THE IMPACT OF BLOOD CULTURE CONTAMINATION ON PATIENT SAFETY, CLINICAL OUTCOMES AND HOSPITAL REIMBURSEMENT About the Presenter: *Cheryl Kelley RN BSN, VA-BC*™



WELCOME! Let me introduce myself . . .

- Extensive knowledge in central and peripheral venous access with extensive experience in both clinical and manufacturing arenas
- Proud 15-year member of AVA
- 2010 Chairperson of AVA conference

"In order to be forward-thinking and effective health care providers, high-quality, patient-centered medical devices are required. Delivery of in-depth, thorough clinical education is a responsibility I eagerly accept."





The Impact of *Blood Culture Contamination* on:

Patient Safety

Clinical Outcomes

Hospital Reimbursement

Association for Vascular Access ANNUAL SCIENTIFIC MEETING September 15-18 • Columbus, OH

Financial Disclosures

I have the following financial relationships to disclose:

- Stockholder in: Teleflex, Terumo, Magnolia Medical Technologies
- Honoraria from: None
- Employee of: Magnolia Medical Technologies

I will only present on methods and devices with peer-reviewed published clinical data

I will not discuss off label use and/or investigational use in my presentation.





Welcome to Columbus, Ohio

Interesting facts . . .

- State capitol of Ohio, which means 'the great river'
- Largest city in Ohio; 880,000 residents
- Recognized in 2016 as one of "The 6 Best Cities" in Midwest
- Columbus was named after Christopher Columbus
- Neil Armstrong, first man to step foot on the moon was born in Ohio



It's a buckeye....seriously!





Learning Objectives

- 1. Define the process for accurate blood culture collection and how breaks in this process results in contamination.
- 2. Define the process for accurate blood culture collection.
- 3. Identify patient safety and reduced quality outcomes associated with blood culture contamination (BCC).
- 4. Describe the financial impact of contaminated blood cultures on hospital systems.
- 5. Review current methods and devices with peer-reviewed published clinical data





What are blood cultures?

- A microbiological culture of the blood, used to detect bacteria or fungi in the blood.
- Used to identify organisms and guide treatments.

The blood culture remains the

"gold standard"

for diagnosing sepsis.



Blood Cultures & Misdiagnosing Sepsis

Blood cultures are critical to an accurate sepsis diagnosis. But they require an uncontaminated sample...

The National 'Standard'

for Blood Culture Contamination

College of American Pathologists (CAP)



is the current **O** benchmark for biest on culture contamination rates in the US.

BUT IS THIS 'STANDARD' GOOD FOR YOUR PATIENTS?

Sepsis Test Results are Frequently WRONG



Impacted Patients at your Hospital

At the current benchmark, the extent of the patient impact in an average sized hospital is significant...



Clinical Decision Dilemma



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*data on file



Blood Culture Contamination is a Serious Problem

An average of over **1.2 million**

patients have false positive blood culture results annually in the United States¹

Majority

of patients with a false-positive results are treated with antibiotics³

Our healthcare system spends **over \$4 billion**

each year on unnecessary treatment ²

Due to antibiotic resistance,

over 2 million

people acquire serious illness and 23,000 people die each year⁴



¹Richard G. Patton Blood Culture Contamination Definitions Can Obscure the Extent of Blood Culture Contamination: A New Standard for Satisfactory Institution Performance Is Needed. Infection Control & Hospital Epidemiology, Available on CIO 2016 doi:10.1017/ice.2016.30

³Ventola C.L. "The Antibiotic Resistance Crisis Part 1: Causes and Threats". Pharmacy and Therapeutics 2015 Apr; 40(4): 277–283. ⁴Antibiotic Resistance Threats in the United States, 2013. US Centers for Disease Control and Prevention.





Definition of BCC

- Recovery of *normal skin flora* from a *single* blood culture within a 24-hour period
- Two sets of BC should be drawn
- Common commensal organisms include:
 - Coagulase negative staphylococci (CoNS)

Let's complicate the picture

contaminant

CoNS accounts for ~ 209 of all true bacteremia, yet it

is the most common

- Viridans group streptococci
- Bacillus
- Micrococcus
- Corynebacterium
- Proprionibacterium

Is this culture contaminated?







Method for Drawing Accurate Blood Cultures

- 1. Prepare to collect 2 sets of blood cultures (4 bottles total) from two sites
 - Avoid drawing from existing central venous catheters
- 2. Patient preparation
 - Disinfect skin
 - Allow to dry
- 3. Bottle preparation
 - Scrub bottle tops with alcohol
 - Allow to dry
 - Mark fill volume on bottle
- 4. Cannulate vessel using aseptic non-touch technique
- 5. Bottle fill
 - Mark fill lines during bottle preparation
 - Fill bottle with blood to mark—don't go over the marked line
 - Collect aerobic bottle, then anaerobic bottle



АVA 2018 социмви́я



Training and Education Will Not Solve the Problem

Neither can current best practices!



<u>⊥.</u>

Human Factor(s):

Risk of contamination during assembly and preparation of supplies, and skin prep



Skin Flora:

Skin can be disinfected but not sterilized.

Up to 20% of skin flora remains viable even after skin prep¹



3.

Skin Plug and Fragments:

when present, will ALWAYS enter the culture specimen bottle.

Commonly will contain viable microorganisms

¹Anjanappa T. et al; Preparative Skin Preparation and Surgical Wound Infection. *Journal of Evidence based Medicine and Healthcare*, (January 2015) ²M. Rupp, et al; Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device. *Clinical Infectious Diseases* (August 2017)





Let me introduce you to my state—West Virginia!

The best mode of transportation!







Associated Risks of a Sepsis Misdiagnosis

Many of these patients are misdiagnosed with sepsis and are unnecessarily put at risk.

ANTIBIOTIC RESISTANT

ANTIBIOTIC UTILIZATION

RISK OF ACQUIRING

EXTENDED LENGTH OF STAY

MISDIAGNOSED PATIENT EXPOSURE TO HACS It is the end of the road for antibiotics unless we act urgently."

Tom Frieden, Former CDC Director
 July 2016

Clostridium difficile Infection (CDI)

- CDI is a HAC: average LOS 10 additional days; average cost \$34K (BMC Infectious Diseases 2016)
- Reducing the use of high-risk, broad spectrum antibiotics by 30% could lower CDI by 26% (Centers for Disease Control 2014)
- Antibiotic exposure is the most important risk factor for CDI." (Kelly Reveles, PharmD, PhD, UTHSC at San Antonio, American Journal of Infection Control 2014)

American Journal of Infection Control



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





Risk Factors for Clostridium difficile Infection

Although longer durations of therapy are associated with a greater risk of CDI, it is important to remember that **even single doses of antimicrobials can still increase a patient's risk.**"

Clinical Infectious Diseases

Robert C. Owens, Jr. et al, Clin Infect Dis (2008) 46 (Supplement_1): S19-S31





Patient Centered Ramifications

Inaccurate Diagnosis of Sepsis

- Contaminated cultures can cause difficulty with interpretation of culture
- Also, confusion regarding antibiotic regimens
- Endangers patient safety/outcomes

Acute Kidney Injury (AKI)

- Most clinically significant adverse reaction reported with antibiotics
- AKI costs over \$15,000 per incidence

Allergic Reaction

- Accounts for 11.3% of adverse drug reactions¹
- Most common with hospitalized patients

¹Y Nasr et al., J Med Microb Diagn 2016, 5:3





Consequences Affecting Hospital Quality

Antibiotics create a lot of collateral damage!

Counter to Antibiotic Stewardship

 Establish antibiotic stewardship programs in all acute care hospital

- Center for Disease Control and Prevention, 2014

 "Reduction of inappropriate antibiotic use by 20% in inpatient settings."

– White House Executive Order, 2015







Antimicrobial Resistance

Financial Impact of AMR

With continued rise in AMR, at today's pace, would result in:

10,000,000 (M) people dying every year
Cost \$100,000,000,000 (T) by 2050

This dollar amount lost is equivalent to loss of one year's total global output over the period.

AMR's Impact on World GDP





Other consequences associated with "Quality of Care"

Negative Laboratory Impact

- Contributes to overtime
- Unnecessary testing
- Negative impact on workflow, processes, productivity
- Significantly increases avoidable costs



• Multiple venipunctures

patient

satistaction

- Dis-satisfaction with unnecessary extended LOS
- Unhappy with administration of potentially unnecessary antibiotics

Increased Length of Stay (LOS)

- Unnecessary hospital admission
- Potential hospital re-admission (ED patient)
- Contributes to exposure HAC/HAI



Risk of Penalties and Reduction of CMS Hospital Reimbursement



Directly impacts key CMS quality outcome metrics dictating hospital reimbursement (readmissions, complications, length of stay, patient experience)

- Reduces hospital reimbursement
- Impacts on Value-Based Purchasing incentive dollars.

Unnecessary false positive CLABSI reporting due to BC contamination

Virulent organisms (Entercoccus, VRE, MRSA, etc.) can be located on skin
 If patient has CVC and BC is contaminated with these organisms, it qualifies as CLABSI
 Average non-reimbursable cost of a CLABSI is over \$45,000¹





Cost of Blood Culture Contamination Core Drivers



- 1. Lab Workup Staff time, Supplies, Assay Costs
- 2. Clinical Coordination

Communications within the clinical team

3. Antibiotics Drug, compounding & administration costs

Procedures

4. Follow-Up tests Additional Cultures, Other

- 5. Length of Stay Impact on LOS from False Positives
- 6. Antibiotic-Related Complications MRSA, VRE & C. diff
- 7. HAI & HAC Increase in other HAIs and HACs
- 8. Reimbursement

CMS Reimbursement penalties and loss of VBP incentive dollars

ABC Hospital Patient Safety and Hospital Economic Implications of BCC



360 Patients per Year x \$3,500 Cost per BCC = \$1,260,000 in Avoidable Costs

¹Alahmadi Y.M, M.A. Aldeyab, J.C. McElnay, M.G. Scott, F.W. Darwish Elhajji, F.A. Magee, et al. Clinical and economic impact of contaminated blood cultures within the hospital setting. J Hosp Infect. 2011 Mar; 77(3): 233-6. ²Gander R.M., L. Byrd, M. DeCrescenzo, S. Hirany, M. Bowen and J. Baughman. Impact of Phlebotomy-Drawn Blood Cultures on Contamination Rates and Health Care Costs in a Hospital Emergency Department. JCM 2009 Apr: 47(4): p. 1021-1024



Economic Implications of False Positive Blood Cultures

Costs associated with false positive blood cultures to be in excess of \$3,500 per patient-instance

Publication	Estimated Incremental Charges	Adjusted for 40% Cost-to- Charge Ratio	Extended Length of Stay
Journal of Hospital Infection	\$8,210 ^{1*}	\$3,284 ¹	5.4
Journal of Clinical Microbiology	\$9,665 ^{2*}	\$3,866 ²	1+
Journal of Hospital Medicine	\$10,692 ^{3*}	\$4,277 ³	3.0
Clinical Performance Quality Healthcare	\$9,226 ^{4*}	\$3,690 ⁴	8.4
Journal of American Medical Association	\$7,6825*	\$3,073⁵	4.5
The American Journal of Medicine	\$10,331 ^{6*}	\$4,132 ⁶	4.2
Average	\$9,301* (\$3,720	4.42

SOURCES

¹Alahmadi Y.M., M.A. Aldeyab, J.C. McElnay, M.G. Scott, F.W. Darwish Elhajji, F.A. Magee, et al. Clinical and economic impact of contaminated blood cultures within the hospital setting. J Hosp Infect. 2011 Mar; 77(3): 233-6.

²Gander R.M., L. Byrd, M. DeCrescenzo, S. Hirany, M. Bowen and J. Baughman. Impact of Phlebotomy-Drawn Blood Cultures on Contamination Rates and Health Care Costs in a Hospital Emergency Department. JCM 2009 Apr: 47(4): p. 1021 -1024

³Zwang O., R.K. Albert. Analysis of strategies to improve cost effectiveness of blood cultures. Journal of Hosp Med. 2006 Sep;1(5):272-6

⁴Surdulescu, S., D. Utamsingh, and R. Shekar. Phlebotomy teams reduce blood-culture contamination rate and save money. Clin. Perform. Qual. Health Care 6:60-62. 1998.
⁵Bates D.W., L. Goldman, T.H. Lee. Contaminant blood cultures and resource utilization. The true consequences of false-positive results. JAMA. 1991 Jan 16;265(3):365-9
⁵Dunagan W.C., R.S. Woodward, G. Medoff, J.L. Gray, E. Casabar, M.D. Smith, C.A. Lawrenz and E. Sptiznagel. Antimicrobial misuse in patients with positive blood cultures. The American Journal of

Medicine. Volume 87, Issue 3, Pages 253-259, September 1989. * -- CPI adjusted to 2015 \$s

(full publications available upon request)



Passing time on Friday night in West Virginia (aka date night)







IS BLOOD CULTURE CONTAMINATION PREVENTABLE?

Methods, Practices and Devices that can Reduce BCC

Peer Reviewed Clinical Evidence

- 1. Education and training
- 2. Phlebotomy team formation
- 3. Manual diversion technique
- 4. Initial Specimen Diversion Device





Clinical Education

(ED staff, phlebotomy or house wide)

Focus

- Effective preparation of supplies
 Bottle top scrub
- Proper collection of specimen
 Skin disinfection
- Performance of actual venipuncture
 No re-palpation of site
- Proper procedure
 Fill volume

Strengths

- Easy to implement
- Initial success is quickly realized
- Financially neutral to present method

Clinical Outcomes

• Can reduce BCC rate by up to 50%

Weakness

- Will not address skin plug and fragments
- Unsustainable
 - Requires frequent re-education
 - Overloads staff with repetitive education

Peer Reviewed Data

Roth, A., Wiklund, A. E., Pålsson, A. S., et al. (2010). Reducing blood culture contamination by a simple informational intervention. *Journal of Clinical Microbiology, 48*(12), 4552–4558. doi:10.1128/JCM.00877-10 Harding, A. D., & Bollinger, S. (2013). Reducing blood culture contamination rates in the emergency department. *Journal of Emergency Nursing, 39*(1), e1–e6. doi:10.1016/j.jen.2012.10.009





Dedicated Phlebotomy Teams

Options include

- Whole house phlebotomy team
- ED based only phlebotomy teams

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Strengths

- Increased patient satisfaction
- Designated personnel increases outcomes
- More timely collection of BC?
- BC can be drawn at same time of other routine labs

Weakness

- Does not address skin plug
- Venipuncture draws only may not include IV start draws
- Extremely expensive; incudes wages, benefits
- Development of team is time consuming and impractical
- Difficulty in development and maintaining of team
 Hiring
 Training

Outcomes

- Can reduce BCC rates to ~~1% but higher in the ED
- May increase patient satisfaction due to skilled clinicians drawing blood

Peer Reviewed Data Mermel, L. A., Allon, M., Bouza, E., Craven, D. E., Flynn, P., O'Grady, N. P., . . . Warren, D. K. (2009). Clinical practice guidelines for the diagnosis and management of intravascular catheter-related infection: 2009 update by the Infectious Diseases Society of America. *Clinical Infectious Diseases, 49*(1), 1–45. doi:10.1086/599376



What are Manual Diversion Techniques?

What is it?

 Process in which first ml's of blood are discarded (or used for another lab test) prior to sample collection

Strengths

Easy to perform

• Can provide modest reduction in BCC rates

Weakness

- Adds additional steps and touch point contamination
- Difficult to disinfect top of waste tube
- Difficult to sustain
- Compliance issues
- Limited clinical evidence on effectiveness and sustainable BCC reduction

Published Outcomes

- Lowest manual diversion BCC rate in published literature is 2.2%
- Average BCC reduction is 36%





Manual Diversion Techniques

Bundled Kit

- ED staff collects necessary supplies for BC collection
- Includes usual supplies but also a waste tube

Pre-packed Kit

 Pre-packed kit with supplies and waste tube





Peer-Reviewed Published Results with Manual Diversion



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Peer Reviewed Data

Initial Specimen Diversion Device (ISDD)

How does the ISDD Work?

- Diverts initial 1.5-2.0 mL of blood and potential skin contaminates
- An additional diversion chamber is located between venipuncture site and BC bottle—isolates blood
- Creates independent second sterile blood flow path
- Appropriate for adults and peds over 6kg





Initial Specimen Diversion Device (ISDD)

Configurations

• Luer configuration attaches to newly started IV

Extension set is high pressure purple (400 psi) 9 inches and attached to device; extension set can be left in place

• 21g and 23g butterfly for phlebotomy and 2nd set of BC

Evidence

• Two (2) peer-reviewed published controlled clinical studies and seven (7) clinical abstracts presented a major medical conferences

¹M. Rupp, *et al*; Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device. *Clinical Infectious Diseases* (August 2017)
 ²C. Lanteri, et al; Reduction of Blood Culture Contamination in the Emergency Department. Department of Defense Healthcare Quality and Safety Award (2016)
 ³D. Chang, *et al*; Impact of Blood Culture Diversion Device and Molecular Pathogen Identification on Vancomycin Use. *Society of Healthcare Epidemiology of America (SHEA) Conference* (Spring 2017)

AVA 2018 COLUMBUS

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

Clinical Infectious Diseases - 2017:65 (15 July)





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

Clinical Infectious Diseases - 2017:65 (15 July)



Peer Reviewed Data



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

Clinical Infectious Diseases - 2017:65 (15 July)



Peer Reviewed Data



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

Journal of Emergency Nursing – 2018 (April)

Trial Overview:

- Four-hospital system in Florida with data collection over seven-month period
- Blood cultures with ISDD (6,293 cultures) were compared to historical rates obtained with standard collection techniques (35,392 cultures)

Results:

- 83% reduction in blood culture contamination rate with ISDD
- Standard rate pre-trial was 3.5%
- Rate with ISDD was 0.6% system-wide contamination rate in 6,293 cultures (P=0.0001)

Conclusion:

- Prevented 1,008 false positives (annualized basis)
- Cost savings of \$641,792 during a 7-month period

Peer Reviewed Data







West Virginians wear lots of plaid!







Antibiotics have become the underpinning of what we do in 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 for Healthcare-Associated Infection Prevention Program, Division of Healthcare Quality Promotion, Center for Disease Control and Prevention (CDC) June 2017



Summary

- Blood culture contamination is a serious preventable problem that leads to sepsis misidentification
- Significant ramifications and negative consequences present for patients and hospitals
- Solutions are available—many have been in place for long periods of time, but with less than stellar results
- Initial Specimen Diversion Device can offer promising solutions
- Can we get to ZERO?

Thank you!



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