

# Development and Implementation of Sepsis Alert Systems

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## **KEYWORDS**

• Sepsis • Automated alert systems • Critical care • Intensive care unit • Hospital

#### **KEY POINTS**

- Barriers to implementation of sepsis alert systems include evolving clinical definitions of sepsis, delayed availability of data through the electronic medical record, information overload, and alert fatigue.
- To be clinically useful, alert systems of the future will need to be more reliable with lower rates of false-positive alerts and be much better integrated into clinical workflow.
- Emerging concepts and strategies that may increase the clinical utility of alerts include wearable physiologic monitoring devices; cognitive ergonomics; human-centered interface design; use of more sophisticated mathematical modeling and machine learning techniques; and integrated prevention, patient education, and public awareness.

### INTRODUCTION

Development and implementation of sepsis alert systems has occurred primarily in acute care settings, such as the intensive care unit (ICU) and emergency department (ED).<sup>1</sup> The development and implementation of these systems outside the acute care setting (ICU and ED) is limited for a variety of reasons. As a critical care syndrome,<sup>2,3</sup> the pathogenesis of sepsis has been studied. Thus, the basic pathophysiology of sepsis is best understood primarily in this context.<sup>4,5</sup> Sophisticated technologies and large quantities of data present in the acute care setting, combined with relatively short lengths of stay and clear outcomes (eg, mortality), provide a natural environment for clinical informatics research in general.<sup>6</sup> However, sepsis is not limited to the ICU setting. As a result of advances in the technology and data granularity underlying clinical informatics systems, it is now possible to consider the development and implementation of sepsis alert systems within and outside the ICU.

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The reason for considering electronic sepsis surveillance is ultimately to facilitate timely and error-free treatment through early recognition and decision support. However, multiple barriers prevent the development and implementation of hospital-wide sepsis alert systems. These barriers and potential solutions to these barriers are explored. A vision of alert systems of the future is presented.

#### DEVELOPMENT AND IMPLEMENTATION OF SEPSIS ALERT SYSTEMS

Early sepsis alert systems were developed primarily for clinical trial enrollment purposes. In 2003, Thompson and colleagues<sup>7</sup> published a sepsis alert and diagnostic system for integrating clinical systems to enhance study coordinator efficiency. In 2005, Embi and colleagues<sup>8</sup> published the effects of a clinical trial alert system on physician participation in clinical trial recruitment. In 2008, Herasevich and colleagues<sup>9</sup> published а computer-based screening engine for severe sepsis and septic shock, which was subsequently used to enroll patients in the critical care setting into a time sensitive clinical study.<sup>10</sup> The development of these early alert systems generated considerable interest in how to best use electronic data to find and treat critically ill patients,<sup>11</sup> as well as lay the foundation for the implementation of sepsis alert systems in the ICU setting (Table 1).<sup>12–15</sup>

The first methodologically rigorous clinical trials have failed to demonstrate improvements in clinically significant endpoints. In the first study, Hooper and colleagues<sup>15</sup> deployed a modified systemic inflammatory response syndrome (SIRS) detection algorithm within an ICU setting. They randomized subjects to groups monitored with the algorithm and those who were not. When modified SIRS criteria were met, clinicians were notified via text message. The hypothesis being tested was that automated notification would facilitate a diagnosis of sepsis and shorten the time to initiation of antibiotics, fluid administration, and other sepsisrelated cares. The study demonstrated the feasibility and safety of the approach but failed to demonstrate a difference in the time to administration of appropriate cares. In 2015, the same Vanderbilt group, Semler and colleagues,<sup>16</sup> performed another randomized trial of an electronic tool for the evaluation and treatment of sepsis in the ICU. This system combined their existing automated, electronic monitoring system with a clinical decision support system. As with their previous study, this system did not improve clinically significant outcomes in the ICU setting, including length

of stay in the hospital or ICU, and timely completion of appropriate interventions.

At Mayo Clinic, an ICU-specific patient viewer has been clinically validated and implemented in the medical ICU setting.<sup>17–19</sup> In this context, Harrison and colleagues<sup>20</sup> developed a surveillance system for the detection of failure to recognize and treat severe sepsis. The rationale for this system was to not only detect sepsis but also to prevent clinically important deterioration and complications due to failure to treat this underlying illness in a timely manner (failure to rescue).<sup>21,22</sup> However, the validity of this or any other implementation approach has yet to be tested in a clinical trial.

#### BARRIERS TO DEVELOPMENT AND IMPLEMENTATION OF CLINICALLY USEFUL SEPSIS ALERT SYSTEMS

In addition to real-time availability of accurate electronic data, the ability of a sepsis detection algorithm to reliably identify sepsis is influenced by many external factors. Critically, algorithms are developed using current knowledge of the condition of sepsis and on data derived from a particular health care setting or patient population. The performance is optimized for those conditions and will be unpredictably altered if used in any other context. In the face of evolving definitions of sepsis and treatment guidelines, changing patient populations or clinical settings, the performance of sepsis algorithms must be continuously monitored and tweaked. Even small changes in the sensitivity or specificity of these algorithms can lead to high rates of false-positive or negative alerts. These changes can undermine confidence in the alert and render it ineffective in clinical practice (Fig. 1).

#### Clinical Diagnostic Cues Not Available in the Electronic Medical Record

Often, the critical rate-limiting step for efficacy of sepsis alert systems is the availability of real-time data in the electronic medical record (EMR). The data have to be in the record before the algorithm can register it and make a prediction about whether the patient is at risk of sepsis. Delayed data entry or validation, lack of interconnectivity of EMR department systems, and infrequent sampling times all contribute to patchy, absent, or much delayed data availability in the EMR. Furthermore, the clinical diagnosis of sepsis often relies on judgments and measurements not easily captured in the EMR. These measurements can range from physical findings (eg, patient not looking good, rigors, increased capillary refill time, bounding pulse, or increased work of breathing)

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