

Challenging the Status to Improve Patient Outcomes

Carleen Merola, DNP, RN, TCRN, PCCN April 4, 2023

Disclosure

• Dr. Carleen Merola was provided with an honorarium by Magnolia Medical Technologies to participate in this webinar



Carleen Merola, DNP, RN, TCRN, PCCN Nursing Director | Critical Care & Emergency Ascension Seton Williamson

- 15 years as Emergency Nurse
 - Level 1 & 2 Trauma
 - Comprehensive/Primary Stroke
 - Mental Health Screening Center
 - Urban & Suburban Settings
- 9 years of progressive leadership
 - Charge Nurse
 - Educator
 - Supervisor
 - Manager
 - Director



Poll Question

What is your role?

Learning Objectives

- Identify the principles of a high reliability organization (HRO) and how they can be applied within a hospital to optimize patient outcomes.
- Review the recent national movement toward a 1% or less blood culture contamination goal and the critical step every hospital should make to achieve sustained reductions in blood culture contamination.
- Discuss the importance of a multi-disciplinary, team-based approach along with evidence-based best-practice techniques and technology to realize sustainable improvements in blood culture quality.



High Reliability Organization (HRO)

Safe, Reliable and Effective Care



When it comes to patient safety, Healthcare " organizations have more work to do. Most healthcare organizations have implemented patient safety improvements by adopting standardized ways of providing care such as using checklists and other tools to reduce variation. Yet, even these approaches can be limited as they don't by themselves achieve educational whole system safety, nor do they embed safety into the organization's DNA. A more promising approach is becoming a high reliability organization."



What is a High Reliability Organization (HRO)

Definition of an HRO

An organization that has maintained high levels of safety, quality, and efficiency over an extended period.

What makes them "different"?

- Developed ways of "managing the unexpected" better than most organizations.
- Prepared to address the growing complexity of operations in healthcare and the risk of significant consequences when failures occur.



Poll Question

What is a realistic goal when it comes to a key performance indicator?



Why 100% Matters Every Time...



Air Traffic Control

In the United States, 45,000 average daily flights handled by the FAA. If 99% was acceptable, then **450 flights would crash each day.**



Postal Service

In the United States, the Postal Service processes and delivers 162.1 million pieces of First-Class Mail each day. If 99% was acceptable, 1,621,000 pieces of mail would go missing each day.



Operative Services

In the United States, 136,986 major surgeries are performed each day. If 99% was acceptable, there would be an error in 1,370 of these surgeries.



What Makes an HRO?

The Principles of High Reliability Organizations

The 5 Principles of an HRO



successful models of care.

Focus on deviation from the expected and on what could fail.

The Role of Leaders in a Culture of High Reliability

Becoming an HRO is not simply a matter of completing a series of improvement projects. As with any improvement, it is necessary to change culture, develop a different way to work, maintain constancy of purpose and ensure improved processes are sustained over time.

As a team supporter:

- A leader listens to their team
- A leader connects the team and its work to the bigger picture
- A leader sets clear expectations and reinforces accountability
- A leader follows up and ensures execution
- A leader recognizes and celebrates
- A leader coaches and develops

As a team model:

- A leader lives the high reliability leader behaviors
- A leader applies error prevention and other high reliability techniques
- A leader adheres to best practices
- A leader commits to rounding and daily huddles

A leader who cultivates relationship and actions to tackle challenges and make the impossible possible"



Carleen Merola, DNP, RN, TCRN, PCCN Nursing Director | Critical Care Ascension Seton Williamson



High Reliability Organization (HRO)

Why Apply HRO Principles to Blood Culture Contamination



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 bacteremia, including sepsis

¹Liu 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.

²Weiss AJ, Jiang HJ. Overview of clinical conditions with frequent and costly hospital readmissions by payer, 2018. HCUP Statistic: Brief #278. July 2021. Agency for Healthcare Research and Quality, Rockville, MD.

Blood cultures are the gold standard test for bacteremia diagnosis, including sepsis



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

Test Results for Sepsis are Frequently Wrong





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

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 antibiotics¹



\$6 billion +

is spent by our healthcare system each year on unnecessary treatment associated with false-positive blood culture results²



3 million +

antibiotic-resistant and *C. difficile* infections each year and 48,000 people die based on the CDC's 2019 report³



1 in 5 patients

experience adverse drug event (ADE) associated with antibiotic administration in acute care hospital setting⁴

¹Patton 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;77(6): 8.06:10.1017/ice. 2016.3.0. *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.2019.3.0.12. *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/dcb:252. *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.2017.1788.



The Clinical Decision Dilemma

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University of Arkansas BCC Publication (2022)

Risk factors and clinical outcomes associated with blood culture contamination

Risk of In-Patient Mortality increased 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"

Conclusion:

- "Blood-culture contamination increased length of stay, length of antibiotic treatment, hospital costs, acute kidney injury, and in-patient mortality"
- This study highlights the "devastating clinical outcomes for patients with contaminated blood cultures"



CovHys

Peer-Reviewed Publication

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Old National 'Standard'

for blood culture contamination



Old CLSI standard for blood culture contamination rates in the U.S.¹

BUT WAS THIS 'STANDARD' GOOD FOR PATIENTS?

¹CLSI M47 Principles and Procedures for Blood Cultures; Approved Guidelines. CLSI document M47-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2007.

What this means at a typical hospital

3.0% blood culture contamination rate in an Emergency Department



1Skoglund E, Dempsey CJ, Chen H, Garey KW. Estimated clinical and economic impact through use of a novel blood collection device to reduce blood culture contamination in the emergency department: a cost-benefit analysis. J Clin Microbiol. 2019;57(1):e01015-18. doi:10.1128/JCM.01015-18. Geisler BP, Jilo N. Patton RG. Pietzsch JB, Model to evaluate the impact of hospital-based interventions taroeting false-positive blood cultures on economic and clinical outcomes. J Hosp Infect. 2019;102(4):438-444. doi:10.1016/j.ihin.2019.03.012. 23

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

Controllable



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 prep¹

Uncontrollable



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

¹Anjanappa 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/jbbmh/19. ²Rupp 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. ³Bell 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.

Manual Diversion (waste tube) Will Not Solve The Problem

Manual diversion of the initial volume of blood

- Peer-reviewed published data has shown only modest unsustainable reductions in contamination
- Lowest published contamination rate achieved is 2.0%¹ (best case controlled clinical study scenario)



¹Zimmerman FS, Karameh H, Ben-Chetrit E, Zalut T, Assous M, Levin PD. Modification of blood test draw order to reduce blood culture contamination: a randomized clinical trial. Clin Infect Dis. 2020;71(5):1215-1220. doi:10.1093/cid/ciz971.



TITLE:	Getting to Zero: Impact of a Device (Steripath) to Reduce Blood Culture Contamination and False-Positive Central Line-Associated Bloodstream Infections	8.0%	6
CONFERENCE	Infection Control & Hospital Epidemiology (2022)	7.0%	6
INSTITUTE:	Stanford Health Care		۶
AUTHORS:	Lucy Tompkins, MD, PhD, et al		~
DESIGN	Single-center, prospective, controlled study	%0.5 gate	6
DEGICIN.	March 2019–January 2020 (10-months)	tion F	
METHOD:	Blood cultures were obtained hospital-wide by Phlebotomy team using the Steripath compared to standard method.	e 4.0%	o -
	100% reduction in blood culture contamination	то 5.0% О	⁶ 2.3%
RESULTS:	Steripath ISDD: 0.0% (0/11,202) contamination rate	2.0%	6
	12-Fold decrease in NHSN/CMS reportable False-Positive CLABSIS		100%
	Steripath ISDD: 1, Standard method: 12	1.0%	
	SIR fell by 33-57% when contaminants were removed	0.09	0.0%
	a consortium of 101 academic medical centers that each member on HAI rates and many other factors		Standard Method Steripath

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 2022, 1-5. doi:10.1017/ice.2022.284

New National 'Goal'

for blood culture contamination









CLSI M47 2022 and CDC's new goal with best practices for blood culture contamination rates¹

All six cited studies examined the clinical efficacy of **Steripath** and/or referenced **Steripath-specific** datasets, and reported a sustained **1% or lower** contamination rate

THE RIGHT 'STANDARD' FOR PATIENTS

¹CLSI. M47 2nd Edition Principles and Procedures for Blood Cultures; 2022.

The Results of an HRO and Steripath® Initial Specimen Diversion Device®

Applying the HRO Principles to Blood Culture Contamination

The 5 Principles of an HRO



successful models of care.

Focus on deviation from the expected and on what could fail.

Preoccupation with Failure

Identify processes that are not reliable or sustainable and monitor performance.

HRO Questions

- When changes are made to processes, are all of the possible downstream effects considered?
- Are near-misses brushed off and forgotten?

- We've tried training and education with standard method and had no significant or sustainable impact.
- Our blood culture contamination rates are consistently above 3% each month.



Reluctance to Simplify

Create an environment that supports and practices continuous learning.

HRO Questions

- Is what we are doing working?
- What is the root cause of the problem?
- Are there any resources to help optimize the process?

- There are controllable and uncontrollable factors to blood culture contamination
- Achieving sustained reductions in blood culture contamination rates requires tackling both
 - Controllable: Reinforce evidence-based techniques
 - Uncontrollable: Employ an evidence-based technology that has already been validated through evidence and guidelines to address this issue



Clinical Practice Guidelines













Prevention of Blood Culture Contamination

Which preanalytic variables related to peripheral venous specimen collection and transportation decrease blood culture contamination?



Blood Culture Contamination: An Overview for Infection Control and Antibiotics (Stewardship Programs Working with the Clinical Laboratory Paper Resolution of the Clinical Culture of the steward state of the steward Resolution of the steward state is also in steward on the steward of the steward state is a state in state in state in state of the steward state is also also state in the state of the state is also in state of the steward on the state of the steward state is also in the state in state in state of the steward on the state of the steward state is also in the state in state in state is also in the state is also also in the state is also in state in state in state in state in state is also also in the state is also in the state is also in the state in the state of the state is also in the state in state in state in state in the state of the state is also in the state is also in state in state in state in the state of the state is also in the state is also in the state is also in the state in the state of the state is also in the state is also in the state in the state is also also in the state is also also in the state is also also in the state is also in the state is also in the state is also also in the state is also in the state is also in the state is also also in the state is also in the state is also in the state is also also in the state is also in the state is also in the state is also also in the state is also in the state is also in the state is also also in the state is also in the state is also in the state is also also in the state is also also in the state is also in the state

ed to optimize multidisciplinary quality in



The **only** device clinically proven to meet all evidence-based guidelines

1.0–2.0 mL diversion volume

1.5 mL or greater diversion volume

1% goal for blood culture contamination

1% goal for blood culture contamination (M47 ED2 2022)



Engineering Out Human Factors

Only FDA 510(k)-cleared device indicated to reduce blood culture contamination



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	0	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	0	2021	14 months	14 months 31% reduction in vancomycin DOT				
19	University of Houston	Journal of Clinical Microbiology	0	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	0	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. <i>diff</i>					

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National Peer-Reviewed Publication 🙎 Best Evidence-Based Project 🏮 Peripheral IV Start

Sensitivity to Operation

Focus on deviation from the expected and on what could fail.

HRO Questions

- . How do we know that the correct work is being done?
- Where are the possible failure points and how will be proactively mitigate that while being sensitive to every step of the process?

- Effective daily huddles and rounding to influence and reinforce safety measures and practice change
- Ensure Ease of Use
- Tracking Product Utilization and Compliance



Commitment to Resistance

Staff continuously learn from errors and near misses and share successful models of care.

HRO Questions

- How does your hospital respond in the face of failure?
- · How are broken processes fixed so that failures are not repeated?
- · How do you support the 'just culture' dialogue and practice?

- · Continuously sharing successes
- Hardwiring change through expectations and accountability:
 - Pre-collection
 - During collection
 - Post-collection
 - And a defined escalation plan escalation plan
- · Containing errors effectively is critical to long-term success



Deference to Expertise

Assign to the person who truly has the needed skill, not the person who has authority.

HRO Questions

- Do you have the right stakeholders to support this change?
- Are the end users included in the planning process?
- · How does this process change impact other departments?

- · Anyone can ask questions, provide feedback, and suggest new ideas
- Listen to input from the end-users
- Transparent communication is critical when creating a culture of HRO



HRO and Steripath® Initial Specimen Diversion Device ®

The Results

Initial Specimen Diversion Device Associated with a 94% Lower Blood Culture Contamination Rate CARLEEN MEROLA, DNP. RN. TCRN. PCCN

PURPOSE

Up to half of all positive blood cultures are falsely positive due to sample contamination.12 an unacceptable failure rate in a technique widely utilized to direct therapeutic outcomes for patients suspected of having a bloodstream infection.³ Standard methods of sample collection fail to prevent common skin flora (which remain viable in the keratin laver after antiseptic application) from entering the blood culture bottle.3-5 The Initial Specimen Diversion Device (ISDD®) can sequester these contaminants in a closed process, without introducing the additional opportunities for touchpoint contamination associated with manually diverting the sample. but are not yet standard practice.3-5 We incorporated this emerging technology into our practice with the objective of assessing the efficacy of the technology at reducing blood culture contamination relative to standard methodology.

DESIGN

This was a quality improvement study designed to evaluate a potential process improvement for reducing blood culture contamination

SETTING

This study took place in a 118-bed, multi-specialty community hospital and Level III trauma center at Baylor Scott & White Medical Center - Centennial.

SUBJECTS

All subjects were adult emergency department patients suspected of bloodstream infection.

METHODS

Over a four-month period, 527 blood culture sets were drawn using standard methodology and 448 blood culture sets were drawn using the Initial Specimen Diversion Device.



Steripath® Gen2 ISDD® (made by Magnolia Medical Technologies®)

All samples were collected via fresh venipuncture with or without intravenous catheter start. Alcohol pads were used to disinfect all blood culture bottle tops and a chlorhexidine gluconate solution was applied to the skin for 30 seconds before venipuncture. Contamination events were recorded, and Fisher's exact test was utilized, with p < 0.05considered significant.



During this period, 17 contamination events were associated with using standard methodology (3.2% contamination rate) and 1 contamination event was associated with use of the Initial Specimen Diversion Device (0.22% contamination rate). Use of the ISDD was associated with a significant 94% reduction in blood culture contamination, relative to standard methodology (p = 0.0002).



Estimated ISDD Cost Savings \$87,964



Published Abstract

IMPLICATIONS

The extreme reduction in blood culture contamination observed when utilizing the Initial Specimen Diversion Device supports the hypothesis that this technology mitigates an unaddressed and costly source of clinical frustration.⁶ Blood culture contamination contributes to hospital bed shortages as patients find their length of stay extended, and the unnecessary broad-spectrum antibiotics administered to these patients can prove harmful.3-6 The prevalence of adverse reactions, such as acute kidney injury, and the threat posed by multi-drug resistant organisms necessitate improvements to nationwide antibiotic stewardship.3.4.6.7 If the dramatic results observed during the study are sustainable, future studies might investigate the reduction of antibiotic use associated with lowering blood culture contamination rates. Based on the observed results, we strongly advocate consideration of the ISDD technology by nursing leaders and quality control personnel, as a means of improving patient outcomes.



\$100,000

\$90.000

Clinical Results at 90 Days



Blood Culture Contamination Rates

Overall Reduction in Contamination



Μ

New Hospital. New Team. New Change.

Using the foundations on HRO and putting them into action.

My Questions

- Is there an HRO philosophy within my current organization?
- · What and when is the needed data available to me?
- What resources at the hospital do I have?
- Do you have the right stakeholders to support this change?
- · Will the same process work again?
- What roadblocks do I envision encountering in this process and how will use the 5 principles of HRO to lower the blood culture contamination rate to below 1%?



Tools of HRO

- 1. SBAR (Situation, Background, Assessment, Recommendation)
- 2. Brief and Debrief
- 3. ARCC (Ask a question, Request a change, voice a Concern, Chain of command)
 - Clarify what is happening, encourage the room to consider events and alternatives
 - Everyone receives the ARCC with an open mind
- 4. Read-Back/Repeat-Back
 - Never assume you heard everything correctly the first time
- 5. 200 Percent Accountability
- 6. STAR (Stop, Think, Act, Review)
 - It is very common that after a safety event, those involved agree that they could have seen it coming if they had slowed down to consider

Continuous Learning and Improvement

- Most problems do not stay solved permanently. As the world turns, good processes slowly become less effective.
- It is important to review processes periodically to see if they still apply
- Available data sets will often tell us what is coming using leading indicator metrics
- The best processes make doing the right thing easy, while making the wrong thing hard to do



- The goal is zero harm to patients and the only way to do that is to follow the example of a High Reliability Organization (HRO).
- Establish clear lines of communication to the staff, accept the challenges that you are facing and continuously be seeking ways to improve the process.
- Change is hard; be a champion for change and challenge the status quo of how things are done in your hospital.

MAGNOLIA MEDICAL TECHNOLOGIES

Every false positive could result in patient harm. Steripath® enables sustained, near-zero blood culture contamination rates¹ and we believe the only acceptable number for sepsis misdiagnosis is zero.



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