Magnolia Medical Reduces False-Positive Blood Cultures With Novel Collection Tech

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NEW YORK (360Dx) – A positive blood culture initiates immediate antibacterial intervention, but false-positive cultures can lead to expensive and toxic overtreatment.

A new technology, however, could improve diagnostic accuracy by reducing tenfold the rate of blood cultures that incorrectly indicate the presence of a pathogen, making sepsis misdiagnosis a remnant of the past, according to Magnolia Medical Technologies which developed the technology.

Blood stream infections, or sepsis, have become a growing problem, and according to the National Institutes of Health, more than 1 million people in the US are affected by severe sepsis every year, with a mortality rate of between about 30 to 50 percent.

Sepsis is not only deadly; it is also costly. The US Centers for Disease Control and Prevention has found that sepsis-related hospitalization rates doubled between 2000 and 2008, with the inflation-adjusted aggregate cost to treat hospitalized patients increasing, on average, by almost 12 percent per year, to $14.6 billion. By 2011, the cost of treating sepsis patients was an estimated $20 billion, making it the most expensive condition treated in US hospitals, according to a report from the Agency for Healthcare Research and Quality.

Magnolia CEO Greg Bullington added that about 30 million blood cultures are run in US labs per year and 75 million worldwide. But about 1 million of the results are falsely positive for the presence of pathogens due to contamination from the hospital environment or the patient's skin.

According to a 2006 review, the rate of false-positive blood cultures hover between 2 and 3 percent, but vary by hospital and can be as high as 6 percent.

Determining whether a sample is falsely positive takes physician expertise and can be time-consuming, and "during that time, patients undergo treatment as if they were septic when, in fact, they are not," explained Bullington.

Magnolia's device — which essentially "engineers out the human factor," he said — was developed with Richard Patton, a pathologist who spent four decades at Northwest Hospital in Seattle, where he was chief of pathology and medical director of clinical laboratories. Patton observed some of the ill effects of false-positive cultures, such as complications from unneeded antibiotic treatment, and in 2006 he developed a prototype device using what he called the Initial Specimen Diversion Technique.

The technique results in "pure blood flow from the patient's vein into the collection bottle, eliminating inaccurate diagnoses," Bullington said.

Magnolia's product is a closed system, pre-assembled and sterilized by the company, providing "a portable sterile field," he said, that is also a "forced compliance device," meaning the user does not have to add any steps or remember any workflow procedures. It automatically isolates a very small volume of the initial sample, about 2 milliliters, which is thought to contain the majority of contaminants that cause false-positive sepsis diagnoses. After the potentially contaminated sample is sequestered, a second, sterile blood flow path opens up to direct the blood into whatever culture bottle the lab or hospital is using.

In a recent *Clinical Infectious Diseases* study conducted at the University of Nebraska, the device was shown to reduce the false-positive rate from nearly 2 percent to 0.2 percent. The study "used the patient as their own control – so we did one blood culture with the standard procedure and one blood culture with our device," Bullington said, adding that a 0.2 percent contamination rate is "a completely novel and revolutionary finding for microbiology and sepsis blood testing," particularly when coupled with a finding of no reduction in sensitivity.

The firm has conducted a clinical trial with the US Army at San Antonio Military Medical Center, also demonstrating a nearly tenfold reduction in contaminated blood cultures, Bullington said. And a poster presented at the Institute for Healthcare Improvement conference by researchers from the Medical University of South Carolina showed similar results. In the poster, the researchers estimated that the diagnostic microbiology lab avoided spending $2,654, plus an estimated $8,720 in overall healthcare costs, per false positive sample, such that the hospital saved about $190,000 overall during the eight month trial period using SteriPath.

Blood culture-based diagnostic tests for sepsis can be standard microbiology assays, immunoassay-based, or molecular diagnostic assays. The latter, like the PCR-based BioFire Diagnostics' FilmArray Blood Culture ID panel test, or an assay in development using Oxford Nanopore's MinIon sequencing device, can be extremely sensitive, and thus could potentially be at a higher risk of detecting contaminants. This may also be a risk in tests that can use whole blood as a sample type, such as ones in development from Nanomix or Qvella. Bullington said Magnolia has a portfolio of products in its development pipeline that address different collection scenarios, as well as whole-blood samples.

Increased use of antibiotics and increased length of a patient's hospital stay are important from a hospital's standpoint. Bullington postulated that, if false-positive sepsis tests can now be essentially preventable, the Centers for Medicare and Medicaid Services, the College of American Pathologists, and the American Society of Microbiologists, may someday classify them as reportable, and as "never events," and alter CMS guidelines accordingly.

"We have the ability to prevent the misdiagnosis of over a million patients per year, and all of the ensuing downstream costs and negative impacts for the patient," he said. The device also provides significant advantages to public health, he said, because without it, "we are using some of our most powerful antibiotics inappropriately and building up the resistance profile."

The patient safety aspects of false-positive results are also a high priority for many of the large companies in the diagnostics space. Magnolia is in ongoing early-stage dialogue with many of these firms, Bullington said, because they tend to have a focus on driving antibiotic stewardship programs and antimicrobial resistance.

The next steps for Magnolia include collaborations with academic institutions to further evaluate the economic impact of SteriPath, as well as patient safety, effects on antibiotic stewardship, and morbidity and mortality associated with false-positive blood cultures.

"As those research efforts are completed and put out in the literature, we think that those will be really important additional supporting elements that will drive a formal shift in the standard of care and guidelines," Bullington said.

The company on Tuesday announced a new chief commercialization officer, Robert Gerberich, brought on in part to expand the Seattle-based firm's presence in the Bay Area. The firm's marketing strategy also includes attending trade shows for ER medicine, infectious diseases, microbiology, and infection prevention to engage new customers.

The cost of the SteriPath device will be determined by using performance-based models, with the firm negotiating a price with users of the technology, who are primarily hospitals, that is a small percentage of the anticipated cost savings.

Magnolia has been funded to date by venture capital and private investors to the tune of $30 million, including a recent raise of $7.25 million. Its institutional investors include HealthQuest Capital, Canepa Healthcare, and SiteLine partners, Bullington said.

The firm holds 36 patents and has more than 50 others that are pending, he said. And although the technology is straightforward, the sterile system is novel in the market, which Bullington noted is not the blood collection space, per se, but more in the preanalytical space of the diagnostics market, concerned with the capture, transport, and preparation of samples in a way that maintains specimen integrity.

The firm has also identified a series of test categories — which Bullington is not yet prepared to disclose — that have high false-positive and false-negative rates and may benefit from Magnolia's core intellectual property and product development capabilities. "We believe that the footprint that we have from an intellectual property standpoint and a product portfolio standpoint puts us in a very unique position to move the needle on the quality, consistency, predictability, and accuracy of *in vitro* diagnostic testing across the board," he said.

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