

THE PROBLEM, IMPACT AND SOLUTION FOR

BLOOD CULTURE CONTAMINATION

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Blood cultures are the 'gold standard' for laboratory diagnosis of blood-stream infections and sepsis. The goal is to identify 'true' pathogens while minimizing 'false-positives' or bacterial contamination of the blood sample. False-positive results can be misinterpreted as clinically relevant, resulting in antimicrobial administration that is not necessary and potentially harmful. Blood culture contamination impacts antibiotic utilization, length of stay, readmissions, clinical laboratory workload and flow, development of *Clostridioides difficile* infection and emerging antibiotic-resistant bacteria.

These false results confound the clinical decisions regarding antibiotic therapy including targeting and de-escalation of broad-spectrum antibiotic therapy. Understandably, due to the risk of a *potential* blood culture contaminant being a clinically relevant pathogen, the patient is often prescribed antibiotics that may not be indicated and continues down the sepsis protocol treatment pathway. Even when rapid molecular diagnostic technologies are used for organism identification, final diagnosis and clinical decision-making can be a challenge since 22%-38% of potential contaminants, such as coagulase-negative staphylococci (CoNS), can also be a source of true bacteremia.^{1,2,3,4}

What is the problem?

On average, eight percent of all blood cultures performed across the U.S. are reported as 'positive'. Of these 8%, on average 35% and even up to 50% are 'false positive'.⁵ Therefore, a 'positive blood culture' result in many institutions is only accurate about 50% of the time. Let that sink in. Decisions that determine the rest of the patient's pathway in acute care can be as accurate as a coin toss. If we continue to rely on our current standard for blood culture collection practices, we will continue to only get it right about half the time which sometimes leads to significant and potentially devastating consequences.

What about 3% is good for the patient?

Infection Preventionists are data driven. Data motivates us and helps us determine whether we are good, lucky, or possibly not paying enough attention. We seek to achieve or exceed goals that are either driven by published clinical outcomes or arbitrarily established. The target may be extremely lofty and seemingly unrealistic or, in some cases, simply mediocre.

For over two decades, the laboratory standard to determine 'acceptable' blood culture contamination performance has been set at <3% of the total number of blood cultures drawn.⁶ In an Emergency Department that performs 10,000 blood cultures per year, a 3.0% contamination rate translates to more than 300 patients impacted by false positive blood cultures every year. This means that over 300 patients may be treated with unnecessary antibiotics with attendant risks of secondary infections such as *C. difficile*, multidrug-resistant organisms and other antibiotic-associated complications. It is estimated that blood culture contamination results in over \$1 million dollars in avoidable costs to an average-sized (250-300 bed) hospital every year.^{7,8} This estimate doesn't include the impact on key Centers for Medicare and Medicaid Services (CMS) quality outcome metrics, such as the public reporting of false positive CLABSIs and MRSA bacteremia that result in associated Healthcare Associated Condition (HAC) financial penalties.

So, what about a 3% blood culture contamination rate is good for the patient? Not a thing. We now have evidence that shows us the bar has been moved and this outdated goal must be abandoned.



Connecting the Dots

Laboratory Stewardship and Antibiotic Stewardship

Laboratory stewardship directly impacts Antibiotic Stewardship. The quality of the clinical specimen and how it is interpreted influences the decision to treat with antibiotics or not. The old adage; *garbage in, garbage out* is a common term used among clinical microbiologists to describe the current state of blood culture accuracy.

Sepsis is a leading cause of death. Clinicians are more

apt to err on the side of 'treat and ask questions later' or 'continue to treat rather than deescalate' when they are lacking confidence in the accuracy of the blood culture result and sepsis is a real possibility. An indeterminate blood culture result is likely to be considered 'real' because the perceived risk of NOT treating may be death. Death is much more dramatic and immediate than harms associated with unnecessary antibiotics. The dots get connected

between a diagnosis of sepsis, failure to treat, and subsequent death. The dots between interpretation of a blood culture result (that may be false) and the ultimate outcomes due to unnecessary antibiotics may not be so linear.

Why are blood cultures contaminated so often and what have we done to try to fix the problem?

When attempting to make an improvement or fix a problem, there is a tendency to focus on 'the person'. The suggested solution to infection related problems in healthcare is often to 'have another in-service' or 'competency training' or 'get staff to do what they are trained to do'. We try to fix the person, not the problem.

Intensive training and education have been the standard interventions to address blood culture contamination for decades, but it cannot address the viable organisms that remain on the skin, as well as skin plugs and fragments that cause contamination. Improvement post-training is often a modest and unsustainable reduction in blood culture contamination.

The problem is that the *best* people, in the *best* hospitals, with the *best* technique cannot effectively reduce and sustain blood culture contamination below 0.5%.⁹ It's a process problem, not a people problem.

The objective of skin antisepsis prior to insertion of a needle to draw a blood culture is to reduce as much skin flora as possible. Yet we know that skin antisepsis cannot eliminate resident flora nor does it impact the bacteria that live in the deep layers of the skin. The needle that penetrates the skin and enters the vein is a hollow bore, therefore it is reasonable to expect that a skin plug and fragments will be captured by the needle as it passes through the skin and enters the vein. The skin plug and fragments naturally hitch a ride along with the blood into the blood culture bottle. Ask anyone who has performed a blood culture collection and they will likely describe the 'swirling objects' that are small pieces of skin that were lodged in the needle and subsequently transferred into the blood culture bottle.

THE PROBLEM IS THE *BEST* PEOPLE, IN THE *BEST* HOSPITALS, WITH THE *BEST* TECHNIQUE CANNOT EFFECTIVELY REDUCE AND SUSTAIN BLOOD CULTURE CONTAMINATION BELOW 0.5%.

It is well known that the initial portion of the blood withdrawn is most likely to be 'contaminated'. Therefore, it makes sense to try to capture that initial amount of blood and avoid allowing it to enter the blood culture bottle. Manual diversion methods, where a tube of the patient's blood is withdrawn

and discarded to remove contaminants prior to specimen collection, have inherent limitations and are prone to human error. Studies have demonstrated that manual diversion has shown only minimal and unsustainable reductions in blood culture contamination. The lowest published contamination rate in a controlled clinical study using manual diversion is 2.2% (P=0.0067).¹⁰

At this point, a 2.2% contamination rate may be sounding pretty good. After all, the current 'goal' is less than 3%. But let's take a closer look and see whether this is really good for patients.

The Research Behind Effective Diversion Volumes

Since logic tells us that it makes sense to capture and discard or sequester the part of the blood sample that is most likely to be contaminated, the question is 'how much?' We want to assure that we capture true positives yet eliminate false positives. This important question has been studied, answered and published

by Dr. Patton who evaluated over 3,700 blood cultures and determined that the most effective diversion volume is between 1.5 and 2.0mL of blood. Diversion volumes of 0.5-1.0mL, 1.0-1.5mL, 1.5-2.0mL, and over 2.0mL were evaluated. The data showed that 1.5-2.0mL had the greatest reduction in blood culture contamination without compromis-

ing the detection of true bacteremia. Over 2.0mL would be even better but not practical.¹⁵ Not too little, not too much- just right. In fact, all peer-reviewed published data on effective blood culture diversion volume supports 1.5-2.0mL.

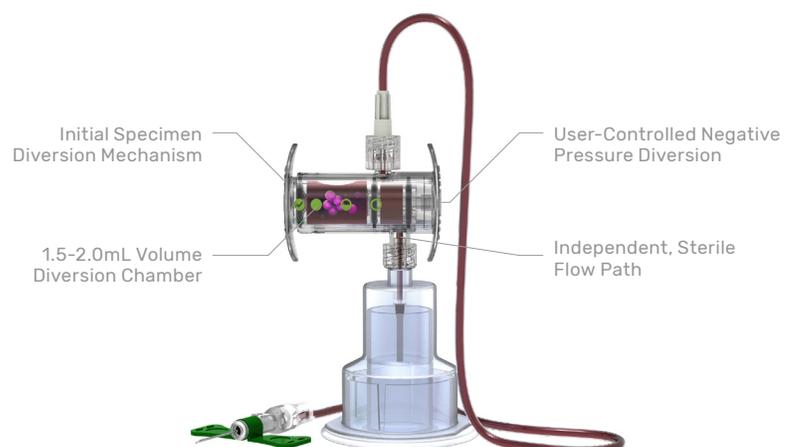
Is there a solution?

Yes, there is. Staff training about the 'basics' and optimal sterile technique remains paramount. Yet, despite herculean efforts to reduce blood culture contamination by improving 'standard technique', most of us find ourselves hovering around the 'just below 3% contamination rate', especially in the Emergency Department, which we have already agreed, is not good for the patient. The use of a closed system, mechanical Initial Specimen Diversion Device® (ISDD®) technique has been demonstrated to dramatically and sustainably reduce blood culture contamination.^{11,12,13,14}

Steripath® Gen2 ISDD® is an example of human factor engineering control. It eliminates the problem at the source. It does not rely on 'the *best* people with the *best* technique'. Exemplary staff can obtain a blood culture with the best possible technique; however, this doesn't get to the root of the problem. Steripath Gen2 removes the contaminated portion (1.5-2.0mL) of the specimen and has an independent sterile blood flow pathway that allows collection of the blood sample that is most likely to provide a true and accurate picture of what bacteria, if any, are circulating in the patient's bloodstream. The goal is to eliminate false positives, while capturing true positives.



Engineering Out Human Factors



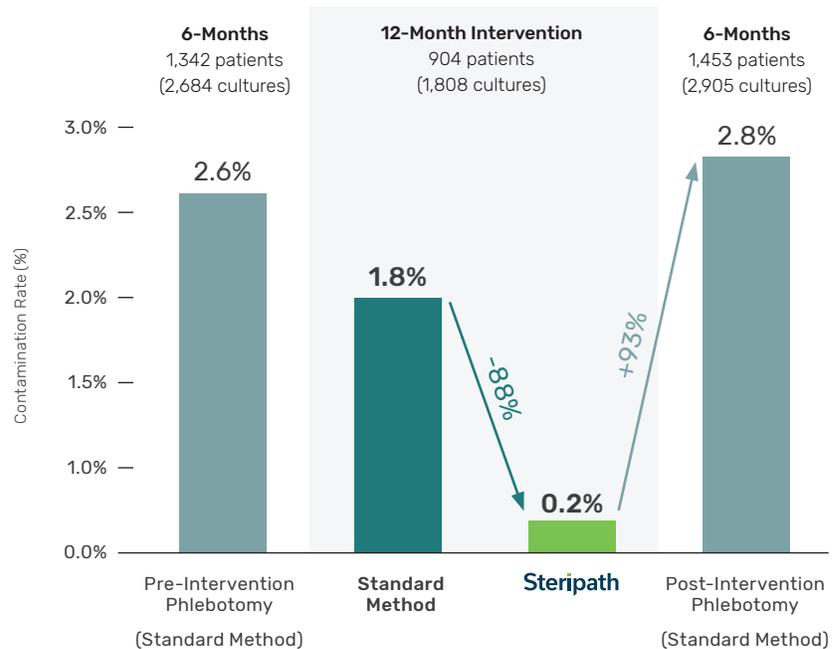
A UNIVERSITY OF NEBRASKA CONTROLLED CLINICAL TRIAL SHOWED A 0.2% CONTAMINATION RATE IN THE ED, SUSTAINED FOR 12-MONTHS.

The Steripath Gen2 technology solution to eliminating false positive blood culture results and optimizing Antibiotic Stewardship has been demonstrated and published in multiple peer-reviewed journals and clinical study abstracts.^{11,12,13,14}

A University of Nebraska controlled clinical trial that evaluated the use of the Steripath ISDD in the ED showed 88% reduction of blood culture contamination down to 0.2% rate (P=0.001) sustained for 12-months with no reduction in detection of true bacteremia, yielding a positive predictive value of 97%.¹¹

University of Nebraska Medical Center Clinical Trial

Clinical Infectious Diseases 2017;65 (15 July)

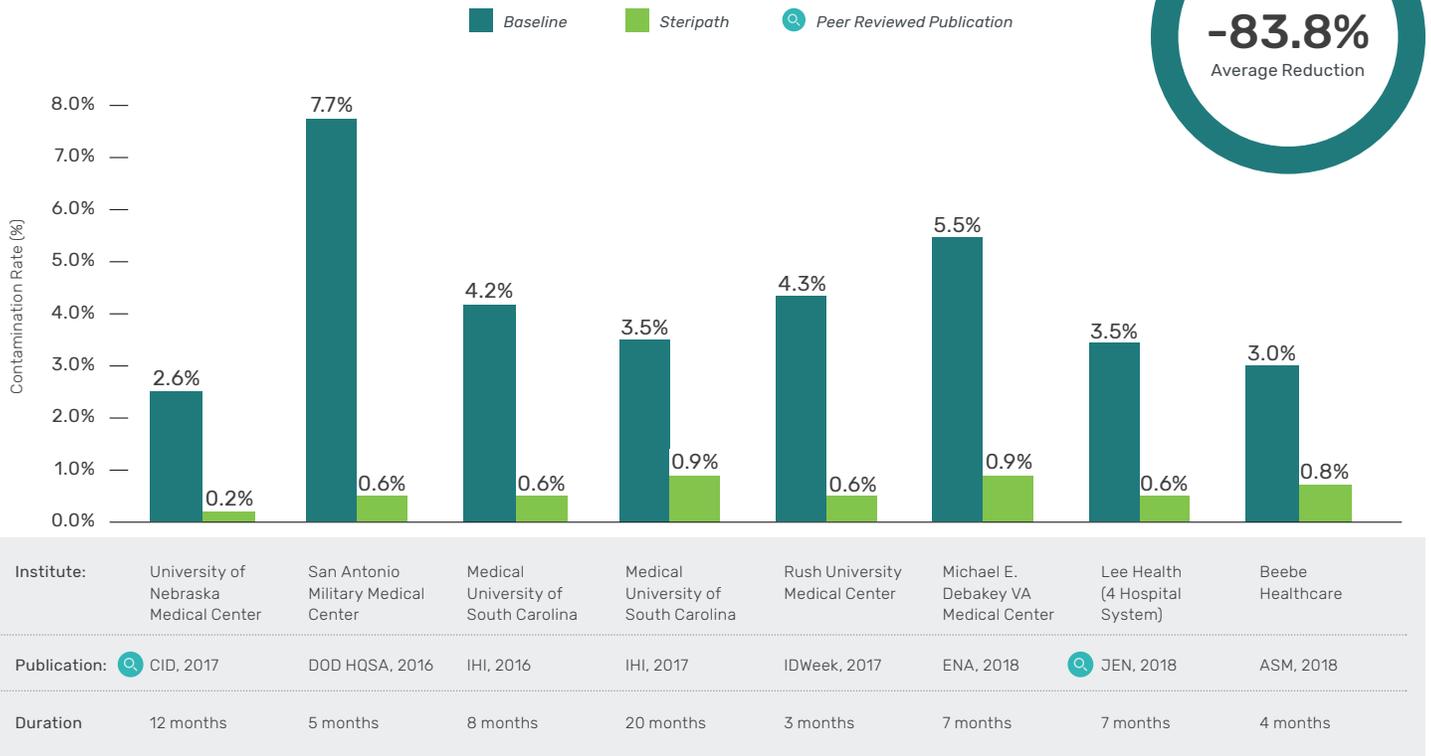


- No change in true bacteremia detection
- Researcher calculated the study institution would save \$1.8 million per year with Steripath.

Additionally, a Lee Health multi-center controlled clinical study which evaluated the use of the Steripath ISDD device on venipuncture and peripheral IV start blood culture draws (n=41,685) in four emergency departments, obtained an 83% reduction in blood culture contamination down to a rate of 0.6% (P=0.0001) sustained for 7-months.¹²

San Antonio Military Medical Center evaluated the Steripath ISDD and achieved a 92% reduction in blood culture contamination with a sustained rate of 0.6% when Steripath was used on both venipuncture and peripheral IV start blood culture draws in the ED. A retrospective analysis of the impact of the reduction of blood culture contamination on vancomycin hospital days of therapy (DOT), led by the department of Infectious Diseases, Clinical Microbiology and the Antimicrobial Stewardship committee, demonstrated a 37% reduction in DOT (P=0.007) after the adoption of Steripath.^{13,14}

Reduction in Blood Culture Contamination (%)



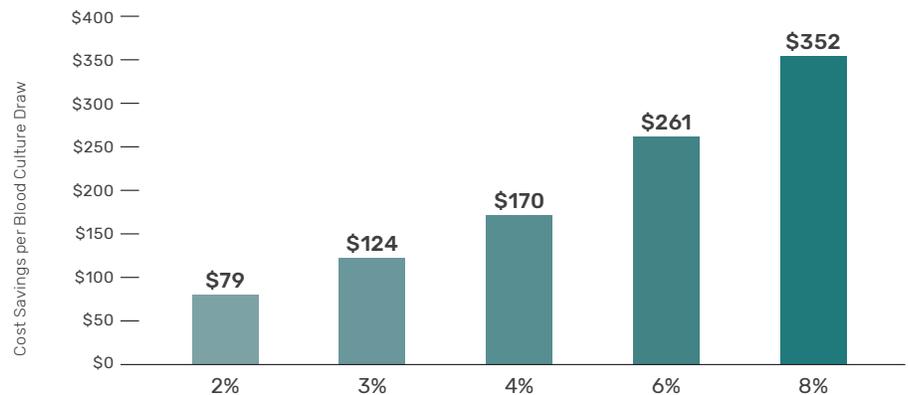
Building the business case: because you can't always get what you want

The Infection Preventionist must critically evaluate new technology and determine whether the cost of the device or equipment is justified. We have limited political and financial capital and must spend it wisely.

It is estimated that blood culture contamination results in over \$1 million dollars in avoidable costs to an average sized hospital every year.^{4,5} In 2018, University of Houston described a Steripath ISDD cost-benefit analysis and determined that a single blood culture contamination event costs the hospital \$4,738. The researchers estimated that the routine use of Steripath in the ED would result in a cost savings of \$79-\$352 per blood culture collection at baseline contamination rates ranging from 2%-8%, respectively. An incremental cost savings was reported when rapid diagnostics technology was routinely used.¹⁶

Steripath ISDD® Cost-Benefit Study

J. Clin. Micro., Oct. 2018 - Total Estimated Net Cost-savings per Blood Culture Collection Associated with Routine Steripath Implementation in the ED



• Incremental cost-savings were shown with routine use of rapid diagnostics

Infection Preventionists rely on blood culture results to be accurate as they directly impact the facility's reportable central line-associated bloodstream infection (CLABSI) surveillance events and reduce healthcare associated financial expenditures that are avoidable. A recent survey of the National Corporate Infection Prevention Director Network revealed that nearly 60% of hospitals reported a CLABSI to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) that was probably contaminated, therefore not a true CLABSI.⁹

In peer reviewed literature, Enterococcus was the most common causative organism for this unnecessary CLABSI reporting yet this can also occur with Candida and other non-common commensal organisms that are picked up on the patient's skin during blood culture collection.¹⁷

Summary

It is time to reject the conventional thinking that a 3% blood culture contamination rate is acceptable. It is not even close. We now have an abundance of reproducible evidence to demonstrate that the use of the Steripath Gen2 Initial Specimen Diversion Device can achieve significant and sustainable blood culture contamination rates well below 1% in the ED.

This is a human factor engineered device that directly drives Antibiotic Stewardship and prevents significant potential harm associated with treating patients who have false positive blood culture results. It removes the person from the problem and inserts a technology solution that engineers out the problem at the source allowing for consistent, reliable and sustainable rates of less than 1%.

It is a new day and we have new knowledge. It's time to set a new benchmark and do the right thing for our patients.

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Disclosures

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