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A Quality Improvement Project to Improve Sepsis-related Outcomes at an Integrated Healthcare System

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Abstract

Hospitals are encouraged to take steps to improve outcomes for patients with sepsis, a leading cause of morbidity and mortality. A retrospective analysis examined data (n=4475) from three health systems to better determine the impact of a 10-month sepsis quality improvement program that consisted of clinical alerts, audit and feedback, and staff education. Compared to the control group, the intervention group significantly decreased length of stay and costs per stay. The intervention group increased sepsis bundle compliance by more than 40%. A sepsis quality improvement program may improve sepsis health outcomes and decrease costs.

Keywords

Sepsis, Infection, Quality Improvement, Provider Education

Introduction

Sepsis, the body's systemic response to an infection[1], is a leading cause of mortality and morbidity in hospitalized patients accounting for 6.2% of total hospital costs in the U.S., or $23.7 billion in 2013 [2], and claiming 250 000 lives every year [3]. An international task force defined sepsis as "life-threatening organ dysfunction caused by a dysregulated host response to infection," while organ dysfunction is represented by an "increase in the Sequential [Sepsis-related] Organ Failure Assessment (SOFA) score of 2 points or more, which is associated with

an in-hospital mortality greater than 10%" [4]. The same task force defined septic shock as "a subset of sepsis in which particularly profound circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than with sepsis alone. Patients with septic shock can be clinically identified by a vasopressor requirement to maintain a mean arterial pressure of 65 mm Hg or greater and serum lactate level greater than 2 mmol/L (>18 mg/dL) in the absence of hypovolemia" [4].

Early identification of symptoms can be complex and difficult for clinicians[5]. In one recent study, 60% of patients who eventually progressed to septic shock presented without hypotension and manifested only non-specific signs at triage [6]. However, early recognition is critical because treating sepsis early can significantly help improve outcomes [7]. In October 2015, the Centers for Medicare and Medicaid Services (CMS) mandated that U.S. hospitals report the sepsis bundle compliance. These bundle elements are time-based, and their overall compliance is part of a quality process measure [8]. Congruent with CMS' focus on sepsis, there is a need for research studies examining Sepsis identification and prevention. The purpose of this study was to examine a quality improvement project that consisted of clinical alerts, audit and feedback, and staff education at an integrated healthcare system in the Midwest.

Methods

The patient data came from a deidentified dataset: 583 sepsis patients in the intervention group and 3892 sepsis patients in the control group. Cases were ran through a third party vendor using CMS specifications for selection. These specifications included coding of any ICD-10 codes related to sepsis, severe sepsis, or sepsis with septic shock regardless of code placement or POA status. The cases were then abstracted in accordance to CMS specifications for inclusions,

exclusions and bundle requirements. Of note, the population did exclude transfers from acute short-term hospitals.

Patients were all aged 18 and over and from one of three health systems. One of the health systems, [*Organization 1*], is a nonprofit health system in [*State*] and served as the intervention group. The control group, that, like [*Organization 1*], had small hospital sizes, similar average annual payer mix, and served rural populations, contributed data from two other regional health organizations. The IRB our institution uses reviewed the study and declared it exempt from informed consent requirements because the data could not be identified, directly or through identifiers linked to the subjects.

The intervention in this retrospective cohort study lasted ten months, from January 2017 through October 2017, and consisted of three main components: 1) clinical alerts, 2) audit and feedback, and 3) staff education. [*Organization 1's*] electronic health records contained alerts for sepsis bundle components. The purpose of the alerts was to capture the care provider's attention to take the necessary steps required to comply with the sepsis bundle in the amount of time required by CMS. The clinical alerts were fired to nursing staff when two indicators of systemic inflammatory response syndrome and organ failure were identified, flagging the patient for possible severe sepsis. Nursing then addressed the alert and notified the provider. At that point, providers were encouraged to address orders needed to assess and treat the patient.

An audit and feedback process is often used in healthcare organizations to improve health professional's performance by measuring their professional performance and comparing the results to targets or professional standards. [*Organization 1*] used data analytics from [*Organization 2*], a healthcare performance solution company based in North Carolina, as audit and feedback to identify and report variations related to the difference in sepsis-related outcomes

between providers, specialties, hospital units, onset, progression, and severity of illness. This data was reported back to the physicians. A main focus was outlier patients and what [*Organization 1*] could learn from their care. Quality improvement professionals examined the records of each of the outliers to determine if they were outliers due to a quality of care issue or due to more of a technicality (diagnosis was determined in the 3-hour window, but documentation lagged). To analyze the outlier data, the analytics company created trend reports that linked the outlier data to overall patient outcomes.

The clinical staff received education about rewriting order sets, sepsis recognition, and adherence to the sepsis order set and bundle. Throughout the entire intervention, [*Organization 1]* held weekly meetings for physicians, nurses, and care coordinators from a variety of hospital departments that were focused on sepsis bundle compliance and improving care for sepsis patients. Another form of education that care providers received was feedback within 24 hours of treating any patient who was indicated as having sepsis (or within 72 hours if treatment occurred over a weekend). This feedback included whether CMS criteria for both the 3-hour and 6-hour Surviving Sepsis Campaign (SSC) bundle were met for each indication, the result, and the amount of time it took. [*Organization 1]* encouraged care providers receiving the feedback to discuss any difficulties in providing the expected care. [*Organization 1*] used such comments from the care providers, particularly when hearing consistent comments, to determine opportunities for system-level changes. For the control group sites, treatment as usual occurred during this same time period without these intervention elements that were done at [*Organization 1*].

The intervention measures are described in Table 1. These measures were chosen because they are endorsed by the National Quality Forum and are the main measures used in the sepsis-

related literature[9]. The measures were examined for the four-month period before the intervention was implemented, the ten-month intervention period, and the four-month period after the intervention ended. Multiple linear regression analyses were used to test if the change in outcomes over time for the intervention group was significantly different from that of the control group. We controlled for the patient demographics of gender and age. Additionally, to test for the prevention of sepsis, the authors compared the incidence of sepsis among overall hospitalizations for both study groups over time. Data were analyzed using STATA version 15.0. (StataCorp LP, College Station, Texas).

Results

Results of the multiple linear regression indicated that the change in both length of stay and costs per stay from pre- to post-intervention were significantly different for the intervention group versus the control group as evidenced by the statistically significant interaction term between intervention group and post-intervention time (see Table 2). Length of stay was .30 days less, on average, for patients in the intervention group pre- to post-intervention than patients in the control group over the same time ($p < .001$). Costs per stay was $6883.43 less, on average, for patients in the intervention group pre- to post-intervention than patients in the control group over the same time ($p < .001$). There was not a statistically significant difference between the two study groups for sepsis-related mortality. Sepsis bundle compliance for the intervention group increased from 18.6% to 58.8% from pre- to post-intervention. Sepsis bundle compliance was not tracked for the control group. In the comparison between the intervention and control group regarding sepsis prevention, there were no statistically significant differences.

Limitations

There are some limitations to this study. First, the intervention and control group were not randomly assigned, so there may be selection bias. Rather, assignment to intervention and control groups was based on whether the health system implemented a system-wide sepsis outcome improvement program. There is a chance that [*Organization 1*], the health system that initiated implementing the intervention, may be more inclined to improve certain outcomes, which could affect the results of the study. Second, we were dependent on available data and limited to the health systems to which [*Organization 2*] had access. There were no data regarding sepsis bundle compliance for the control group or data on readmissions for either group. There may have been health care industry-wide factors that made an impact on sepsis bundle compliance. However, given the large increase in less than a year, it is highly likely that the intervention was a factor in compliance increase. In addition to obtaining sepsis bundle compliance and readmissions data for both study groups in future sepsis quality improvement research, comparing health systems with more similar baseline measures of the outcome variables would strengthen findings.

Another limitation is that the study data set was limited, and [*Organization 2*] did not have access to health indicators such as primary diagnosis prior to sepsis and comorbidities. While variables were limited, the study sample size was very large. Future researchers should examine sepsis quality improvement programs using a smaller sample size to ensure that the statistically significant findings herein are meaningful while also controlling for observable health indicators. Lastly, the control group is comprised of a convenience sample. While the authors do not know of a sepsis-related organization-wide initiative implemented at the control group health systems, there may have been smaller efforts undertaken to improve sepsis-related outcomes of which the authors were not aware. However, if the control systems did initiate

sepsis initiatives, this would have decreased the chances of finding a significant difference in any measures with the intervention system.

Discussion

It is well-documented that sepsis is a leading cause of morbidity and mortality in hospitals. One proposed method to improve sepsis care is the implementation of sepsis quality improvement programs in health systems. This study provides data showing that clinical alerts, audit and feedback, and staff education in a hospital system may improve sepsis-related health and cost measures. Improvement in sepsis bundle compliance and outcome measures is consistent with a recent study examining compliance after implementation of a sepsis core measure [10], and improvement across the measures is not surprising given the strong agreement among many international experts regarding the sepsis bundle recommendations [7]. A recent study showed that adherence to mandated evidence-informed sepsis protocols in New York State resulted in statistically significant decreases in length of hospital stay and morality [11].

The greater decrease in costs per stay for the intervention group compared to the control group is consistent with another study showing costs savings after improving sepsis outcomes. That study showed that patients with sepsis had more than double the amount of risk-adjusted costs than patients without sepsis [12]. Decreasing sepsis-related costs is especially important given that sepsis is the most expensive condition treated in U.S. hospitals [2]. In our study, while the sepsis-related mortality average rate decreased for both study groups, there was no statistically significant difference between the two groups. This finding suggests that a sepsis-focused quality improvement program may have more of an impact on length of stay and costs per stay than on mortality rates. Although the New York State study noted above showed a significant decrease in

mortality following initiation of a state-mandated sepsis protocol and reporting system, that study did not have a contemporaneous control group making it unclear if the sepsis protocol was responsible for the decrease in mortality. The finding that sepsis prevention did not statistically significantly differ between the intervention and control group may be due to the fact that the intervention was more focused on improving quality of care for patients with sepsis rather than preventing sepsis altogether.

Conclusions

A sepsis quality improvement program that includes clinical alerts, provider education, and audit and feedback may be effective for increasing sepsis bundle compliance, decreasing length of stay, and decreasing patient health care costs. We recommend further research using a randomized controlled trial to better determine the impact of a sepsis-focused quality improvement program on sepsis-related health and cost outcomes. Furthermore, future studies should also examine outcomes related to health systems providing education about infection prevention strategies and antibiotic-resistant pathogens that commonly cause sepsis-related infections[13] as well as outcomes related to providing education about sepsis-related treatment. Collaborative action by health systems and policy makers is needed to reduce the morbidity, mortality, and high costs related to sepsis and septic shock that is prevalent in the U.S. hospitalized patient population.

Implications

Providing data on sepsis bundle compliance and outcome measures along with education to providers and administrators is important for identifying quality improvement areas and

employing staff with the knowledge and tools to positively change behaviors and processes. Understanding the potential impact that a multicomponent sepsis intervention can have in a health care system is a critical step toward informing sepsis quality improvement programs in other health care systems and lowering rates of morbidity and mortality nationally.

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Table 1: Intervention Components

Component	Purpose	Details
Clinical alerts	Capture provider's attention to take necessary steps to comply with sepsis bundle	- Electronic alerts - Fired to nursing staff - Fired when two indicators of systemic inflammatory response syndrome and organ failure were identified for a patient. - Nursing then notified the provider - Provider addressed orders needed to assess and treat the patient.
Audit and feedback	Measure professional performance and compare the results to targets, professional standards, and peers.	- Used data analytics to - Identify and report variations related to the differences between providers, specialties, hospital units, onset, progression, and severity of illness.
Staff education	Teach physicians, nurses, and care coordinators about sepsis bundle compliance and improving care for sepsis patients.	- Weekly meetings for physicians, nurses, and care coordinators from a variety of hospital departments - Focused on rewriting order sets, sepsis recognition, and adherence to the sepsis order set and bundle. - Feedback within 24 hours of treating any patient who was indicated as having sepsis.[1]

Note:
Providers received feedback within 72 hours if treatment occurred over a weekend.

Table 2: Study Measures

Measure	Numerator	Denominator	Source
Length of stay	Number of inpatient days	Number of admissions	American Hospital Association[1]
Sepsis-related mortality	Number of deaths (DISP=20)[2] among cases meeting the rules for the denominator	Count of all encounters	Agency for Healthcare Research and Quality[3]
Costs / stay	Sum of gross facility costs for the entire hospital stay for all stays in the denominator. This does not include professional billing by providers involved in the care	Count of stays	Agency for Healthcare Research and Quality[4]
Sepsis Bundle Compliance	The number of patients in the denominator who received ALL of the following components (if applicable) for the early management of severe sepsis and septic shock: initial lactate levels, blood cultures, antibiotics, fluid resuscitation, repeat lactate level, vasopressors, and volume status and tissue perfusion reassessment	Inpatients aged ≥ 18 with an ICD-10-CM[5] Principal or Other Diagnosis Code of Sepsis, Severe Sepsis, or Septic Shock	Centers for Medicare and Medicaid Services (CMS)[6]

Notes:
[1]American Hospital Association (AHA). Annual survey of hospitals. Hospital statistics 2016 edition. Chicago, IL.
[2]DISP = Disposition of patient at discharge
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Table 3: Regression Results

Model	Coefficients		*t*	Sig.
	β	St. Error		
Length of stay (days)				
Constant	10.81	.54	20.19	< .001
Intervention group	1.82	0.93	3.42	.451
Post-intervention	-0.68	0.72	-1.02	.307
Intervention group * post-intervention	-0.30	0.22	-0.23	<.001
Age	-0.01	0.01	-2.07	.039
Gender	0.18	0.24	0.74	.462
Sepsis-related mortality				
Constant	0.00	0.12	0.08	.937
Intervention group	-0.10	0.04	-4.63	<.331
Post-intervention	-0.00	0.03	-0.14	.891
Intervention group * post-intervention	-0.70	0.60	0.21	.321
Age	0.00	0.00	5.44	<.001
Gender	0.00	0.01	0.18	.859
Charges / stay				
Constant	60,655.10	4926.87	12.31	<.001
Intervention group	1786.26	333.37	3.33	.197
Post-intervention	-8331.07	6694.41	-1.24	.519
Intervention group * post-intervention	-6883.43	2267.70	.96	<.001
Age	-187.18	69.25	12.31	.007
Gender	5451.86	2438.16	2.24	.025

Note. Gender = male.