

Using Procalcitonin to Determine Which Patients with Overlapping Symptoms are Likely to Suffer Sepsis

Case Study

*Morton Plant Mease Hospital
Clearwater, FL*

Perspective by Devendra N. Amin MD, FCCM, FCCP
Medical Director Critical Care Services



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Challenge	Solution	Impact
To improve risk stratification of suspected sepsis patients at a time when sepsis is on the rise and the patient population most at risk, those 65 years of age and older, is growing rapidly.	Adopted the bioMérieux VIDAS® Procalcitonin (PCT) test, which can reveal in less than 30 minutes if a patient with overlapping symptoms has a severe bacterial infection. While the test cannot definitively predict that a patient will suffer from septic shock, knowing that a patient likely does have a severe bacterial blood infection allows for early goal-directed therapy to mitigate the potential of septic shock.	bioMérieux VIDAS PCT test was adopted at a single site within the Morton Plant Mease system and is now part of the entire 4-hospital network's "Sepsis Alert" protocol.

Challenge

- A recent study reveals that doctors who clinically attempt to make the diagnosis of sepsis at the bedside are usually only about 70-80% accurate ⁽¹⁾. At the same time, the patient population that typically suffers the most from sepsis is growing rapidly. While patients who are 65 years of age or older represent about 12 percent of the U.S. population, this group represents 60 percent of all sepsis cases in the U.S. ⁽²⁾. And, according to the U.S. Dept. of Census, this age group is about to double, growing from approximately 30 million Americans today to over 70 million by 2030.

Morton Plant Mease Hospital in Clearwater, FL, sees a great deal of patients who are 65 years of age and older. Morton Plant Hospital, part of a 4-hospital system, is a 687-bed, community-owned facility that is recognized as a Top 100 Hospital in the country. Morton Plant Hospital's range of medical-surgical services includes cardiology, emergency medicine, oncology, women and children's services, neurosciences, orthopaedics, diabetes care, rehabilitation, vascular surgery and neurosurgery.

Only heart attack takes more lives than sepsis in U.S. hospitals. As many as 750,000 patients progress to severe sepsis each year in hospitals in the United States, with mortality rates reaching 25 percent ⁽³⁾. Despite the advances in critical care, sepsis is still an enormous challenge. Early-goal directed therapy has proven that the sooner the risk of sepsis can be identified, the more likely intervention can help.

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However, while identifying these patients as soon as possible is key, it's not as easy as it may sound. ICUs and Emergency Departments (ED) across the country face the same dilemma daily. An elderly or immunocompromised patient presents with an inventory of alarming symptoms: elevated temperature, heart rate and rapid respiration. Elevated white blood counts point to an infection, but what type? Patients with these symptoms can quickly progress into sepsis, severe sepsis, and finally septic shock, so there is no time to wait for a lab culture. The patients could have systemic inflammatory response syndrome (SIRS), a much less dangerous condition. If they are progressing to sepsis, what's the root cause: bacterial, viral or fungal infection? With current tools, there are still many unknowns.

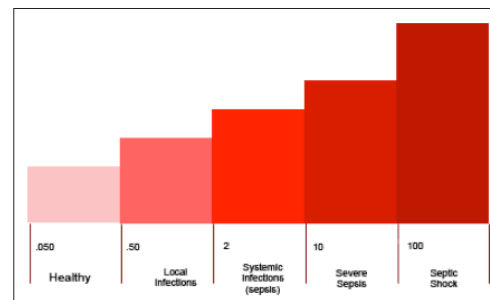
Typically, these patients are started on antibiotics as a precaution. If the lab culture proves that the infection was bacterial, the decision to start antibiotics was sound. If, however, the cause is viral or not an infection at all, the antibiotics were wasted and the patient's underlying condition wasn't addressed.

Solution

- In February of 2008, Morton Plant Hospital included a biomarker test for procalcitonin (PCT) in its new “Sepsis Alert” protocol. This natural human molecule is the prohormone of calcitonin and is released by many cell types and organs during inflammation, particularly when bacterial infection triggers that inflammation. The PCT test adopted, bioMérieux VIDAS® PCT, had just entered the U.S. market and was the first rapid test available. A staff physician, who was aware of the test and how it was used in Europe, was eager to use it at Morton Plant Mease and was a strong advocate for its addition to the hospital’s repertoire of diagnostics.

The bioMérieux VIDAS PCT assay was cleared for marketing by the FDA in October of 2007. The assay is an enzyme-linked fluorescent immunoassay. PCT concentrations from a serum sample are measured by intensity of fluorescence. Test results are available in 20 minutes on the VIDAS platform made by bioMérieux, already installed at Morton Plant Mease. The box has a small footprint and is ideal even when space is an issue.

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Key thresholds of PCT concentrations have been validated as a gauge for sepsis progression. In healthy people, PCT levels are typically below 0.05 ng/ml. Minor infections see a slight increase up to 0.5 ng/ml. Above 0.5 up to 2 ng/ml, the risk of severe sepsis exists, but is unlikely. Between 2 and 10 ng/ml, the risk of severe sepsis is high and levels above 10 ng/ml strongly indicate severe sepsis and possible progression to septic shock.

Impact

- Upon admission, PCT levels are tested in ED patients suspected of having a significant bacterial infection. The protocol calls for a patient who enters the ED with suspected pneumonia, LRTI, or sepsis, to have three PCT tests performed in the first 12 hours.

PCT typically spikes within the first 6-12 hours of systemic bacterial infection. Serial PCT tests can then be used to aid in diagnosis and risk assessment for an improving or worsening condition. A PCT score on the decline indicates that the patient is being treated appropriately. When PCT continues to increase, this is a strong indication that the root cause of the problem is not bacterial sepsis, which helps physicians as they reassess the true root cause.

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The primary use of PCT at Morton Plant Mease is to stratify risk for patients who could progress to severe sepsis or septic shock. Feedback from hospital physicians and medical staff has been very positive. The test provides some much needed lead time in predicting how a patient will progress.

The Morton Plant Mease lab has formed a committee with the department of pharmacy and ICU and ED physicians to review the current status of the data being collected on PCT usage with the goal of developing a more robust utilization protocol. In the meantime, as the only hospital in the area to offer this test and because the Morton Plant lab is used as a reference lab in the region, the hospital has been performing PCT tests on an increasing number of patients from locations around the Tampa Bay area.

All 4 Morton Plant Mease hospitals, and one free-standing emergency room, are in the process of adopting PCT into their physician order sets for suspected sepsis. In fact, all the hospitals currently run the test and have seen its utilization rise steadily. All indications are that the tool takes much of the subjectivity out of sepsis diagnosis and risk stratification in assessing patients from the moment they enter the ED or ICU.



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