Research and Applications

Evaluating the impact of a computerized surveillance algorithm and decision support system on sepsis mortality

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ABSTRACT

Objective: We created a system using a triad of change management, electronic surveillance, and algorithms to detect sepsis and deliver highly sensitive and specific decision support to the point of care using a mobile application. The investigators hypothesized that this system would result in a reduction in sepsis mortality.

Methods: A before-and-after model was used to study the impact of the interventions on sepsis-related mortality. All patients admitted to the study units were screened per the Institute for Healthcare Improvement Surviving Sepsis Guidelines using real-time electronic surveillance. Sepsis surveillance algorithms that adjusted clinical parameters based on comorbid medical conditions were deployed for improved sensitivity and specificity. Nurses received mobile alerts for all positive sepsis screenings as well as severe sepsis and shock alerts over a period of 10 months. Advice was given for early goal-directed therapy. Sepsis mortality during a control period from January 1, 2011 to September 30, 2013 was used as baseline for comparison.

Results: The primary outcome, sepsis mortality, decreased by 53% ($P=0.03$; 95% CI, 1.06-5.25). The 30-day readmission rate reduced from 19.08% during the control period to 13.21% during the study period ($P=0.05$; 95% CI, 0.97-2.52). No significant change in length of hospital stay was noted. The system had observed sensitivity of 95% and specificity of 82% for detecting sepsis compared to gold-standard physician chart review.

Conclusion: A program consisting of change management and electronic surveillance with highly sensitive and specific decision support delivered to the point of care resulted in significant reduction in deaths from sepsis.

Key words: sepsis, septic shock, clinical decision support, change management, electronic surveillance, sepsis mortality
Original Contribution

Effect of an electronic medical record alert for severe sepsis among ED patients

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Abstract

Background: Severe sepsis and septic shock are a major health concern worldwide. The objective of this study is to determine if Severe Sepsis Best Practice Alert (SS-BPA) implementation was associated with improved processes of care and clinical outcomes among patients with severe sepsis or septic shock presenting to the emergency department (ED).

Methods: This is a single-center, before-and-after observational study. The intervention group (n = 103) consisted of adult patients presenting to the ED with severe sepsis or septic shock during a 7-month period after implementation of the SS-BPA. The control group (n = 111) consisted of patients meeting the same criteria over a prior 7-month period. The SS-BPA primarily acts by automated, real-time, algorithm-based detection of severe sepsis or septic shock via the electronic medical record system. The primary outcome was in-hospital mortality. Secondary outcomes included hospital length of stay (LOS), time to antibiotic administration, and proportion of patients who received antibiotics within the target 60 minutes.

Results: Time to antibiotics was significantly reduced in the SS-BPA cohort (29 vs 61.5 minutes, P < .001). In addition, there was a higher proportion of patients who received antibiotics within 60 minutes (76.7 vs 48.6%; P < .001). On multivariable analysis, in-hospital mortality was not significantly reduced in the intervention group (odds ratio, 0.64; 95% confidence interval, 0.26-1.57). Multivariable analysis of LOS indicated a significant reduction among patients in the SS-BPA cohort (geometric mean ratio, 0.66; 95% confidence interval, 0.53-0.82).

Conclusion: Implementation of the SS-BPA for severe sepsis or septic shock among ED patients is associated with significantly improved timeliness of antibiotic administration and reduced hospital LOS.
Electronic health record-based clinical decision support alert for severe sepsis: a randomised evaluation

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ABSTRACT
Background. Sepsis remains the top cause of morbidity and mortality of hospitalised patients despite concerted efforts. Clinical decision support for sepsis has shown mixed results reflecting heterogeneous populations, methodologies and interventions.

Objectives. To determine whether the addition of a real-time electronic health record (EHR)-based clinical decision support alert improves adherence to treatment guidelines and clinical outcomes in hospitalised patients with suspected severe sepsis.

Design. Patient-level randomisation, single blinded.

Setting. Medical and surgical inpatient units of an academic, tertiary care medical centre.

Patients. 1123 adults over the age of 18 admitted to inpatient wards (intensive care units (ICU) excluded) at an academic teaching hospital between November 2014 and March 2015.

Interventions. Patients were randomised to either usual care or the addition of an EHR-generated alert in response to a set of modified severe sepsis criteria that included vital signs, laboratory values and physician orders.

Measurements and main results. There was no significant difference between the intervention and control groups in primary outcome of the percentage of patients with new antibiotic orders at 3 hours after the alert (33% vs 37%, p=0.53). There was no difference in secondary outcomes of in-hospital mortality at 30 days, length of stay greater than 72 hours, rate of transfer to ICU within 48 hours of alert, or proportion of patients receiving at least 30 mL/kg of intravenous fluids.

Conclusions. An EHR-based severe sepsis alert did not result in a statistically significant improvement in several sepsis treatment performance measures.
A Trial of a Real-Time Alert for Clinical Deterioration in Patients Hospitalized on General Medical Wards

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BACKGROUND: With limited numbers of intensive care unit (ICU) beds available, increasing patient acuity is expected to contribute to episodes of inpatient deterioration on general wards.

OBJECTIVE: To prospectively validate a predictive algorithm for clinical deterioration in general–medical ward patients, and to conduct a trial of real-time alerts based on this algorithm.

DESIGN: Randomized, controlled crossover study.

SETTING/PATIENTS: Academic center with patients hospitalized on 8 general wards between July 2007 and December 2011.

INTERVENTIONS: Real-time alerts were generated by an algorithm designed to predict the need for ICU transfer using electronically available data. The alerts were sent by text page to the nurse manager on intervention wards.

MEASUREMENTS: Intensive care unit transfer, hospital mortality, and hospital length of stay.

RESULTS: Patients meeting the alert threshold were at nearly 5.3-fold greater risk of ICU transfer (95% confidence interval [CI]: 4.6-6.0) than those not satisfying the alert threshold (358 of 2353 [15.2%] vs 512 of 17678 [2.9%]). Patients with alerts were at 8.9-fold greater risk of death (95% CI: 7.4-10.7) than those without alerts (244 of 2353 [10.4%] vs 206 of 17678 [1.2%]). Among patients identified by the early warning system, there were no differences in the proportion of patients who were transferred to the ICU or who died in the intervention group as compared with the control group.

CONCLUSIONS: Real-time alerts were highly specific for clinical deterioration resulting in ICU transfer and death, and were associated with longer hospital length of stay. However, an intervention notifying a nurse of the risk did not result in improvement in these outcomes. Journal of Hospital Medicine 2013;8:236–242. © 2013 Society of Hospital Medicine
Effect of a machine learning-based severe sepsis prediction algorithm on patient survival and hospital length of stay: a randomised clinical trial

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ABSTRACT

Introduction Several methods have been developed to electronically monitor patients for severe sepsis, but few provide predictive capabilities to enable early intervention; furthermore, no severe sepsis prediction systems have been previously validated in a randomised study. We tested the use of a machine learning-based severe sepsis prediction system for reductions in average length of stay and in-hospital mortality rate.

Methods We conducted a randomised controlled clinical trial at two medical-surgical intensive care units at the University of California, San Francisco Medical Center, evaluating the primary outcome of average length of stay, and secondary outcome of in-hospital mortality rate from December 2016 to February 2017. Adult patients (18+) admitted to participating units were eligible for this factorial, open-label study. Enrolled patients were assigned to a trial arm by a random allocation sequence. In the control group, only the current severe sepsis detector was used; in the experimental group, the machine learning algorithm (MLA) was also used. On receiving an alert, the care team evaluated the patient and initiated the severe sepsis bundle, if appropriate. Although participants were randomly assigned to a trial arm, group assignments were automatically revealed for any patients who received MLA alerts.

Results Outcomes from 75 patients in the control and 67 patients in the experimental group were analysed. Average length of stay decreased from 13.0 days in the control to 10.3 days in the experimental group (p=0.042). In-hospital mortality decreased by 12.4 percentage points when using the MLA (p=0.018), a relative reduction of 58.0%. No adverse events were reported during this trial.

Conclusion The MLA was associated with improved patient outcomes. This is the first randomised controlled trial of a sepsis surveillance system to demonstrate statistically significant differences in length of stay and in-hospital mortality.

Trial registration NCT03015454.
External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients

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**IMPORTANCE** The Epic Sepsis Model (ESM), a proprietary sepsis prediction model, is implemented at hundreds of US hospitals. The ESM's ability to identify patients with sepsis has not been adequately evaluated despite widespread use.

**OBJECTIVE** To externally validate the ESM in the prediction of sepsis and evaluate its potential clinical value compared with usual care.

**DESIGN, SETTING, AND PARTICIPANTS** This retrospective cohort study was conducted among 27,697 patients aged 18 years or older admitted to Michigan Medicine, the academic health system of the University of Michigan, Ann Arbor, with 38,455 hospitalizations between December 6, 2018, and October 20, 2019.

**EXPOSURE** The ESM score, calculated every 15 minutes.

**MAIN OUTCOMES AND MEASURES** Sepsis, as defined by a composite of (1) the Centers for Disease Control and Prevention surveillance criteria and (2) International Statistical Classification of Diseases and Related Health Problems, Tenth Revision diagnostic codes accompanied by 2 systemic inflammatory response syndrome criteria and 1 organ dysfunction criterion within 6 hours of one another. Model discrimination was assessed using the area under the receiver operating characteristic curve at the hospitalization level and with prediction horizons of 4, 8, 12, and 24 hours. Model calibration was evaluated with calibration plots. The potential clinical benefit associated with the ESM was assessed by evaluating the added benefit of the ESM score compared with contemporary clinical practice (based on timely administration of antibiotics). Alert fatigue was evaluated by comparing the clinical value of different alerting strategies.

**RESULTS** We identified 27,697 patients who had 38,455 hospitalizations (21,904 women [57%]; median age, 56 years [interquartile range, 35-69 years]) meeting inclusion criteria, of whom sepsis occurred in 2552 (7%). The ESM had a hospitalization-level area under the receiver operating characteristic curve of 0.63 (95% CI, 0.62-0.64). The ESM identified 183 of 2552 patients with sepsis (7%) who did not receive timely administration of antibiotics, highlighting the low sensitivity of the ESM in comparison with contemporary clinical practice. The ESM also did not identify 1709 patients with sepsis (67%) despite generating alerts for an ESM score of 6 or higher for 6971 of all 38,455 hospitalized patients (18%), thus creating a large burden of alert fatigue.

**CONCLUSIONS AND RELEVANCE** This external validation cohort study suggests that the ESM has poor discrimination and calibration in predicting the onset of sepsis. The widespread adoption of the ESM despite its poor performance raises fundamental concerns about sepsis management on a national level.
Rigor: Study Designs

Observational

- Case reports / case series
- Case control studies
- Cohort studies
- Quasi-experiments (pre/post, non-randomized)
- Randomized trials
- Systematic review
- Synthesis

Interventional

- Expert opinion / anecdote

- Rigor: Study Designs
- Observation
- Intervention
Workplace Wellness Programs Don’t Work Well. Why Some Studies Show Otherwise.

Randomized controlled trials, despite their flaws, remain a powerful tool.

By Aaron E. Carroll
Aug. 6, 2018

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