Health systems and hospitals continue to deploy sepsis detection solutions and software that is not FDA Class II cleared

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I know most healthcare professionals are focused on the current pandemic. However, with sepsis awareness month in September fast approaching, as you read this, I challenge you to think about a couple of things. One, what are you doing to improve sepsis outcomes in your hospital or health system? Two, do you have a sepsis detection solution that is not an FDA Class II cleared product, what exposure does a non-FDA cleared sepsis detection solution give you, and how well is it really performing?

While organizations like Sepsis Alliance, SCCM (Surviving Sepsis Campaign) & The Patient Safety Movement Foundation are doing incredible things to drive patient safety and sepsis awareness, a huge gap still exists in the general population on understanding the signs of sepsis. If recognized and acted upon, many patients would still have their legs and fingertips and many more would still be alive. As technology and healthcare providers, we must do better in educating the general population and even more so in detecting sepsis earlier in the hospital setting.

However, sepsis detection is only a tiny sliver of the entire sepsis detection solution. CMS data have shown that since implementation, organizations that follow all the steps have significantly lower mortality rates for patients diagnosed with severe sepsis and septic shock[1]. I was speaking with a sepsis subject matter expert from a large 40 hospital health system in the U.S. last week. She told me they had installed the recommended sepsis detection solution from their major EHR provider to deal with the sepsis crisis in their hospitals. She also told me it didn't work and a few months ago they went back to a manual paper process and using egg timers to track 1, 3, & 6-hour bundle delivery. I was shocked. Minus the egg timer,

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we hear this story over and over. In today's age of digital technology, even large health systems are failing to recognize they are tying providers hands by providing substandard sepsis detection solutions for patient care. Solving sepsis is not an algorithm race. Health systems continue to deploy non-FDA cleared algorithmic EHR electronic sepsis detection solutions that have proven to be ineffective rather than deploy FDA cleared sepsis solutions. Sepsis detection solutions that are clinically vetted and FDA cleared can facilitate accurate and early sepsis detection and more importantly, drive delivery of the sepsis bundle within the appropriate time windows. Carrying pocket sepsis bundle cards, using egg timers and other manual labor-intensive approaches is never the answer, and neither is a non-FDA cleared EHR deployed sepsis detection solution.

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With the current health system model of deploying a non-FDA cleared EHR's sepsis detection solution driving a U.S. national average of 49% bundle compliance for sepsis[2], is it any wonder that health systems lose enormous amounts of money on treating sepsis patients? This means that less than 50% of patients with sepsis receive appropriate treatment and signifies a massive failure in the current deployment model and that the current strategy needs to be fixed. Clearly the EHR isn't the answer. In the U.S. we have the greatest healthcare system in the world, and for sepsis patients we are failing in over half of that population when it comes to sepsis treatment. Again, *we must do better*.

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A lagging indicator of poor clinical performance is elevated costs of care, and excellent clinical outcomes are typically followed by indications of a lower cost of care. There are several sources and articles over the years that prove this. Specific to sepsis treatment, according to a recent article in HFMA, small hospitals experience net margin losses of ~$9.9M and larger hospitals experience a net margin loss of ~$33.9M on sepsis treatment[3]. A fully FDA compliant solution deployed in a 1,200-bed system costs *less than $400K* a year and will deliver bundle compliance into the high 70th to mid 80th percentile in under 30 days versus 49%, not to mention change the financial picture for hospitals. Even more important, deploying an FDA complaint sepsis detection solution drives massive positive change for patient outcomes.

Failure by hospitals and health systems to deliver appropriate care in the appropriate timeframe, because they choose to use non-FDA cleared sepsis detection solutions, that don't drive the clinical process, is not an excuse for the loss of life or limbs.

For more information on how you can drive sepsis improvement in your organization with Ambient Clinical Analytics please contact tim.kuebelbeck@ambientclinical.com.

About Ambient Clinical Analytics - As an industry leader, Ambient is supporting leading healthcare systems and has done so since its founding in 2013. Our solutions are designed by clinicians to be easy-to-use by every caregiver in your organization and are configured to be up and running rapidly. We are trusted by a community of high-performing healthcare providers across the United States. Our solutions are powerful real-time point-of-care and

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remote healthcare platforms designed to deliver data visualization, communication, and analytics based clinical decision support solutions.

Ambient's AWARE™ solution is an exceptionally secure, high-performance, FDA Class II approved and CE Marking certified Software as a Medical Device (SaMD) platform. Ambient's Sepsis DART™ product has been accepted into the Patient Safety Movement's Actionable Patient Safety Solutions (APSS) #9 for Sepsis. Ambient has achieved ISO 13485:2016 certification, an internationally recognized quality standard specific to the medical device industry. The ISO 13485 standard sets out the requirements for a quality management system specific to the medical device industry. Ambient is also deploying the AWARE™ family of solutions, to help manage COVID-19. Ambient's Virtual ICU platforms are ideal for dealing with current and possible future outbreaks. For more information, visit https://ambientclinical.com.

Footnotes:
1. HHS.gov, Largest Study of Sepsis Cases among Medicare Beneficiaries Finds Significant Burden, HHS.gov, February 14, 2020
2. Castellucci, M., Just 49% of hospitals follow CMS' sepsis treatment protocols, Modern Healthcare, July 27, 2018
3. Kulick, D., et al., Sepsis poses a cost-containment challenge in the face of the COVID-19 pandemic, HFMA, July 20, 2020