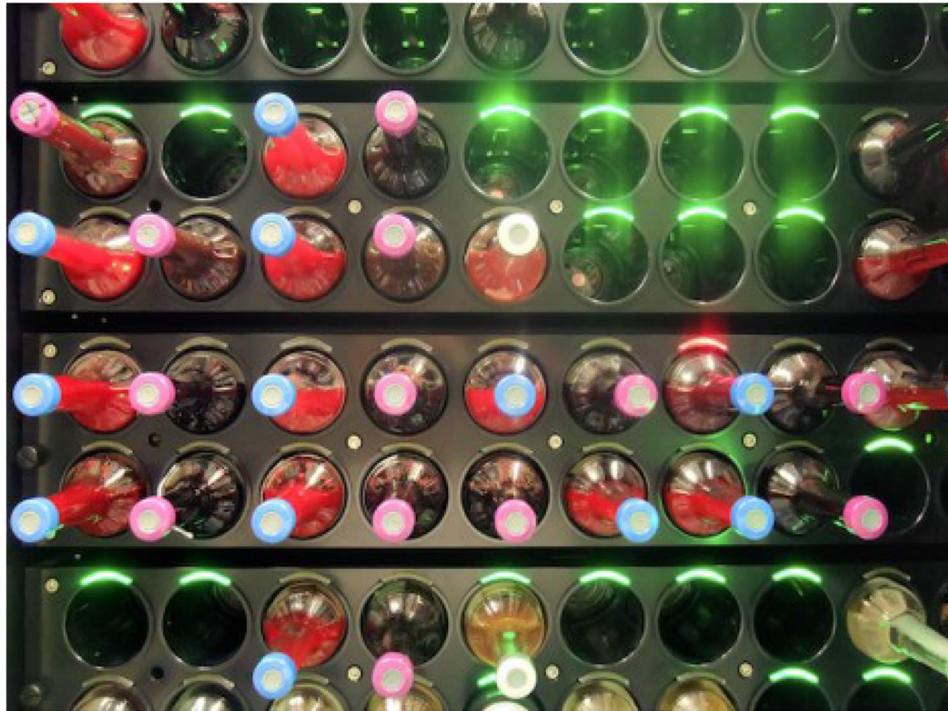


Reducing Blood Culture Contamination

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A novel device promises better blood cultures and more-appropriate antibiotic use at reduced cost

By Lisa L. Steed, PhD, D(ABMM)

When physicians detect the first symptoms suggesting that a patient may have sepsis—a frequently fatal immune system response to infection—clinical care protocols call for rapid blood culture collection and initiation of antibiotics. If the patient's blood culture exhibits microbial growth, antibiotic administration is initiated or continued (when already under way) while a clinical laboratory performs identification and antibiotic susceptibility testing of the organisms isolated from the blood culture.

Blood cultures are designed to detect the presence of microorganisms in the blood and identify the pathogens responsible for the infection. However, blood samples can be contaminated during collection, and additional processing of positive blood cultures is often required to inform appropriate clinical decisionmaking. Consequently, physicians are frequently required to initiate a plan of treatment before they have the comprehensive information needed to determine whether the positive culture is accurate. Most importantly, they must select an appropriate antibiotic therapy. False-positive results are common, and often trigger a cascade of negative consequences, both clinical and financial.

Statistically, up to 50% of patients inaccurately diagnosed with sepsis will be prescribed an unnecessary course of antibiotics.³⁻⁵ This practice increases costs without providing any clinical benefit to the patient. Inappropriate antibiotic use can also result in side effects, including avoidable-exposure anaphylaxis and toxicities, as well as infection with such dangerous hospital-acquired pathogens as *Clostridium difficile*, vancomycin-resistant enterococci (VRE), and other multidrug-resistant



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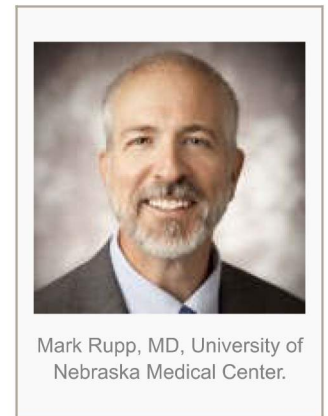
organisms (MDROs).

Financially, possible downstream effects include the costs associated with unnecessary hospitalization; extended length of hospital stay and risk of associated hospital-acquired conditions; additional diagnostic tests; various costly clinical procedures that were originally unnecessary; and increased work for the lab and other clinical staff.⁶

Unnecessary antibiotic use resulting from blood culture contamination contributes to antibiotic resistance, which the World Health Organization and other healthcare bodies consider to be a major threat to global health security. In the United States, the Joint Commission now requires all accredited hospitals, critical access hospitals, and nursing care centers to have an antimicrobial stewardship program in place to decrease inappropriate antibiotic use.

A recent study has shown that a novel initial specimen diversion device (ISDD), commercially known as SteriPath, from Magnolia Medical Technologies, Seattle (www.magnolia-medical.com), can reduce blood culture contamination rates by nearly 90%.⁷ The study was led by Mark Rupp, MD, professor and chief of the division of infectious diseases at the University of Nebraska Medical Center (UNMC), where the study was conducted.

The UNMC research findings are consistent with this author's own experience at the Medical University of South Carolina (MUSC), and point the way toward a technological, engineered solution that delivers sustained results. The approach documented in the UNMC study nearly eliminates contamination and avoids the associated clinical and financial effects of false-positive blood cultures.



This article summarizes the UNMC study; considers the category of devices to which the study device belongs; and delves into the economic data and potential cost savings from implementing a technological solution.

Recent Research and Clinical Experience

Blood culture contamination is thought to arise from a variety of root causes. One of the major causes is the skin fragments that are created during a blood draw. These fragments can contain bacteria that survive the antiseptic a healthcare worker applies to the patient's skin before performing venipuncture. Those bacteria then contaminate the blood sample.

Pathologist Richard G. Patton, MD, associate professor of pathology at the University of Washington and chief pathologist and medical director of clinical laboratories at UW Medicine/Northwest Hospital and Medical Center, first noticed the skin fragment problem while examining the results of needle biopsies. His subsequent insights spurred the development of the SteriPath device (see Figure 1).

"It occurred to me that if needle biopsies push skin fragments into the samples they yielded, the same thing likely happens when a phlebotomist inserts a needle for a blood draw," says Patton. Following this path of inquiry, Patton became a cofounder of Magnolia Medical Technologies, where he now also serves as medical director.

The UNMC study was designed to compare contamination rates for blood cultures drawn with the SteriPath device to the contamination rates for cultures drawn with standard phlebotomy procedures. Conducted in the academic center's ED, the study was a prospective, controlled trial that encompassed 904 patients and 1,808 blood cultures. Phlebotomists collected two cultures from each subject, one using the ISDD and one using standard phlebotomy best practices.

The SteriPath device is designed to mitigate the problem of skin fragment contamination by diverting the first 1.5 mL to 2.0 mL of the blood draw—the portion that includes the problematic skin fragments—and directing it into a separate isolation chamber of the device. The device then creates a second, independent sterile blood flow path, from which the remaining portion of the blood sample is collected into culture bottles and sent to the lab. The initially

diverted blood containing skin fragments is thus excluded from the cultured specimen (see Figure 2).

The UNMC study found that use of the SteriPath ISDD reduced blood culture contamination by 88% (see Figure 3). When blood cultures were performed using standard phlebotomy procedures, the contamination rate was 1.78% (16 contaminated samples in 904 cultures). When the ISDD was deployed, the contamination rate was 0.22% (2 contaminated samples in 904 cultures; see Figure 4).

To put the results of the UNMC study another way, when the ISDD was used a positive culture was a true positive 97% of the time (65 out of 67 instances); but when only standard phlebotomy procedures were used a positive culture was a true positive just 81% of the time (69 out of 85 instances). The device's ratio of true positive to false positive cultures was 33:1 (65 and 2 instances, respectively), while the equivalent ratio for standard procedures was 4.3:1 (69 and 16 instances, respectively). "In other words, the standard cultures give you an awful lot of false signal or noise compared to the diversion device," says Rupp.

The ISDD also showed no loss in sensitivity (see Figure 5). With the ISDD, true bacteremia was found in 65 of 904 cultures (7.2%)—roughly the same proportion observed with standard procedures (69 of 904 cultures, or 7.6%).

The UNMC findings accord with this author's experience at MUSC. The 88% reduction in blood culture contamination found in the UNMC study is comparable to the 86% reduction in false-positive blood cultures found when MUSC trialed the same device in the adult ED, where only nursing personnel draw blood cultures. That trial occurred over an 8-month period and encompassed 2,755 blood cultures (1,801 with the ISDD, 954 without).⁸

A third facility at Beebe Healthcare, Lewes, Del, has had a similar experience with the SteriPath engineered ISDD solution. Jennifer Blakeney, a microbiologist and lead technologist in the lab, hoped to reduce the community hospital's blood culture contamination rate below its historical rate of 2.5%. As of this writing, initial findings after introduction of the SteriPath device have shown a drop of more than 75%—reducing the facility's contamination rate to just 0.6%.

At Blakeney's facility both nurses and phlebotomists are using the SteriPath ISDD, drawing approximately 175 blood cultures a week. "Our results so far have been very promising, both in terms of a much lower contamination rate and potential costs savings that come with the substantial reduction in false-positive blood cultures," says Blakeney.



Figure 1. Rendering of the SteriPath initial specimen diversion device (side view).



Figure 2. The SteriPath initial specimen diversion device with IV needle set.

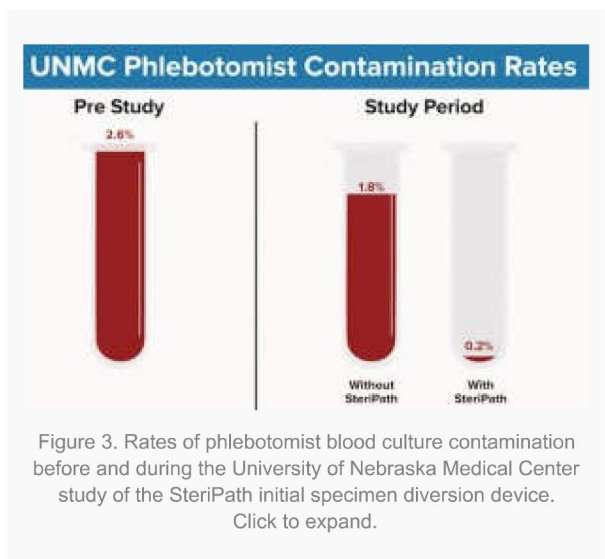


Figure 3. Rates of phlebotomist blood culture contamination before and during the University of Nebraska Medical Center study of the SteriPath initial specimen diversion device. [Click to expand.](#)

Clinical Implications

It is widely recognized that a lower rate of blood culture contamination can lead to more-appropriate use of antibiotics and help to avoid unnecessary use. It's also clear from the UNMC study—which compared the ISDD to phlebotomy best practices—that simply improving compliance with phlebotomy best practices may not be sustainable, and is therefore unlikely to lead to those same benefits.

The UNMC study acknowledges that phlebotomy best practices are not perfectly preventive: “unfortunately, none of these preventative measures will eliminate blood culture contamination due to the microbes that survive local skin disinfection and are inadvertently included in the blood specimen with dislodged dermal cells,” the authors write.

The work of other researchers bears out this conclusion of the UNMC team. In a meta-analysis assessing studies of phlebotomy best practices aimed at minimizing blood culture contamination rates, the lowest reported contamination rate was 1.13%.² The UNMC study's reported rate of 0.22%, using the SteriPath ISDD, represents an 80.5% improvement on the lowest rate reported by the meta-analysis.

The UNMC study also showed a stark difference between the contamination rate achieved using the SteriPath ISDD and the rate produced using standard best practices. Using standard procedures, healthcare workers in the UNMC ED achieved a baseline blood contamination rate of 1.78%. The 0.22% rate achieved in the UNMC study was 87.6% better than the researchers' baseline.

Earlier this year, the Clinical and Laboratory Standards Institute published an updated guideline on standard venipuncture procedures and a second document outlining the key requirements of a phlebotomy training program.^{9,10} According to Dennis J. Ernst, MT(ASCP), NCPT(NCCT), director of the Center for Phlebotomy Education, Corydon, Ind, and head of the committee that compiled the two documents, rigid adherence to the standard, along with rigorous enforcement by healthcare institutions, can minimize human errors.¹¹

In the context of efforts to foster antibiotic stewardship, hospitals that implement and enforce the new venipuncture standard and follow CLSI's guidance on training phlebotomists can certainly demonstrate that they have made a good start on reducing the unnecessary use of antibiotics. Still, even the total elimination of human error—an unlikely achievement—would not eradicate the contamination produced by the problematic flora that skin antisepsis fails to kill.

The UNMC study demonstrates that blood culture contamination rates can be driven down even further by facilitating sterile culture specimen collection following sequestration of the initial portion of a blood draw. And the lower the contamination rate, the more accurate blood cultures will be overall, leading to more-appropriate use of antibiotics and helping to prevent antibiotic resistance. Use of the SteriPath ISDD meaningfully contributes to a comprehensive approach to antimicrobial stewardship.

Financial Implications

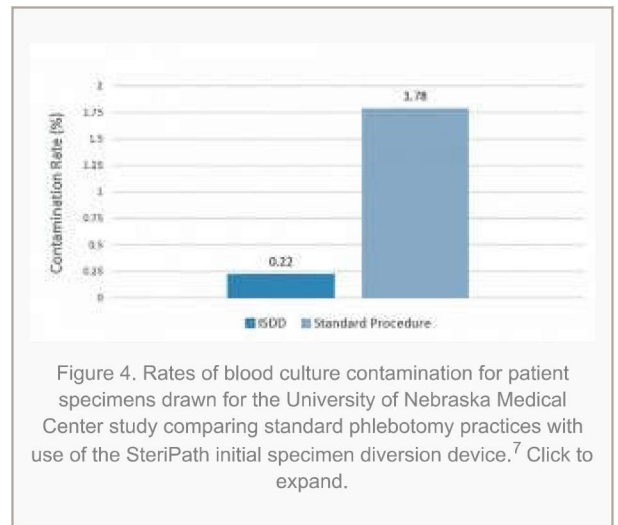


Figure 4. Rates of blood culture contamination for patient specimens drawn for the University of Nebraska Medical Center study comparing standard phlebotomy practices with use of the SteriPath initial specimen diversion device.⁷ Click to expand.

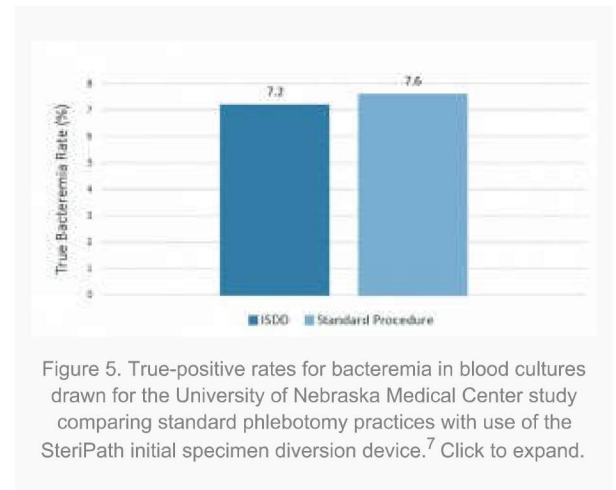


Figure 5. True-positive rates for bacteremia in blood cultures drawn for the University of Nebraska Medical Center study comparing standard phlebotomy practices with use of the SteriPath initial specimen diversion device.⁷ Click to expand.

A recent study found that the annual cost to the US healthcare system for blood culture contamination was \$6.64 billion.¹² “Although only a few percent of blood cultures are contaminated when using standard techniques,” explains Rupp, “when you multiply it by the millions of blood cultures that are done, it actually ends up having a very big impact.”

A number of studies have tracked the cost implications of blood culture contamination for individual healthcare institutions, providing a trail that extends for nearly three decades. In 1989, researchers found that inappropriate antimicrobial use added 4.2 days to each patient’s length of stay, and resulted in additional costs averaging \$5,368 per patient (\$10,848 in May 2017 dollars, according to the inflation calculator of the US Bureau of Labor Statistics).¹³ In 1991, researchers calculated that inappropriate antimicrobial use added 4.5 extra days of hospitalization, and resulted in a total of \$4,385 of excess charges per patient (\$7,973 in May 2017 dollars).³ In 1998, researchers found that the cost of unnecessary antibiotic use alone averaged \$1,000 per patient (\$1,514 in May 2017 dollars).⁴ And in a single-institution study from 2009, researchers found that inappropriate antimicrobial use resulted in 4 to 5 additional days of hospital stay, plus a median of \$8,720 in excess charges per contamination (\$10,107 in May 2017 dollars).⁶

For their study, the UNMC researchers drew from the literature, including most of the studies cited above, and conservatively estimated that the cost for each incident of blood culture contamination at UNMC would be \$4,850. Presuming that they could achieve the low blood culture contamination rate obtained in the SteriPath ISDD study, the researchers calculated that adopting the SteriPath device could save their institution approximately \$1.8 million per year (373 prevented contamination incidents at \$4,850 per incident). This calculation is a reasonable one, and on a per-incident basis represents, at minimum, the savings this author’s institution would also expect to achieve with ongoing use of the SteriPath ISDD.

Of course, any calculation of cost savings must also take into account the cost of the product, which typically varies in accord with purchasing volume, compliance commitments, and contract terms. For the SteriPath ISDD, Magnolia Medical Technologies acknowledges that the device is priced at a premium relative to standard blood culture collection devices, but estimates that device costs will average less than 15% of the overall cost savings derived on a per-blood-culture basis. Using this figure, the annual net savings at UNMC are estimated to be more than \$1.5 million annually.

For some medical devices, training and ease-of-use can also become significant cost factors. This does not appear to be the case with the SteriPath ISDD used at UNMC and at this author’s facility. The device is not complicated. Healthcare professionals who are already trained and licensed to collect blood samples can readily learn the hand memory required to use the system. According to the UNMC study, “phlebotomists noted that the ISDD was easy to use, and it was versatile in collecting blood for both cultures and other laboratory tests.”

Competing Approaches

Development of the SteriPath ISDD was informed by research demonstrating that it is necessary to divert the first 1.5 mL to 2 mL of blood so that subsequent blood collection from the same patient would have no contaminants. Smaller diversion amounts may result in samples that could still be contaminated by skin fragments.¹² In addition, use of the SteriPath device creates a closed system that is not susceptible to contamination during the switch from diversion to collection. These capabilities are not found together in other ISDD products.

The Kurin blood collection set by Kurin Inc, San Diego (www.kurin.com), passively diverts less than 0.15 mL of blood. However, there are no peer-reviewed published data supporting the efficacy of such a small diversion volume. It’s also important to note that a large proportion of blood cultures collected using the SteriPath device—including more than half of those collected at this author’s facility—are collected through an IV line, which the Kurin product is not configured to support.

Another approach to resolving blood collection issues is the manual diversion method, as represented by the Clean Collect blood collection system by Stone Medical Corp, Moline, Ill (www.stonemedcorp.com). As this approach requires the healthcare worker to manually switch the intravenous line from a sterile diversion tube to a collection tube or culture bottle, it raises again the open-system issues inherent in standard blood collection techniques. For instance, the healthcare worker can contaminate the blood collection tubes simply by handling them without appropriate aseptic technique—a particular challenge in a busy ED. Or, when using a red top tube for diversion, a nurse may forget to disinfect the tube top before blood collection, or mix up the order of draw, thereby creating the risk of exposure to additives from other tubes in the collection path prior to culture specimen collection. Moreover, because manual use of a diversion tube is not part of an integrated system, an extra step is required for the operator to switch from blood diversion to collection of a testable sample. Because of these issues, it may be difficult for such manual diversion techniques to achieve the consistency, reliability, and sustainability needed to address the issue of blood culture contamination.

Conclusion

The potential downstream effects of false-positive blood cultures—including overuse of antibiotics, hospital-acquired infections, extended length of stay, risk of associated hospital-acquired conditions, and thousands of dollars in added costs for each misdiagnosed case of infection—make blood culture contamination a notable healthcare issue. The magnitude of the problem may not be immediately obvious because blood culture contamination occurs in only a small percentage of cultures. However, given the large number of blood cultures performed in individual institutions, the number of affected patients as well as the clinical and financial effects of blood culture contamination can quickly mount if a facility performing blood cultures fails to address contamination at its source.

A recent study of the novel SteriPath technology suggests that this approach to blood collection can sharply reduce instances of contamination and their related consequences. Implementation of this approach can enhance patient care, help hospitals utilize lab and other clinical resources more efficiently, and make caregivers more responsible stewards of antimicrobial use.

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