Barriers to implementation of an automated severe sepsis alert system in the ICU setting

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ABSTRACT

Background. Automated, electronic medical record (EMR)-based sepsis alert systems have failed to demonstrate improvements in clinically meaningful endpoints. However, the effect of implementation barriers on the success of new sepsis alert systems is rarely explored.

Objective. To test the hypothesis an automated, EMR-based severe sepsis alert system would reduce time to alert acknowledgement by critical care clinicians in the intensive care unit (ICU) setting compared to text paging.

Study Design. In one arm of this simulation study, real alerts for patients in the medical ICU were delivered to critical care clinicians through the EMR. In the other arm, simulated alerts were delivered through text paging. The primary outcome was time to alert acknowledgement. The secondary outcomes were a structured, mixed quantitative/qualitative survey and informal group interview.

Results. The alert acknowledgement rate from the severe sepsis alert system was 3% (N=148) and 51% (N=156) from simulated severe sepsis alerts through traditional text paging. Time to alert acknowledgement from the severe sepsis alert system was median 274 minutes (N=5) and median 2 minutes (N=80) from text paging. The response rate from the EMR-based alert system was insufficient to compare primary measures. However, secondary measures revealed important barriers.

Conclusion. Alert fatigue, interruption, human error, and information overload are barriers to alert and simulation studies in the ICU setting.

Word count: 215

INTRODUCTION

Electronic health record (EHR)-based, automated sepsis alert systems have failed to demonstrate improvements in clinically meaningful endpoints (Hooper et al. 2012; LaRrosa et al. 2012; Nelson et al. 2011; Sawyer et al. 2011). This includes intensive care unit (ICU)-specific and non-ICU specific alert systems, as well as the detection of sepsis, severe sepsis, and/or septic shock (Dellinger et al. 2013). Clinically meaningful endpoints range from compliance with the international Surviving Sepsis Campaign (SSC) guidelines to hospital length of stay (LOS), ICU LOS, and mortality.

Time to alert acknowledgement is one proxy for time to recognition of sepsis by critical care clinicians. The failure of EHR-based, automated sepsis alert systems to ~~demonstrate~~ be directly correlated with improvements in clinically meaningful endpoints is frequently attributed to limitations of detection algorithms and/or the need for clinical decision support (CDS) systems (Semler et al. 2015). Human factors, such as the impact of workflow changes or the influence of method of alert delivery, are known to be ~~a~~ barriers to the implementation of new alert systems in the clinical setting (Harrison et al. 2015a). However, the effect of implementation barriers on the success of new sepsis alert systems is rarely explored.

As “alarm hazards” have been ranked as the top health technology hazard in the United States (ECRI-Institute 2013), it is important to explore the effect of implementation of new alert systems on workflow changes and other human factors in the clinical setting. Despite outcome improvements in recent decades (Kaukonen et al. 2014), sepsis remains one of the most expensive in-hospital conditions (Torio CM 2013). As one of the most technologically sophisticated hospital environments, the critical care setting serves as a model to explore the impact of implementation of new alert systems. ~~The objective of this study was to test the~~

Comment [JL1]: Be careful here as you said EMR in the abstract and are using the term HER here. They are defined differently. See 8. Seidman J. EMR vs HER – What is the difference? Health IT Buzz. https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/emr-vs-ehr-difference January 4, 2011.

Comment [JL2]: I would define what you mean by endpoints here. Specifically which ones? Bundle compliance, LOS, quality of life, survival?

Comment [JL3]: I think what you are trying to say here is something more like this, There are ICU-based and hospital wide means to trigger an alert for the early recognition of sepsis. Most EHRs now have a built in system to support this alert.

Comment [JL4]: This bellows above where I made the initial comment.

Comment [JL5]: Has this been validated and if so, reference it.

Comment [JL6]: But you just gave examples the sentences before wherein this WAS explored.

~~hypothesis~~ We hypothesized that an automated severe sepsis alert system would reduce time to alert acknowledgement by critical care clinicians in the ICU setting compared to text paging.

Comment [JL7]: As compared to what? what is the "nonautomated" alert system.

METHODS

Study design and setting

This study was performed in February 2015 in the medical ICU at Mayo Clinic in Rochester, MN, USA. This ICU setting has been described previously (Afessa et al. 2005). Severe sepsis alerts were delivered to critical care clinicians, including attending physicians, fellows, residents, and nurse practitioners/physician assistants (NPs/PAs). ~~Simulated severe sepsis alerts were delivered to critical care clinicians in the medical ICU~~ using traditional text paging. This study was approved by the Mayo Clinic Institutional Review Board (IRB) for clinician-participant enrollment by oral consent.

Comment [JL8]: I am not sure what the purpose of this sentence is or what it means….

Comment [JL9]: Number text only wherein call back was required or also with words, patient data, etc. If the latterm make sure to make note of HIPAA compliance.

Study participants and medical ICU workflow

The medical ICU at Mayo Clinic consists of 2 physically adjacent 12-bed units, in close proximity to a nearby 9-bed respiratory care unit (RCU). For any given month, there are approximately 15 attending physicians, 6 fellows, 4 postgraduate year 3 residents (PGY-3), 6 PGY-1 residents, and 9 dedicated medical ICU NPs/PAs. There are 2 shifts: 6am to 6pm (AM) and 6pm to 6am (PM). On any given day, the ~~AM~~ morning shift is further divided into 2 teams. Team 1 is assigned to the majority of the medical ICU patients. Team 2 is assigned the remaining patients, as well as the RCU, which is further staffed by an additional fellow and dedicated NP/PA from the same group of approximately 40 clinicians in the medical ICU that month.

Comment [JL10]: What speciality (-ies)

AWARE (Ambient Warning and Response Evaluation)

Comment [JL11]: Ok not sure where this came from and why it is here. Relevance?

AWARE is an ICU-specific patient viewer/monitoring system. It was developed at Mayo Clinic and has been in routine clinical use in the medical ICU at Mayo Clinic since July 2012 (Pickering

et al. 2015; Pickering et al. 2010). AWARE has been demonstrated to improve clinician task load, errors of cognition, and performance (Ahmed et al. 2011).

Severe sepsis alert system

The severe sepsis detection algorithm was developed at Mayo Clinic and implemented into AWARE in December 2014 (Harrison et al. 2015b). Within AWARE, the severe sepsis alert system displays a passive, yellow alert icon when severe sepsis is detected. This yellow alert icon can also be activated manually by clinicians for specific patients, when severe sepsis is suspected, but not detected by the automated alert system. This yellow alert icon is automatically updated to display a passive, green alert icon within AWARE after completion of the 4 elements of the 3-hour Surviving Sepsis Campaign (SSC) bundle (Dellinger et al. 2013). Once activated, the yellow alert icon will persist for at least 6 hours, unless completion of the SSC bundle is detected (green alert icon) or manual deactivation by clinicians occurs. In the context of prolonged severe sepsis and/or septic shock, the yellow alert icon can persist indefinitely. The green alert icon automatically reverts back to “no sepsis detected” after 3 hours, unless additional automatic (or manual) activation occurs.

Comment [JL12]: I think you mean the 6 hour bundle here. If so, please state that.

Study procedures

Clinicians agreed to participate in this study from February 02 through February 28 in 2015. The evening before each AM shift and the next PM shift, clinician participants for these upcoming shifts received a detailed email reminder with instructions (Figure 1). The number of severe sepsis system alerts per shift through AWARE (yellow or green icon alerts) was entirely dependent on the number of septic patients in the medical ICU during any specific shift. Clinician participants randomly received no more than 3 simulated severe sepsis alerts per shift via text paging. In both cases, clinician participants were instructed to acknowledge all AWARE and traditional text paging severe sepsis alerts by email response. The difference between the

time to severe sepsis alert activation in AWARE (or alert delivery via text page) and email response was defined as the time to alert acknowledgement.

Survey design

Upon completion of the severe sepsis alert acknowledgement portion of this study, clinician participants completed a structured, mixed quantitative/qualitative survey (full survey facsimile in Results, Figure 2). These questions were designed partially on existing clinician satisfaction surveys of alert methods for use in the hospital and critical care settings (Embi et al. 2008; Wagner et al. 1998).

Comment [JL13]: So are we studying earlier acknowledgement with the paging system or provider satisfaction?

Statistical analysis

Severe sepsis alert system data was extracted directly from AWARE using METRIC Data Mart, a near-real time relational database of the complete EHR, which was developed at Mayo Clinic and has been described previously (Herasevich et al. 2010). Data was queried using JMP Pro (SAS Institute, Inc). Data collection and statistical analyses, such as the two-sided Student's t-test and the Chi-squared test, were also performed in JMP Pro. For all statistical analyses, a *p*-value of less than 0.05 was considered to be statistically significant. For all median values from the survey results, interquartile range (IQR) was reported.

RESULTS

Prior to initiation of this study, a 1-day feasibility pilot was performed in January 2015 using 7 medical ICU clinicians. Based on the result of this feasibility study (data not shown), it was determined that a sufficiently high clinician participant alert acknowledgement rate could be obtained from both severe sepsis system alerts through AWARE (yellow or green icon alerts) and simulated severe sepsis alerts through traditional text paging in the ICU setting. Based on the results of this feasibility pilot, participant instructions were optimized (Figure 1).

Of the 40 clinicians staffing the medical ICU in February 2015, 13 (32%) were recruited to participate in this study. However, it was decided after 2 weeks (February 02 AM through February 15 PM) to prematurely terminate this study, due to sufficient statistical power for time to alert acknowledgement analysis, as well as feedback from clinician participants. As a result, it was necessary to exclude 1 NP/PA due to unavailability in the medical ICU during this shortened study period (RCU only). Ultimately, 12 clinicians participated: 5 NPs/PAs (out of 9), 3 attending physicians (out of 15), 2 fellows (out of 6), 2 PGY-3s (out of 4), and 0 PGY-1s (out of 6). The median number of potential AWARE alert acknowledgements per shift was 2 (IQR 1 to 4). The minimum and maximum numbers were 0 and 5. The number of patients who trigged at least 1 severe sepsis system alert through AWARE (yellow or green icon alert) was 28. Of the 28 shifts that occurred during this shortened study period, 23 shifts (82%) were covered by at least 1 participant (Table 1).

Comment [JL14]: The enormous degree of experience in this small group is a bias factor

The alert acknowledgement rate from the severe sepsis alert system through AWARE was 3% (N=148) and 51% (N=156) from simulated severe sepsis alerts through text paging (Table 2). Time to alert acknowledgement from the severe sepsis alert system through AWARE was median 274 minutes (N=5) and median 2 minutes (N=80) from simulated severe sepsis alerts through text paging. The 5 alert acknowledgements from the severe sepsis alert system through AWARE came from only 3 clinician participants (NP/PA #01, NP/PA #04, and NP/PA #05), while all 12 participants acknowledged at least 1 simulated severe sepsis alert through text paging.

All participants completed a structured, mixed quantitative/qualitative survey. For the quantitative portion of the survey (Figure 2), clinicians found alert by AWARE to be slightly less disruptive than alert by text paging. Clinicians found acknowledgement of AWARE and text paging alerts to be equally disruptive. When AWARE and text paging alerts were directly

compared, a clear preference for text paging for both “urgent” and “non-urgent” alerts was present. When asked to “select one or more” (text paging, AWARE, email, phone call, text message, or other), the results for non-urgent alerts were mixed. However, when asked the same question for urgent alerts, the preference was once again clearly for text paging.

For the qualitative portion of the survey (Figure 3), 11 out of 12 clinician participants provided “at least one suggestion for improving alert/notification delivery”. Clinicians commented on inhomogeneous overall use of AWARE in the medical ICU, despite implementation several years prior (July 2012). Of the same 11 clinicians, 4 provided “any additional comments”: the same 3 NPs/PAs who responded to at least 1 alert acknowledgement from the severe sepsis alert system through AWARE, as well as Attending #03. A clear theme concerning alert fatigue, interruption, human error, and information overload was present.

Comment [JL15]: So you have gone from comparing alert systems to provider satisfaction to provider recommendations to revamp the system

An informal group interview in the form of a noon pizza party was held to thank all clinician participants and gather additional feedback on the barriers to clinician participation and engagement in this implementation study. The 4 clinicians who attended were once again the same 4 clinicians who provided “any additional comments” on the survey. The statements regarding alert fatigue, interruption, human error, and information overload were reinforced, despite a strong interest from these clinicians to participate. Regarding inhomogeneous overall use of AWARE in the medical ICU, specific attention was drawn to a particular lack of interest from residents to use AWARE, as well as a lack of interest from both residents and fellows to participate in any research study during their required rotations through the medical ICU, including implementation of the severe sepsis alert system.

Comment [JL16]: These are not results

DISCUSSION

The objective of this study was to test the hypothesis an automated severe sepsis alert system would reduce time to alert acknowledgement by critical care clinicians in the ICU setting compared to text paging. Based on the limited alert acknowledgement response rate using the severe sepsis alert system compared to traditional text paging, it was not possible to answer this hypothesis. However, feedback from the structured, mixed quantitative/qualitative survey, as well as the informal group interview, provided invaluable insight into the sources of this limited acknowledgement response rate. Implementation barriers included human factors, such as alert fatigue, interruption, human error, and information overload.

With the implementation of increasingly sophisticated EHR systems, interest in the development of novel automated detection and alert systems has increased (Bourgault et al. 2014). However, investigation into best methods of alert delivery (text paging, EHR systems, email, phone calls, and/or text messaging) for urgent and non-urgent alerts in the hospital setting is limited (Gill et al. 2012). Investigation into the most appropriate clinician for alert delivery is also limited (Zhang et al. 2003). Monitoring and alert systems have been developed for patient use in the home setting (Steinman et al. 2011; Tchalla et al. 2012). However, there has been comparatively limited investigation into methods of alert delivery to clinicians in the hospital setting (Loo et al. 2011). Interestingly, many of these studies have been performed in the geriatric patient population, but not in the ICU setting, where the average patient age is often 65 or older (Seferian & Afessa 2006). Thus, there is a clear need for further systematic exploration of human factors barriers to the implementation of new alert systems in the ICU setting, such as the impact of workflow changes and the influence of method of alert delivery.

Implementation of automated detection and alert systems without consideration of these factors is known to have the potential to result in alert fatigue (Singh et al. 2013), interruption (Hodgetts & Jones 2007), human error (Bates et al. 1998), and information overload (Stokstad 2001).

Recognition of the importance of alert fatigue in the hospital setting has increased significantly in recent years (Herasevich et al. 2013). However, implementation of automated alert systems generally must be performed in the context of information overload and complex task interruption (Eppler & Mengis 2004). It is also known that information overload can alter alert perception in the medical setting (Glassman et al. 2006). This can cause clinicians to perceive alert systems negatively and deter future use (Harrison et al. 2016). Thus, the task of generating clinically meaningful alerts while concurrently minimizing information overload and task interruption is challenging.

This study has several limitations. (1) This was a single-center study at an academic medical center. Well-established biases and potential confounders are known to be present with this particular study design (Straus et al. 2005). (2) Unlike the severe sepsis system alerts through AWARE (yellow or green icon alerts), the severe sepsis alerts through text paging were simulated. Comparing non-simulated alerts to simulated alerts may introduce additional confounders into the interpretation of the results of this study. (3) Although not investigated in this study, the feasibility of severe sepsis alert delivery using an EHR-based, automated mobile app for smartphones has been validated (Dziadzko MA and colleagues, in submission). The potential application of this technology for the future of clinical practice and clinical research should not be ignored. Ultimately, a multi-center, non-simulated study in the ICU setting is required to address various aspects of these limitations.

CONCLUSION

It could not be determined whether an automated alert for severe sepsis reduced time to alert acknowledgement by critical care clinicians in the ICU setting compared to text paging. This was due to an extremely limited alert acknowledgement response rate using the severe sepsis alert system compared to traditional text paging. Implementation barriers, including human factors—

such as alert fatigue, interruption, human error, and information overload—were determined to be an important source of this finding.

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360

361 **TABLE LEGEND**

362 Table 1: Number of shifts per clinician participant and number of participants per shift

363 Table 2: Comparison of alert response rate and median time to alert acknowledgement between
364 the severe sepsis alert system through AWARE and simulated severe sepsis alerts through
365 traditional text paging

366

367 **FIGURE LEGEND**

368 Figure 1: Detailed daily email reminder to clinician participants with complete instructions

369 Figure 2: Facsimile of the structured, mixed quantitative/qualitative survey provided to the
370 clinician participants with all quantitative results overlaid: median (IQR)

371 Figure 3: All qualitative responses to the structured, mixed quantitative/qualitative survey
372 reproduced in their entirety, including typographical errors