Tammy Johnson, RN, BS, CPM, AVP

Achievement of AMS and Quality Outcomes Via Diagnostic Safety and Stewardship

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MEDICAL TECHNOLOGIES

Learning Objectives

- Review the history of antibiotic resistance
- Understand the current and predicted future state of AMR
- Detail the causes and mechanisms of resistance
- Describe the impact of contaminated blood cultures on patients, antimicrobial stewardship efforts, quality patient outcomes and hospital economics
- Detail evidence-based practices for blood culture collection
- Illustrate the limitations of standard blood culture practice and the implications of such
- Evaluate the critical role of the clinician in blood culture collection using evidence-based practices
- Identify tools and methods to mitigate false positive cultures leading to diagnostic stewardship, AMS and quality outcomes

February 14, 2022

AMR: The History, Current State and Predicted Future State

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The First Person in the World Saved by Antibiotics

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

Penicillin, Miracle Drug, Soon Out in Patent Forms; But Best See Doctor First

2019 AR Threats Report CDC

The Start of Resistance

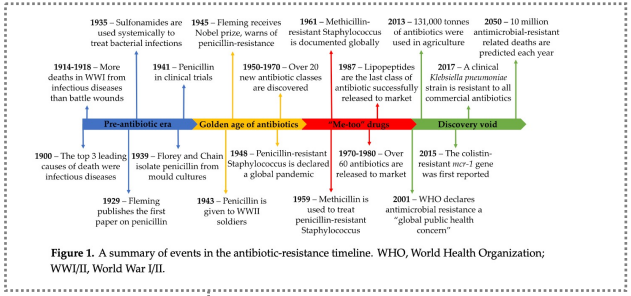


Figure 1. A summary of events in the antibiotic-resistance timeline. WHO, World Health Organization; WWI/II, World War I/II.

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

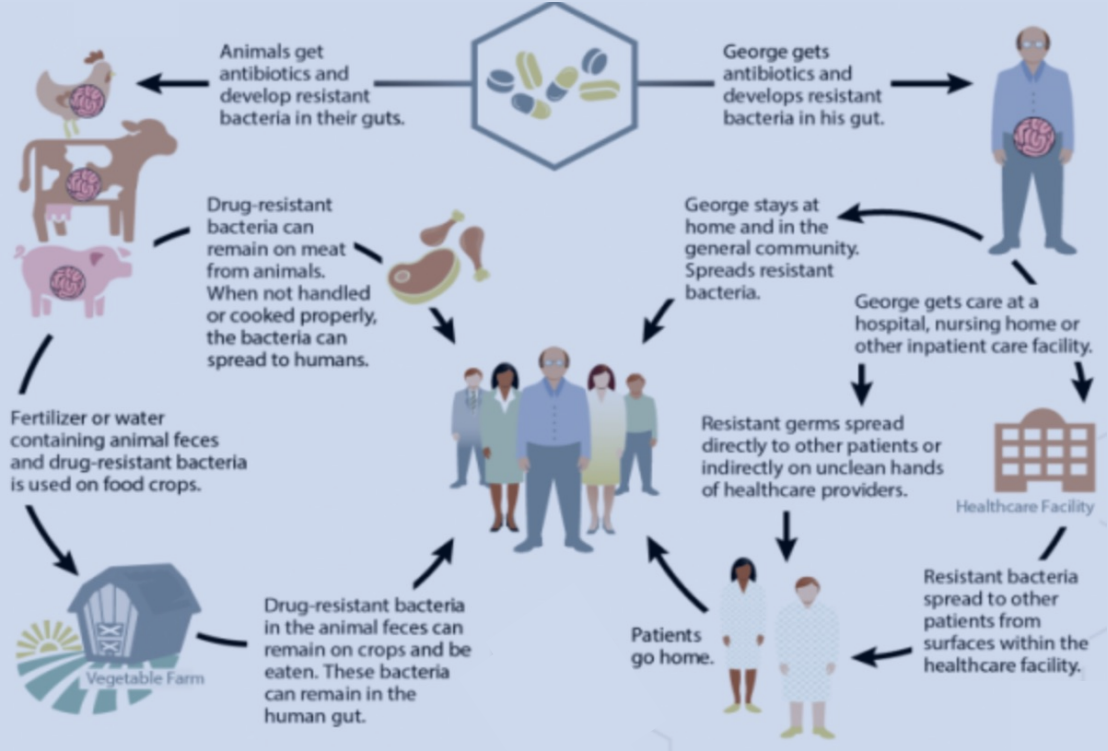
80% of both community- and hospital-acquired staphylococcal isolates were resistant to penicillin.

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

Causes of Antibiotic-Resistant Bacteria

- Overprescribing or misuse of unnecessary and excessive antibiotics
  - Estimated that 1 in 3 prescriptions for antibiotics is unnecessary
- Other causes
  - Antibacterial household products
  - Antibiotic use in livestock

Examples of How Antibiotic Resistance Spreads



Milken Institute School of Public Health Antibiotic Resistance Action Network
2019 AR Threats Report CDC

What Are Antibiotic-Resistant Bacteria?

Bacteria not controlled or killed by antibiotics

- Able to survive and multiply in presence of antibiotic and experts at adaptation

- Some are resistant to a single antibiotic while others are resistant to multiple antibiotics

Issues with antibiotic use on resistant organisms

- 90% can only be killed with only one last-resort antibiotic
- Treatment of second or third-choice antibiotics can be less effective, more toxic and more expensive

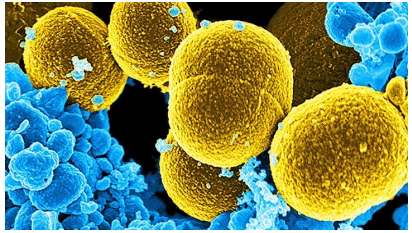
The impact of antibiotic resistant organisms

- 3 million people are infected with hospital-acquired infections in US/year
- Leads to 48,000 deaths in the United States per year-
- 70% of these bacteria are resistant to at least one of the drugs most commonly used to treat them

Common Resistant Organisms

MRSA
Methicillin-Resistant Staph Aureus

- Occurs with common hospital interventions
- Can lead to septicemia
- 2% of people carry MRSA
- Deadly when it spreads to skin or blood and immune system can't control it
- Resistant to most antibiotics, except vancomycin

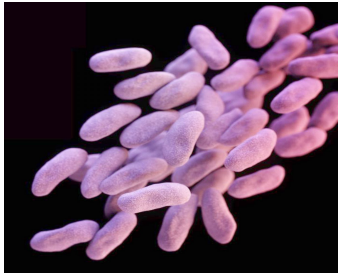


VRE
Vancomycin-Resistant Enterococcus

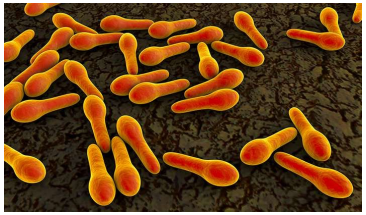
- Bacteria commonly seen in GI tract but is now in another location in body (blood, lungs)
- Enterococcus bacterium that has become resistant to antibiotics that have been used to treat it (penicillin, gentamicin, vancomycin)
- Most VRE infections occur in hospitalized patients

CRE
Carbapenem-Resistant Enterobacteriaceae

- Most often acquired in healthcare setting
- Infects lungs, skin, blood
- Resistant to a class of antibiotics used as a "last resort" against resistant bacteria



C diff
Clostridium difficile



- Caused by overuse of antibiotics when normal gut bacteria are overcome by antibiotics
- Inflammation of the colon with diarrhea is the most common symptom
- Certain strains are one of the fastest growing super-bugs
- Each year 15,000-30,000 patients in the US lose their lives to C.diff infection within the first 30 days of onset

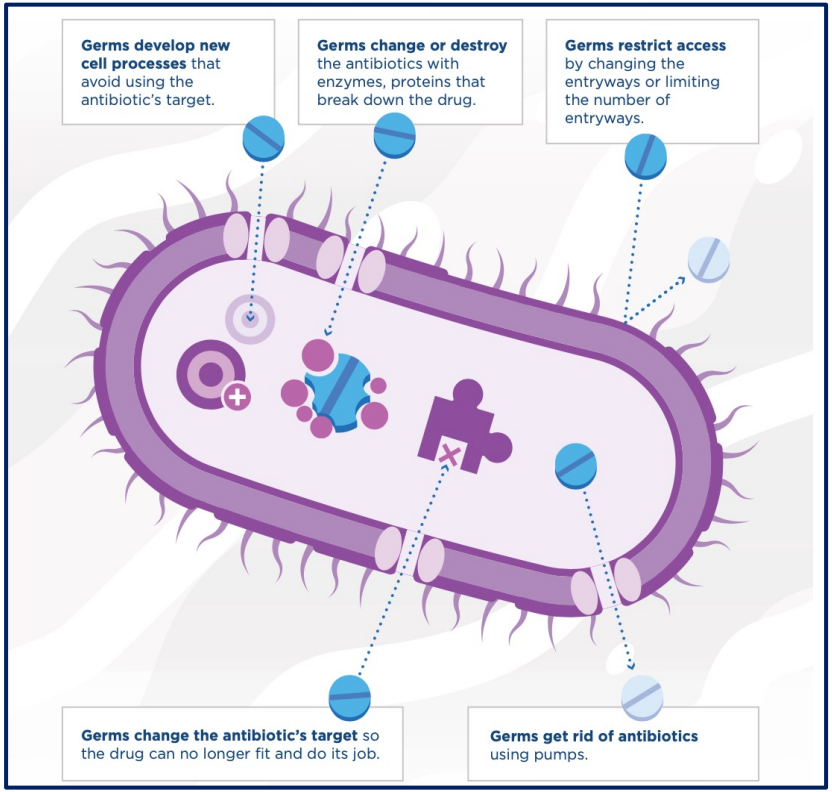
2019 AR Threats Report CDC

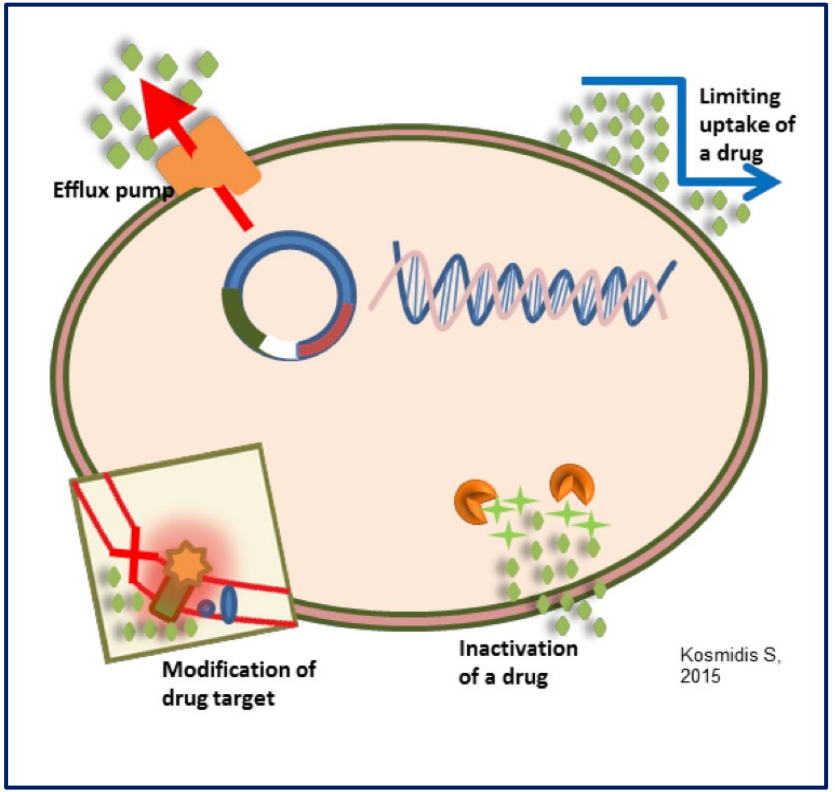
Seeing is Believing

Click on image for hyperlink

Bacteria Fight Back

Mechanisms of Resistance

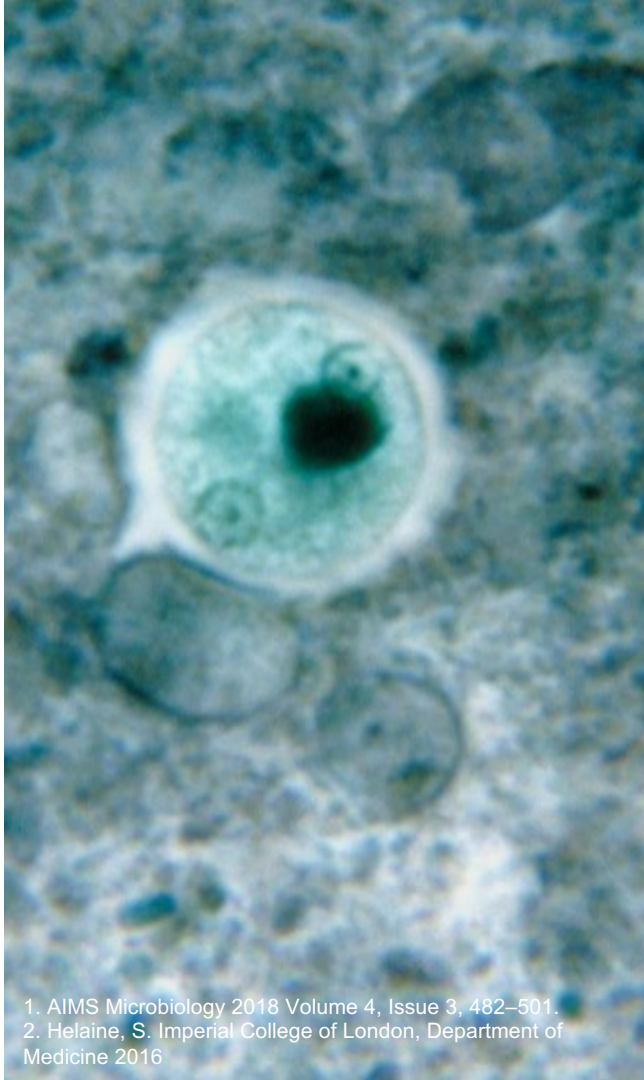




Persistence vs Resistance

Persistence is not resistance but can lead to resistance

- Persistence: bacteria that are in an encysted state during antibiotic administration
- They are not resistant but persistent
- Post adverse conditions these organisms can leave their encysted state and reactivate
- "Persisters fuel antibiotic resistance as they result in patients taking many courses of antibiotics for a single infection. The repeated courses of medication can result in some bacteria developing resistance."[2]



1. AIMS Microbiology 2018 Volume 4, Issue 3, 482–501.
2. Helaine, S. Imperial College of London, Department of Medicine 2016

The Criticality of Antibiotics

Issus 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 2013 Dec; 5(6):229-241
Milken Institute School of Publich Health Antibiotic Resistance Action Network
2019 AR Threat Report CDC

Global burden of bacterial AMR in 2019, a systematic analysis

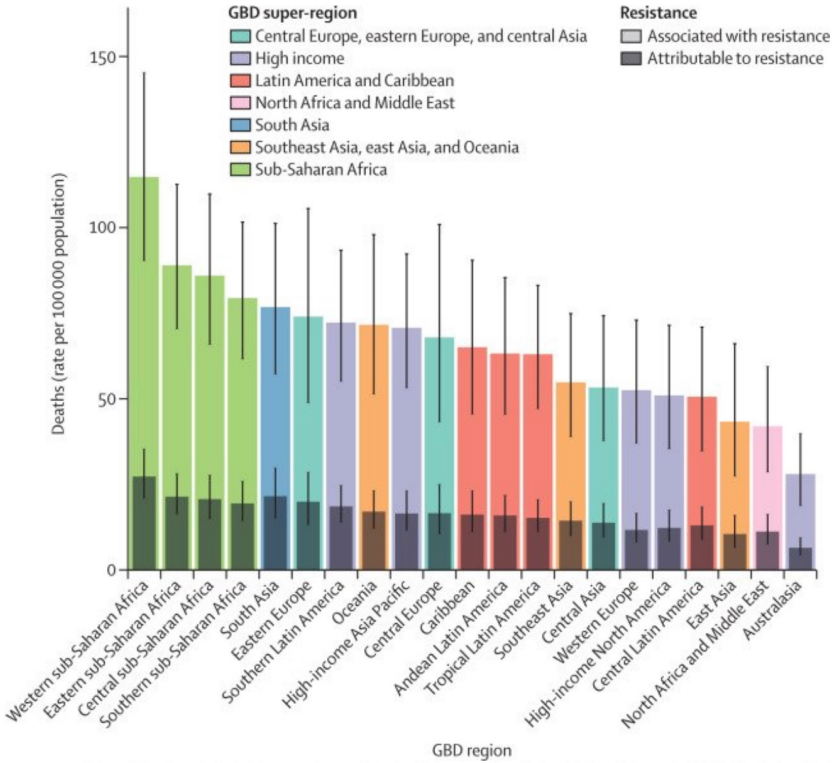
2022 The Lancet

- 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

Murray, Global burden of bacterial AMR in 2019 a systematic analysis, The Lancet 2022



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

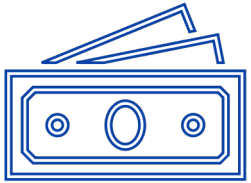
The Public Health Cost of Antibiotic Resistance

$20 Billion

for healthcare

$35 Billion

for loss of productivity

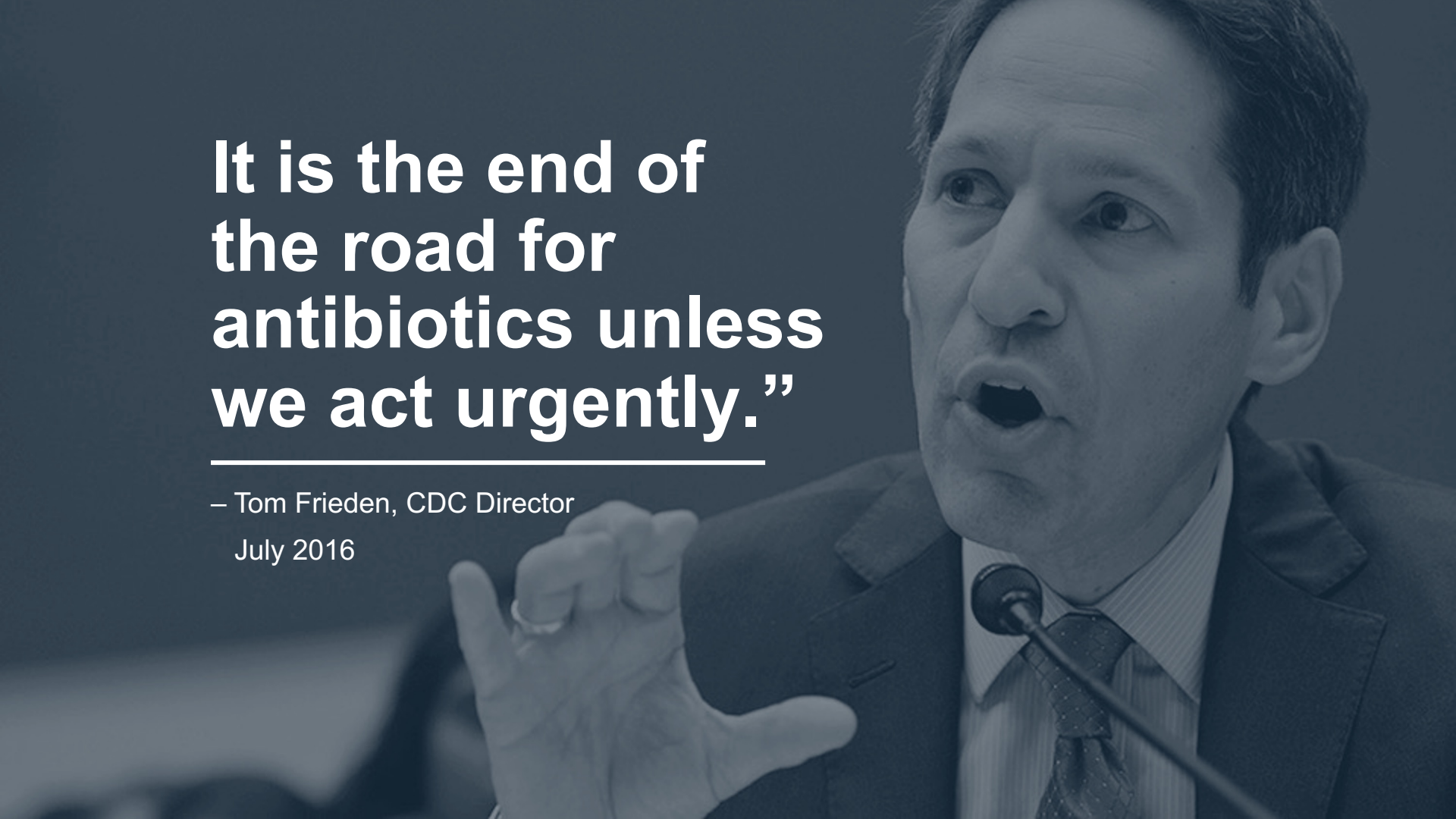


$55 Billion

total annual costs

Porooshat Dadgostar, Journal of Infections and Drug Resistance: Antimicrobial Resistance: Implications and Costs
2019 Dec 20. doi: 10.2147/IDR.S234610 PMCID: PMC6929930

Personalizing The Cost of Resistant Bacterial Infections


It is the end of the road for antibiotics unless we act urgently.”
– Tom Frieden, CDC Director
July 2016

Only Four Ways to Stop Antibiotic 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 resistance

Antibiotic Stewardship

- 55% of all patients get at least one dose of an antibiotic during their hospital visit; Vancomycin use was up 32% from 2006 to 2012.
  – JAMA: Estimating National Trends in Inpatient Antibiotic Use Among U.S. Hospitals from 2006 to 2012
- A continued rise in antimicrobial resistance by 2050 would lead to 10 million people dying every year.
  – Review on Antimicrobial Resistance. Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations, 2014
- Establish antibiotic stewardship programs in all acute care hospitals.
  – Center for Disease Control and Prevention, 2014, The Joint Commission, 2016
- "Reduction of inappropriate antibiotic use by 20% in inpatient settings."
  – White House Executive Order, 2015

JAMA
The Journal of the American Medical Association

Review on Antimicrobial Resistance
Tackling drug-resistant infections globally

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

The Joint Commission

The threat of antibiotic resistance has become **so severe** it is garnering **federal legislative action**.

February 14, 2022

Diagnostic Safety and Stewardship leads to AMS and Quality Outcomes

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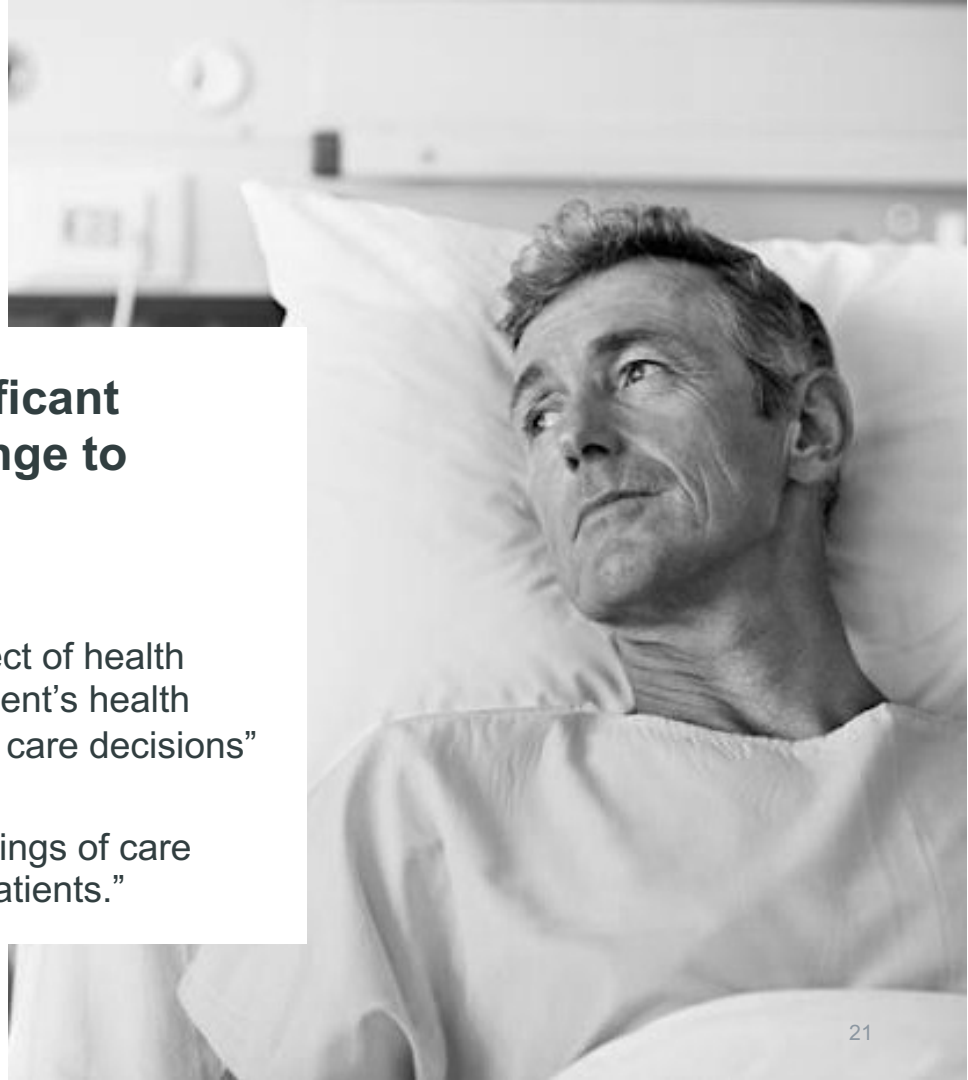
CDC 2019 AR Threat Report

“Diagnostics can be just as critical for fighting infections as antibiotics”

National Academy of Medicine

(f.k.a. Institute of Medicine)



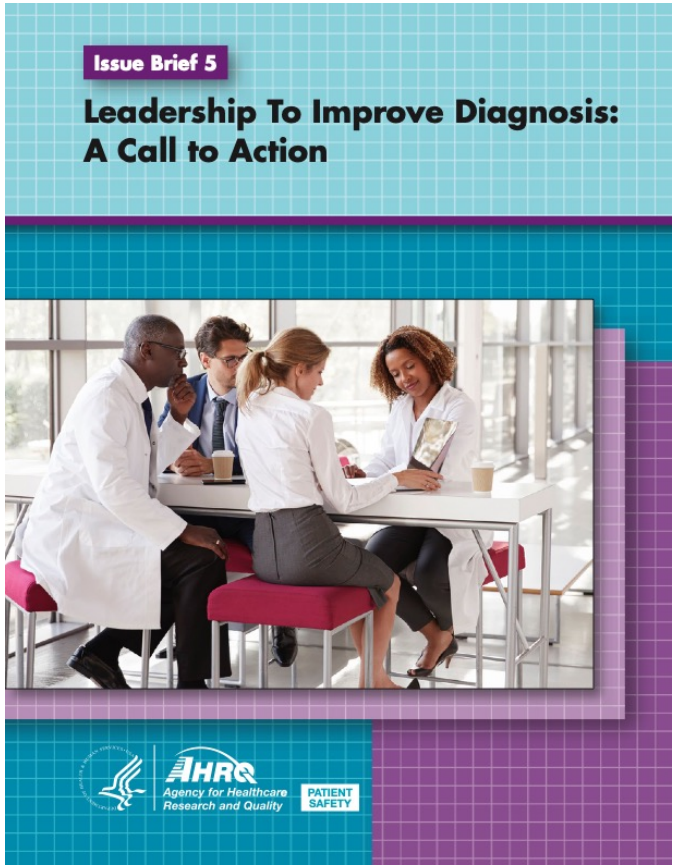
“Diagnostic errors are a significant but underappreciated challenge to health care quality”

“Getting the right diagnosis is a key aspect of health care: it provides an explanation of a patient’s health problem and informs subsequent health care decisions”

“Diagnostic errors persist through all settings of care and harm an unacceptable number of patients.”

Agency for Healthcare Research and Quality

- AHRQ is the lead Federal agency investing in research to improve diagnostic safety and reduce diagnostic error.
- Improving Diagnostic Safety 2016 Diagnostic Safety Summit Information from AHRQ



Murray, Global burden of bacterial AMR in 2019 a systematic analysis, The Lancet 2022

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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 Definition

- 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

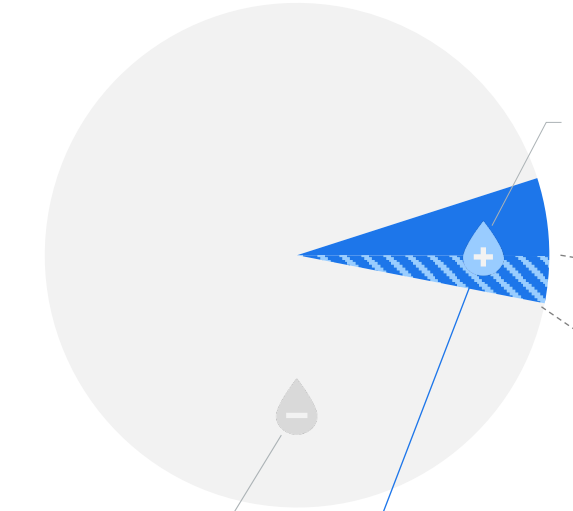
Sepsis is the #1 cause of death, readmissions, and costs in U.S. hospitals[1,2]

… 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

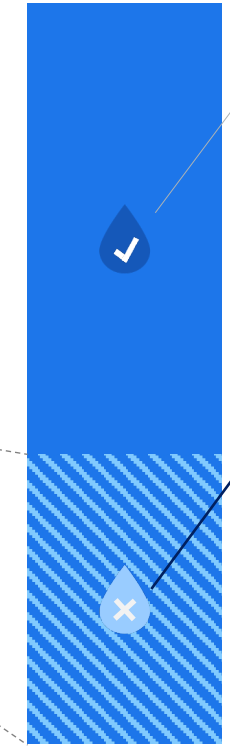


8% Positive[1]

92% Negative

3% Contamination Rate

POSITIVE BLOOD CULTURES



60% *True* Positive

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

“

Blood cultures are one of the ***worst tests*** **in microbiology.**

Christopher D. Doern, PhD. D(ABMM)
Director, Clinical Microbiology,
VCU Health System
Associate Professor, Pathology,
Joint Appointment in Department of Pediatrics

The Clinical Decision Dilemma

The Impact

Patient tests positive…

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*

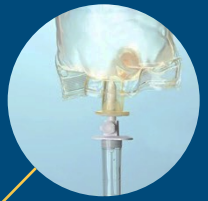
Increased mortality & morbidity risk

[1]Liu 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.

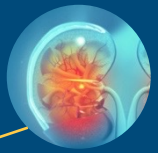
The Impact

False-positive blood cultures increase many harmful patient safety risks

Misdiagnosed **Patient**

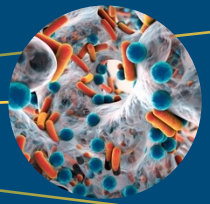


Unnecessary Antibiotics

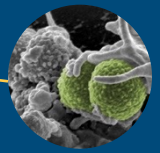


Acute Kidney Injury (AKI)

Extended Length of Stay



Antibiotic-Resistant Infections



Exposure to HAIs & HACs

Risk of *C. difficile*

False-Positive CLABSIs

The Impact

Blood culture contamination can have a devastating impact…

~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]

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.

Blood Culture Contamination Defined

- Clues that may help to differentiate contamination from bacteremia include
  - Identity of the organism
  - Number of positive culture sets
  - Number of positive bottles within a set
  - Time to growth
  - Clinical presentation and other laboratory data
  - Source of culture
  - PCR

Hall and Lyman, CMR: Updated Review of Blood Culture Contamination; 2006

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

Antibiotic Use During COVID

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

HAI Increases During COVID

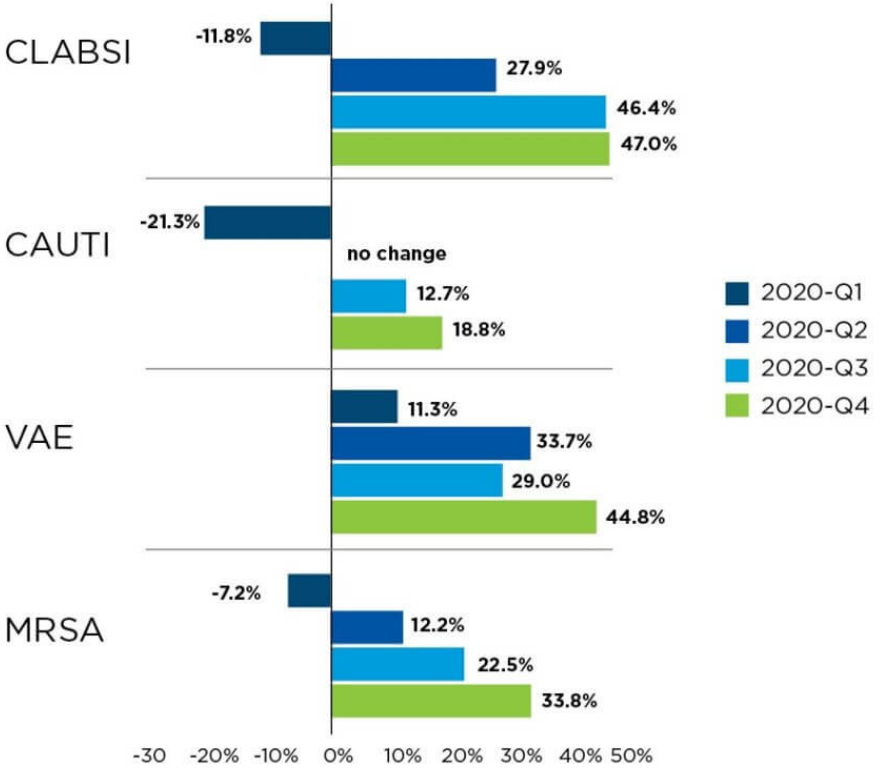
28% YoY increase in CLABSIs in Q2 2020

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

HAIs Increased Dramatically in 2020

Graph shows % change in 2020 by quarter compared to 2019

NHSN National Healthcare Safety Network



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

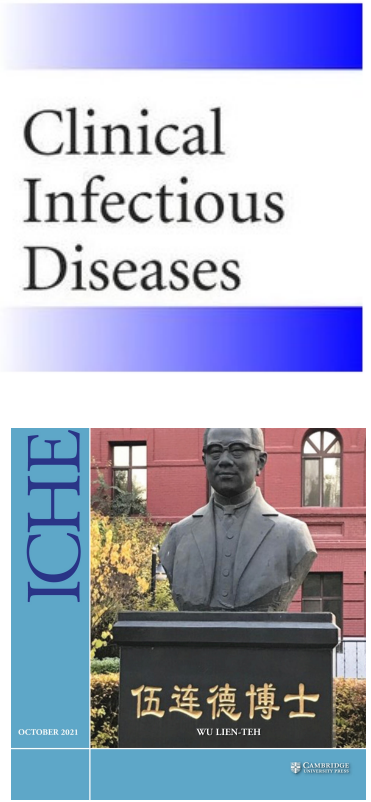
“

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.



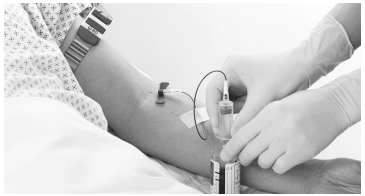
False-Positive CLABSI Reporting
(CMS NHSN Surveillance Definition LCBI1)

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 on the skin during a **peripheral venipuncture** for blood culture collection
- 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

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)

- 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.

Stanford HEALTH CARE

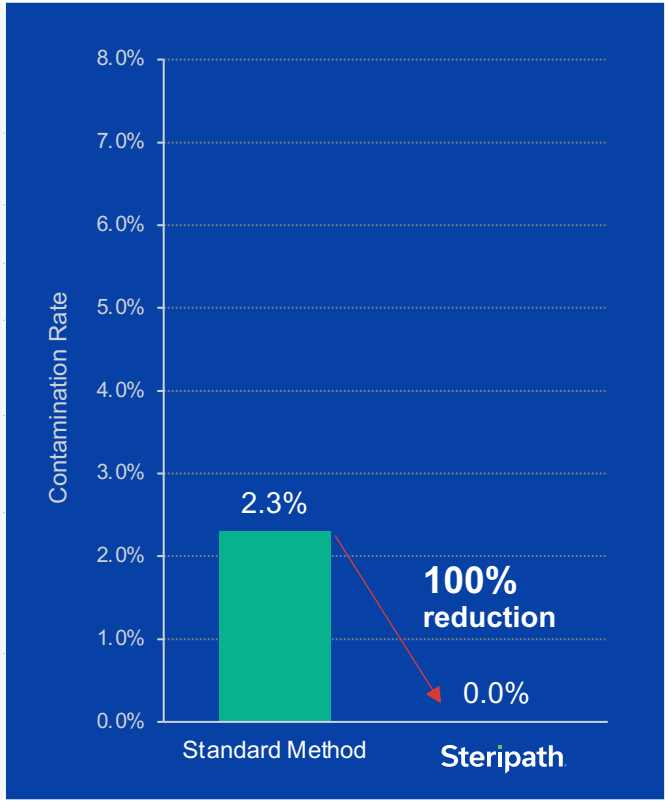
MAGNET RECOGNIZED AMERICAN NURSES CREDENTIALING CENTER

IDWeek 2020 Advancing Science, Improving Care

PACCARB Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

Submitted for Publication

TITLE:	Getting to Zero: Impact of a Device (Steripath) 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 Steripath Gen2 compared to standard method.
RESULTS:	**100%** reduction in blood culture contamination Steripath Gen2: **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** Steripath Gen2: **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.

Improved Patient Safety

by reducing blood culture contamination

1. Can significantly reduce unnecessary and inappropriate antibiotic treatment
2. Drives Antibiotic Stewardship
3. Reduces risk of *C.difficile*, MDROs, AKIs, and other antibiotic-related complications
4. Reduces unnecessary LOS and associated HAIs/HACs
5. Reduces false-positive CLABSIs and NHSN/CMS reporting
6. Conserves laboratory, pharmacy and human resources
7. Increases bed availability and throughput

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

The Joint Commission

February 14, 2022

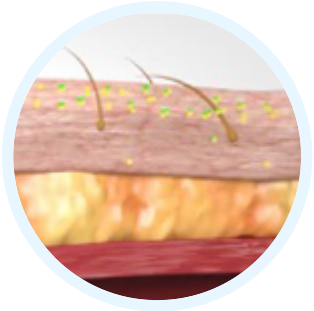
The Challenge and Solution

MAGNOLIA®
MEDICAL TECHNOLOGIES

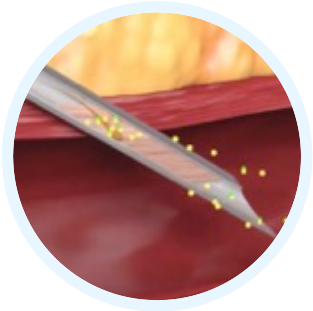
Training and Education on “Best Practices” Alone Will Not Solve the Problem

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]



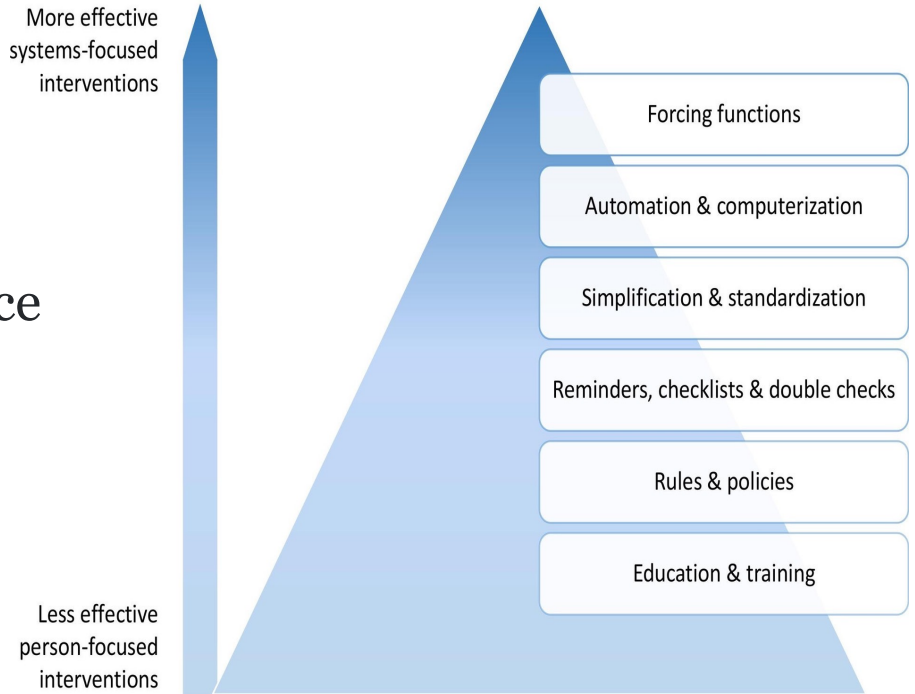
Skin Plug and Fragments
(uncontrollable factors)
will enter the culture specimen bottle and commonly will contain viable microorganisms (when present)

Active diversion of the **initial 1.5-2.0 mL of blood** using a closed system (Steripath) 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.

Limited Impact of Education as 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”

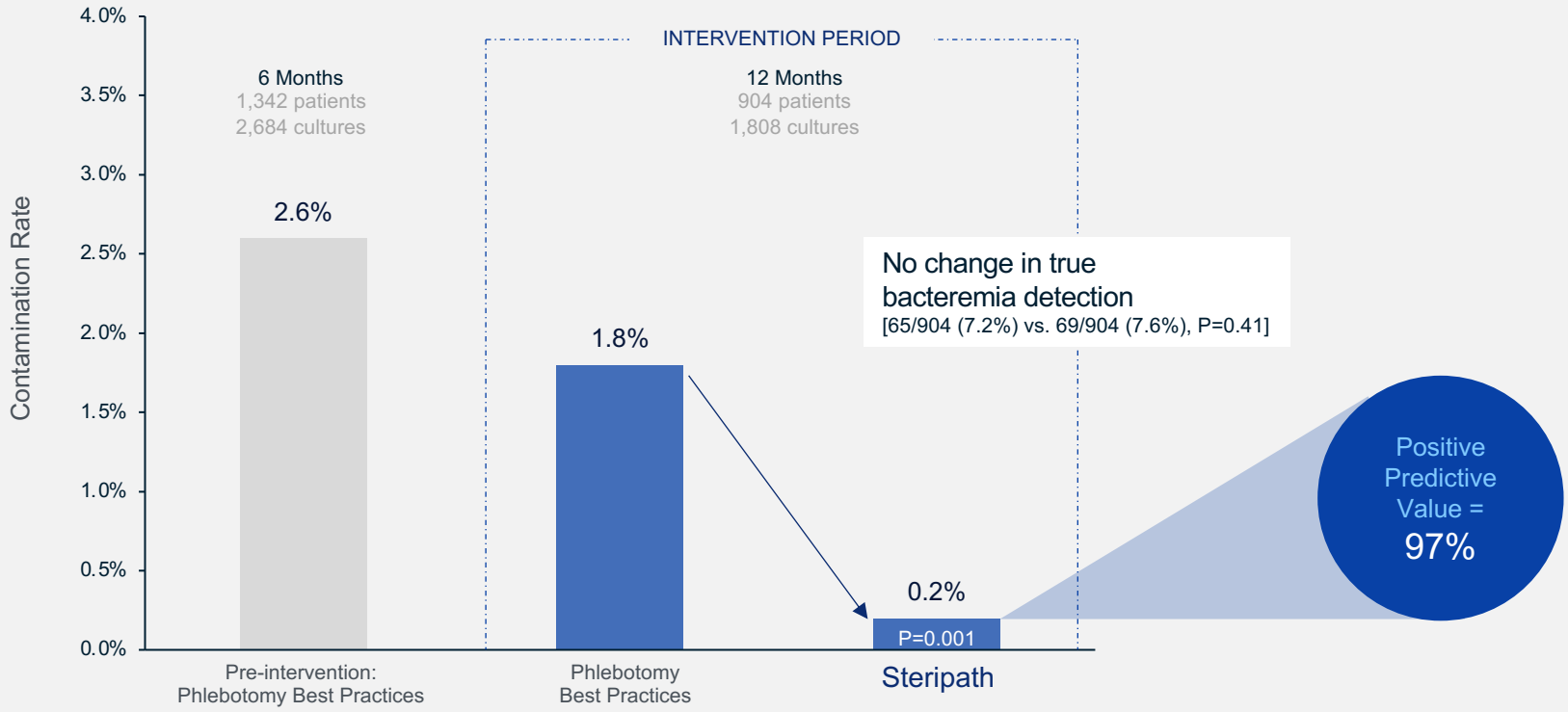


Soong C, Shojania KG. Education as a low-value improvement intervention: often necessary but rarely sufficient. *BMJ Qual Saf*. 2020;29(5):353-357. doi:10.1136/bmjqs-2019-010411.

Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device® [Steripath®]

Clinical Infectious Diseases - 2017:65 (15 July)

University of Nebraska Medical Center



Evidence-Based Solutions

Content written by Dr. Mark Rupp based on recent publication release: Doern GV, Carroll KC, Diekema DJ, Garey KW, Rupp ME, Weinstein MP, Sexton DJ. A comprehensive update on the problem of blood culture contamination and a discussion of methods for addressing the problem. Clinical Microbiology Reviews, January 2020.

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; allow for adequate drying time
Blood Culture Bottle Top Disinfection	Disinfect blood culture vial caps with alcohol
Consideration	Leave an IPA pad on top of the BC bottle until ready to inoculate with blood; IPA takes 5 seconds to dry
Phlebotomy Site	Do not draw blood cultures through indwelling vascular catheters unless the catheter is thought to be the source of sepsis; draw a second set from a peripheral venipuncture; consider time to positivity
Sets	Always draw two sets from different sites
Volume	Is the single most important factor for organism detection
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	Use of ISDD has been shown to decrease contamination rates to less than 1%

The Steripath® Initial Specimen Diversion Device®

Butterfly Needles for Venipuncture

(Design supports Phlebotomy and RN Blood Culture Workflow)

23G Needle

21G Needle

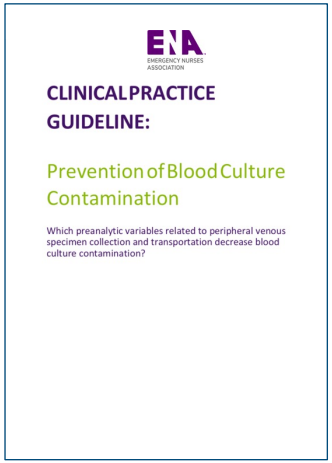
Luer Connect for Peripheral IV Starts

(Design supports RN Blood Culture Workflow)

Luer

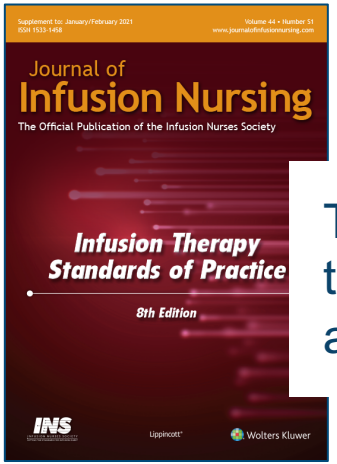
Evidence-based Guidelines and Standards for Diversion

EMERGENCY NURSES ASSOCIATION



1.0–2.0 mL diversion volume

INFUSION NURSES SOCIETY
SETTING THE STANDARD FOR INFUSION CARE®



1.5 mL or greater diversion volume

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1.0 mL diversion volume

(M47 ED2 Proposed Draft - 2021)

The ***only*** device that meets the evidence-based guidelines and standards for diversion

Reduction in Blood Culture Contamination Through the Use of Initial Specimen Diversion Device® [Steripath®]

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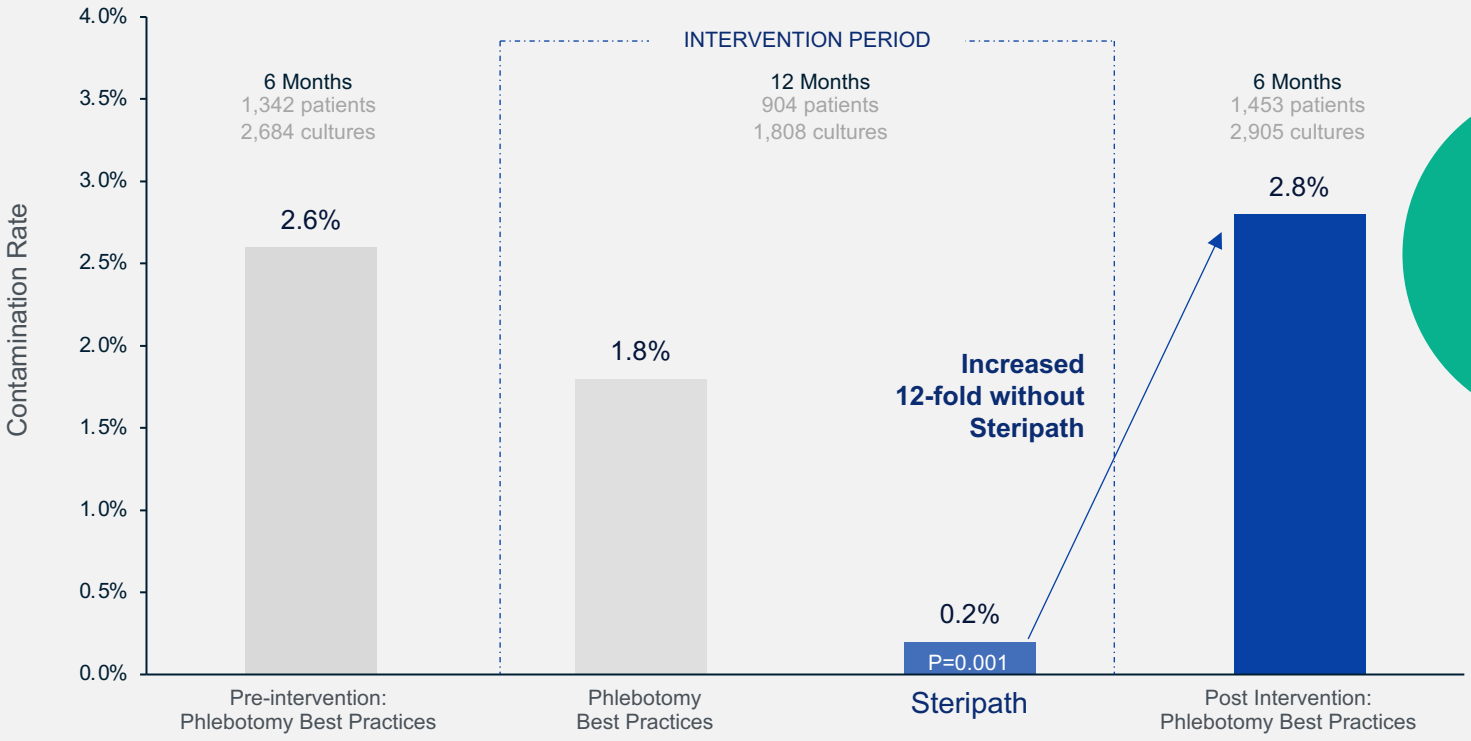
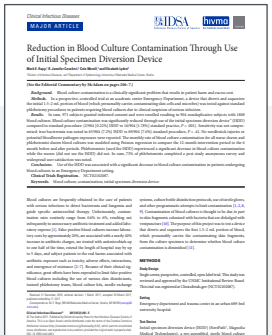


Researchers calculated the study institution would save **1.8 M/year** with Steripath

Peer-Reviewed Published Studies

IDSA Infectious Diseases Society of America

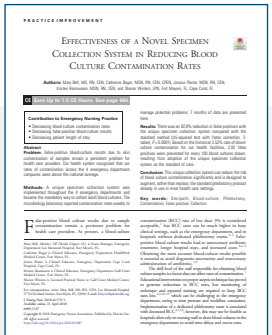
Clinical Infectious Diseases
2017 (July)


Clinical Infectious Diseases

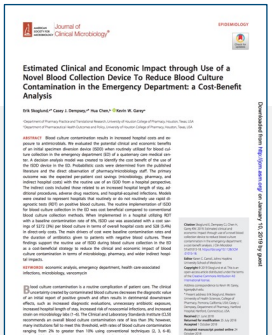
MAJOR ARTICLE

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

Mark J. Rupp, A. Jennifer Crawford, Cole Mundt, and Elizabeth Lyles

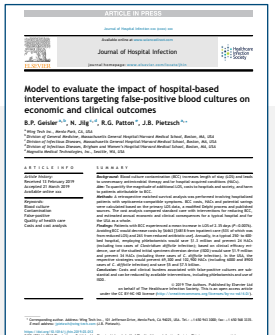

PRACTICE IMPROVEMENT

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


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


ARTICLE IN PRESS

Reducing blood culture contamination using an initial specimen diversion device

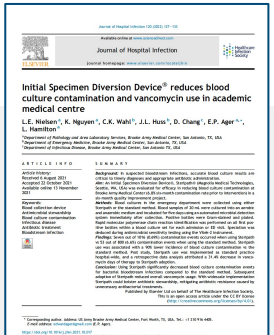

ARTICLE IN PRESS

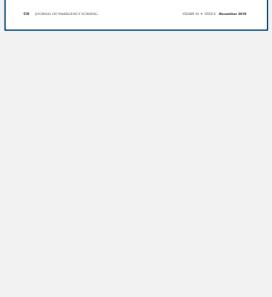
Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures on economic and clinical outcomes


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


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



Journal for Emergency Nursing
2018 (Nov)

AMERICAN SOCIETY FOR MICROBIOLOGY

Journal of Clinical Microbiology
2019 (Jan)

APIC

American Journal of Infection Control
2019 (Jan)

Healthcare Infection Society

Journal of Hospital Infection
2019 (Mar)

EMERGENCY NURSES ASSOCIATION

Journal for Emergency Nursing
2021 (Mar)

Healthcare Infection Society

Journal of Hospital Infection
2021 (Nov)

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

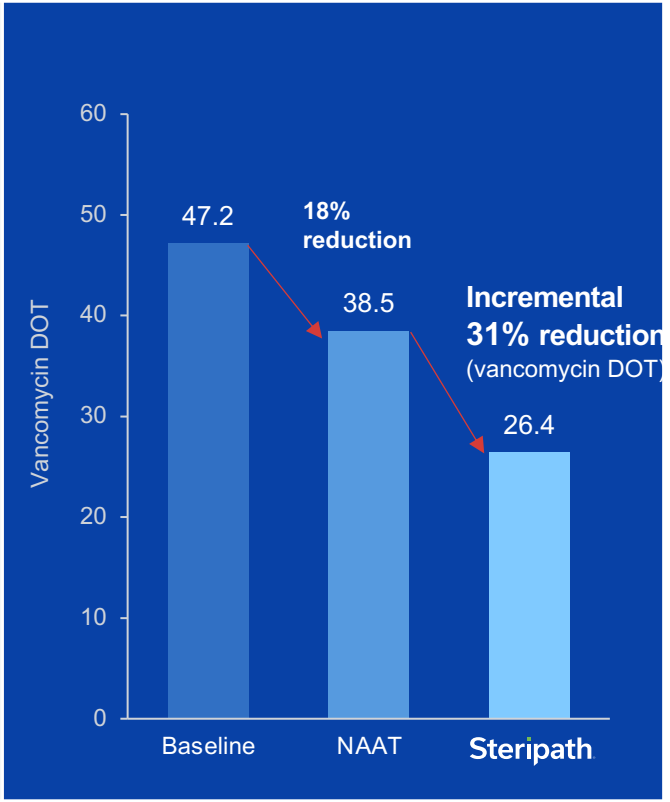
#	Institution	Publication or Conference Presentation	Date	Duration	Baseline or Control Rate	Steripath® Rate	BCC Reduction	Ann. Savings
1	**Stanford Health Care**	IDSA – IDWeek / PACCARB	2020/21	10 months	2.3%	**0.0%**	**100%**	NR
2	**Central Texas VA Medical Center**	Journal of Emergency Nursing	2021	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

BAMC

Peer-Reviewed Publication

TITLE:	Initial Specimen Diversion Device® Reduces Blood Culture Contamination and Vancomycin Use in Academic Medical Center
CONFERENCE:	***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 (Verigene) and blood culture contamination (Steripath®) 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 **Steripath** 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 Steripath contributed to a significant reduction in unnecessary antibiotic therapy.



The Joint Commission

National Patient Safety Goals

NPSG.07.03.01

- **Implement evidence-based practices to prevent health care-associated infections due to multidrug-resistant organisms in acute care hospitals/critical access hospitals.**

  Note: This requirement applies to, but is not limited to, epidemiologically important organisms such as methicillin- resistant staphylococcus aureus (MRSA), Clostridium difficile (CDI), vancomycin-resistant enterococci (VRE), carbapenem- resistant enterobacteriaceae (CRE), and other multidrug-resistant gram-negative bacteria.

- **Measure and monitor multidrug-resistant organism prevention processes and outcomes, including the following**:
  - Multidrug-resistant organism (MDRO) infection rates using evidence-based metrics
  - Compliance with evidence-based guidelines or best practices

Steripath® is an evidence-based practice that supports NPSG.07.03.01

“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