Pilots, peer-reviewed research show VFusion™ artificial intelligence platform finds sepsis earlier than other early warning systems, in time to save countless lives

SAN DIEGO (May 5, 2020) — With recent data showing that sepsis is at once more common, deadly and preventable than previously understood, a new early warning system for both adult and pediatric sepsis provides immense promise for slowing this rising tide of morbidity, mortality and cost. The platform, VFusion™, integrates with any hospital electronic medical records system (EMR) to detect sepsis and alert clinicians on average more than 6 hours faster than prevalent clinical practice.

Unlike previous clinical decision support, screening and alerting tools, the VFusion Sepsis application from Vivace combines evidence-based algorithms capturing the expert knowledge of clinicians with machine learning and natural language processing (NLP) to provide demonstrably superior diagnostic results in real time. The same expert system, along with more than 1 million patient records from several major hospital systems, is also used to train predictive algorithms for prognostic accuracy to assess sepsis risk at any time during the patient encounter – from the ER to discharge.

Early recognition and management of sepsis – the body's dysregulated response to an underlying infection – remain among the greatest challenges in medicine. In 2017 sepsis was a factor for one in every five deaths worldwide, nearly double previous estimates, according to a new study in The Lancet by researchers at the University of Pittsburgh. According to the authors, most previous studies have excluded children, who disproportionately bear the global burden of the condition.

Sepsis is the No. 1 cause of preventable readmissions in the U.S. and has twice the average cost per stay of all other conditions. Studies show that although most people recover from mild sepsis, the mortality rate for septic shock is nearly 50%. Of patients who die, 62.3% do so within 12 hours of the onset of septic shock.

If sepsis is hospital-acquired, average costs to treat it are $51,000, costs payers will not cover. Research in 2019 by a team at Brigham and Women's Hospital confirmed the high prevalence of sepsis in hospital settings and its significant contribution to mortality: Sepsis was present in over 50% of terminal hospitalizations and was the immediate cause of death in 35% of all cases.

In contrast to currently available early warning and clinical decision support tools, VFusion's high sensitivity and specificity allow for more accurate diagnoses and earlier intervention to improve outcomes. In pilots, VFusion has demonstrated extraordinary power to detect the onset of sepsis 6 to 18 hours before usual care baselines, with an area under the curve in receiver operating characteristic analysis (AUC) of .97 – on a scale that tops out at 1.0.

Getting to that level of accuracy and predictability is especially difficult given the many confounding variables in how sepsis patients present when first seen in hospital. Those variables include the initial

site of infection, the stage of sepsis at presentation, causative organism, pattern of acute organ dysfunction, and underlying health status of the patient. Also, data required for comprehensive review of patient status and sepsis diagnosis lives in multiple silos of data – labs, vitals, history, clinical notes – much of which is in free-text notations.

VFusion, designed to integrate with any modern electronic medical record interface, has won multiple National Institutes of Health grants to demonstrate improved disease detection, including adult sepsis, pediatric sepsis and Acute Respiratory Distress Syndrome, teaming with physicians from Johns Hopkins, Children's National Hospital, MedStar Health, Bellevue Health and Scripps Health on research. Combined, these facilities have collaborated with Vivace to provide access to over 1 million patient encounters to refine, train and validate its AI platform for all wards and age groups.

For sepsis, VFusion employs three classes of EMR data analytics:

- Diagnostic analysis of structured, real-time EMR data streams based on physician-guided reasoning expressed as concept maps to identify patients that meet sepsis clinical criteria in early stages of progression.
- Natural language processing of unstructured data such as free-text nursing and physician notes to extract disease-specific clinical features for both diagnostic and predictive analytics.
- Machine learning algorithms trained by retrospective data that has been "semantically enhanced" (including features, feature relationships and outcomes) by experts, seeking to predict early patterns of patient deterioration, which continually learn from clinician validated patient outcomes in a closed-loop system. Expert physicians can directly edit rules and relationships among any clinical concepts or data with traceable attribution.
- Advanced machine learning techniques to sub-classify patients based on their etiology and presentation to achieve exceptional predictive accuracy .

Intelligent alerts are generated within the EMR or sent directly to clinical staff with explanatory text and diagnostic prompts that provide context and identify detection parameters and gaps in diagnoses. Exceptional specificity eliminates alert fatigue, a potentially deadly problem of rules-based clinical decision support and "black-box" machine learning approaches.

VFusion also cuts through the confusion caused by having two quite different definitions of sepsis in operational use today. Sepsis-2, a form of which is used by the Centers for Medicare and Medicaid Services (CMS) as a core measure, has three stages of progression from sepsis to severe sepsis to septic shock. Sepsis-3 is a newer standard used by several commercial payers and has two stages of progression, sepsis and sepsis shock. Vivace can seamlessly flag and alert based on both standards, as directed by approved clinical protocols at each hospital.

The importance of that distinction was highlighted by a retrospective study at one of the pilot facilities, which was mostly focused on a limited definition of sepsis to satisfy CMS reporting compliance. The study found that 66% of the total detected sepsis cases had been missed by the

hospital over a five-month period. Out of 1,225 confirmed cases of sepsis, only 27% satisfied both the criteria of severe sepsis under the Sepsis-2 protocol and sepsis under the sep-3 protocol (which are intended to be equivalent severities). The VFusion platform's ability to simultaneously alert for either protocol makes it a powerful tool to ensure cases are not missed by clinical staff due to ambiguities in definitions – after all, the patient does not care how you 'label' their illness.

VFusion provides two major benefits for ensuring compliance with CMS' sepsis core measure – known as SEP-1 (confusingly being based on Sepsis 2 standards). It extracts most or all of the relevant data required for reporting, saving hours of manual chart extraction. Second, once severe sepsis is triggered, it alerts the clinical staff to all necessary tests and treatment protocols and provides additional alerts on missing orders prior to the expiration of the required treatment window – greatly improving compliance with this protocol, which currently averages less than 60% across US hospitals.

Cost containment and proper coding for severity of illness are also major factors in the VFusion pilot results. During the five-month study period, there were 353 cases of VFusion-identified severe sepsis cases that were not on the SEP-1 report. Of these, there were 83 cases with no antibiotics administered, suggesting under treatment and/or delayed treatment, creating a huge opportunity to improve patient outcomes due to earlier intervention, potentially preventing five deaths. These cases, if properly coded for billing, could have produced up to an additional $10,000 each, or $3.53 million of revenue. For septic shock, 38 cases detected by VFusion were not on the SEP-1 report, resulting in potentially serious delayed or inadequate treatment for those patients. It also resulted in a missed opportunity for revenue for a septic shock case, which can be as high as $30,000 per patient, or well over another $1 million in under billing.

"We have been in test mode for a few years, but now our application is ready for wide adoption in the U.S. hospital market," said Tom Velez, founder and CEO of Vivace and a former NASA engineer. "This is a highly affordable application that will reinvent clinical practice around sepsis and other conditions where disease recognition is difficult and cases are often missed, with the propensity to save lives and save our healthcare system billions of dollars needlessly spent treating preventable illness."

About Vivace

Vivace is committed to using a potent combination of artificial intelligence and physician expertise to provide accurate and timely warning of the presence of conditions such as sepsis and ARDS. The team previously provided strategic portfolio management for over 30 EMR systems and registries serving 8.5 million military personnel through the Defense Health Agency. It developed a semantic-model-based interoperability application for the Department of Defense and the Department of

Veterans Affairs pharmacy Center for Human Drug Research pilot, the most successful example of computable interoperability between the DoD and VA achieved to date.

Media contact
Todd Sloane, Quo Vadimus Communications
224-515-0320
todd@quovadimuscomm.com