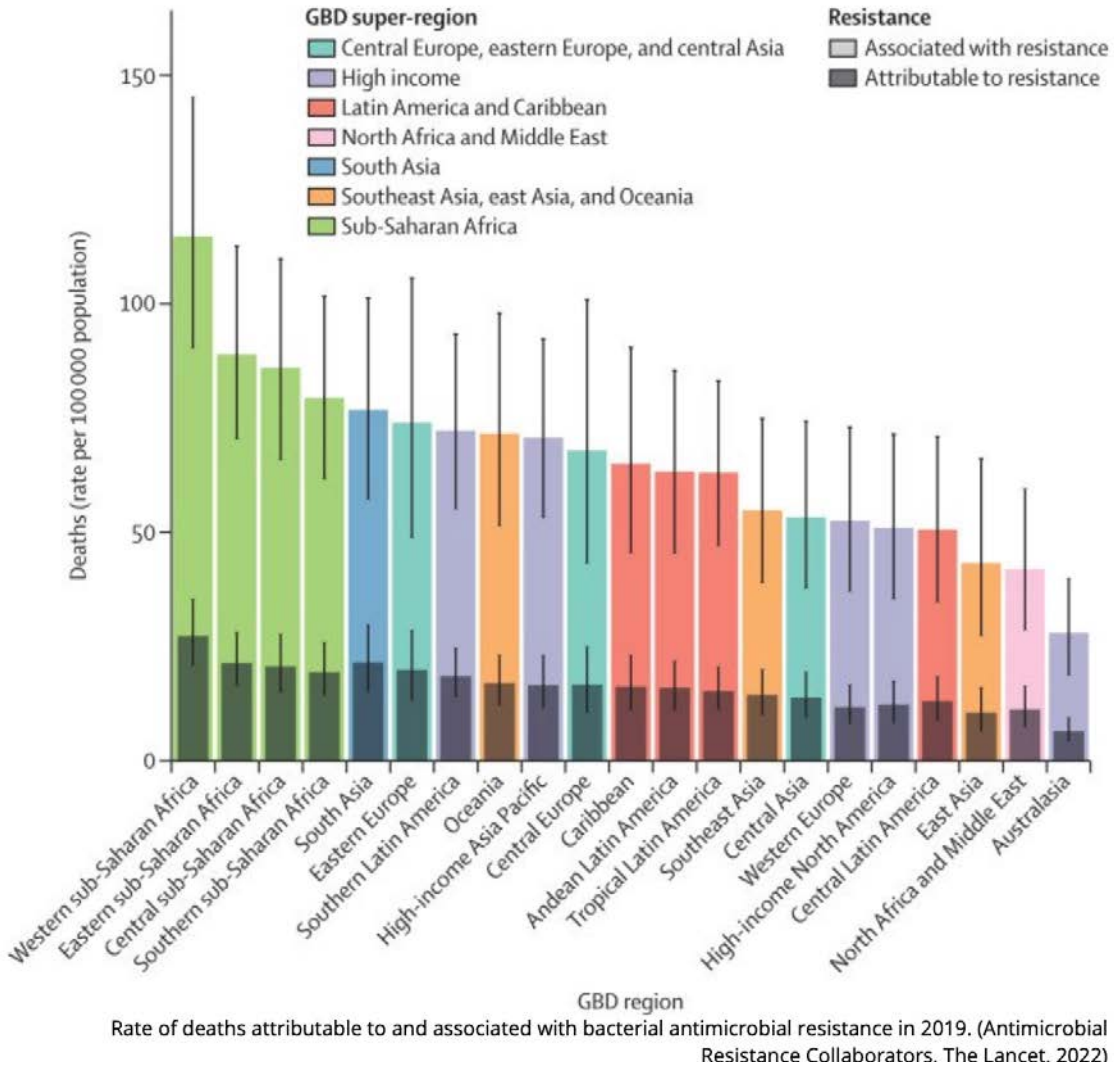
Global Burden of Bacterial AMR in 2019

A Systematic Analysis in 2022 The Lancet

- 4.95 million deaths associated with drug-resistant bacterial infections in 2019
- 1.27 million deaths directly caused by AMR

*"**By 2050, 10 million people will die from antibiotic resistant infections** if there are not changes…that will make antibiotic resistance the leading cause of death, ahead of cancer. This fundamentally challenges the very future of medicine. We know the problem is bad now, but the projections of what's going to happen if we don't do something are terrifying"*

Arjun Srinivasan, MD, Associate Director HAI Prevention Division of Healthcare Quality Promotion, CDC



Rate of deaths attributable to and associated with bacterial antimicrobial resistance in 2019. (Antimicrobial Resistance Collaborators. The Lancet. 2022)

Murray, The Lancet: Global burden of bacterial AMR in 2019 a systematic analysis; 2016

Antibiotic Use During COVID-19

“A recent review of COVID-19 studies published since the pandemic began found that while only **8%** of COVID-19 patients had documented bacterial co-infections, **72%** received antibiotic therapy.”

http://cidrap.umn.edu/news-perspective/2020/05/covid-19-presents-antibiotic-stewardship-challenges-opportunities

CIDRAP

Center for Infectious Disease Research and Policy

University of Minnesota

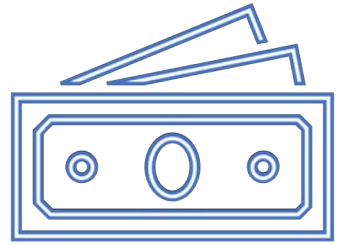
The Public Health Cost of Antibiotic Resistance

$20 Billion

for healthcare

$35 Billion

for loss of productivity



$55 Billion

total annual costs

Porooshat Dadgostar, Journal of Infections and Drug Resistance: Antimicrobial Resistance: Implications and Costs; Dec 20.doi:10.2147/IDR.S234610 PMCID 2019

The Consequences of Inaction

Four Ways to Stop Resistance

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

1

Prevention

Prevent an infection from happening (CDI)

2

Spread

Prevent its spread (E-LOS)

3

Antimicrobial Stewardship

Improve antibiotic use (prevent unnecessary/inappropriate)

4

Development

Develop new drugs and diagnostic tests

Diagnostic Stewardship can help achieve three of these four ways to stop antibiotic resistance

Personalizing The Cost

Antibiotic Stewardship Starts with Diagnostic Stewardship and Blood Culture Accuracy

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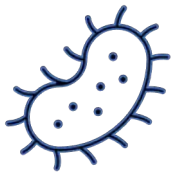
The Purpose of Blood Cultures



Confirm

the presence of microorganisms in the bloodstream

Identify

the microbial etiology of the bloodstream infection

Help

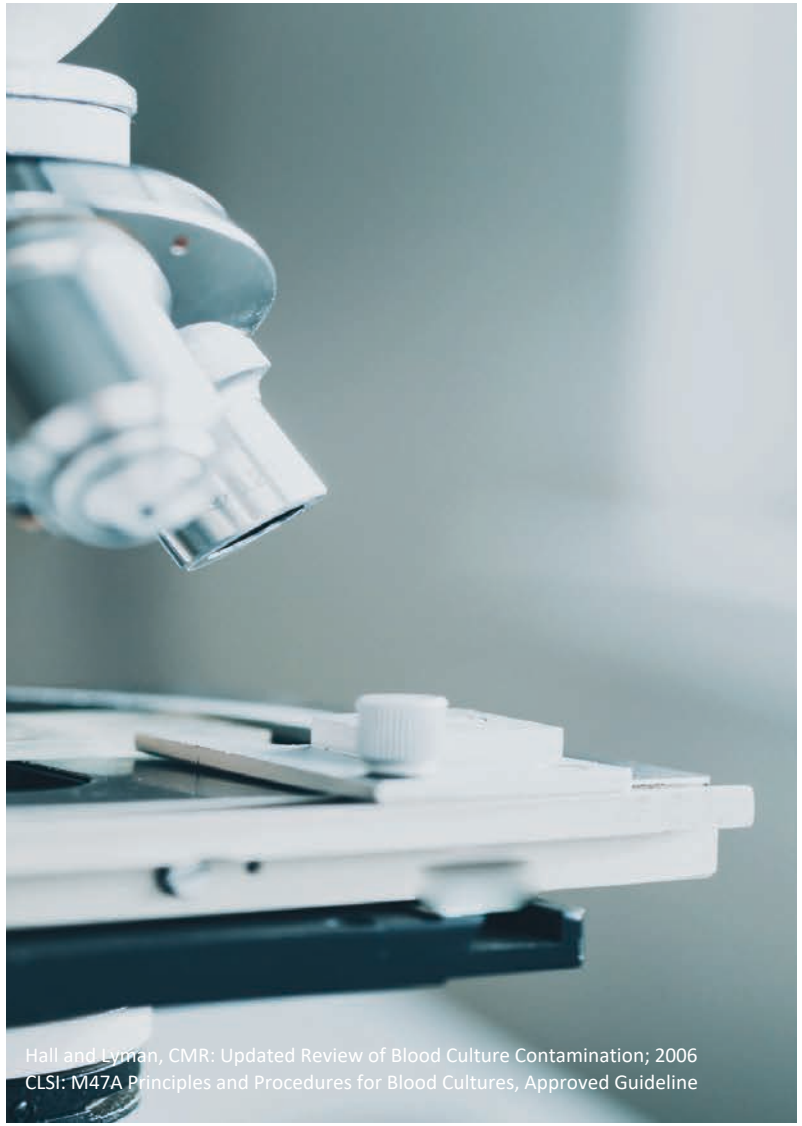
determine the source of infection (e.g., endocarditis)

Provide

an organism for susceptibility testing and optimization of antimicrobial therapy

Blood Culture Definitions

- Blood culture contamination (BCC) is defined as the recovery of **normal skin flora (common commensal)** from a **single blood culture**
- Culture is defined as a specimen of blood that is submitted for bacterial of fungal culture. **This is irrespective of the number of bottles or tubes into which the specimen is divided.**
- A BCC rate represents **common commensal organism occurrence in one set of blood cultures**
- **Blood Culture Set:** the combination of blood culture bottles or tubes **into which a single blood specimen is inoculated**
- **Required volume is essential and assumed**



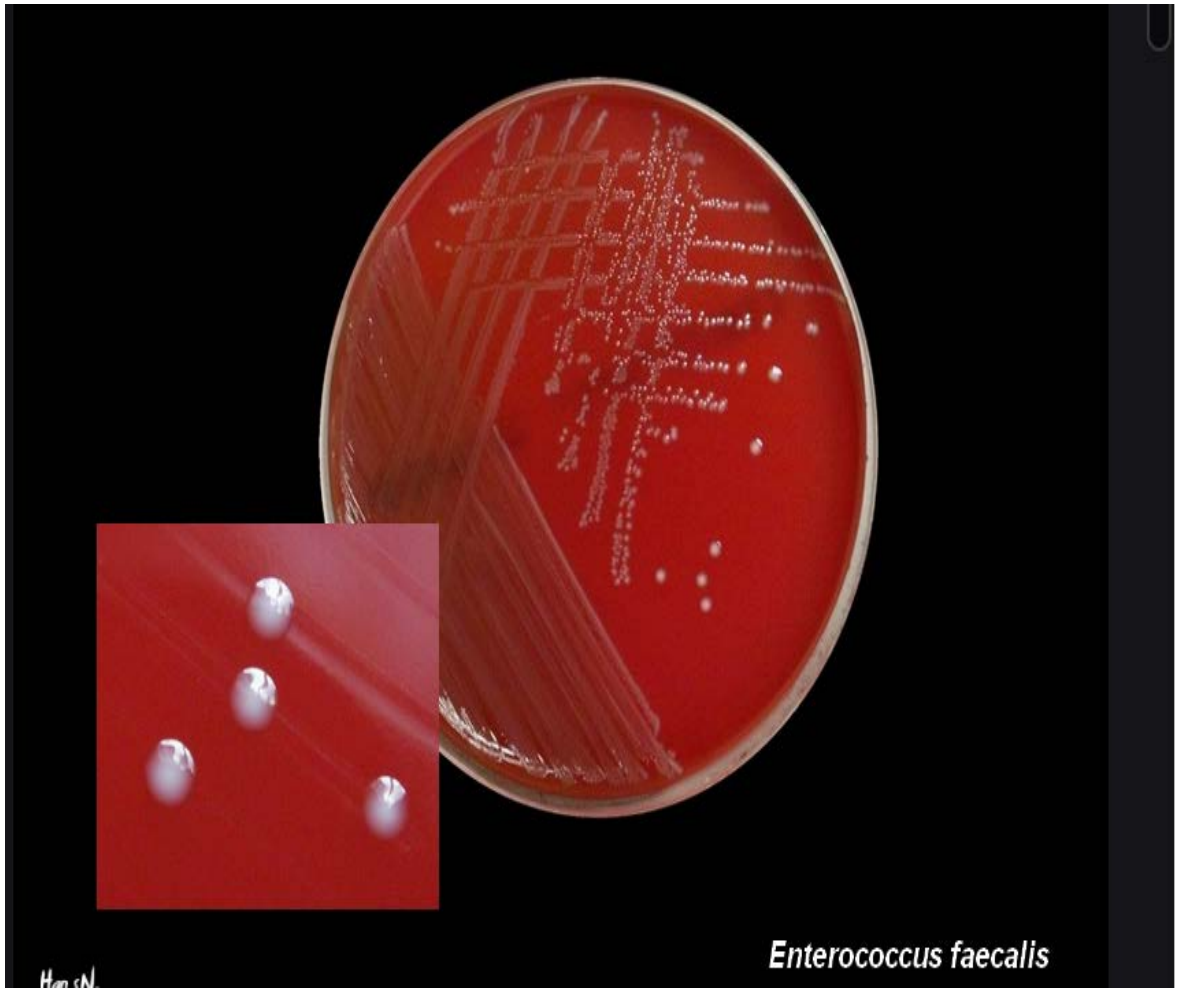
Hall and Lyman, CMR: Updated Review of Blood Culture Contamination; 2006
CLSI: M47A Principles and Procedures for Blood Cultures, Approved Guideline

Identity of the Organism

- Bates et al. found that the identity of the organism was the most important predictor for differentiating contaminated blood culture results from results indicating bacteremia
- **Common Commensal Organisms** or Probable Contaminants:
  - Coagulase-negative staphylococci (CoNS)
  - Propionibacterium spp. (Cutibacterium)
  - Aerococcus
  - Micrococcus
  - Bacillus spp. [not B. anthracis]
  - Corynebacterium spp. [diphtheroids]
  - Alpha-hemolytic streptococci

Identity of the Organism

- **Non-Common Commensal Organisms**
  (Usually a True Bacteremia or Fungemia)
  - Enterococcus
  - VRE
  - MRSA
  - Candida
  - E.coli
- Any organism NOT found on the NHSN Common Commensal list* is considered a recognized pathogen for NHSN reporting purposes



Common Commensal “Contaminators”

- Can be Pathogens
- Organisms can be difficult to interpret when isolated from blood cultures. One study showing:
  - Common Commensal Organisms
    - Clostridium perfringens were contaminants 77% (**27% were pathogens**)
    - Viridans group streptococci were contaminants 62% (**38% were pathogens**)

Pathogens can be contaminators but not defined as a blood culture contamination

  - Non-Common Commensal Organisms
    - Clostridium species were pathogens 80% (**20% were contaminants**)
    - Enterococci were pathogens 70% (**30% were contaminants**)
  - **“Given these data, clinicians attempting to differentiate true infections from simply contaminated blood cultures cannot rely solely on the identity of the organism”**

Survey Question

My hospital's definition of a contaminated blood culture is:

a. Any common commensal organism (normal organisms found on body surfaces) that grows in one set of blood cultures out of two sets drawn.
b. Any non-common commensal organism that grows in one set of blood cultures out of two sets drawn.
c. I don't know

The Problem in the Diagnosis of Sepsis

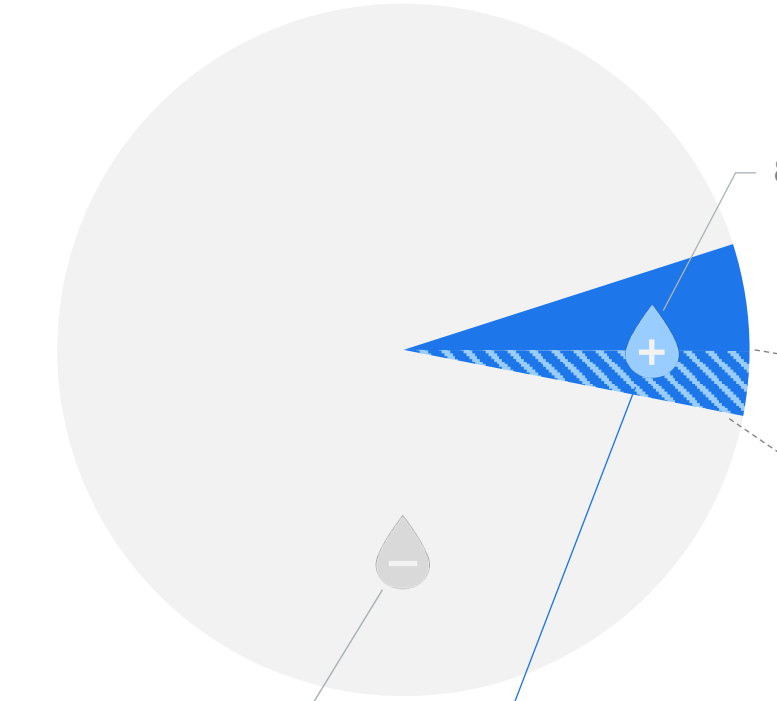
Sepsis is the #1 cause of death, readmissions, and costs in U.S. hospitals[1,2]

… and blood cultures remain the gold standard for diagnosing this disease

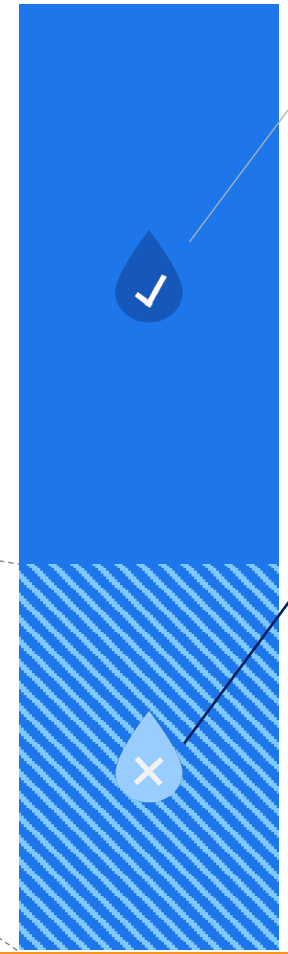
[1]Liu V, Escobar GJ, Greene JD. Hospital deaths in patients with sepsis from 2 independent cohorts. JAMA. 2014;312(1):90-92. doi:10.1001/jama.2014.5804.
[2]Weiss AJ, Jiang HJ. Overview of clinical conditions with frequent and costly hospital readmissions by payer, 2018. HCUP Statistical Brief #278. July 2021. Agency for Healthcare Research and Quality, Rockville, MD.

Test Results for Sepsis are Frequently Wrong

ALL BLOOD CULTURES



POSITIVE BLOOD CULTURES



40% *False* Positive

Nearly half of all positive blood cultures **are actually *false* positive**

False positives are a *preventable* error and can lead to a misdiagnosis of sepsis

[1]Zwang O, Albert RK. Analysis of strategies to improve cost effectiveness of blood cultures. J Hosp Med. 2006;1(5):272-6. doi:10.1002/jhm.115.

What this means at a typical hospital

Patient Safety

Cultures / month:		833
Contamination Rate:	x	3.0%
Patients impacted by false positives / month:	=	**25**

Hospital Economics

Patients impacted / year:		**300**
Average cost per incident[1,2,3]	x	$4,307
Avoidable costs:	=	**$1,292,100**

[1]Skoglund E, Dempsey CJ, Chen H, Garey KW. Estimated clinical and economic impact through use of a novel blood collection device to reduce blood culture contamination in the emergency department: a cost-benefit analysis. J Clin Microbiol. 2019;57(1):e01015-18. doi:10.1128/JCM.01015-18.
[2]Geisler BP, Jilg N, Patton RG, Pietzsch JB. Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures on economic and clinical outcomes. J Hosp Infect. 2019;102(4):438-444. doi:10.1016/j.jhin.2019.03.012.
[3]Data on file.

The Clinical Decision Dilemma

Probable/Possible Contaminant:

- *CoNS*
- *Aerobic Diphtheroids*
- *Anaerobic Diphtheroids*
- *Bacillus Species*

Clinical Dilemma:

Continue Antibiotics *OR* De-escalate?

Continue Antibiotics

De-escalate

Additional Blood Cultures

Negative

Asymptomatic

Positive

Hold *or* Readmit

12-38%[1,2]

of the time, possible/probably contaminants = true bacteremia*

**even after Rapid Organism Identification*

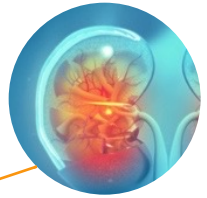
Increased mortality & morbidity risk

[1]Weinstein MP, Towns ML, Quartey SM, et al. The clinical significance of positive blood cultures in the 1990s: a prospective comprehensive evaluation of the microbiology, epidemiology, and outcome of bacteremia and fungemia in adults. Clin Infect Dis. 1997;24(4):584-602. doi:10.1093/clind/24.4.584. [2]Tokars JI. Predictive value of blood cultures positive for coagulase-negative staphylococci: implications for patient care and health care quality assurance. Clin Infect Dis. 2004;39(3):333-41. doi:10.1086/421941. Epub 2004 Jul 12.

The Impact

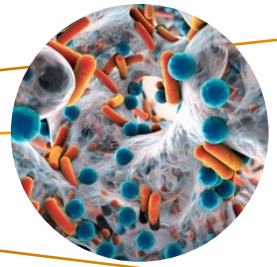
Misdiagnosed
Patient

Unnecessary
Antibiotics

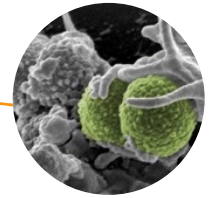


Acute Kidney Injury
(AKI)

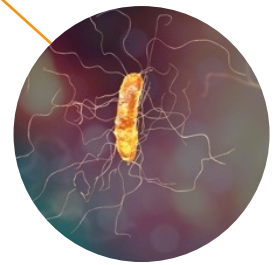
Extended
Length of Stay



Antibiotic-Resistant
Infections



Exposure to
HAIs & HACs



Risk of
C. difficile

False-Positive
CLABSIs

Our Two “Go To” Antibiotics for Sepsis

Vancomycin	• **Implicated in the causation of CDI**
Zosyn	• **Implicated in the causation of CDI**

Diagnostic Stewardship can help reduce both

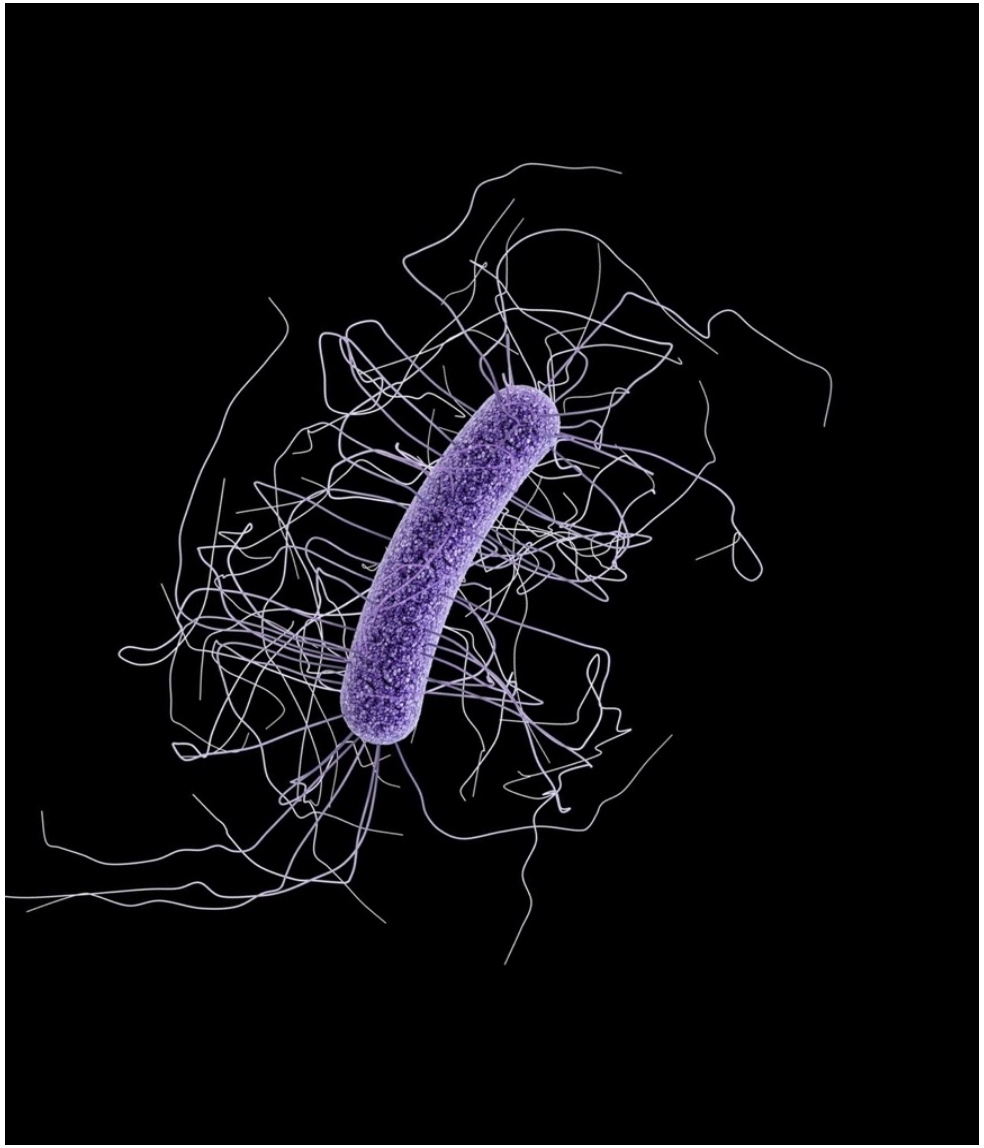
Clinical Infectious Diseases

AJIC American Journal of Infection Control

Official Publication of APIC

Froehlich M, Maymonah B, Bailey L, Ford F, LeMaitre B, Psevdos G. Antimicrobial stewardship program achieved marked decrease in clostridium difficile infections in a veterans hospital. Am J Infect Control. 2020;48(9):1119-1121. doi:10.1016/j.ajic.2019.12.023.
Owens RC, Donskey CJ, Gaynes RP, Loo VG, Muto CA. Antimicrobial-associated risk factors for Clostridium difficile infection. Clin Infect Dis. 2008;46(Suppl 1):S19-31. doi:10.1086/521859.

Antimicrobial-Associated Risk Factors for *Clostridioides difficile* Infection



"Reducing the use of high-risk, broad spectrum antibiotics by 30% **could lower CDI by 26%.**"

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Survey Question

My hospital's go-to antibiotic therapy for rule out or suspected sepsis is:

a. Vancomycin and Zosyn
b. Meropenem and Daptomycin
c. I don't know

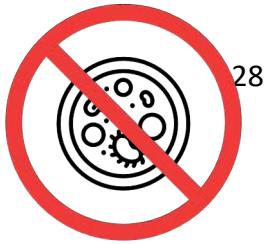
The Devastating Consequences of Blood Culture Contamination

~1.4 million

patients impacted by false-positive blood culture results annually in the United States, the MAJORITY of which are treated with antibiotics[1]

$6 billion +

is spent by our healthcare system each year on unnecessary treatment associated with false-positive blood culture results[2]



28

3 million +

antibiotic-resistant and *C. difficile* infections each year and 48,000 people die based on the CDC's 2019 report[3]

1 in 5 patients

experience adverse drug event (ADE) associated with antibiotic administration in acute care hospital setting[4]

[1]Patton RG. Blood culture contamination definitions can obscure the extent of blood culture contamination: a new standard for satisfactory institution performance Is needed. Infect Control Hosp Epidemiol. 2016;37(6):736-8. doi:10.1017/ice.2016.30. [2]Geisler BP, Jilg N, Patton RG, Pietzsch JB. Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures on economic and clinical outcomes. J Hosp Infect. 2019;102(4):438-444. doi:10.1016/j.jhin.2019.03.012. [3]CDC. Antibiotic Resistance Threats in the United States, 2019. Atlanta, GA: U.S. Department of Health and Human Services, CDC; 2019. doi:http://dx.doi.org/10.15620/cdc:82532. [4]Tamma PD, Avdic E, Li DX, Dzintars K, Cosgrove SE. Association of adverse events with antibiotic use in hospitalized patients. JAMA Intern Med. 2017;177(9):1308–1315. doi:10.1001/jamainternmed.2017.1938.

The Impact of COVID-19 on CLABSIs, Resistant Organisms and Blood Cultures

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50 YEARS 1972-2022

A Requirement to Always Improve

The 2020 target (from 2015 baseline)

25% - 50% reduction in HAIs

50% reduction in CLABSIs

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

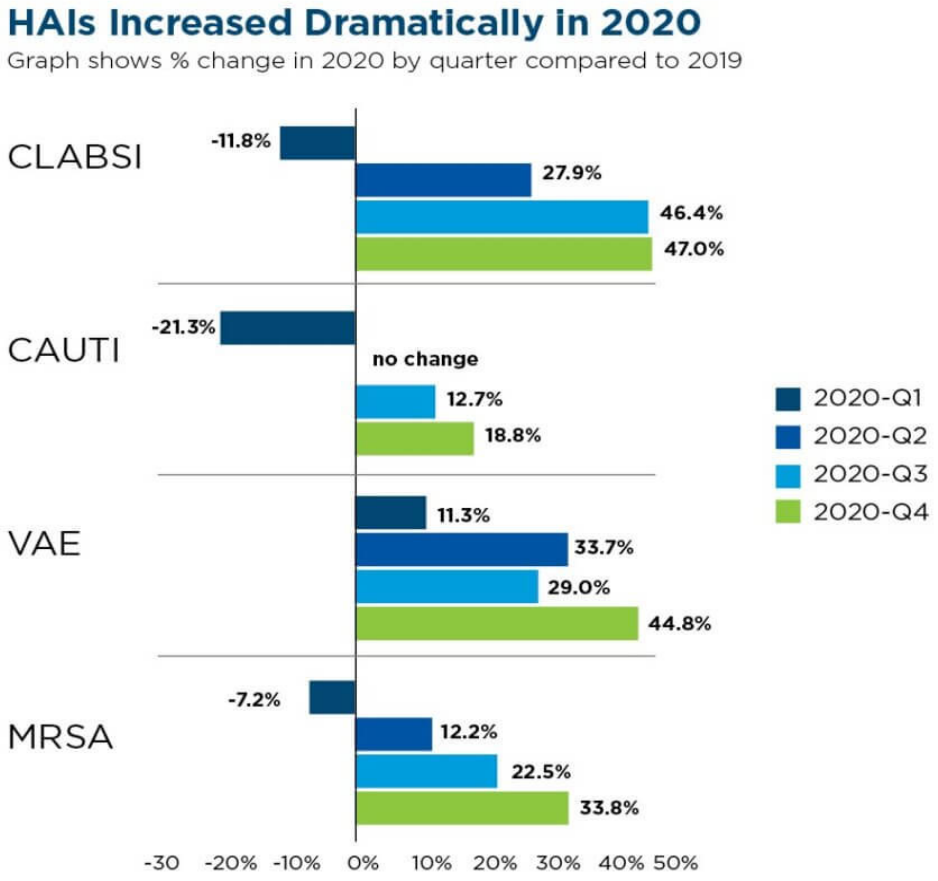
Table 1: 2020 National Acute Care Hospital HAI Metrics

Measure (and data source)	Progress made by 2016	2020 Target (from 2015 baseline)
CLABSI (NHSN)[1]	10% reduction	50% reduction
CAUTI (NHSN)[1]	6% relative reduction	25% reduction
Invasive MRSA (NHSN/EIP[2])	8% reduction	50% reduction
Hospital-onset MRSA (NHSN)	6% reduction	50% reduction
Hospital-onset CDI (NHSN)	7% reduction	30% reduction
SSI (NHSN)	Data to be released in 2018	30% reduction
*Clostridium difficile*hospitalizations (HCUP)[3]	Data pending release	30% reduction

HAI Increases during COVID-19

28% YoY increase in CLABSIs in Q2 2020

46% - 47% YoY increase in CLABSIs in Q3-Q4 2020



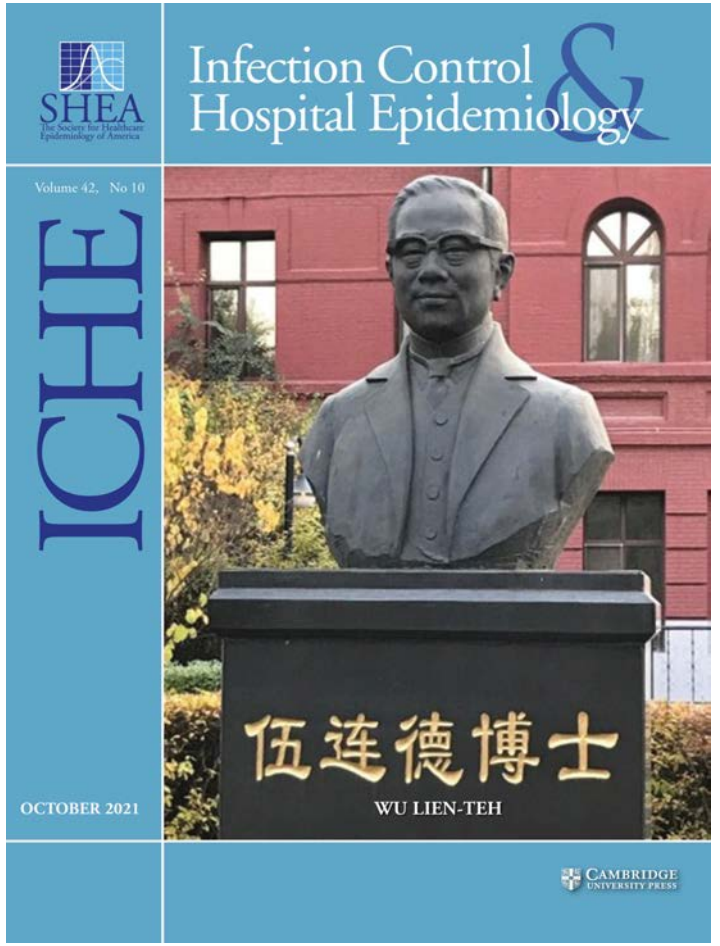
Weiner-Lastinger LM, et al. (2021). The impact of coronavirus disease 2019 (COVID-19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. Infection Control & Hospital Epidemiology, https://doi.org/10.1017/ice.2021.362

COVID-19 and CLABSI

- The Impact of Coronavirus Disease 2019 (COVID-19) response on central line-associated blood stream infections and blood culture contamination rates at a tertiary-care center in the Greater Detroit area (Detroit Medical Center)

325% CLABSI Increase

18% Blood Culture Contamination Increase



Infect Control Hosp Epidemiol: Aug;42(8):997-1000. doi: 10.1017/ice.2020.1335;2021

Blood Culture Contamination and False-Positive CLABSIs

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Past Strategies for CLABSI Prevention

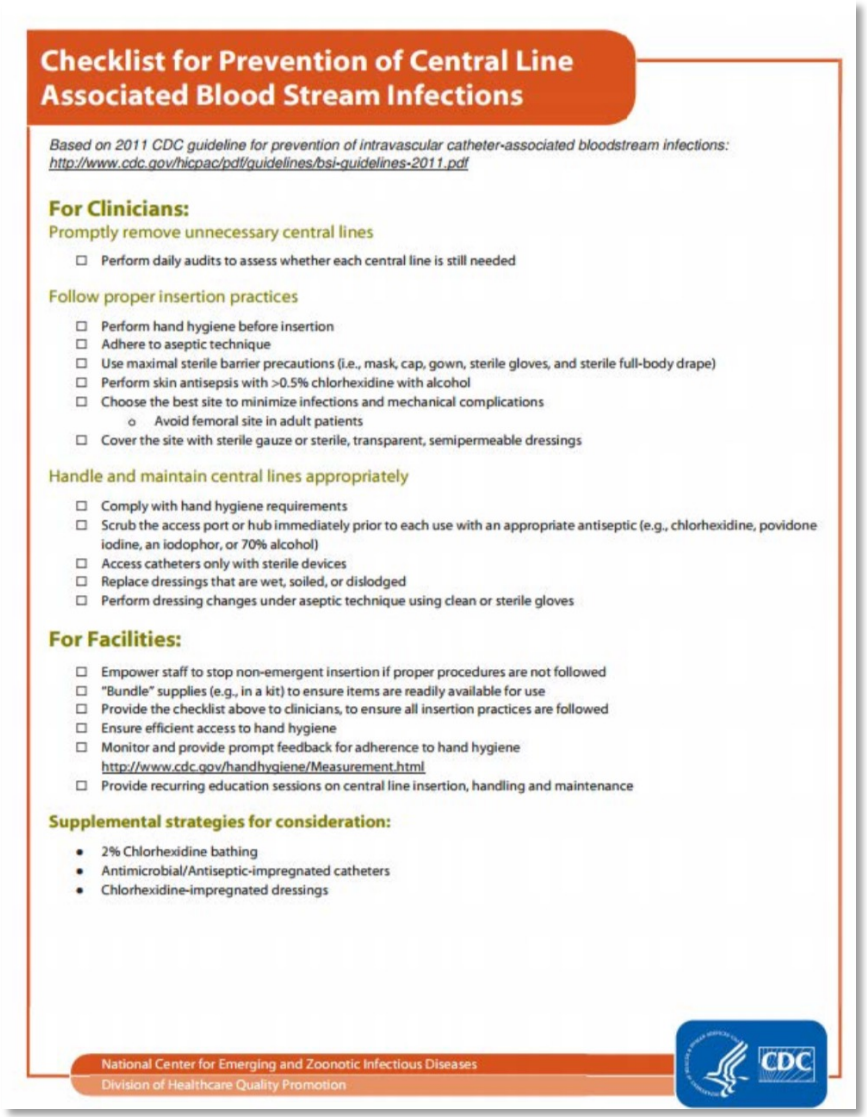
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

1	Education and Insertion Bundles: Hand Hygiene, Maximal Barrier Precautions, CHG use, Optimal Site Selection, Observers, Checklists and Kits
2	Maintenance Bundles: CHG Bathing, Dressing, Connector and Tubing Protocols, Port Protectors, Assessing Catheter Necessity
3	Vascular Access Teams and Nurse/Patient Ratios
4	Daily Rounding and Auditing

2011 IPPS Hospitals' Mandatory Enrollment in NHSN and CLABSI Reporting
2015 CLABSI HAC Penalties started ICT 2011

We Improved!

- In 2003 Dr. Pronovost with the Michigan State Keystone Project released a bundle, CDC and IHI provided guidance, insertion and maintenance bundles
- Technical Interventions
- Socio-adaptive Interventions
- CLABSI rates improved by 44% from 2008 - 2016
- CLABSI rates decreased another 7% from 2018 - 2019



Checklist for Prevention of Central Line Associated Blood Stream Infections

Based on 2011 CDC guideline for prevention of intravascular catheter-associated bloodstream infections: http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

For Clinicians:

Promptly remove unnecessary central lines

- ☐ Perform daily audits to assess whether each central line is still needed

Follow proper insertion practices

- ☐ Perform hand hygiene before insertion
- ☐ Adhere to aseptic technique
- ☐ Use maximal sterile barrier precautions (i.e., mask, cap, gown, sterile gloves, and sterile full-body drape)
- ☐ Perform skin antisepsis with >0.5% chlorhexidine with alcohol
- ☐ Choose the best site to minimize infections and mechanical complications
  - o Avoid femoral site in adult patients
- ☐ Cover the site with sterile gauze or sterile, transparent, semipermeable dressings

Handle and maintain central lines appropriately

- ☐ Comply with hand hygiene requirements
- ☐ Scrub the access port or hub immediately prior to each use with an appropriate antiseptic (e.g., chlorhexidine, povidone iodine, an iodophor, or 70% alcohol)
- ☐ Access catheters only with sterile devices
- ☐ Replace dressings that are wet, soiled, or dislodged
- ☐ Perform dressing changes under aseptic technique using clean or sterile gloves

For Facilities:

- ☐ Empower staff to stop non-emergent insertion if proper procedures are not followed
- ☐ "Bundle" supplies (e.g., in a kit) to ensure items are readily available for use
- ☐ Provide the checklist above to clinicians, to ensure all insertion practices are followed
- ☐ Ensure efficient access to hand hygiene
- ☐ Monitor and provide prompt feedback for adherence to hand hygiene http://www.cdc.gov/handhygiene/Measurement.html
- ☐ Provide recurring education sessions on central line insertion, handling and maintenance

Supplemental strategies for consideration:

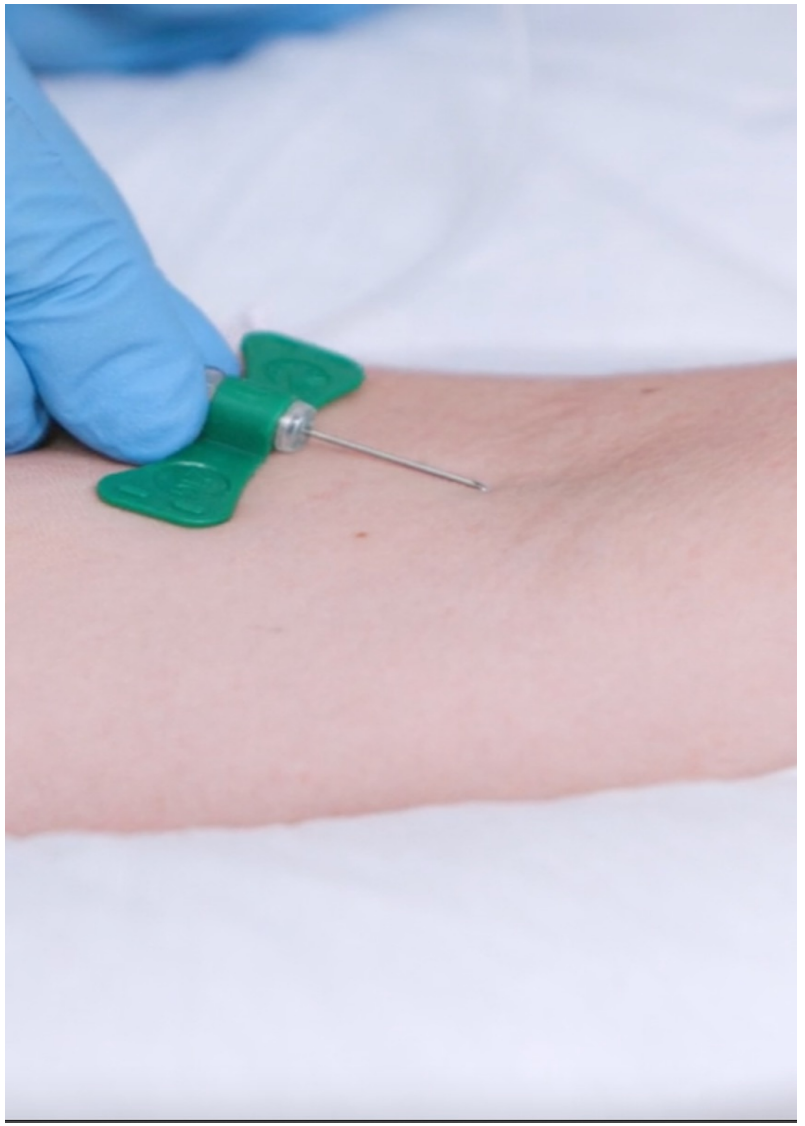
- 2% Chlorhexidine bathing
- Antimicrobial/Antiseptic-impregnated catheters
- Chlorhexidine-impregnated dressings

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion

CDC

What is a False-Positive CLABSI?

- A False-Positive CLABSI is defined in the literature as meeting the NHSN Surveillance Definition of a CLABSI with little to no clinical manifestation of bacteremia/fungemia
- This usually occurs when a **non-common** commensal organism like VRE or Candida is picked up from the skin during a **peripheral venipuncture** for blood culture collection and grows out in one bottle
- This is different than an unnecessarily reported CLABSI when there is a primary infection at another site and a culture was not obtained from the primary site



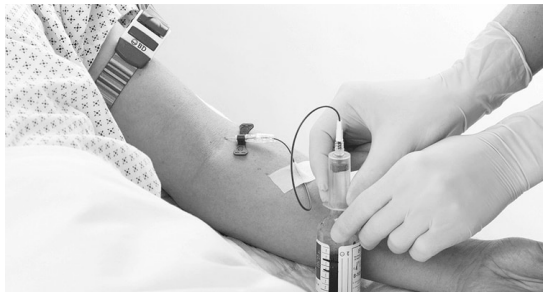
Surveillance vs. Clinical Definitions

Surveillance always trumps clinical

CLABSI Surveillance Definition #1
Non-Common Commensal Organisms

LCBI 1

(Lab Confirmed Bloodstream Infection)



Patient of any age has a recognized bacterial or fungal pathogen, not included on the NHSN common commensal list.

AND

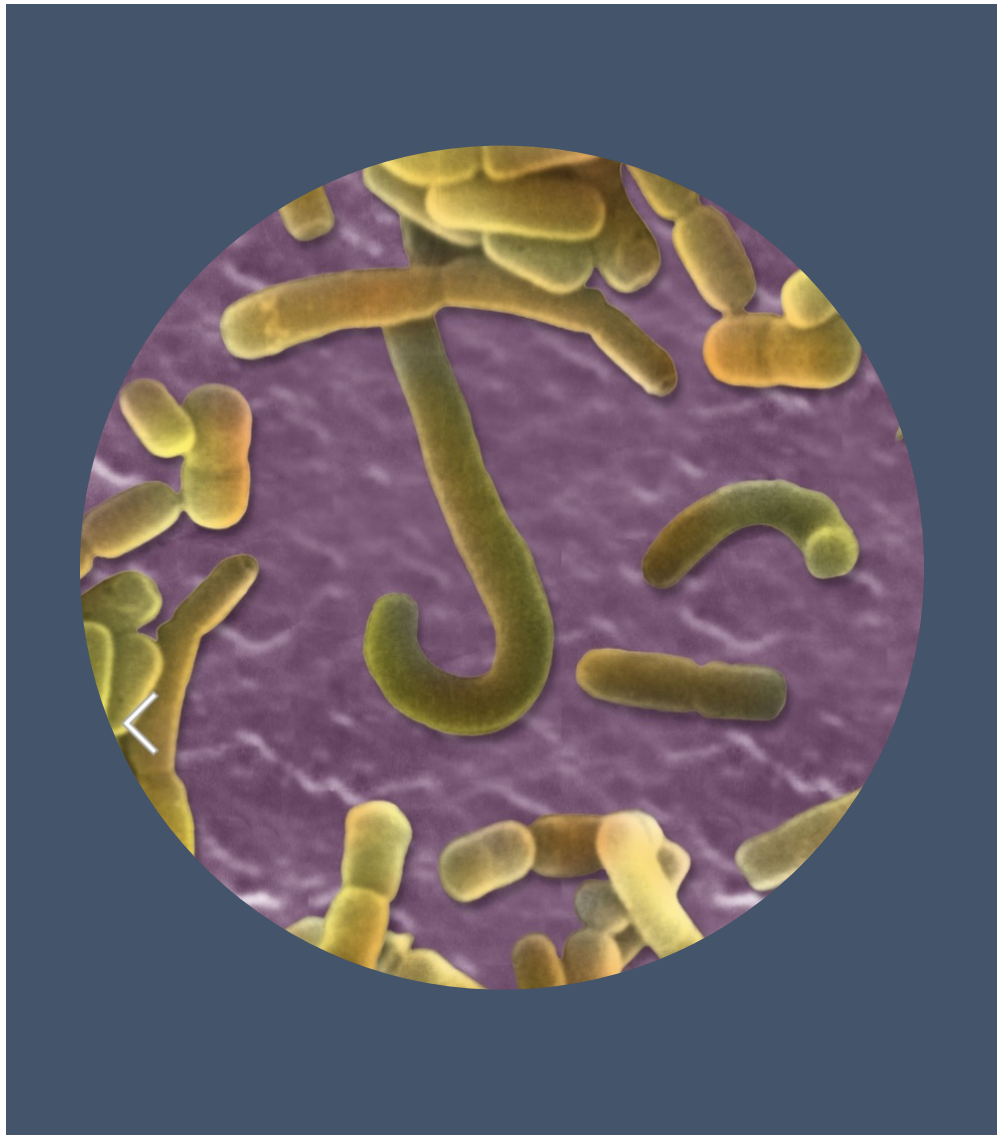
Organism(s) identified in blood is not related to an infection at another site. (See Secondary BSI Guide)

CLABSI

If a patient with a central venous catheter (CVC) has **ONE** bottle become positive with any **non-common** commensal organism i.e. Enterococcus, VRE, MRSA or Candida it qualifies as a CLABSI and **must be reported as a CLABSI**

(Other qualifiers include inpatient 2-day rule)

Lactobacillus CLABSI Case Study



Lactobacillus

- Outlier and resulted from probiotic administration.
- Capsule of probiotics was broken open to administer via OG tube
- Probiotics (including Lactobacillus) aerosolized and landed on the patient's skin, speciated for identification
- Blood culture collection picked this up and they had to **report a false positive CLABSI**

S.Skljarevski, AJIC: Preventing avoidable central line–associated bloodstream infections: Implications for probiotic administration and surveillance; 2016

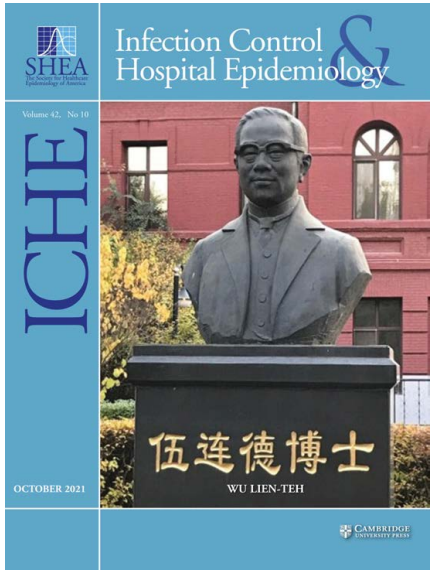
False-Positive CLABSI Reporting

"**42%** of reported CLABSIs represented contaminants"[1]

30% of reported CLABSIs were suspected to represent blood culture contamination"[2]

45% of reported CLABSIs most likely represented contaminated blood cultures rather than true CLABSIs"[3]

[1]Tompkins, LS, et al. Getting to zero: impact of a device to reduce blood culture contamination and false-positive central line-associated blood stream infections. Submitted to Clin Infect Dis in December 2021.
[2]Boyce JM, Nadeau J, Dumigan D, et al. Obtaining blood cultures by venipuncture versus from central lines: impact on blood culture contamination rates and potential effect on central line-associated bloodstream infection reporting. Infect Control Hosp Epidemiol. 2013;34(10):1042-7. doi:10.1086/673142.
[3]Shuman EK, Washer LL, Arndt JL, et al. Analysis of central line-associated bloodstream infections in the intensive care unit after implementation of central line bundles. Infect Control Hosp Epidemiol. 2010;31(5):551-3. doi:10.1086/652157.



False-Positive CLABSI Reporting
(CMS NHSN Surveillance Definition LCBI1)

Survey Question

At my hospital:

a. We have probably had to report some false-positive CLABSIs
b. We know we have had false-positive CLABSIs but feel compelled to treat the patients anyway because we cannot take the chance that these may be true and not treat the patient
c. I don’t think we have ever had a false-positive CLABSI

Economic Impact

APIC
Association for Professionals in Infection Control and Epidemiology
50 YEARS 1972-2022

Hospital's report HACs to NHSN

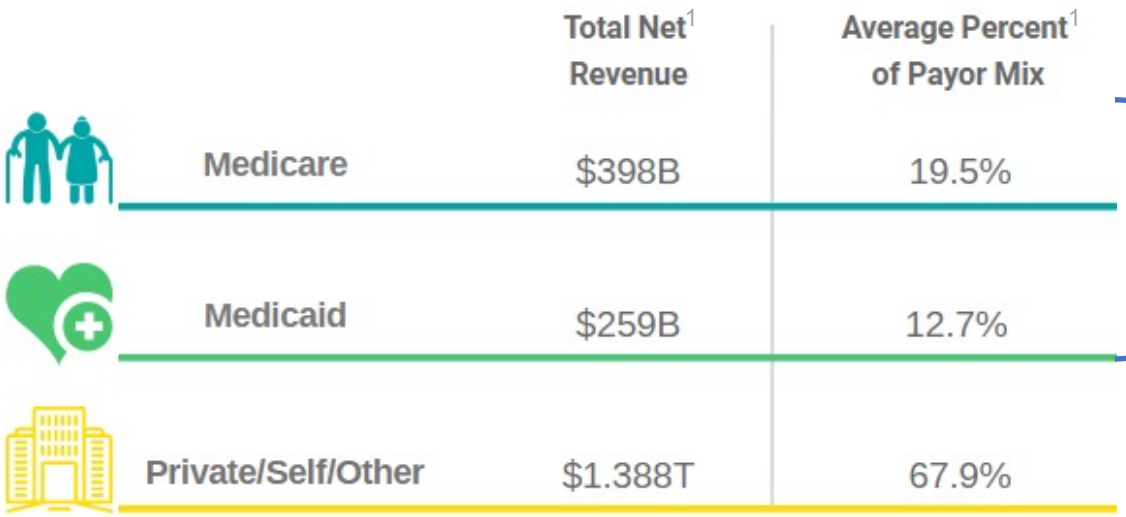
- CAUTI
- SSI
- CLABSI
- *C. difficile*
- MRSA BSI

Significantly impacted by BC contamination (non-common & common commensal organisms)

- National SIR for CLABSIs increased 46% / 47% during COVID (Q3/Q4 ’20 vs. Q3/Q4 ’19)[1]
- National SIR for MRSA increased 23% / 34% during COVID (Q3/Q4 ’20 vs. Q3/Q4 ’19[1]
- NHSN reports HACs to CMS
  - Impacts hospital’s CMS reimbursement and penalties
  - Up to 1% CMS revenue loss plus cost of initial care
    - Can contribute to up to 6% CMS revenue loss

[1]Weiner-Lastinger LM, Pattabiraman V, Konnor RY, et al. The impact of coronavirus disease 2019 on healthcare-associated infections in 2020: summary of data reported to the NHSN. Infect Control Hosp Epidemiol. 2021;1-14. doi:10.1017/ice.2021.362.A39:B40.

HAC Penalty Calculation (example)



Potential Penalty Calculation

Average Percent of Payer Mix	32.2%
Hospital Revenue	$1,000,000,000
CMS Revenue	$322,000,000
Potential CMS Penalty (1.0%)	**$3,220,000**

[1]Definitive Healthcare's proprietary data on payer mix, March 2019

Potential CMS Revenue Loss

Non-Payment

- ***No payment*** from day of HAC diagnosis to discharge
  - CDI ($9-25K)
  - CLABSI ($27-68K)
  - MRSA ($9K)

HAC

- ***Penalty: Up to 1%*** of annual reimbursement
  (Top 25% of worst offenders get max penalty)
  - CDI
  - False-positive CLABSI
  - False-positive MRSA

Readmissions

- ***Penalty: Up to 3%*** of annual reimbursement
  - 33% chance of 30-day readmission with a HAC patient

VBP

- ***Loss: Up to 2%*** of annual reimbursement
  - Top 25% of hospitals receive $ back plus $ from their competing hospitals in the lower 75%

Goal of ZERO blood culture contamination can help prevent up to 6% CMS revenue loss plus cost of initial care

Equitable Care

Marginalized Patient Populations BCC and AMR

Is Blood Culture Contamination and resistance more prevalent in marginalized populations?

- Fewer phlebotomy teams-resource costly for human resource and finances
- Higher rates of resistance
- 4 peer reviewed articles review significantly higher rates of BCC and AMR in Low Income Countries

Contributing Factors for Higher Rates of Resistance in Low Income Countries

Nadimpalli, Chan, Doron, Nature: Published online 18 January 2021
https://doi.org/10.1038/s41591-020-01201-9

Solutions: Evidence Based Technique and Technology Leads to Diagnostic Stewardship, Antimicrobial Stewardship and Quality Patient Outcomes

APIC
Association for Professionals in Infection Control and Epidemiology

50 YEARS 1972-2022

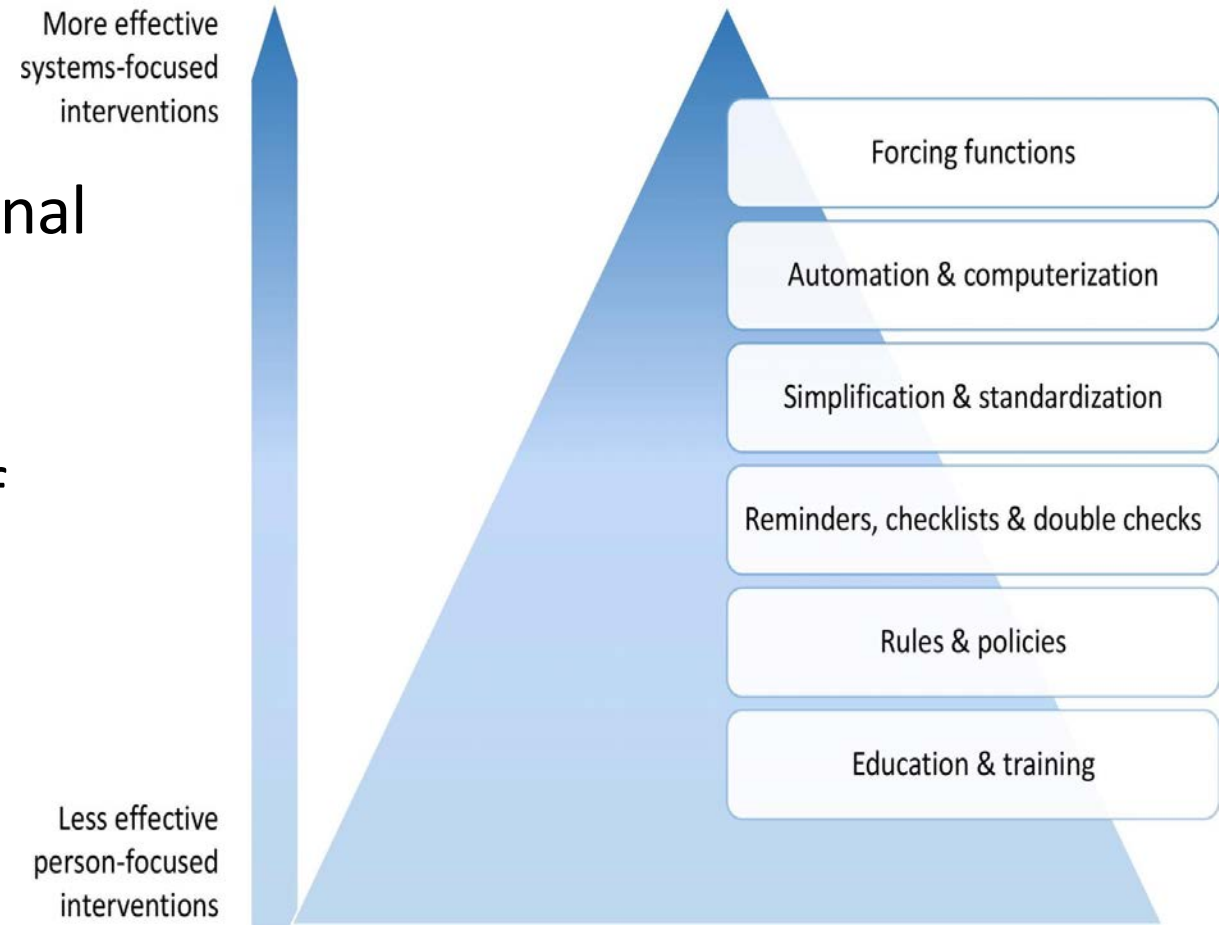
Patient Selection	Blood cultures should only be performed in patients with a reasonable likelihood of bacteremia/fungemia.
Skin disinfection *INS	Use a CHG and alcohol-containing disinfectant to scrub the phlebotomy site; allow for drying time
Blood Culture Bottle Top Disinfection *INS	Disinfect blood culture vial caps with alcohol
Consideration	Leave an IPA pad on top of the BC bottle, to protect from environmental contaminants, until ready to inoculate with blood. IPA takes 5 seconds to dry
Phlebotomy Site *INS	Don't draw blood cultures through indwelling vascular catheters unless the catheter is thought to be the source of sepsis. Draw from each lumen. Remove NC. Draw a second set from a peripheral venipuncture. Consider time to positivity. Send to lab within 2 hours, do not refrigerate sample
Sets *INS	Always draw two sets from different sites. Always draw blood cultures first and prior to antibiotics
Volume *INS	**I**s the single most important factor for organism detection
Standardized Kits *INS	Use of standardized kits and procedures has proven helpful in preventing contamination
Phlebotomy Teams *INS	Educate and train individuals who perform blood cultures in aseptic technique
Surveillance and Feedback *INS QI	Monitor blood culture contamination and provide data to individuals and patient care units
Multidisciplinary Teams *INS	Sustained improvement in blood culture contamination is best achieved through a team approach.
Initial Specimen Diversion Device *INS	Divert and discard > 1mL of initial sample. Use of ISDD has been shown to decrease contamination rates to less than 1%.

Limited Impact of Education Alone as an Improvement Intervention

"

Studies tell us that relying on educational interventions to change clinicians' behaviors tends to produce **no improvement**, making this category of interventions the most predictably disappointing"

BMJ

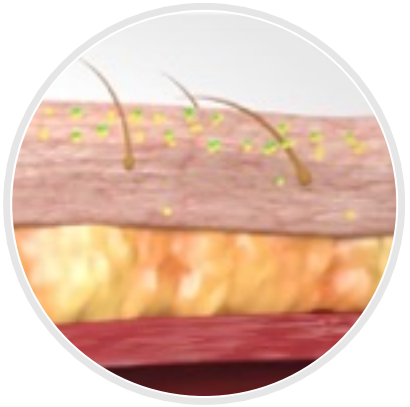


Soong C, Shojania KG. Education as a low-value improvement intervention: often necessary but rarely sufficient. *BMJ Qual Saf*. 2020;29(5):353-357. doi:10.1136/bmjqs-2019-010411.

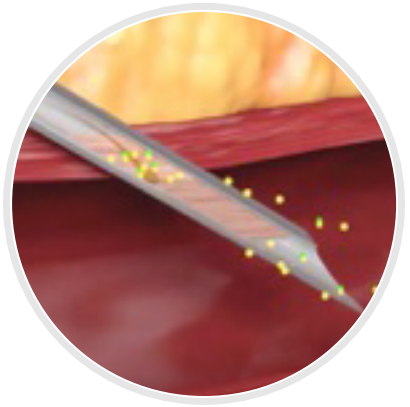
Training and Education on “Best Practices” Alone Will Not Solve the Problem

Contamination, It’s Not Anyone’s Fault

Human Factor(s)
Risk of contamination during assembly, preparation of supplies and skin prep



Skin Flora
You can disinfect but not sterilize the skin. Up to 20% of skin flora remains viable in the keratin layer of the skin even after skin prep[1]

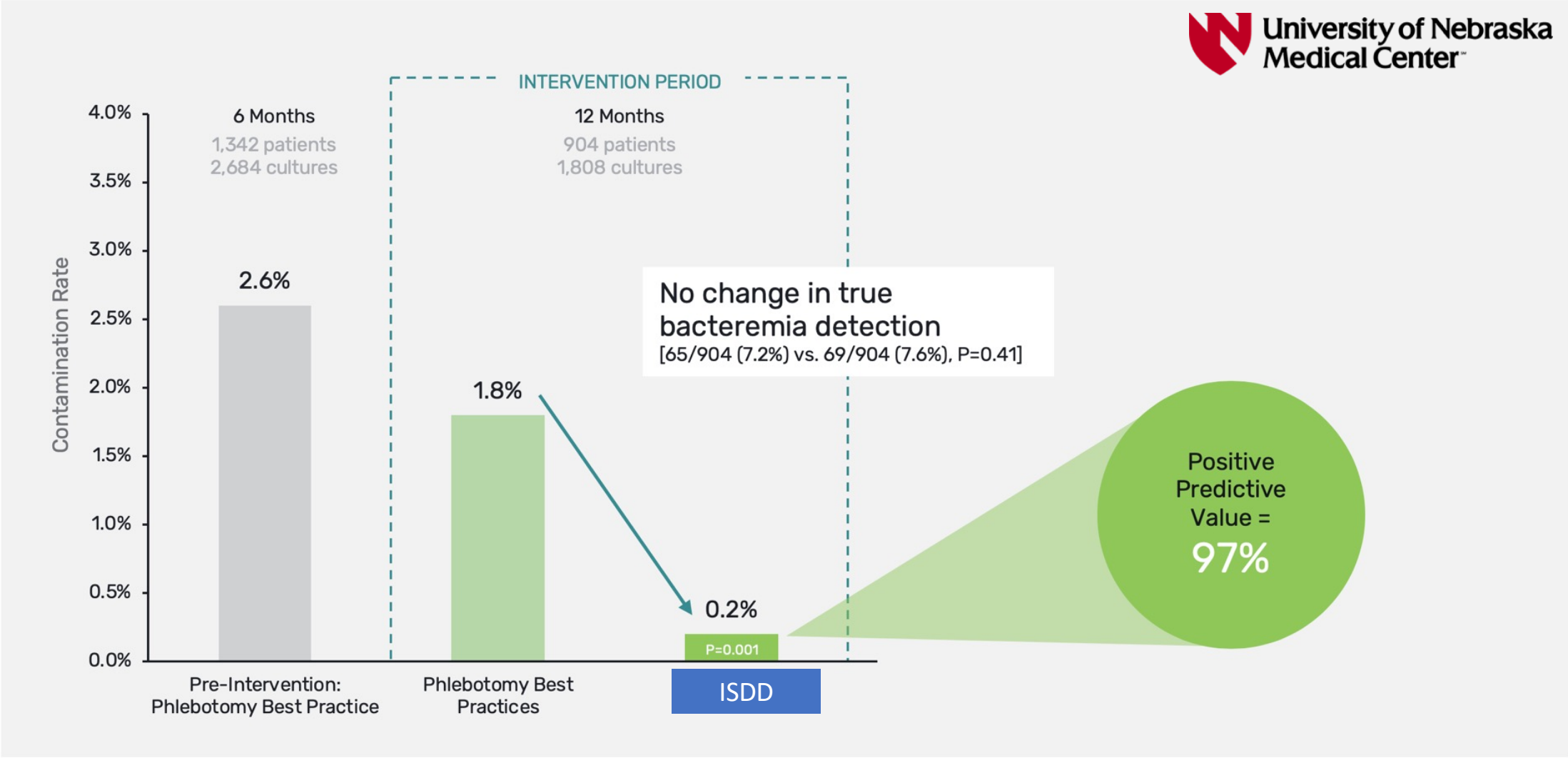


Skin Plug and Fragments
(uncontrollable factors)
will enter the culture specimen bottle and commonly will contain viable microorganisms (when present)

Active diversion of the **initial 1.5-2.0 mL of blood** using a closed system has been clinically proven to reduce blood culture contamination[2,3]

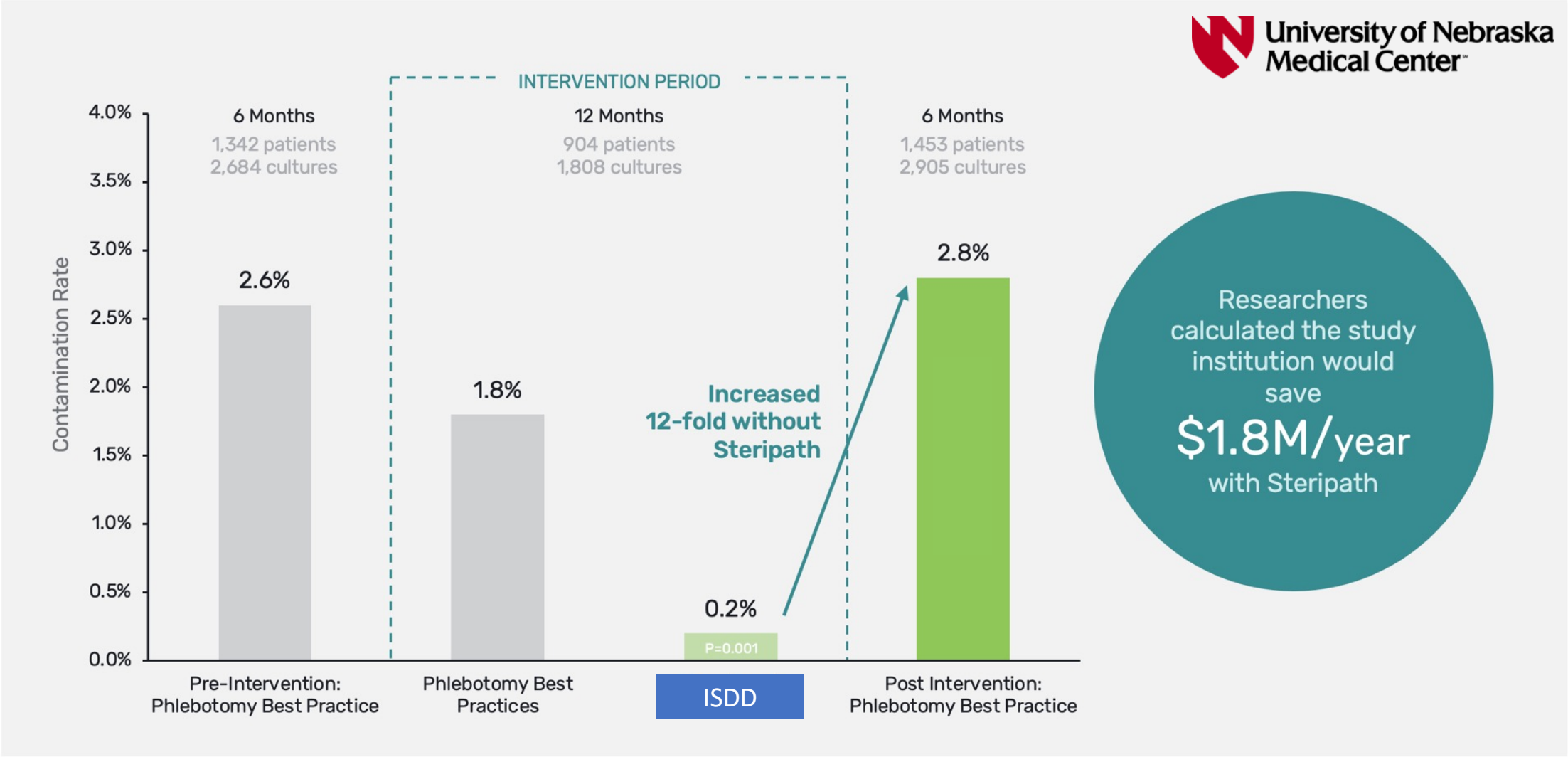
[1]Anjanappa T, Arjun A. Preparative skin preparation and surgical wound infection. J Evid Based Med. 2015;2(2):131-154. doi:https://doi.org/10.18410/jebmh/19. [2]Rupp ME, Cavalieri RJ, Marolf C, Lyden E. Reduction in blood culture contamination through use of Initial Specimen Diversion Device. Clin Infect Dis. 2017;65(2):201-205. doi:10.1093/cid/cix304. [3]Bell M, Bogar C, Plante J, Rasmussen K, Winters S. Effectiveness of a novel specimen collection system in reducing blood culture contamination rates. J Emerg Nurs. 2018;44(6):570-575. doi:10.1016/j.jen.2018.03.007.

Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device



Rupp ME, Cavalieri RJ, Marolf C, Lyden E. Reduction in blood culture contamination through use of Initial Specimen Diversion Device. Clin Infect Dis. 2017;65(2):201-205. doi:10.1093/cid/cix304.

Reduction in Blood Culture Contamination Through the Use of Initial Specimen



Rupp ME, Cavalieri RJ, Marolf C, Lyden E. Reduction in blood culture contamination through use of Initial Specimen Diversion Device. Clin Infect Dis. 2017;65(2):201-205. doi:10.1093/cid/cix304.

The End Game for Blood Culture Contamination and False-Positive CLABSIs

- ✓ ISDD diverts and sequesters both common commensal and non-common commensal skin-dwelling microorganisms
  - Common commensal organisms typically cause contamination
  - Non-common commensal organisms typically cause false-positive CLABSIs
- ✓ Zero blood culture contamination does not equal zero false-positive CLABSIs
- ✓ ISDD reduces both blood culture contamination and false-positive CLABSIs

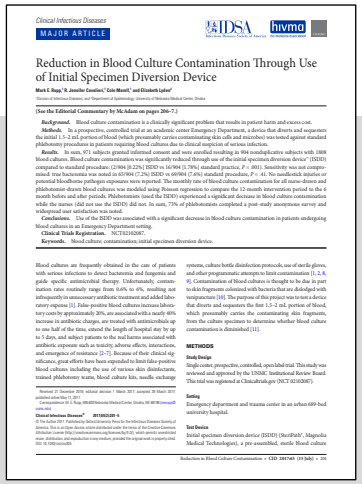
EBP and ISDD Deliver Optimized Patient Outcomes and CMS Reimbursement

ISDD:
Evidence Review and A Call for a New National Standard

APIC
Association for Professionals in Infection Control and Epidemiology

Evidence Review

Clinical Infectious Diseases
2017 (July)

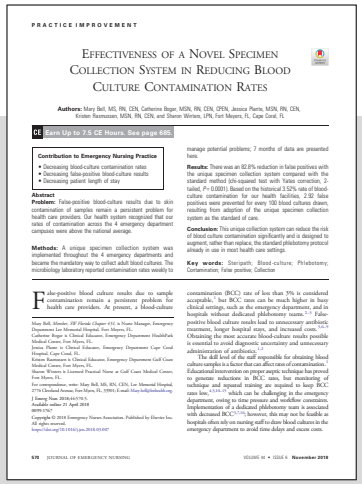


Clinical Infectious Diseases

MAJOR ARTICLE

Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device

Journal for Emergency Nursing
2018 (Nov)



PRACTICE IMPROVEMENT

Effectiveness of a Novel Specimen Collection System in Reducing Blood Culture Contamination Rates

Journal of Clinical Microbiology
2019 (Jan)

Estimated Clinical and Economic Impact through Use of a Novel Blood Collection Device To Reduce Blood Culture Contamination in the Emergency Department: a Cost-Benefit Analysis

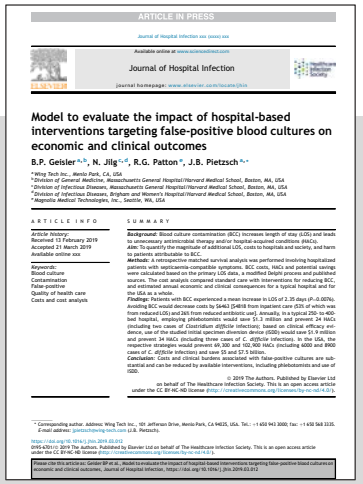
American Journal of Infection Control
2019 (Jan)

ARTICLE IN PRESS

American Journal of Infection Control

Reducing blood culture contamination using an initial specimen diversion device

Journal of Hospital Infection
2019 (Mar)



ARTICLE IN PRESS

Journal of Hospital Infection

Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures on economic and clinical outcomes

Journal for Emergency Nursing
2021 (Mar)

ARTICLE IN PRESS

PRACTICE IMPROVEMENT

Asynchronous Testing of 2 Specimen-Diversion Devices to Reduce Blood Culture Contamination: A Single-site Product Supply Quality Improvement Project

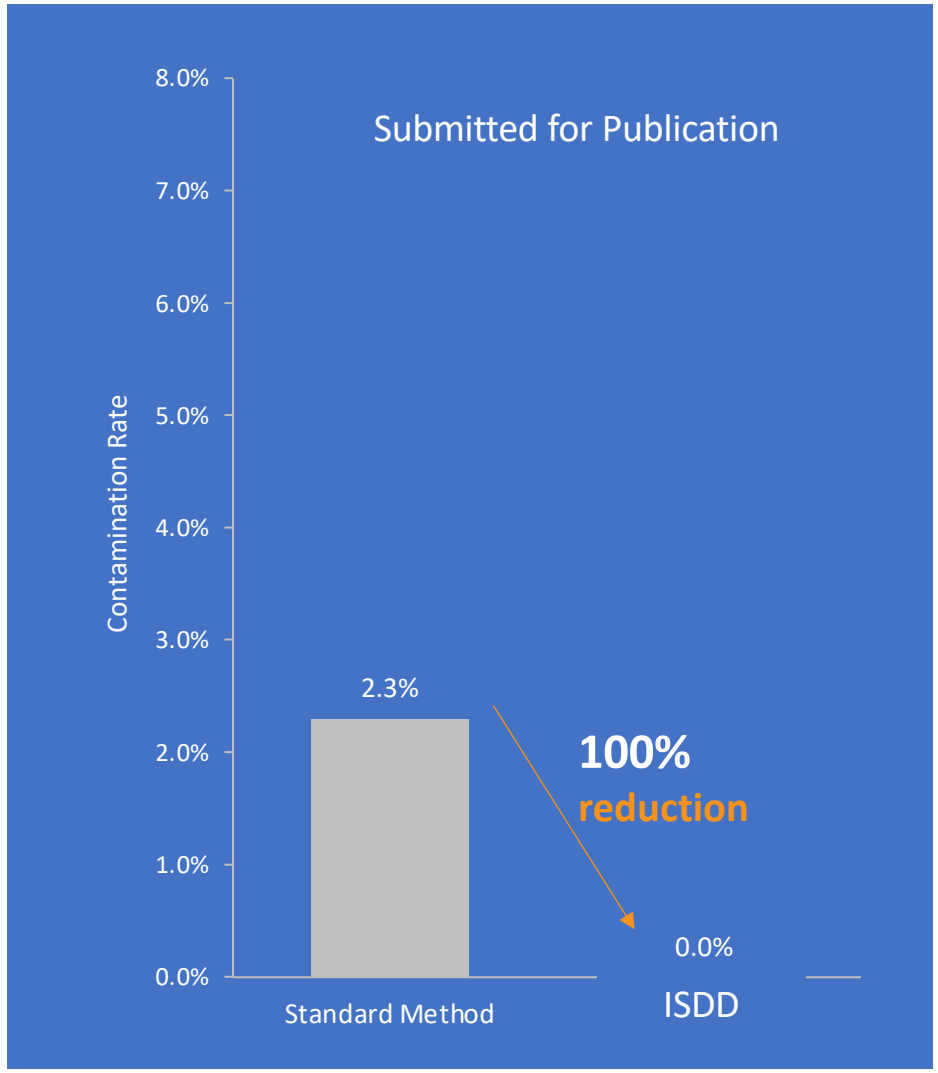
Journal of Hospital Infection
2021 (Nov)

Journal of Hospital Infection

Initial Specimen Diversion Device® reduces blood culture contamination and vancomycin use in academic medical centre

Getting to Zero

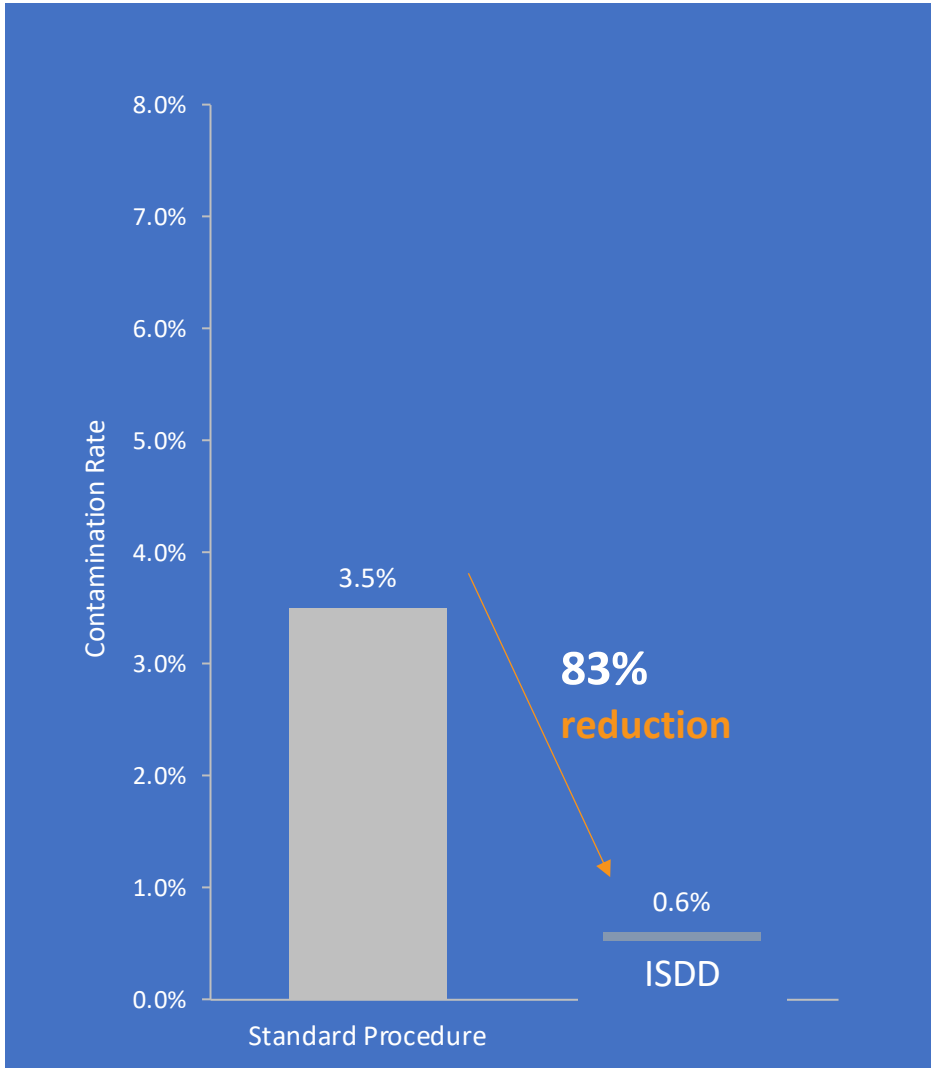
TITLE:	Getting to Zero: Impact of a Device ISDD to Reduce Blood Culture Contamination and False-Positive Central Line-Associated Bloodstream Infections
CONFERENCE	***IDWeek 2020 and PACCARB 2021***
INSTITUTE:	**Stanford Health Care**
AUTHORS:	Lucy Tompkins, MD, PhD, et al
DESIGN:	Single-center, prospective, controlled study March 2019–January 2020 (10-months)
METHOD:	Blood cultures were obtained **hospital-wide** by **Phlebotomy team** using the ISDD compared to standard method.
RESULTS:	**100%** reduction in blood culture contamination ISDD: **0.0% (0/11,202)** contamination rate Standard method: **2.3% (111/4,759)** contamination rate
	12-Fold decrease in NHSN/CMS reportable **False-Positive CLABSIs** ISDD: **1** Standard method: **12** **SIR** fell by **30-50%** when contaminants were removed



Tompkins LS, et al. Getting to zero: impact of a device to reduce blood culture contamination and false-positive central line-associated blood stream infections. Submitted to Clin Infect Dis in December 2021.

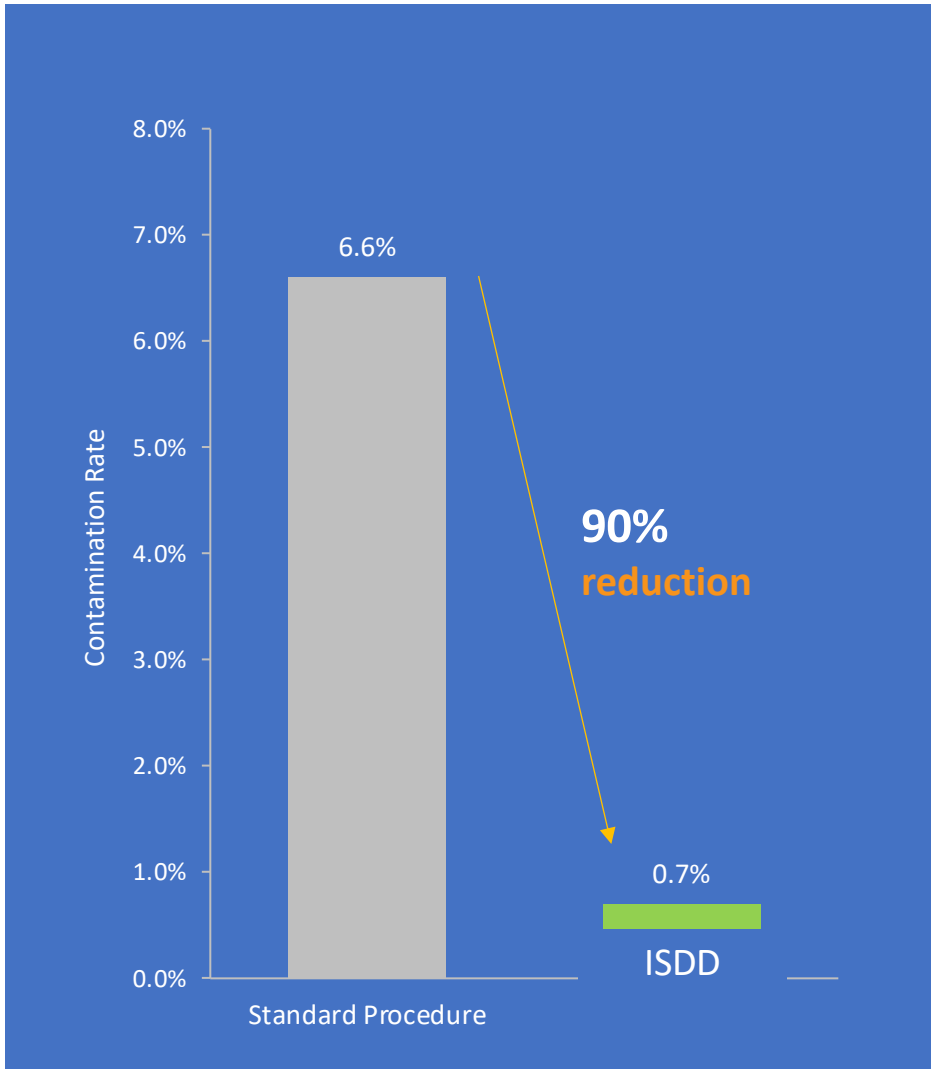
Peer-Reviewed Publication

TITLE:	Effectiveness of a Novel Blood Culture Collection System in Reducing Blood Culture Contamination Rates in the ED
PUBLICATION:	***Journal of Emergency Nursing*** **(2018)**
INSTITUTE:	**Lee Health** (**multi-center trial n=4**)
AUTHORS:	Mary Bell, MSN, RN, CEN, et al
AFFILIATIONS:	Department of Emergency Medicine
METHOD:	Blood cultures contamination rates with ISDD collected via **peripheral IV start** and **venipuncture** were compared with historical rates via standard method.
RESULTS:	**83%** reduction in contamination with ISDD ISDD: **0.6%** (38/**6,293**) contamination rate **(P=0.0001)** Standard procedure: **3.5%** (1,246/**35,392**) contaminate rate
SUMMARY:	Prevented **184** false-positive events **86%** of ISDD draws are via PIV starts Cost savings of **$641,792** during a 7-month trial period



Peer-Reviewed Publication

TITLE:	Initial Specimen Diversion Device® Reduces Blood Culture Contamination and Vancomycin Use in Academic Medical Center
PUBLICATION:	***Journal of Hospital Infection (2021)***
INSTITUTE:	**Brooke Army Medical Center**
AUTHORS:	Lindsey Nielsen, PhD, ASCP(M,MB), et al
AFFILIATIONS:	Pathology, Lab Services, Emergency Medicine, and Infectious Disease
DESIGN:	Single-center, prospective, open-label trial
METHOD:	Blood cultures were collected in the Emergency Department. Patients were randomized to either standard method or use of ISDD via **peripheral IV starts** and **venipuncture**.
RESULTS:	**90%** reduction in contamination with ISDD ISDD: **0.7%** (7/1,016) contamination rate (P=0.0001) Standard procedure: **6.6%** (53/800) contamination rate
SUMMARY:	ISDD was adopted as standard practice hospital-wide for eligible, (non-pediatric) patients.



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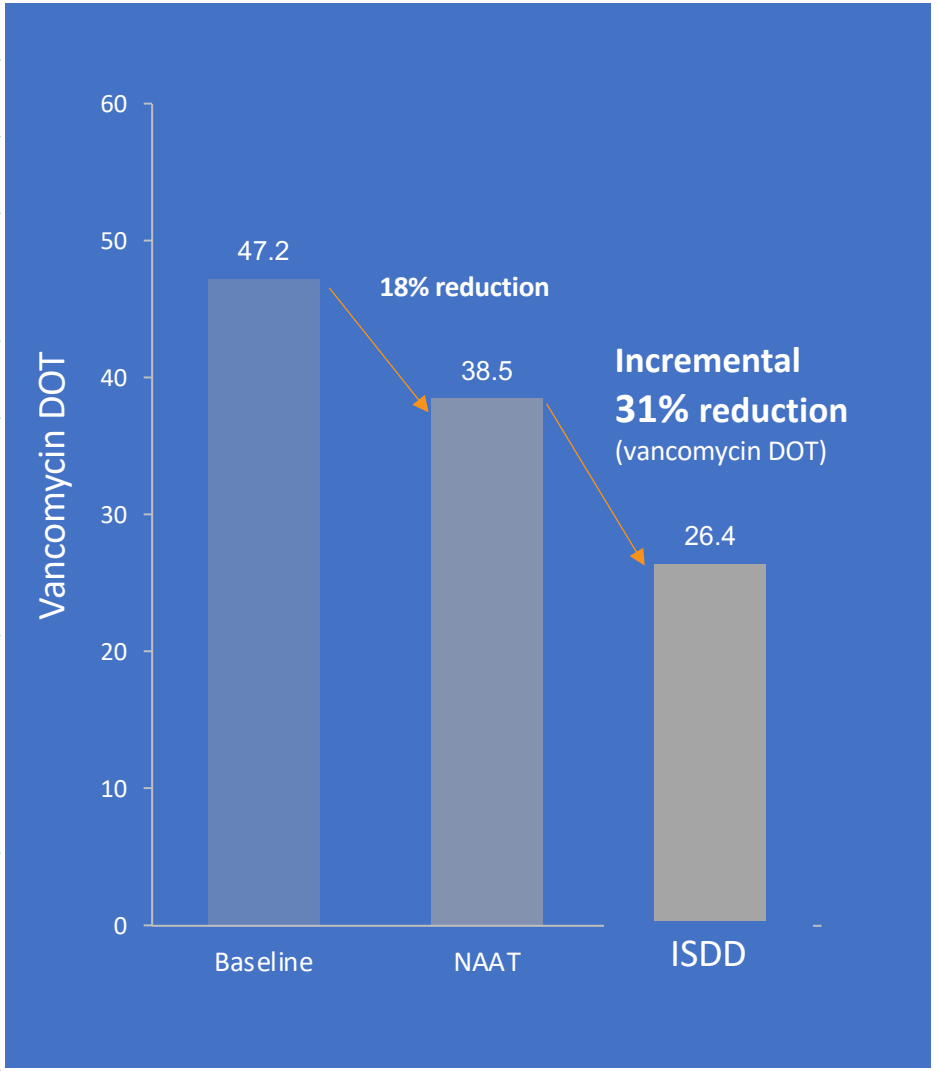
PUBLICATION:	***The Journal of Hospital Infection***
INSTITUTE:	**Brooke Army Medical Center**
AUTHORS:	Lindsey Nielsen, PhD, ASCP(M,MB), et al
AFFILIATIONS:	Pathology, Lab Services, Emergency Medicine, and Infectious Disease
DESIGN:	Single-center, retrospective, non-randomized
METHOD:	**Comparison of Vancomycin DOT** before/after interventions to reduce pathogen detection time (NAAT) and blood culture contamination ISDD in the ED. Hospital-wide vancomycin DOT collected through EMR.
RESULTS:	Vancomycin DOT per 1,000 patient days decreased 18% (47.2 +/-5.4 to 38.5 +/-13.3) after implementation of NAAT **ISDD** resulted in a **significant incremental decrease in vancomycin DOT by 31%** (38.5 +/-13.3 to 26.4 +/- 6.2)
SUMMARY:	Blood culture contamination rate was not significantly altered after implementation of rapid molecular PCR identification method. Reducing contamination with ISDD contributed to a significant reduction in unnecessary antibiotic therapy.



Peer-Reviewed Published Studies and Clinical Study Presentations at Major Medical Conferences

#	Institution	Publication or Conference Presentation	Date	Duration	Baseline or Control Rate	[redacted] Rate	BCC Reduction	Ann. Savings
1	**Stanford Health Care**	IDSA – IDWeek / PACCARB	2020/21	10 months	2.3%	**0.0%**	**100%**	NR
2	**Central Texas VA Medical Center**	Journal of Emergency Nursing	2021	5 months	2.2%	**0.0%**	**100%**	NR
3	**Univ. of Nebraska Medical Center**	Clinical Infectious Diseases	2017	12 months	1.8%	**0.2%**	**88%**	$1,800,000
4	**Baylor Scott & White Med Ctr.**	Emergency Nurses Association (ENA)	2021	4 months	3.2%	**0.2%**	**93%**	NR
5	**Kern Medical Center**	APIC - Submitted for publication	2021	18 months	2.4%	**0.4%**	**83%**	NR
6	**Lee Health System (4 sites)**	Journal of Emergency Nursing	2018	7 months	3.5%	**0.6%**	**83%**	$1,100,000
7	**Brooke Army Medical Center**	Journal of Hospital Infection	2021	6 months	6.6%	**0.7%**	**90%**	NR
8	**Medical Univ. of South Carolina**	Institute for Healthcare Improvement (IHI)	2016	8 months	4.2%	**0.6%**	**86%**	NR
9	**Rush University Medical Center**	IDSA - IDWeek	2017	3 months	4.3%	**0.6%**	**86%**	NR
10	**Inova Fairfax Hospital**	Emergency Nurses Association (ENA)	2019	12 months	4.4%	**0.8%**	**82%**	$932,000
11	**Regional Community Hospital**	Submitted for publication	2021	8 months	4.1%	**0.8%**	**81**	NR
12	**SCL St. Mary's Medical Center**	American Organization for Nursing Leadership (AONL)	2020	6 months	3.3%	**0.8%**	**76%**	NR
13	**Beebe Healthcare**	American Society for Microbiology (ASM)	2018	4 months	3.0%	**0.8%**	**75%**	NR
14	**Medical Univ. of South Carolina**	Institute for Healthcare Improvement (IHI)	2017	20 months	4.6%	**0.9%**	**80%**	$447,000
15	**Ascension Via Christi (3 sites)**	Society of Hospital Epidemiology of America (SHEA)	2021	3 months	4.3%	**0.9%**	**79%**	NR
16	**VA Houston**	Emergency Nurses Association (ENA)	2018	7 months	5.5%	**0.9%**	**83%**	NR
17	**Shaare Zedek Medical Center**	American Journal of Infection Control	2019	6 months	5.2%	**1.0%**	**81%**	NR
18	**Brooke Army Medical Center**	Journal of Hospital Infection	2021	14 months		**31% reduction in vancomycin DOT**		
19	**University of Houston**	Journal of Clinical Microbiology	2019	Steripath ISDD can save the hospital **2.0 bed days** and **$4,739 per false-positive** blood culture event				
20	**Mass General/ Harvard/ WingTech**	Journal of Hospital Infection	2019	Steripath ISDD can save the hospital **2.4 bed days**, **$4,817 per false-positive** blood culture event and **$1.9M annually and prevent 34 HACs including 3 C.*diff***				

National Peer-Reviewed Publication

Best Evidence-Based Project

Peripheral IV Start

Multi-Discipline Consensus Publication

January 2020

Standard of Care Initiative

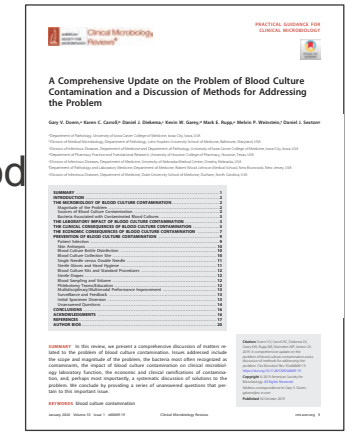
Gary Doern, PhD
Professor Emeritus, Dept of Pathology
University of Iowa
Former Editor-in-Chief, J Clin Micro

Dan Sexton, MD
Professor, Infectious Diseases
Duke University
Chair, Duke IC and AMS Outreach Network

AMERICAN SOCIETY FOR MICROBIOLOGY | Clinical Microbiology Reviews

Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem

Call-to-action: New National Blood Culture Contamination Benchmark of ***≤1.0%***



A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem

Melvin Weinstein, MD
Professor, Chief Infectious Diseases
Robert Wood Johnson University Hospital

Dan Diekema, MD
Professor, Director Infectious Diseases
University of Iowa Medical Center

Karen Carroll, MD
Professor, Director Div. Microbiology
Johns Hopkins University Medical Center

Kevin Garey, PharmD
Professor, Chair Pharmacy and Research
University of Houston College Pharmacy

Mark Rupp, MD
Professor, Chief Infectious Diseases
University of Nebraska Medical Center

Proposed New National Standard
for blood culture contamination

Standard of Care Initiative

benchmark for blood culture contamination rates in the U.S.

achieved by using Mechanical Initial Specimen Diversion Device

THE RIGHT 'STANDARD' FOR PATIENTS

CLSI M47 ED2-2021 (Proposed Draft)

Principles and Procedures for Blood Cultures January 2020

National Movement to 1%

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

"It should be possible to achieve blood culture contamination rates substantially lower than ***3%*** even if ***0%*** is not reached; when best practices are followed, a target contamination rate of ***1%*** is achievable."

Quality Indicator:

The benchmark for blood culture contamination rate is less than ***3%***, with a benchmark of ***1%*** with best practices."

U.S. Department of Veterans Affairs

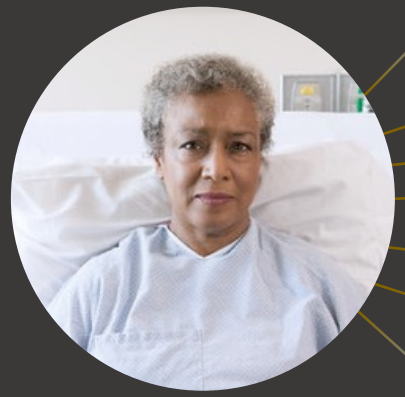
House of Representatives passage of H.R. 4355, Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2022 ("MILCON-VA") July 2021

Congressional Directive

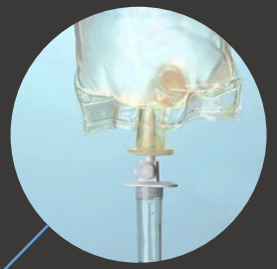
"The Committee directs VA to prioritize the development of a **specific quality measure** for blood contamination based on the recommendation of **less than 1%** blood culture contamination rate within 6 months of enactment.

VA is directed to report to the Committees on Appropriations of both Houses of Congress **within 180 days of enactment** of this Act detailing the implementation of this standard of care across the VA medical system."

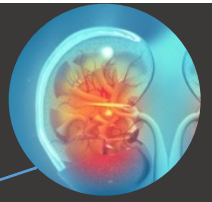
Diagnostic Safety and Stewardship with Blood Cultures Leads to Antimicrobial Stewardship and Quality Patient Outcomes



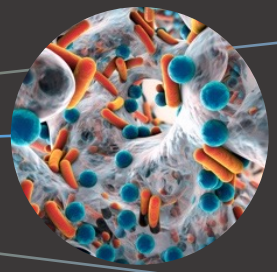
CORRECTLY DIAGNOSED PATIENT



Unnecessary Antibiotics

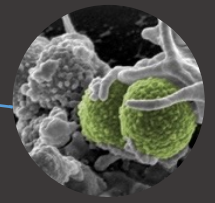


Acute Kidney Injury (AKI)

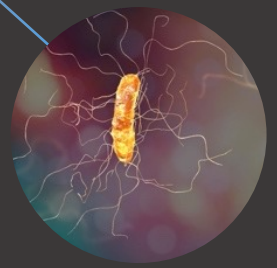


Antibiotic-Resistant Infection

Extended Length of Stay



Exposure to HAIs & HACs



Risk of *C. difficile*

False Positive CLABSIs

THANK YOU!

“The names of the patients whose lives we save can never be known. Our contribution will be what did not happen to them. And, though they are unknown, we will know that mothers and fathers are at graduations and weddings they would have missed, and that grandchildren will know grandparents they might never have known, and holidays will be taken, and work completed, and books read, and symphonies heard, and gardens tended that, without our work, would never have been.”

- Donald Berwick, MD, Founder of IHI