The Importance of Blood Culture Contamination as a Metric for Hospital Rate Improvement Program (HRIP)

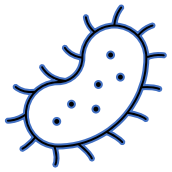
What if one practice change could…*

Empower Hospital Staff
Provided Patient Satisfaction and Quality Outcomes With Better Equitable Care and Reduced Costs
Enable Reimbursement for Services Provided

- ✓ Reduce unnecessary/prolonged antibiotic treatment
- ✓ Reduce the risk of *C.difficile*, MDROs, AKIs
- ✓ Reduce false-positive CLABSIs and MRSA
- ✓ Reduce unnecessary lab ID events
- ✓ Reduce unnecessary LOS and associated HAIs/HACs
- ✓ Reduce in-patient mortality
- ✓ Help meet CDC and The Joint Commission Antibiotic Stewardship Guidelines and CMS Star Ratings and mitigate BCC which CDC: calls a **"Patient Safety Event"**
- ✓ Help meet Magnet Requirements for Global Issues, Structural Empowerment, Transformational Leadership, New Knowledge Innovations and Improvement, Exemplary Professional Practice and Exceptional Empirical Outcomes
- ✓ Reduce laboratory and nursing labor
- ✓ Increase bed availability and throughput. NQF estimates **1,000,000 bed days** would open nationally if blood cultures were accurate
- ✓ Save the typical 250-400-bed hospital $1.9M annually (not inclusive of mitigation of FP CLABSIs, FP MRSA and CDI

Reducing blood culture contamination achieves all

The Purpose of Blood Cultures. *



Confirm

the presence of microorganisms in the bloodstream

Identify

the microbial etiology of the bloodstream infection

Help

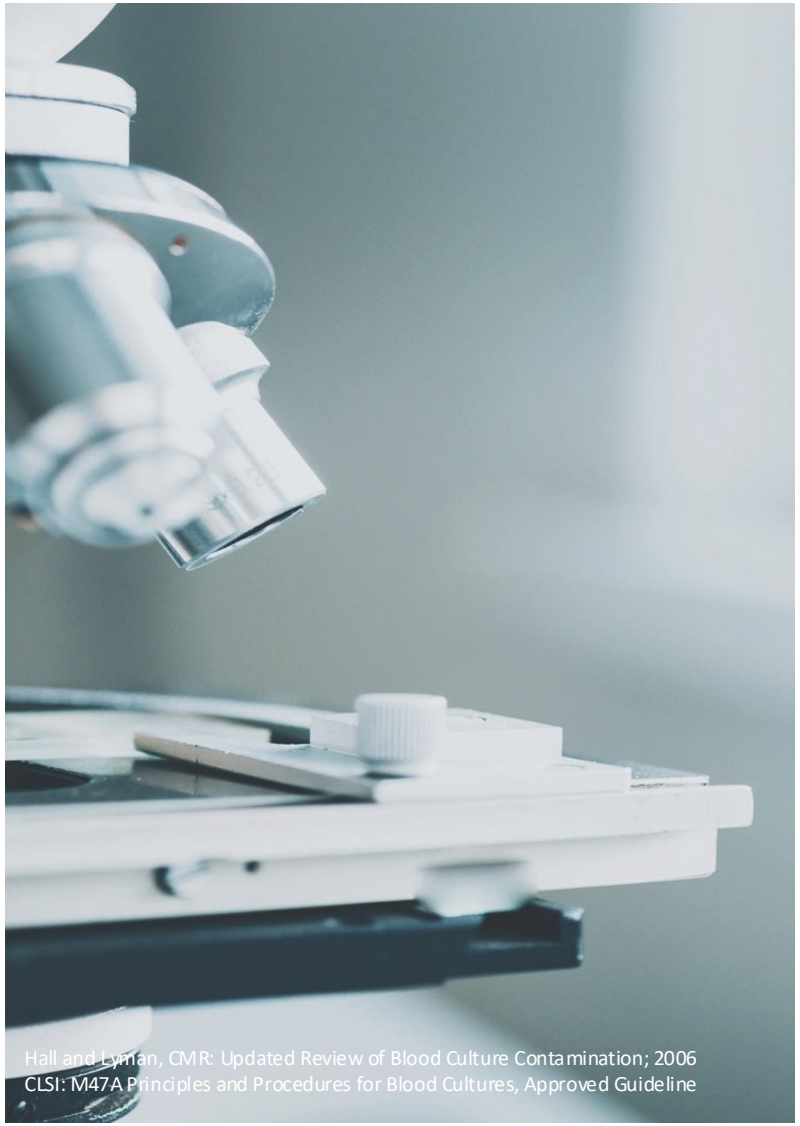
determine the source of infection (e.g., endocarditis)

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 set when two sets are obtained**
- 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 out of two sets obtained**
- **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

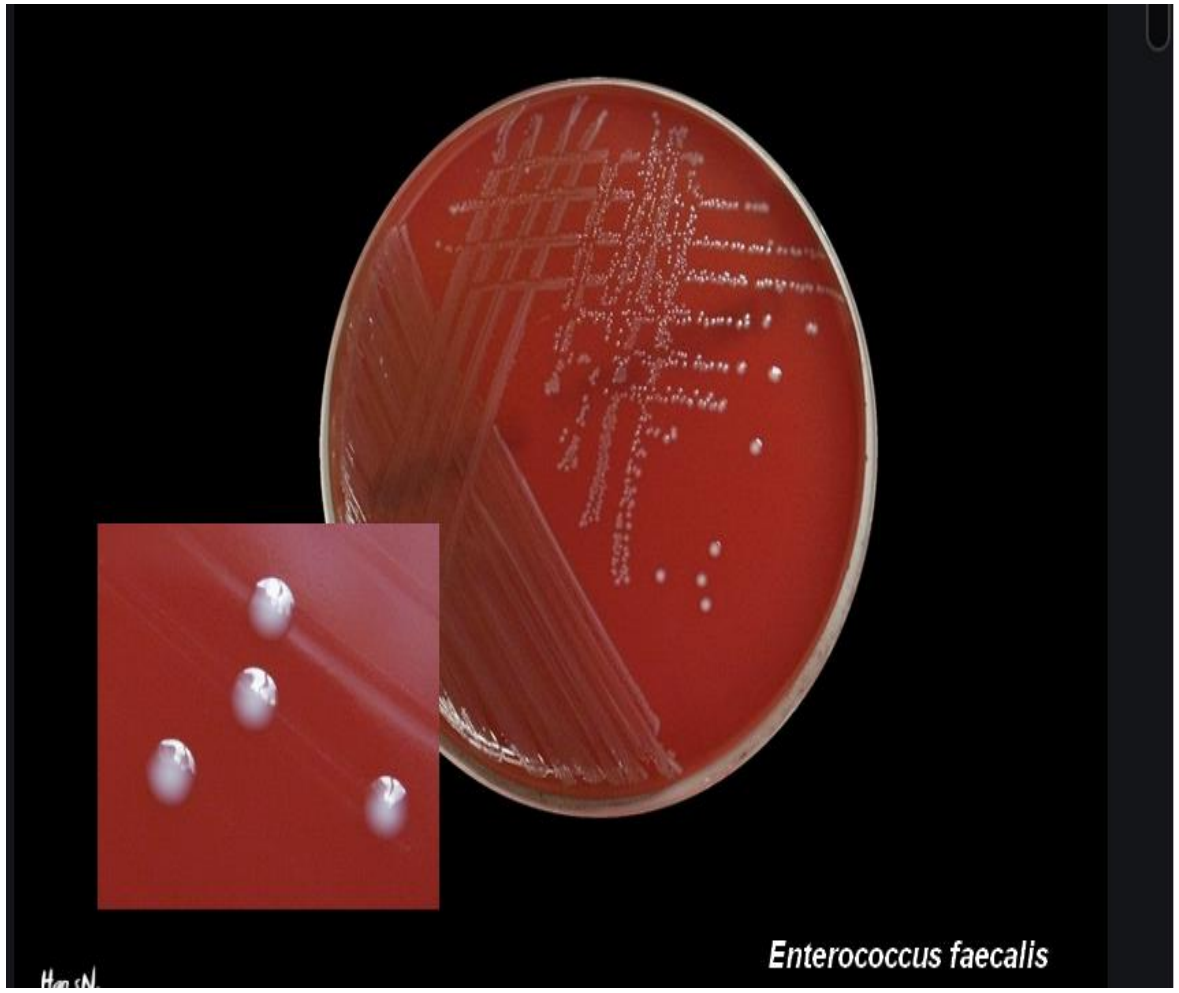
Identity of the Organism

- 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

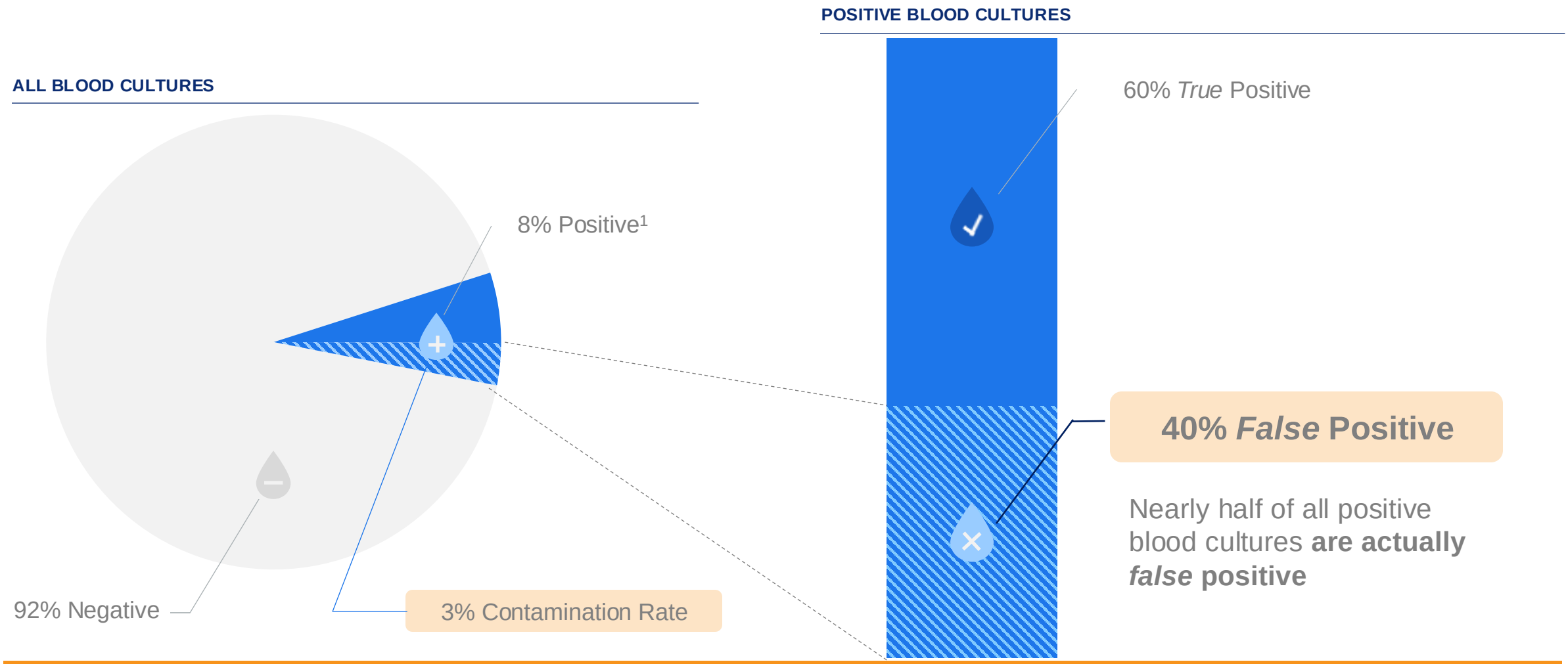
"These organisms may be considered contaminants unless recovered from multiple Blood cultures obtained in sequence, in which case, careful assessment of patients and additional laboratory information is required in defining significance (or lack thereof)" Doern

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



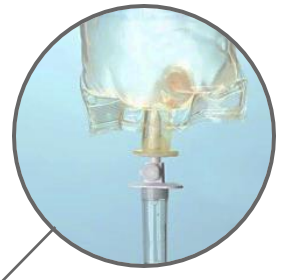
Test Results From Blood Cultures are Frequently Wrong *



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

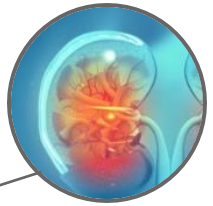
[1]Zwang O, Albert RK. Analysis of strategies to improve cost effectiveness of blood cultures. J Hosp Med. 2006;1(5):272-6. doi:10.1002/jhm.115.

False-positive blood cultures increase many harmful patient. * safety risks and CDC calls contaminated blood cultures a patient safety event.



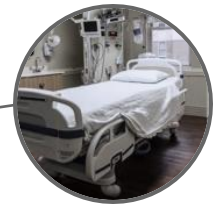
Unnecessary Antibiotics

200,000 extra **courses** of antibiotics.



Acute Kidney Injury (AKI)

Incidence 36-40% w Vancomycin and Zosyn

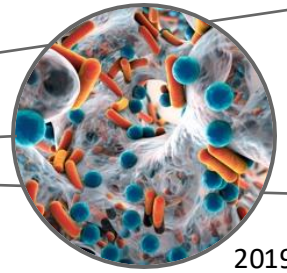


Extended Length of Stay

Avg. 2.2 days

Misdiagnosed Patient

Avg. 40% of positive blood cultures
Blood culture contamination is inequitable



Antibiotic-Resistant Infections

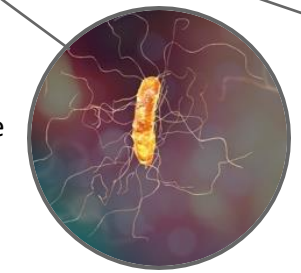
2019 US: 172,900 deaths associated with AMR
2019 US: 41,900 deaths attributable to AMR

Exposure to HAIs & HACs

Incidence 1/31 patients
10%-25% mortality
33% have a 30-day readmission

False-Positive CLABSIs

Incidence 30-45% of all CLABSIs



Risk of C. *difficile*

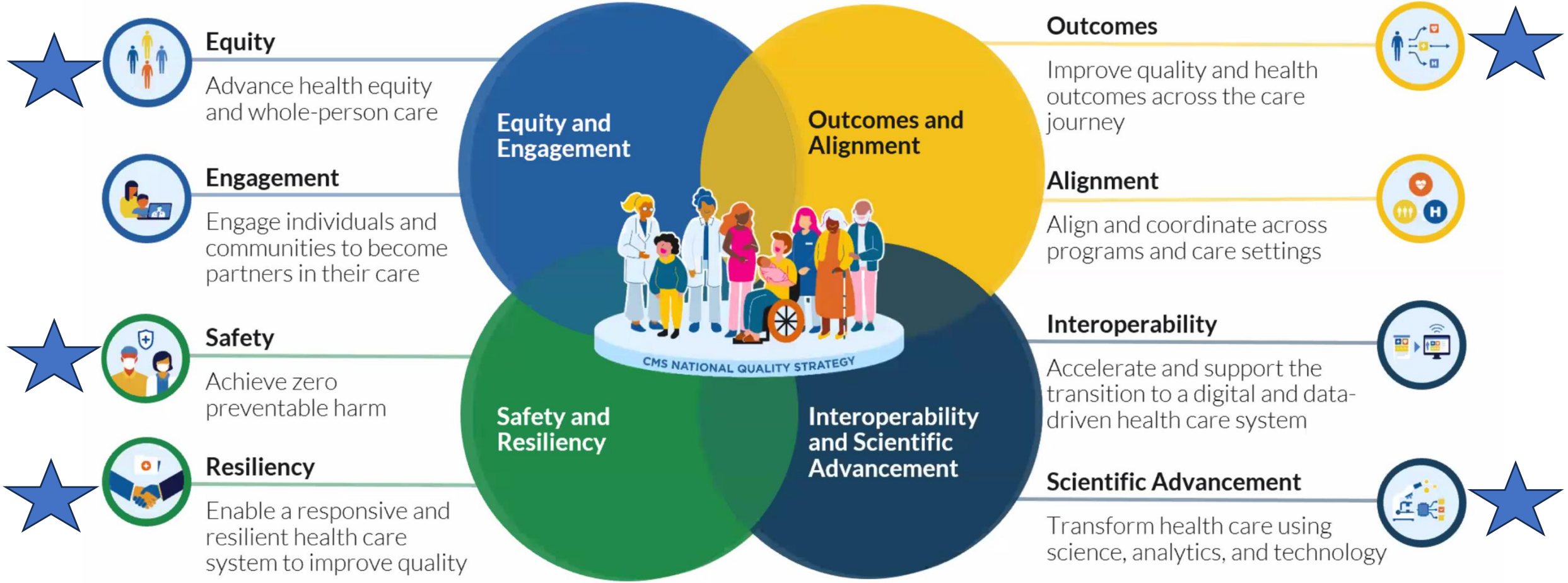
Reducing risk of high-risk broad-spectrum antibiotics by 30% could lower CDI by 26%
We still lose ~13,000 Americans each year within the first 30 days of onset

Increased Mortality

Increase of 74% in patient mortality 4.6% to 8%

CMS National Quality Strategy Goals

The Eight Goals of the CMS National Quality Strategy are Organized into Four Priority Areas:



Equity

Advance health equity and whole-person care

Engagement

Engage individuals and communities to become partners in their care

Safety

Achieve zero preventable harm

Resiliency

Enable a responsive and resilient health care system to improve quality

Outcomes

Improve quality and health outcomes across the care journey

Alignment

Align and coordinate across programs and care settings

Interoperability

Accelerate and support the transition to a digital and data-driven health care system

Scientific Advancement

Transform health care using science, analytics, and technology

AKI and Health Equity

"AKI is the **most clinically significant** adverse drug reaction reported with antibiotics, and **risk may be as high as 36%**."

Results: University of Arkansas; ICHE "The patients most at risk for contamination were of older age, black race, higher BMI, and had comorbidities such as CHF, COPD, and paralysis. **Black patients were disproportionately at increased risk for blood-culture contamination (aOR, 1.32; 95% CI, 1.15–1.51), whereas white patients demonstrated a protective trend."**

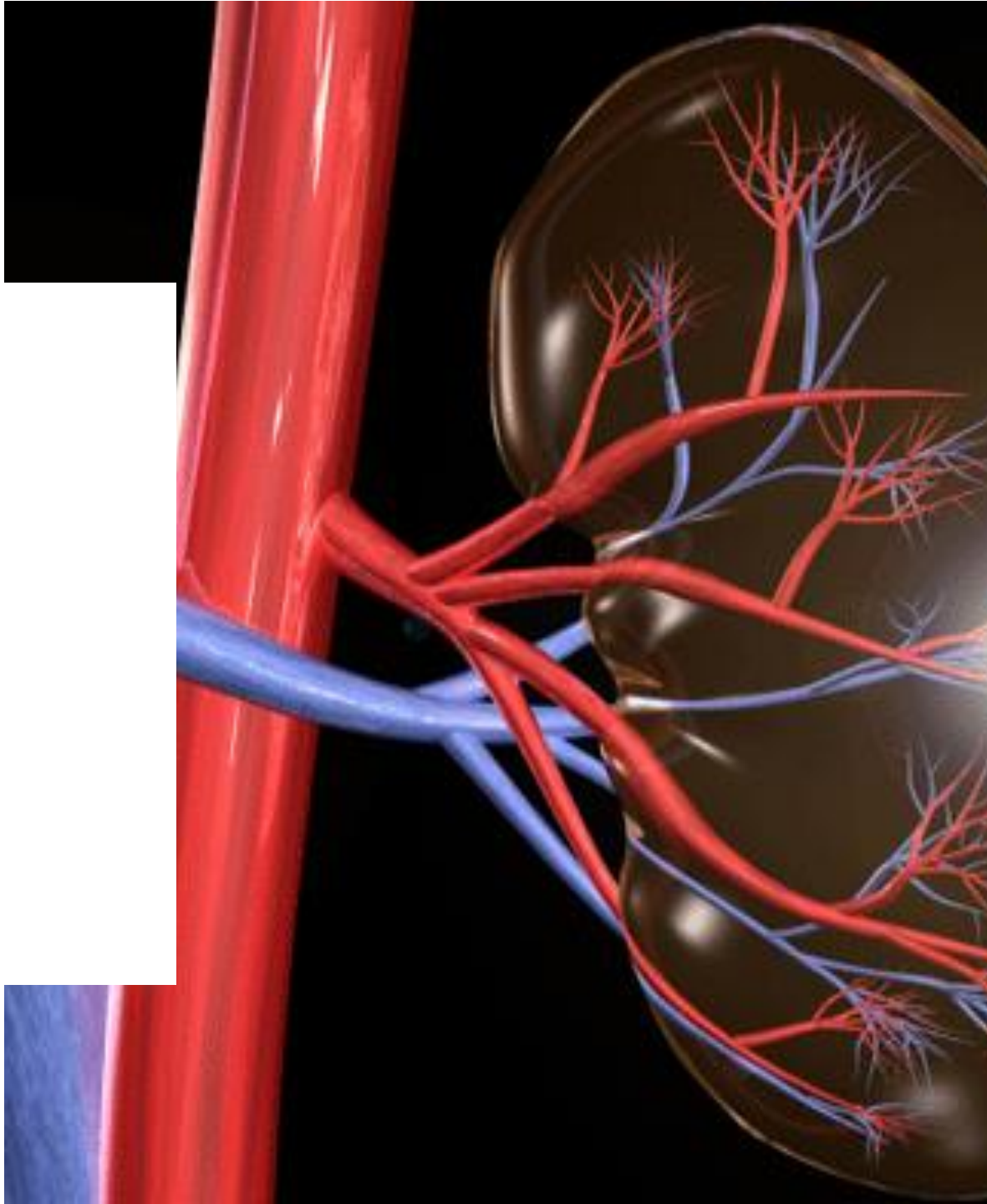
After controlling for age, race, BMI, comorbidities, and sepsis
blood-culture contamination increased… **Acute kidney injury**
40% higher risk

New IPPS/ e-Quality Reporting 2025 AKI Adding 15 new health equity categorizations for FY2024 payment impacts. Secondary to Equitable Care and higher incidence of AKI in Black hospitalized patients

"Hospitals that fail to submit quality data or to meet all Hospital IQR Program requirements are subject to a one-fourth reduction in their Annual Payment Update under the IPPS.

Hospital Harm — Acute Kidney Injury eCQM, with inclusion in the eCQM measure set beginning with the CY 2025 reporting period/FY 2027 payment determination

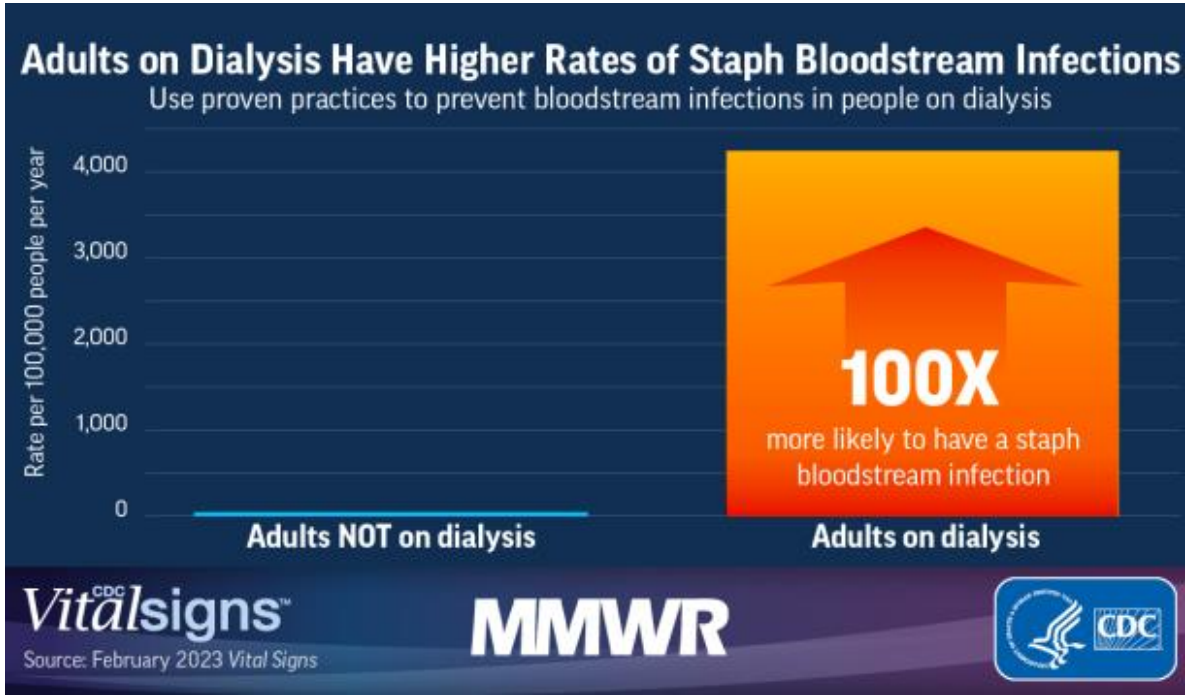
CMS believes the adoption of the Hospital Harm-AKI and Hospital Harm-PI eCQMs will support CMS' goal of advancing health equity. AKI is more common in Black hospitalized patients than non-Black patients"



BSI Causation Secondary to Broad-Spectrum Antibiotics

The Impact

- Prolonged **Vancomycin and Zosyn** leads to a **36-40%** risk of **AKI**[1]
- **AKI** can lead to **hemodialysis (30%)**
- Adults on dialysis are **100 times** more likely to have a **Staph Bloodstream Infection**[2]

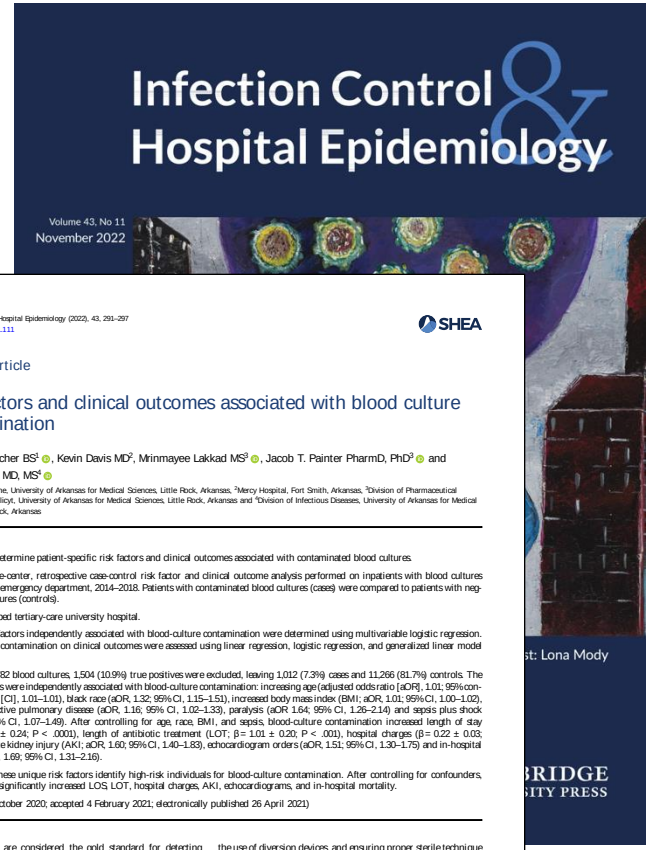


[1]Khalili H, Bairami S, Kargar M. Antibiotics induced acute kidney injury: incidence, risk factors, onset time and outcome. Acta Med Iran. 2013;51(12):871-8.
[2]Rha B, See I, Dunham L, et al. *Vital Signs:* Health Disparities in Hemodialysis-Associated *Staphylococcus aureus* Bloodstream Infections — United States, 2017–2020. MMWR Morb Mortal Wkly Rep 2023;72:153–159. DOI: http://dx.doi.org/10.15585/mmwr.mm7206e1.

Risk of In-Patient Mortality Increases 74% Due to Blood Culture Contamination

“

Significant, near doubling (8% vs 4.6%) of in-patient mortality rate for patients that had contaminated blood cultures vs. the true negative blood culture control group”



Infection Control & Hospital Epidemiology (2022), 43, 291–297
doi:10.1017/ice.2021.111

SHEA

Original Article

Risk factors and clinical outcomes associated with blood culture contamination

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Abstract

Objective: To determine patient-specific risk factors and clinical outcomes associated with contaminated blood cultures.

Design: A single-center, retrospective case-control risk factor and clinical outcome analysis performed on inpatients with blood cultures collected in the emergency department, 2014–2018. Patients with contaminated blood cultures (cases) were compared to patients with negative blood cultures (controls).

Setting: A 509-bed tertiary-care university hospital.

Methods: Risk factors independently associated with blood-culture contamination were determined using multivariable logistic regression. The impacts of contamination on clinical outcomes were assessed using linear regression, logistic regression, and generalized linear model with γ log link.

Results: Of 13,782 blood cultures, 1,504 (10.9%) true positives were excluded, leaving 1,012 (7.3%) cases and 11,266 (81.7%) controls. The following factors were independently associated with blood-culture contamination: increasing age (adjusted odds ratio [aOR], 1.01; 95% confidence interval [CI], 1.01–1.01), black race (aOR, 1.32; 95% CI, 1.15–1.51), increased body mass index (BMI; aOR, 1.01; 95% CI, 1.00–1.02), chronic obstructive pulmonary disease (aOR, 1.16; 95% CI, 1.02–1.33), paralysis (aOR 1.64; 95% CI, 1.26–2.14) and sepsis plus shock (aOR, 1.26; 95% CI, 1.07–1.49). After controlling for age, race, BMI, and sepsis, blood-culture contamination increased length of stay (LOS; β = 1.24 ± 0.24; P < .0001), length of antibiotic treatment (LOT; β = 1.01 ± 0.20; P < .001), hospital charges (β = 0.22 ± 0.03; P < .0001), acute kidney injury (AKI; aOR, 1.60; 95% CI, 1.40–1.83), echocardiogram orders (aOR, 1.51; 95% CI, 1.30–1.75) and in-hospital mortality (aOR, 1.69; 95% CI, 1.31–2.16).

Conclusions: These unique risk factors identify high-risk individuals for blood-culture contamination. After controlling for confounders, contamination significantly increased LOS, LOT, hospital charges, AKI, echocardiograms, and in-hospital mortality.

(Received 27 October 2020; accepted 4 February 2021; electronically published 26 April 2021)

Blood cultures are considered the gold standard for detecting bloodstream infections; they facilitate prompt and directed antimicrobial therapy for patients with sepsis.[1–4] However, false-positive blood culture results can lead to inappropriate clinical evaluation and treatment, leading to unnecessary patient risk.[2,5–7] Blood culture contamination with skin microflora is believed to be the primary cause of false-positive blood culture results; however, needle contamination and collector contamination have also been implicated.[2,8,9] Reported institutional blood-culture contamination rates vary significantly, from 0.6% to 10%, and the Clinical Laboratory Standards Institute recommends that institutions strive to achieve a contamination rate <3%.[2,4] Efforts to reduce blood-culture contamination include the use of dedicated phlebotomists, the use of diversion devices, and ensuring proper sterile technique when collecting cultures.[2,4,7–15]

Reported risk factors associated with blood-culture contamination include poor collection method, staff competency, increased patient age, presence of comorbidities, and patient illness severity.[2–5,16,17] However, most of the relevant studies are relatively small, are performed over short periods, or focus on provider-specific risk factors rather than patient-specific risk factors. Additionally, with the introduction of the Centers for Medicare and Medicaid Services sepsis core measure (SEP-1),[18–21] the practice of "code sepsis" in emergency departments to expedite blood culture collection is increasing. Although this intervention likely improves time to antibiotic administration, it may compromise sterile technique, which worsens contamination rates. Since the introduction of code sepsis at our institution, emergency-department blood-culture contamination rates have increased to >6%.

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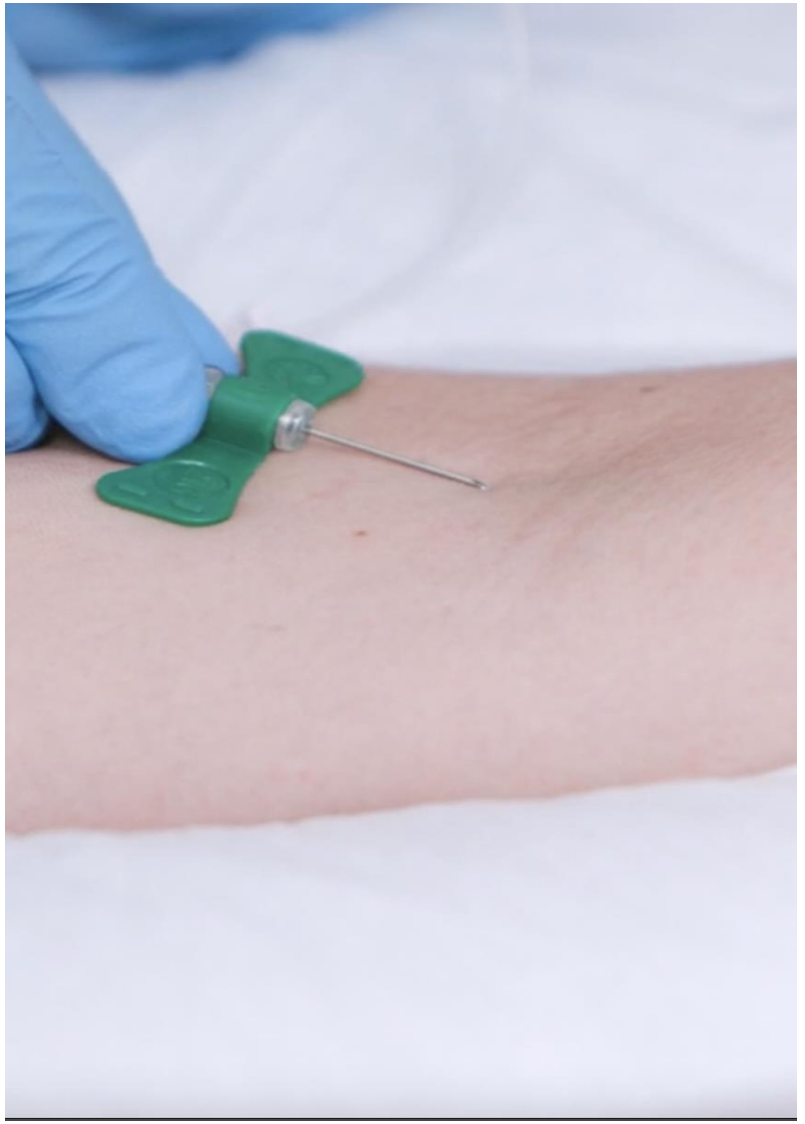
Cite this article: Klucher JM, et al. (2022). Risk factors and clinical outcomes associated with blood culture contamination. Infection Control & Hospital Epidemiology, 43: 291–297, https://doi.org/10.1017/ice.2021.111

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. **Gram positive organisms. Required aerobic volume (3 bottles)**
- 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 or other studies completed to show origin of infection



False-Positive CLABSI Reporting

42% of reported CLABSIs represented contaminants”[1]

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

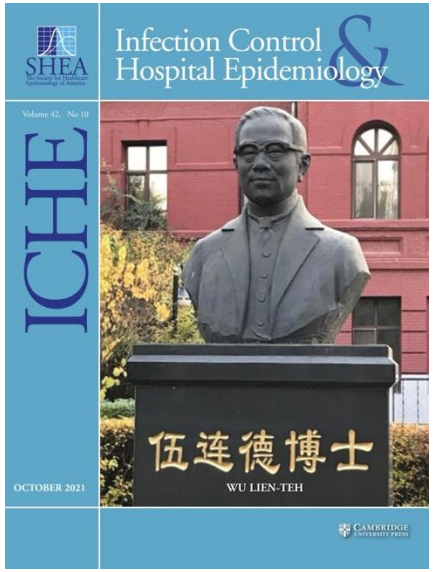
45% of reported CLABSIs most likely represented contaminated blood cultures rather than true CLABSIs”[3]

[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. ICHE Sept.2023

[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.

Clinical Infectious Diseases



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

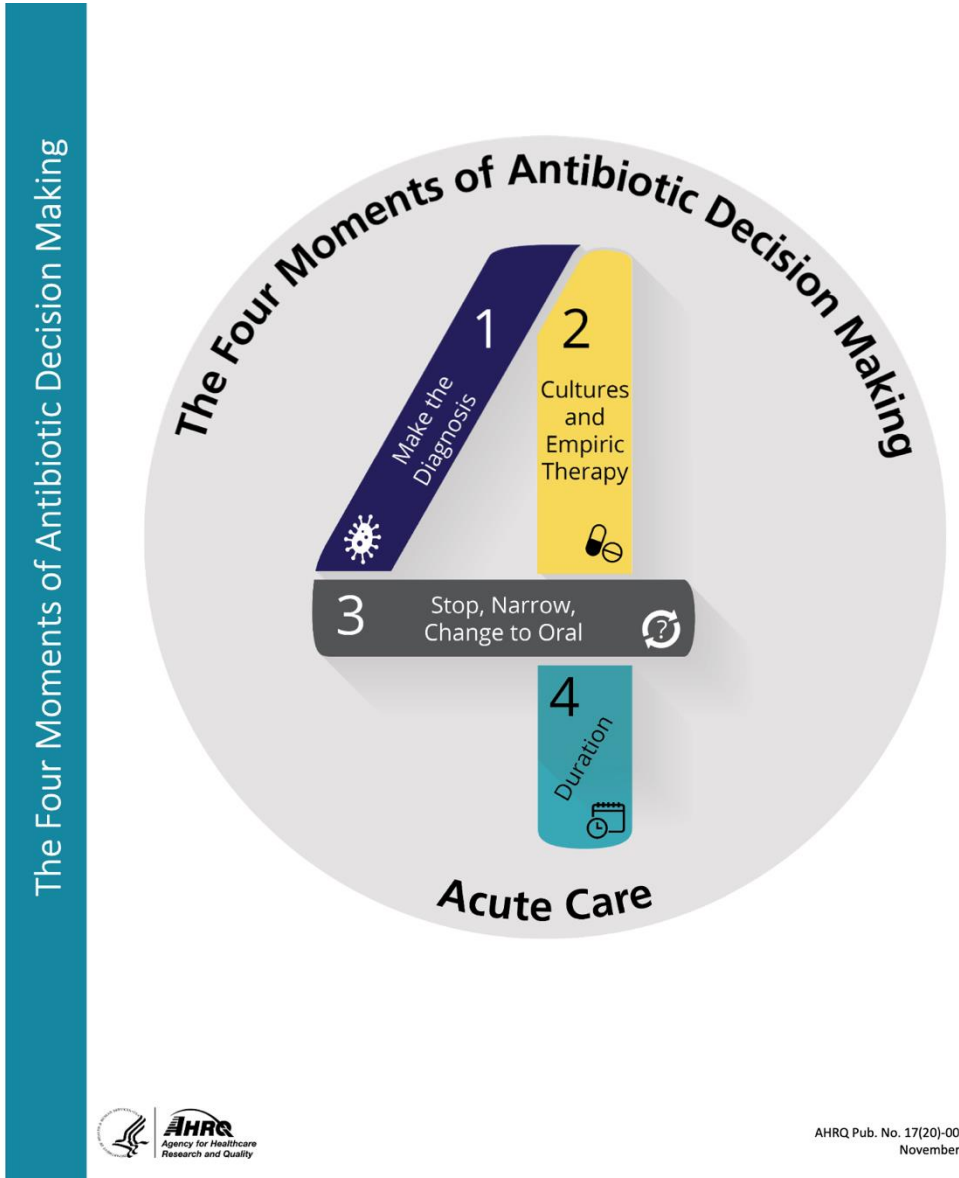
Our Two “Go To” Antibiotics for Sepsis

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

Diagnostic Stewardship can help reduce both

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.

Agency for Healthcare Research and Quality



AHRQ Pub. No. 17(20)-0028-EF
November 2019

Hospitals report HACs to NHSN

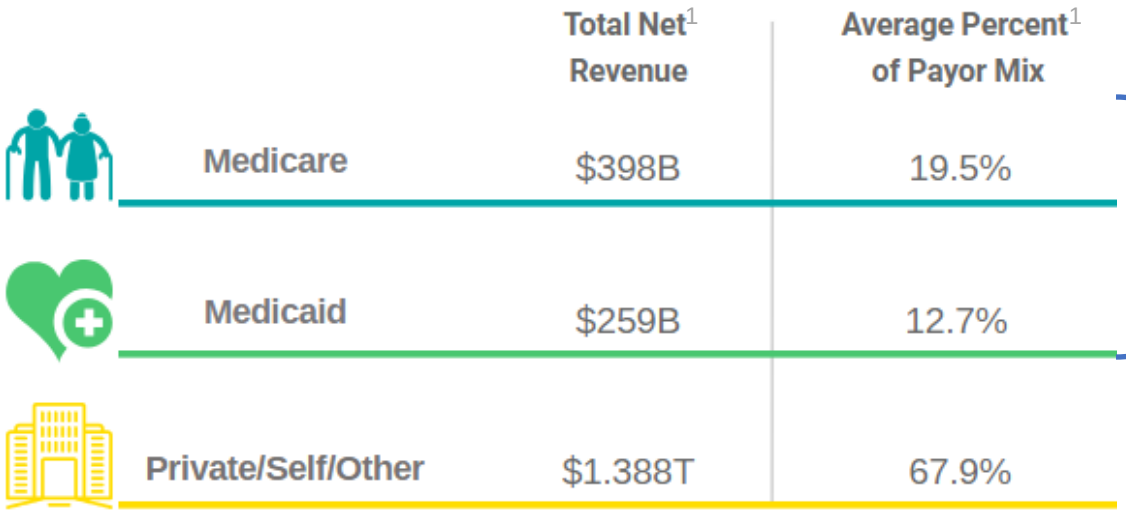
- CAUTI
- SSI
- CLABSI
- *C. difficile*
- MRSA BSI

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

- National SIR for CLABSIs increased 46% / 47% during COVID (24% 2020 average increase)
  (Q3/Q4 '20 vs. Q3/Q4 '19)[1] AND remained 7% higher than pandemic levels for 2021. 2022 had a 9% decrease still leaving us at a 22% average increase over pre-pandemic levels. **2023 had a 15% decrease and we remain 7% over pre-pandemic rates**
- National SIR for MRSA increased 23% / 34% during COVID (15% 2020 average increase)
  (Q3/Q4 '20 vs. Q3/Q4 '19[1] AND remained 14% higher than pandemic levels for 2021. 2022 saw a 16% decrease still leaving us at an average 13% increase over pre-pandemic levels. **2023 had a 16% decrease making us finally below our pre-pandemic rates**
- **AKI started and HOB coming soon**

[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.
CDC 2023 HAI Progress Report

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 –It's back!

- ***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-It's back!

- ***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

* Using 2015 AHRQ Data Published in 2017

AJIC 2024 https://doi.org/10.1016/j.ajic.2024.07.014
CLABSI,CAUTI, SSI cost and LOS increased 150% 2019-2024

CMS Star Ratings

- Measures across 5 Quality Areas into a Star Rating for each hospital
- Hospitals report to CMS via Inpatient and Outpatient Quality Reporting Program, Readmission Reduction Program, Hospital Acquired Condition, and VBP Program
- It is a weighted measure for each group
- Began July 2023
- First calculation July 2024
- These Star Ratings affect the hospital's Value Based Purchasing Score, HAC Score, Readmissions and IQR Score

Measures and Weighting for Star Ratings

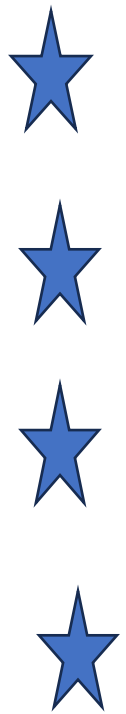
Measure group	Weight used in calculation
Mortality	22%
Safety	22%
Readmission	22%
Patient Experience	22%
Timely & Effective Care	12%

MRSA, CDI, CLABSI

All Cause Readmission Rate

Rating of who would recommend hospital to family and friends

Time in ED, those who left Without being seen, those who Received timely and effective care for Sepsis



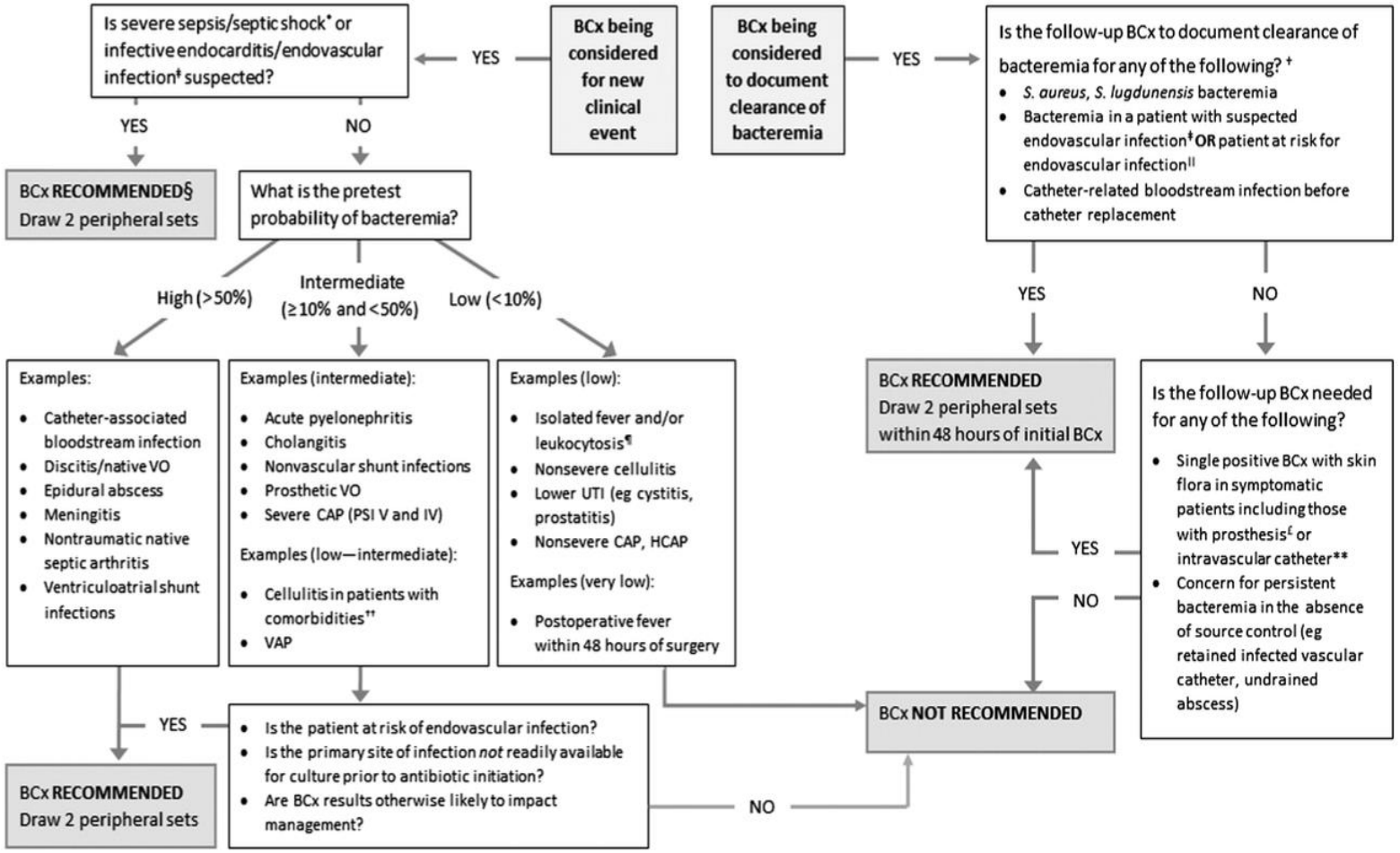
Solution:

Evidence Based Technique and Technology lead to Diagnostic Stewardship, Antimicrobial Stewardship and Quality Patient Outcomes

Patient Selection	Blood cultures should only be performed in patients with a reasonable likelihood of bacteremia/fungemia.
Skin disinfection	Use a CHG and alcohol-containing disinfectant to scrub the phlebotomy site; adhere to recommended scrub and dry times
Blood Culture Bottle Top Disinfection	Disinfect blood culture vial caps with alcohol for 15 seconds
Consideration	Leave an IPA or sterile pad on top of the BC bottle, to protect from environmental contaminants, until ready to inoculate with blood. IPA typically takes 5 seconds to dry
Phlebotomy Site	Don't draw blood cultures through indwelling vascular catheters unless the catheter is thought to be the source of infection. In that case, replace NC and draw via new NC, consider draw from each lumen. Do not waste, understand locking solution may interfere with results. Draw a second set from a peripheral venipuncture. Consider differential time to positivity. Send to lab within 2 hours, do not refrigerate sample
Sets	Always draw two sets from **different** sites. Always draw blood cultures first and prior to antibiotics
Volume	I**s the single most important factor for organism detection**. Draw volume per bottle IFU
Standardized Kits	Use of standardized kits and procedures has proven helpful in preventing contamination
Phlebotomy Teams	Educate and train individuals who perform blood cultures in aseptic technique
Surveillance and Feedback	Monitor blood culture contamination and provide data to individuals and patient care units
Multidisciplinary Teams	Sustained improvement in blood culture contamination is best achieved through a team approach.
Initial Specimen Diversion Device	Divert and discard > 1mL of initial sample. Use of ISDD has been shown to decrease contamination rates to less than 1%.

Gorski LA, Hadaway L, Hagle ME, et al. Infusion therapy standards of practice, 8th edition. J Infus Nurs. 2021 Jan-Feb 01;44(1S Suppl 1): S1-S224.doi: 10.1097/NAN.0000000000000396 ENA Clinical Practice Guidelines
Doern GV, Carroll KC, Diekema DJ, et al. Practical guidance for clinical microbiology laboratories: a comprehensive update on the problem of blood culture contamination and a discussion of methods for addressing the problem. Clin Microbiol Rev. 2020;33(1):e00009-19. doi: 10.1128/CMR.00009-19.
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.
Novak S, Dunne WM. Blood Culture: a key investigation for diagnosis of bloodstream infections. bioMerieux
CLSI. Principles and Procedures for Blood Cultures; Approved Guidelines. CLSI document M47-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.

Algorithm for bacterial blood cultures in nonneutropenic inpatients



Efficacy of using an algorithm Sept 2024 AJIC

Valeria Fabre et al. Does This Patient Need Blood Cultures? A Scoping Review of Indications for Blood Cultures in Adult Nonneutropenic Inpatients, Clinical Infectious Diseases 2020:71 September

Theophalus, R. Blood culture algorithm implementation in emergency department patients as a diagnostic stewardship intervention. American Journal of Infection Prevention May 2024 https://doi.org/10.1016/j.ajic.2024.04.198

Evidence-Based Checklist for Adult Peripheral Blood Culture Collection Summary

Look to Process Discovery Tool

- ❑ Utilize astute patient selection and check order.
- ❑ Identify and inform patient.
- ❑ Ensure environmental surfaces used are disinfected.
- ❑ Perform hand hygiene. Use aseptic non touch technique throughout entire process.
- ❑ Mask self and patient.
- ❑ Prepare to draw 2-3 sets of blood cultures within a short time frame. Each set to be drawn from a different site. Avoid single bottle sets and drawing more than 3 sets within a 24 hour period if indicated.
- ❑ Select a site opposite of any infusion or if not possible, distal to any infusion. The cubital fossa is a preferred site.
- ❑ Each set to be drawn from a different venipuncture or new start PIV and include one aerobic and one anaerobic bottle per policy.
- ❑ Mark bottles for fill volume and fill to that volume. Most manufacturers require 8-10mL per bottle.
- ❑ Disinfect venipuncture site with 2% Chlorhexidine and Alcohol product per manufacturer's directions.
- ❑ Remove bottle cap and scrub bottle septum with a 70% alcohol prep pad for a full 15 seconds.
- ❑ Consider covering bottle top with a sterile 1x1 or new alcohol prep pad and leave on until placing bottle in adapter.
- ❑ Select site and apply single patient tourniquet - validate site, then remove tourniquet and don clean gloves.
- ❑ Consideration: Sterile set up with sterile barrier, gloves and tourniquet. Don gloves, apply barrier, apply tourniquet and perform venipuncture procedure.
- ❑ Draw blood cultures first, making sure to draw the recommended volume into the aerobic bottle first.
- ❑ Divert and sequester initial milliliter of blood drawn for culture into a sterile receptacle to minimize the risk of contamination. Use of ISDDs have been shown to reduce blood culture contamination rates to less than 1%.
- ❑ Finish procedure, applying a sterile dressing and light pressure after completing blood draw. Place sharps in sharp's disposal containers compliant with local and federal regulations.
- ❑ Label bottles in presence of the patient, agitate gently per manufacturer's instructions, and place in biohazard bag and send to lab immediately.

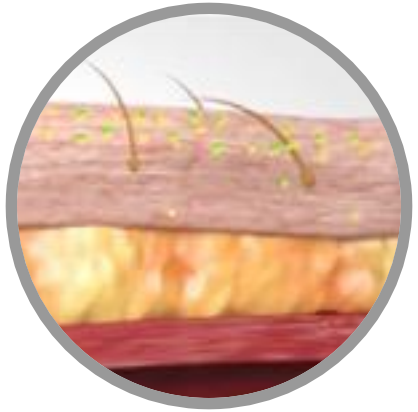
Training and Education on “Best Practices” and/or Phlebotomists Alone **Will Not** Solve the Problem:

*KYHA Successes and Process Discovery Tool

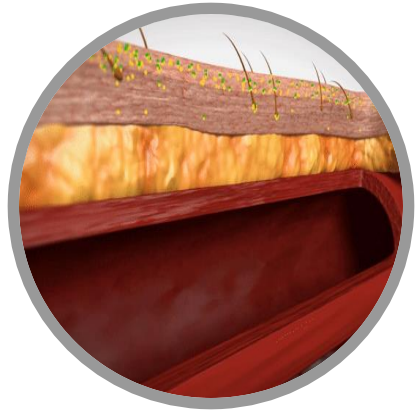
Controllable

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

Uncontrollable



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]



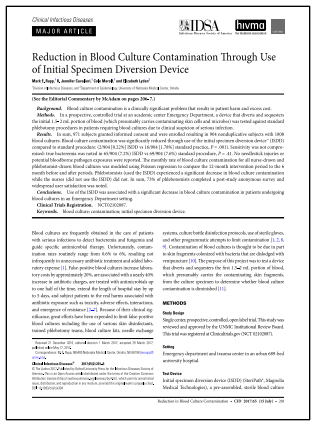
Skin Plug and Fragments
(uncontrollable factors)
will enter the culture specimen bottle and commonly will contain viable microorganisms (when present)

Active diversion of the **initial 1.5-2.0 mL of blood** using a closed system (Initial Specimen Diversion Device®) has been clinically proven to significantly 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.

ISDD: Nine Peer-Reviewed Published Studies

Clinical Infectious Diseases
2017 (July)

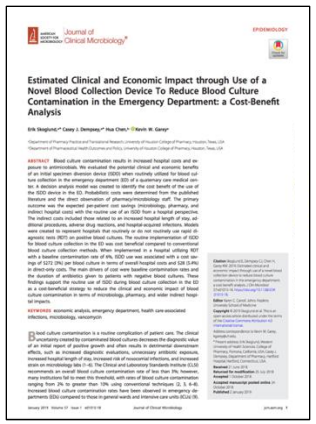


Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device

Journal for Emergency Nursing
2018 (Nov)

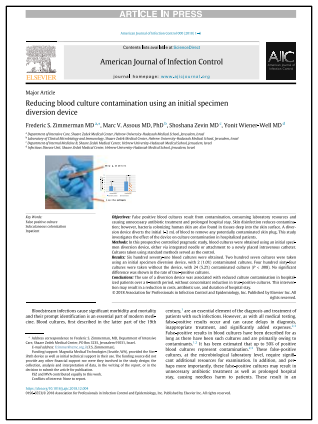
Effectiveness of a Novel Specimen Collection System in Reducing Blood Culture Contamination Rates

Journal of Clinical Microbiology
2019 (Jan)



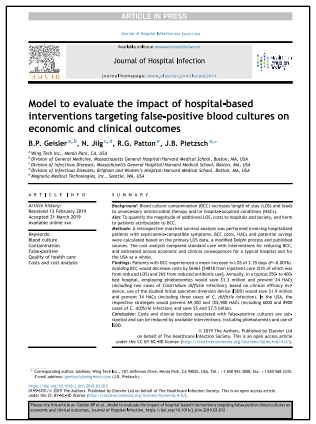
Estimated Clinical and Economic Impact through Use of a Novel Blood Collection Device To Reduce Blood Culture Contamination in the Emergency Department: a Cost-Benefit Analysis

American Journal Infection Control
2019 (Jan)



Reducing blood culture contamination using an initial specimen diversion device

Journal of Hospital Infection
2019 (Mar)



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

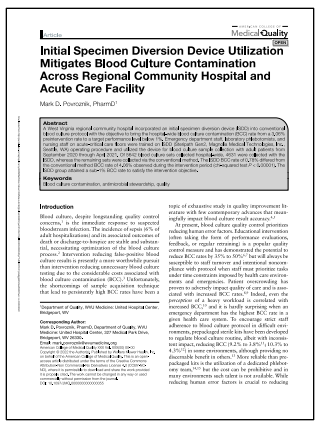
Journal for Emergency Nursing
2021 (Mar)

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)

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

American Journal Medical Quality
2022 (April)

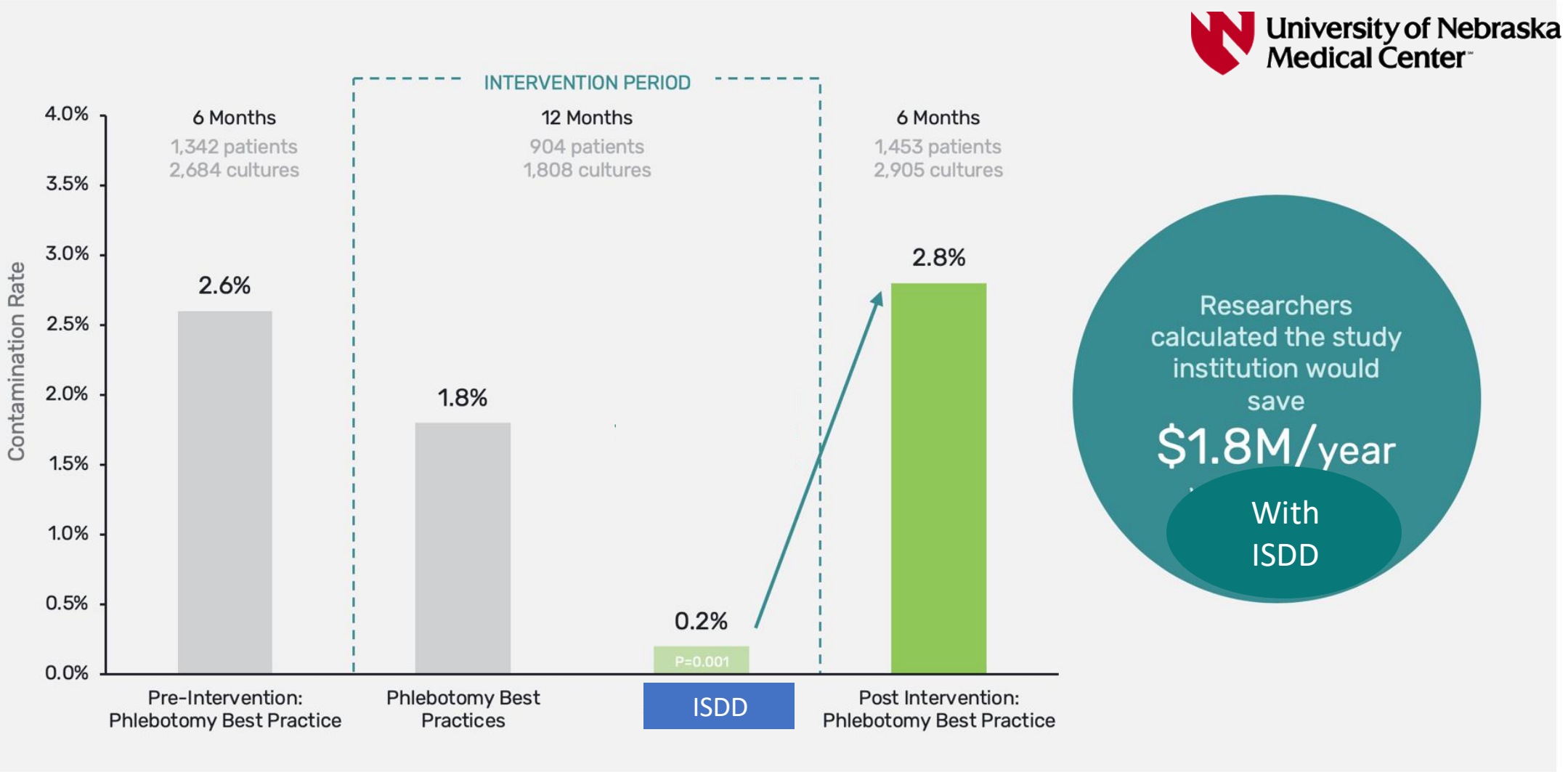


Initial Specimen Diversion Device Utilization Mitigates Blood Culture Contamination Across Regional Community Hospital and Acute Care Facility

Infection Control & Hospital Epidemiology
2022 (December)

Getting to zero: Impact of a device to reduce blood culture contamination and false-positive central-line–associated bloodstream infections

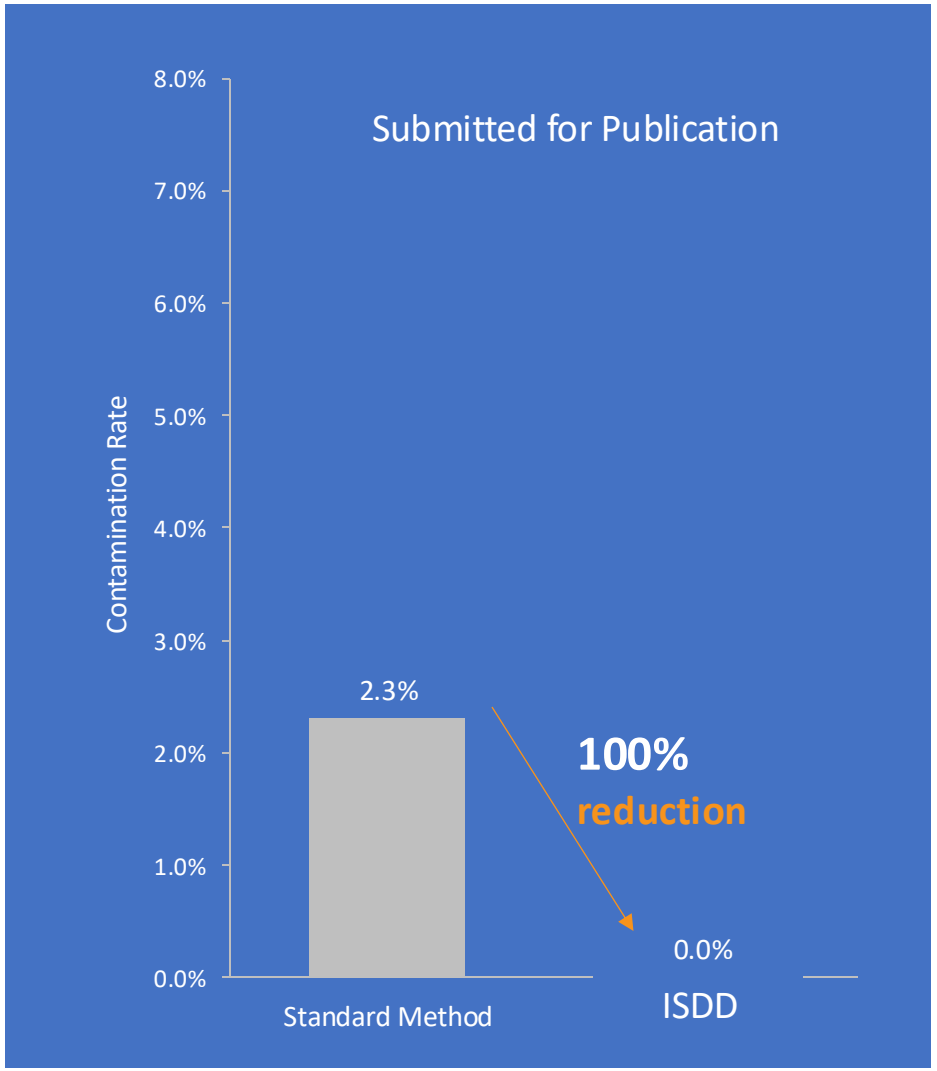
Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device



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.

Getting to Zero

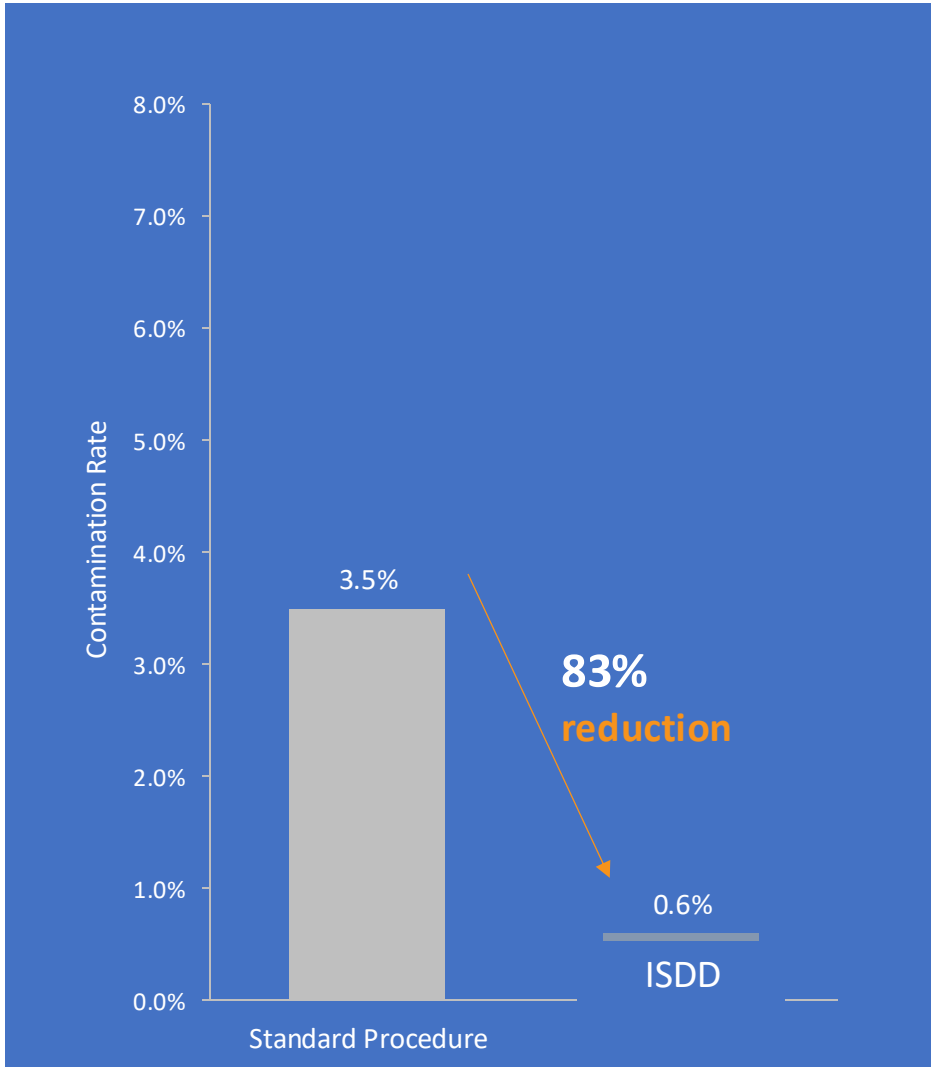
TITLE:	Getting to Zero: Impact of a Device ISDD to Reduce Blood Culture Contamination and False-Positive Central Line-Associated Bloodstream Infections
CONFERENCE	***IDWeek 2020 and PACCARB 2021***
INSTITUTE:	**Stanford Health Care**
AUTHORS:	Lucy Tompkins, MD, PhD, et al
DESIGN:	Single-center, prospective, 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.

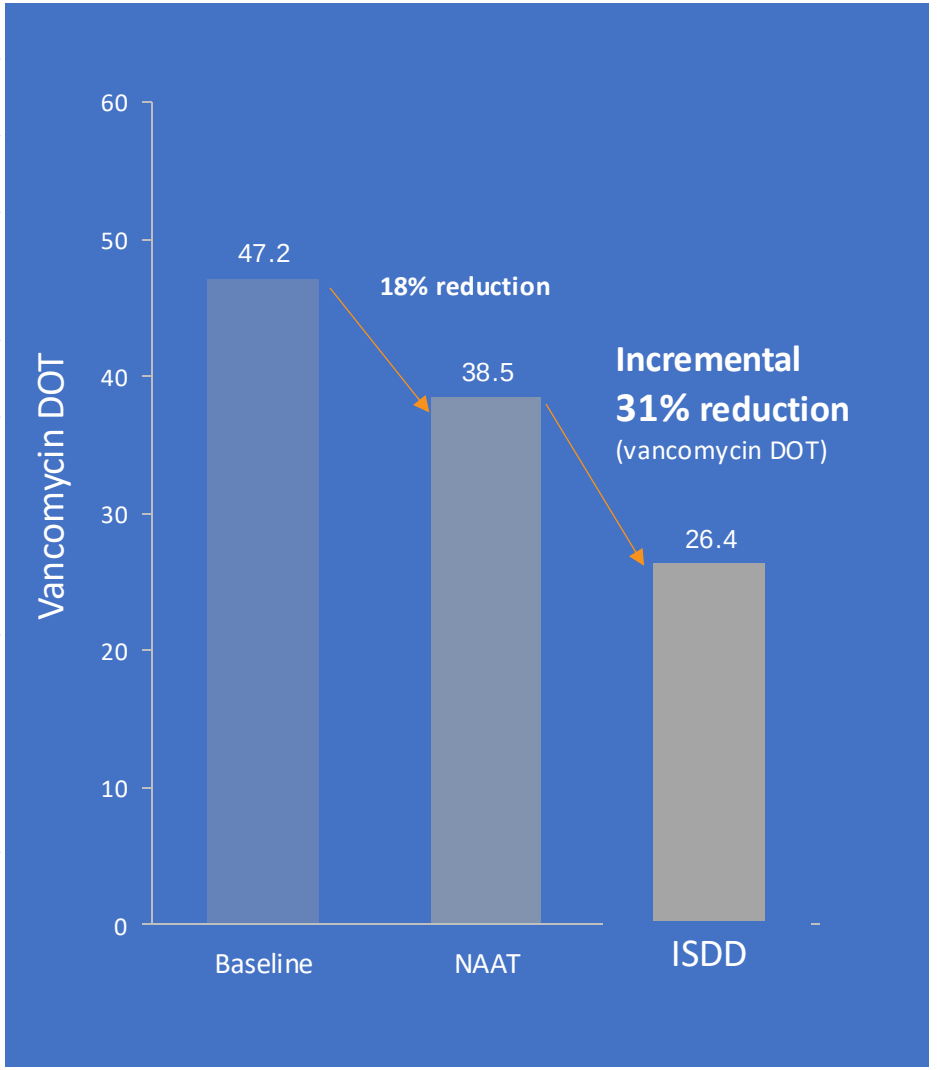
Peer-Reviewed Publication

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:	***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.



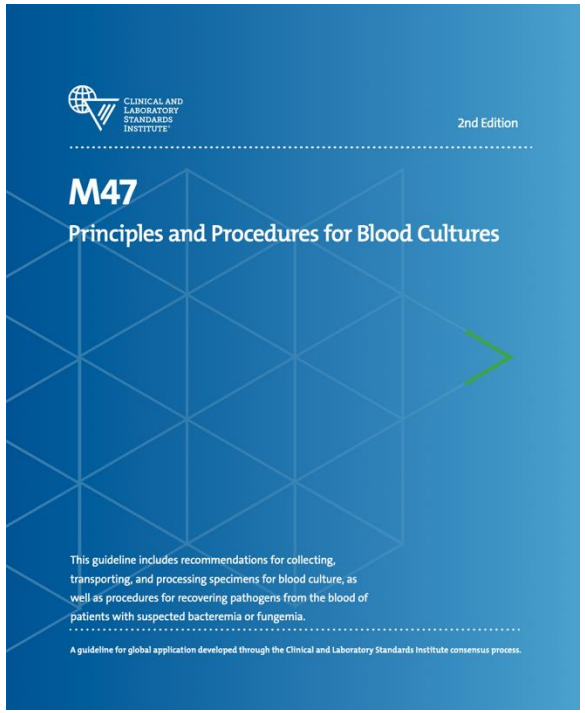
Peer-Reviewed Published Studies and Clinical Study Presentations at Major Medical Conferences

#	Institution	Publication or Conference Presentation	Date	Duration	Baseline or Control Rate	ISDD Rate	BCC Reduction	Ann. Savings
1	**Stanford Health Care**	IDSA – IDWeek / PACCARB/ **ICHE**	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	**WVU United Hospital Center**	American Journal for Medical Quality	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	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	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

CLSI M47 2nd Edition 2022

Principles and Procedures for Blood Cultures



"Even when optimal blood specimen collection protocols are used, completely eliminating blood culture contamination may be impossible. However, laboratories should still be able to achieve blood culture contamination rates ***substantially lower than 3%***. When best practices are followed, a ***target contamination rate*** *of* ***1%*** is achievable."

- Six studies were cited within the CLSI guidelines regarding the clinical impact of self-contained devices that achieve initial specimen diversion on reducing contamination rates
- ALL studies examined the clinical efficacy of ISDD with diversion of >1ML and/or referenced said ISDD specific datasets and reported a sustained 1% or lower contamination rate.

Evidence-Based Guidelines to Reduce Blood Culture Contamination

EMERGENCY NURSES ASSOCIATION

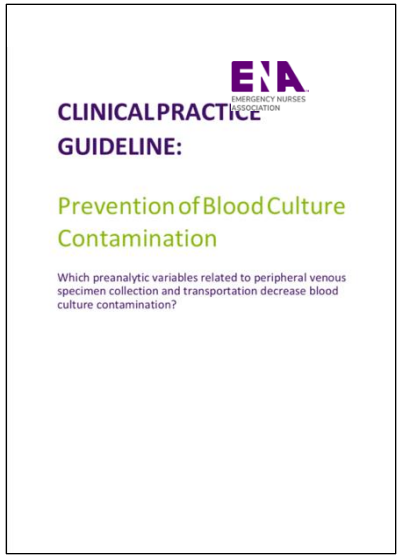
INFUSION NURSES SOCIETY
SETTING THE STANDARD FOR INFUSION CARE®

CLSI

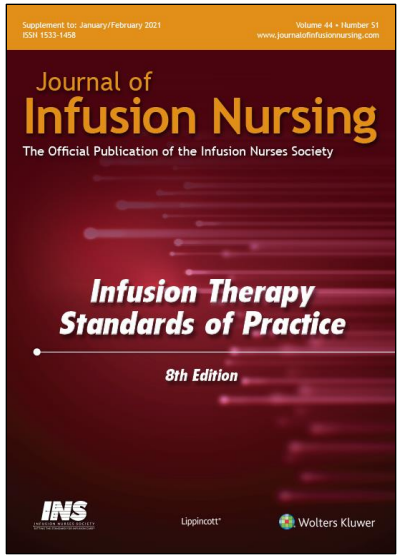
DEPARTMENT OF HEALTH & HUMAN SERVICES USA
CDC

IDSA
Infectious Diseases Society of America

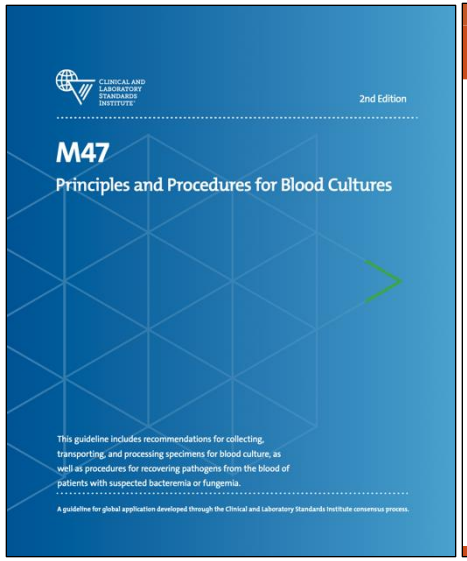
SHEA
The Society for Healthcare Epidemiology of America



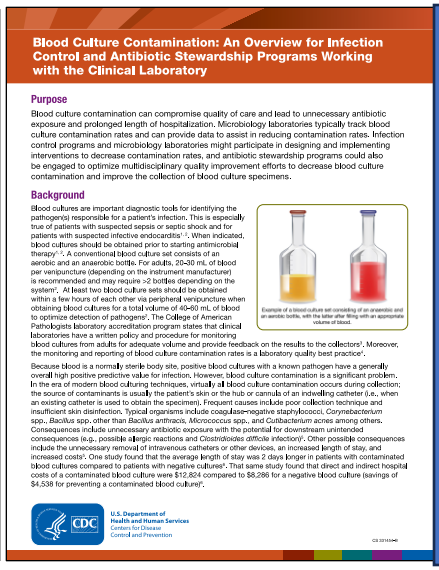
1.0–2.0 mL diversion volume



Diversion Devices



1.0 mL diversion volume
1% goal for blood culture contamination
(GP41 ED7 2017)
(M47 ED2 2022)



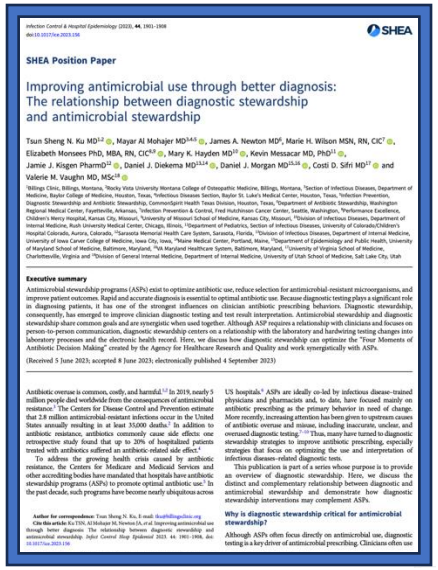
1% goal for blood culture contamination

Diversion Devices

(CDC Guidelines, 2022)

"In addition, products are available that allow diversion and discard of the first few milliliters of blood that are most likely to contain skin contaminants. Target rate of 1%"

IDSA Guidelines 2024 CID

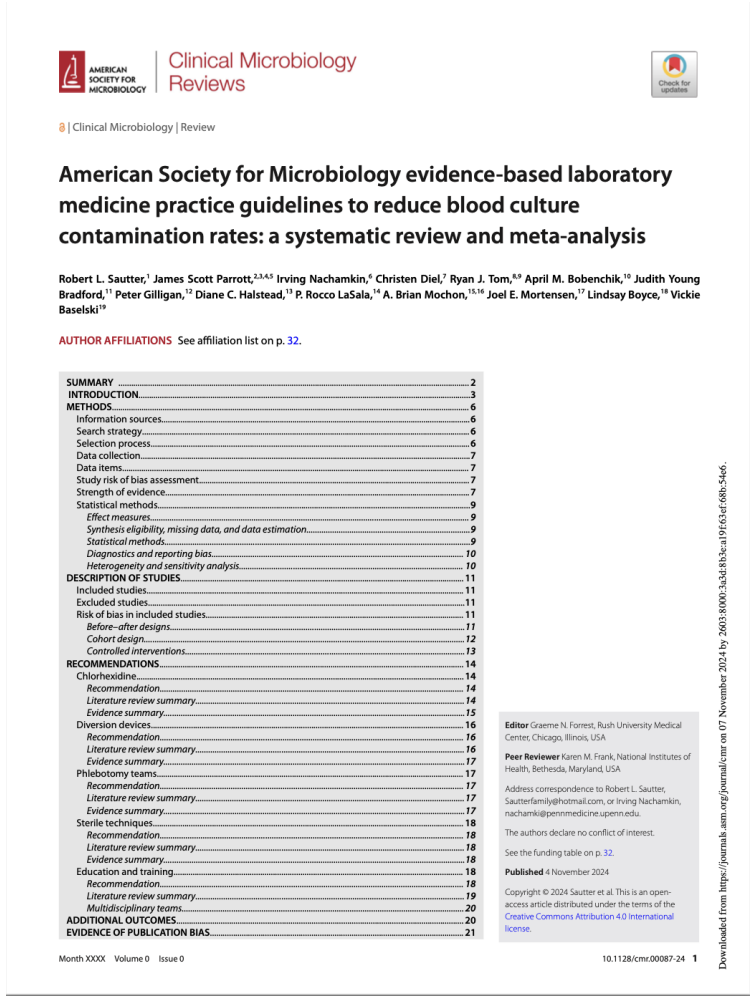


Blood culture **diversion technique or devices**

SHEA Position Statement
ICHE 2023

2024 ASM/SHEA Guidelines for Blood Culture Collection

AMERICAN SOCIETY FOR MICROBIOLOGY



AMERICAN SOCIETY FOR MICROBIOLOGY | Clinical Microbiology Reviews

8 | Clinical Microbiology | Review

American Society for Microbiology evidence-based laboratory medicine practice guidelines to reduce blood culture contamination rates: a systematic review and meta-analysis

Robert L. Sautter,[1] James Scott Parrott,[2,3,4,5] Irving Nachamkin,[6] Christen Diel,[7] Ryan J. Tom,[8,9] April M. Bobenchik,[10] Judith Young Bradford,[11] Peter Gilligan,[12] Diane C. Halstead,[13] P. Rocco LaSala,[14] A. Brian Mochon,[15,16] Joel E. Mortensen,[17] Lindsay Boyce,[18] Vickie Baselski[19]

AUTHOR AFFILIATIONS See affiliation list on p. 32.

Editor Graeme N. Forrest, Rush University Medical Center, Chicago, Illinois, USA

Peer Reviewer Karen M. Frank, National Institutes of Health, Bethesda, Maryland, USA

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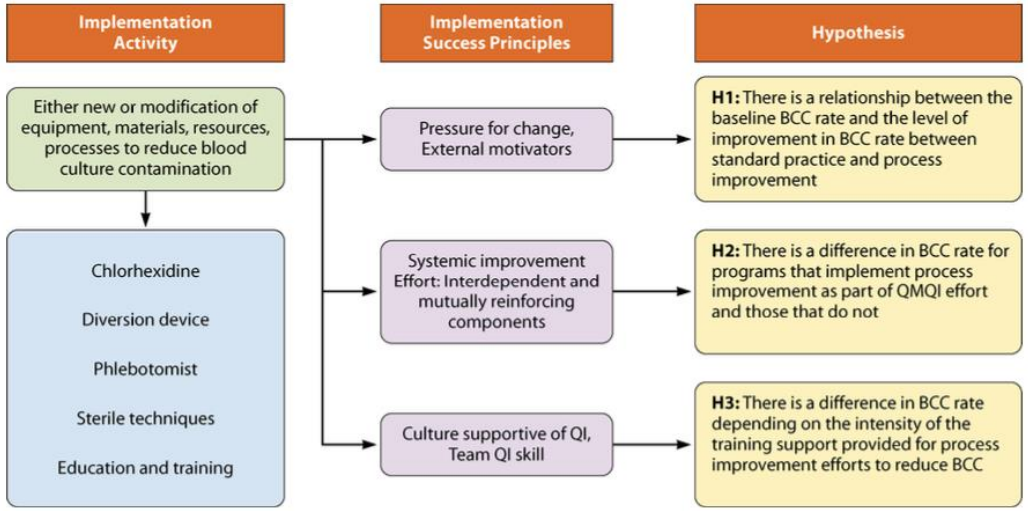
The authors declare no conflict of interest.

See the funding table on p. 32.

Published 4 November 2024



"There was a range of blood volume discarded in the six studies from 1 to 7 mL of discard per draw. While small volume discards (<2 mL) are likely to cause little harm to patients, discarding larger volumes of blood (e.g., 7 mL in the Syed et al. study) might contribute to the development of iatrogenic anemia in patients with prolonged hospital stays and frequent BCs"

Major steps toward CMS adoption of CDC/NQF Blood Culture Quality Measure

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

NATIONAL QUALITY FORUM

CDC-initiated blood culture quality measure developed and submitted to NQF, April 2022

Published evidence-based guidelines including Diversion Devices and citing a **1% goal** for blood culture contamination, 2022

NQF Consensus Standards Approval Committee (CSAC) formally **endorsed** the **CDC's** blood culture quality measure in December 2022

Finding: On a national scale, BCC results in nearly 1,000,000 extra hospital days, 200,000 courses of unneeded antibiotics and over $1 billion in excess costs, Up to 40% of patients with contaminated blood cultures are started on antibiotics resulting in nephrotoxicity, CDI, allergic reaction, AMR, ELOS, HAI/HAC, Costs, and unnecessary utilization of resources.

Standard of Care

Hospital-Onset Bacteremia & Fungemia (HOB) Quality Measure

Blood Culture Contamination *will be an* ***NHSN/CMS/CDC reportable quality metric, part of HOB composite score***
Hospital is ***accountable to prove*** *that the patient had a* ***BSI prior*** *to day four*

Patient Example	Blood Culture Drawn ED or On Admission and Through Day 3	Additional Blood Culture Drawn On Day 4 or Later After Admission	HOB
Patient #1	True Positive	True Positive	No
Patient #2	True Negative	True Positive	Yes
Patient #3	False Negative	True Positive	Yes
Patient #4	False Positive (common commensal)	True Positive	Yes
Patient #5	False Positive (common commensal / skin residing organism)	False Positive (non-common commensal / pathogenic organism from skin) (I.e. false positive MRSA, CLABSI, BSI)	Yes

34% of HOB did not meet criteria due to positive blood culture on admission or up to day 3[1]

AJIC study: the most common cause of preventable HOB is blood culture contamination; non common commensal organisms

Accurate blood cultures will be more critical than ever to mitigate a HOB

[1]Yu KC, et al. (2022). Hospital-onset bacteremia and fungemia: An evaluation of predictors and feasibility of benchmarking comparing two risk-adjusted models among 267 hospitals. Infection Control & Hospital Epidemiology, https://doi.org/10.1017/ice.2022.211
Am J Infect Control 2024 Feb;52(2):195-199. doi: 10.1016/j.ajic.2023.06.002. Epub 2023 Jun 7.

Broadened Surveillance Definition of BSI Passed by NQF 2.23

HOB

(Hospital Onset Blood Stream Infection)

Purpose: Surveillance for broader reduction of BSI regardless of organism (eg. MRSA) or association with Device (eg. CLABSI)

Definitions: HOB Blood culture collected on day 4 or later with pathogenic bacteria or fungi

Serious: 24% mortality compared to patients without HOB.
Higher cost $44K vs $25 K

Common Up to 115,000 cases or 0.34% of all admissions

Preventability: Many cases are preventable

Timeline: Voluntary Reporting Now

“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

THANK YOU

FOR ALL OF YOUR WORK ON BEHALF OF PATIENT QUALITY OUTCOMES!