Effectiveness of a Sepsis Response Team in the Treatment of Severe Sepsis and Septic Shock: A 20 Patient Feasibility Study

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ABSTRACT
Background: The Society of Critical Care Medicine (SCCM) advocates use of a national data collection tool to measure compliance with treatment guidelines for severe sepsis. Some facilities utilize a Sepsis Response Team (SRT) to manage sepsis; however, their effectiveness has not been published. ***Purpose:*** Provide information to aid in the design of an appropriate study methodology, develop a multidisciplinary research team, create a paper data collection tool, utilize the SCCM data collection tool, and develop resource expectations needed to perform larger-scale studies. ***Setting:*** 760-bed tertiary care teaching hospital. ***Methods:*** This feasibility study describes the process to form a multidisciplinary research team, select patients, create a paper data collection form, utilize the SCCM tool, and retrospectively collect data from 20 patient charts, 10 treated by a SRT and 10 treated by individual prescribers. ***Results:*** Mean hours required for chart abstraction dropped significantly as the team gained experience with the abstraction process. Several SCCM data points were subjective, requiring a team consensus of definitions to maintain consistency. A difference in mean age between groups was identified. Other confounding variables that may be encountered in a larger-scale study were identified and are discussed. ***Conclusion:*** Large-scale studies evaluating efficacy of a SRT using the SCCM tool, will likely require significant resources and a multi-disciplinary team of researchers. A case-matched study design may be needed to mitigate population differences.

1. INTRODUCTION

The debilitating consequences of severe sepsis are devastating. Severe sepsis/septic shock is a life-threatening, systemic (body-wide) inflammatory response resulting from infection.[1] An estimated 215,000 patients will die from either sepsis or sepsis-related complications in the U.S. this year.[2] Excluding coronary patients, severe sepsis/septic shock is the leading cause of death in the intensive care unit (ICU).[3] The annual U.S. healthcare cost associated with severe sepsis/septic shock is $16.7 billion. Although progress has been made in the diagnosis and treatment of severe sepsis/septic shock, the morbidity rate is still rising and unacceptably high.[2] In 2003, critical care and infectious disease experts representing 11 international organizations developed sepsis management guidelines designed to increase awareness and improve patient outcomes.[4] Their goal is a 25% reduction in sepsis-related mortality by 2009. In the U.S., this goal will be measured by asking facilities to provide aggregate data via the Society of Critical Care Medicine (SCCM) data collection tool.

In June 2004, these guidelines were adopted to implement an aggressive protocol to manage severe sepsis/septic shock utilizing a Sepsis Response Team (SRT). The SRT consists of an attending critical care surgeon, a mid-level practitioner (Physician Assistant/Nurse Practitioner), a laboratory technician, a radiology technician, an emergency department nurse, an ICU nurse, a pharmacist, and a respiratory therapist. The SRT can be dispatched via page by the patient's physician. Following the page, all members respond to the bedside to initiate the sepsis treatment guidelines. The SRT was based on the Code-Blue rapid response team model.

The purpose of this feasibility study is to provide information to aid in the design of an appropriate study methodology, develop a multidisciplinary research team, create a paper data collection form, utilize the SCCM data collection tool, and develop resource expectations needed to perform larger-scale studies.

2. METHODS, RESULTS, SIGNIFICANCE

Methods: A retrospective chart review was conducted at a 760-bed, tertiary-care, teaching hospital with a 45-bed ICU. The SRT group consisted of 10 patients randomly selected from a computer-generated list of patients treated by the SRT between 1 Jun 2004 and 31 Dec 2005. Patients for the non-SRT group were similarly selected from a list of persons with a diagnosis of severe sepsis/septic shock treated by individual prescribers. The same data that would normally be collected to complete the SCCM tool or conduct a comparative outcomes study were collected..

This project was approved by Wichita State University and Wichita Medical Research and Education Foundation Institutional Review Boards.

Feasibility Results: Mean age for the SRT group was significantly lower than the non-SRT group; 54 ± 15 vs. 74 ± 16, p=0.01. Other patient characteristics appeared similar. The feasibility study objective does not include direct outcome comparisons between the two groups; therefore, p values are not provided for these measurements. *Table 1* provides examples of data outcomes collected. For each of these outcomes, several individual data points were frequently required.

TABLE 1: Examples of Data Points Collected	SRT Group	Non-SRT
Blood culture obtained prior to antibiotics	100%	90%
Antibiotics given within 1hr for ICU and 3hrs for emergency room patients	30%	30%
Central venous pressure goals were met	70%	0%
Oxygen saturation goals were met	80%	0%
Corticosteroids given according to protocol	80%	0%
Drotrecogin alfa given according to protocol	10%	0%
Mechanical ventilation goals were met	0%	0%
Blood glucose maintained < 150mg/dL	70%	0%
In-Hospital Mortality	10%	50%

Figure 1 shows distribution in chronological order of the length-of-time needed for data abstraction. The first chart was completed by all six researchers; therefore, man-hours to complete this chart were excluded from analysis. Mean length of time was longer for charts 2 – 4, as compared to the last three charts, 17 – 20. Mean time was 4.2 ± 0.20 man-hours vs. 1.2 ± 0.23 man-hours, p<0.05.

Figure 1: Man-hours Required for Data Extraction per Chart, in Chronological Order
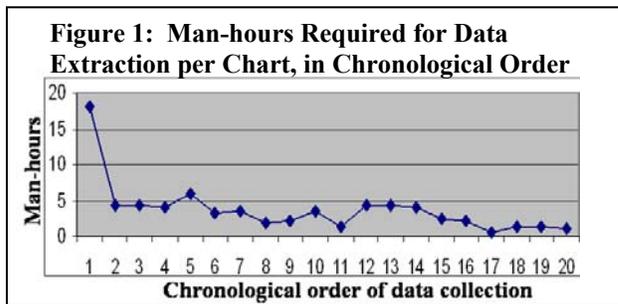
Confounding variables that may be encountered in a larger-scale study or during data collection via the SCCM tool were identified:

- A large number of data points were required to complete the SCCM tool; over 340 data points per patient, requiring a 9-page data collection form.
- Because of the large number of data points collected and variety of locations of those data, individual data collection was not feasible. A three person team worked well; one researcher documenting data and verbally requesting data

points, one researcher extracting data from the chart, and one extracting data from the computer.
- Several data points were subjective, requiring a consensus of definitions to maintain consistency. This may limit external validity or direct comparisons with other facilities collecting data.
- The research team should consist of persons with expertise in chart extraction, computerized data extraction, medical statistical analysis, and/or sepsis expertise to make inferences and diagnosis for some of the more complex data points.
- Future studies will require significant resources in man-hours and a multidisciplinary research team.
- As indicated by preliminary feasibility results for patient characteristics, lack of randomization in a retrospective study may lead to variations between study groups. A case-matched study design may be needed to mitigate population differences.

Clinical Significance: Based upon these pilot study results, a multidisciplinary team has been assembled, a stream-lined, 9-page data collection tool has been developed, study variables have been defined, and resource expectations estimated. A 500 patient outcomes study is anticipated to begin spring 2007 at this same facility. A brief review of the outcomes measurements indicates potential for significant benefits when comparing SRT to non-SRT. These feasibility results will also be valuable to external facilities planning to provide aggregate data via the SCCM data collection tool.

3. CONCLUSION

Large-scale studies evaluating the efficacy of a SRT using the SCCM tool will likely require significant resources and a multi-disciplinary research team. A case-matched study design may be needed to mitigate population differences.

4. ACKNOWLEDGEMENTS

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