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Utilization of Pharmacist Responders as a Component of a Multidisciplinary Sepsis Bundle

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Abstract

Background—Sepsis and septic shock remain a significant burden on the US healthcare system. A multidisciplinary response system (Coordinated Response To Sepsis, CaRTS) that included a pharmacist responder was implemented for patients with newly suspected sepsis.

Objective—Evaluate the time to appropriate antibiotic administration among patients with the CaRTS intervention compared to historical controls.

Methods—The CaRTS intervention included an electronic order set as well as activation of a multidisciplinary team of pharmacy and nursing personnel to coordinate resuscitation and medication administration. The CaRTS group was compared to historical controls. The primary outcome of the study was the proportion of patients with appropriate antibiotic administration within 1 hour of recognition of sepsis. Secondary outcomes included achievement of mean arterial pressure (MAP) ≥ 65 mmHg and central venous pressure (CVP) of 8–12 mmHg within 6 hours.

Results—The CaRTS intervention was used for 49 patients and 59 historical controls were included for analysis. Patients with the CaRTS intervention had a greater than 20x higher odds of antibiotic administration within 1 hour compared to controls (Odds Ratio (OR) 22.4, 95% Confidence Interval (CI): 7.5–69) and were more likely to have a CVP ≥ 8 mmHg at 6 hours (OR

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2.4, 95% CI: 1.0–5.6) compared to controls. CaRTS patients achieved non-statistically significant increases in MAP 65 mmHg (OR 2.2, 95% CI: 0.7 – 7.7).

Conclusions—Utilization of a multidisciplinary sepsis bundle that included a pharmacist responder improved the proportion of patients receiving appropriate antibiotics within 1 hour of recognition of sepsis compared to historical controls.

Background

The management of sepsis remains one of the most common and challenging clinical problems in the United States. Approximately 750,000 cases are treated in U.S. hospitals per year, with approximately 215,000 deaths occurring every year in the U.S.¹ Sepsis is characterized as a dysregulated physiological response to probable or documented infection, with severe sepsis representing sepsis and sepsis-induced organ dysfunction. Septic shock is subsequently defined as sepsis-induced hypotension (systolic blood pressure (SBP) <90 mmHg or mean arterial pressure (MAP) <70 mmHg) that is refractory to adequate fluid resuscitation.² The significant risk of morbidity and mortality requires prompt coordinated medical treatment. The Surviving Sepsis Campaign, a multinational, multidisciplinary effort, has published guidelines for the diagnosis, resuscitation, and treatment of patients with sepsis and septic shock.² Paramount among the recommendations includes the prompt initiation of appropriate antibiotic therapy within 1 hour and achieving early goal-directed resuscitation within 6 hours including: MAP 65 mmHg, central venous pressure (CVP) of 8–12 mmHg, and central venous oxygen saturation (Scvo2) 70%. Achieving these early goals in sepsis management has been associated with reduced mortality.³

Previous efforts to institute standardized order sets or bundle elements of sepsis care have been successful, including reductions in time to antibiotic administration, more aggressive fluid resuscitation, and reductions in mortality.^{4–8} Many of these have focused on the emergency department, where the majority of patients present, and their transition to the ICU rather than sepsis recognition in the ICU and other areas of the hospital. Despite the success of these bundles, time to antibiotic administration remains a challenge. Published reports in the literature, even within the context of successful bundle implementation, show time to antibiotic administration routinely exceeds one hour.^{5–6,8–10} A multidisciplinary group was formed at our hospital to identify barriers and solutions for this and other processes of care within the resuscitation of septic patients.

Our institution developed a Coordinated Response To Sepsis (CaRTS) intervention based on the Surviving Sepsis Campaign's recommendations to reduce our institution's mortality from sepsis and septic shock. CaRTS was a multi-modal intervention designed to improve time to antibiotic administration and achievement of hemodynamic goals in patients newly diagnosed with sepsis or progression of sepsis, including severe sepsis and septic shock. The CaRTS intervention included: 1) An electronic order set for patients suspected of developing sepsis, 2) the automated deployment of pharmacy and nursing personnel after order activation, and 3) placement of hospital-wide "sepsis carts" to assist with bedside resuscitation. The study objective was to determine the impact of the CaRTS intervention

utilizing pharmacist responders on time to antibiotic administration, one of the critical benchmarks of care in the management of sepsis and septic shock.

Methods

Setting and participants

The University of Kentucky Chandler Medical Center is a 825-bed, level-1 trauma center and serves as a major regional medical center for the state. All septic patient cases treated with the CaRTS intervention were identified and included through an automated daily query of the electronic medical record from September 1, 2010 to September 1, 2011. CaRTs patients were included for analysis on an “intent-to-treat” basis without requiring traditional criteria for sepsis. Historical controls from September 1, 2008 to August 31, 2010 were included for analysis. Historical controls were initially selected using Medicare Diagnosis Related Group (DRG) codes for sepsis and septic shock within our institution according to the University HealthSystem Consortium (UHC) database, beginning with the implementation of this intervention and working backward in time until sufficient sample size was collected. If a control subject appeared more than once, only the first occurrence was used for analysis. Subjects less than 18 years old or pregnant women were excluded from both groups. The study was approved by the Institutional Review Board.

Definition of sepsis and interventions

After inclusion, cases were evaluated by chart review for definitions of sepsis and septic shock in concordance with the Surviving Sepsis Campaign guidelines.² Presence of systemic inflammatory response syndrome (SIRS) was defined as two or more of the following: 1) body temperature less than 36°C or greater than 38°C, 2) heart rate greater than 90 beats per minute, 3) tachypnea with greater than 20 breaths per minute, or an arterial partial pressure of carbon dioxide less than 32 mmHg, or 4) white blood cell count less than 4000 cells/mm³ or greater than 12,000 cells/mm³. Sepsis in either group was defined as presence of SIRS plus a positive culture or documented source of infection. Septic shock was defined as the presence of hypotension (SBP <90 mmHg) or need for vasopressor therapy. Sepsis onset (time zero) relative to antibiotic administration and hemodynamic resuscitation was defined as either the time that the electronic sepsis order set was entered for the CaRTS group or the time of the first order for empiric antibiotics, blood cultures, or any vasopressor therapy in the control group. Severity of illness and end organ dysfunction were evaluated using relevant clinical documentation and laboratory results, and summarized with Acute Physiology and Chronic Health Evaluation II (APACHE II) and Sequential Organ Failure Assessment (SOFA) scores.^{11–12}

CaRTS intervention

The CaRTS intervention was a multi-modal intervention with three distinct parts. Prior to this intervention, there were no standardized sepsis bundles or order sets at the institution.

Electronic order set—Upon suspicion of the onset of sepsis, the primary clinician activates the sepsis electronic order set which includes the following: standard laboratory

orders for blood and respiratory cultures, baseline chemistry, hematology and blood gas studies, antibiotics, fluid boluses, and vasopressors.

Personnel Response—An automated response system sends out a series of pages to alert the listed personnel after sepsis order set activation including pharmacists, the nursing rapid response team, bed control administrators, and materials management staffers. The pharmacy residency program has a 24-hour, 365-day per year pharmacist on-call program. The sepsis order set entry automatically pages the pharmacist on-call, who responds to the patient's bedside to assess the patient and facilitate discussion and intervention with medical and nursing staff. The pharmacist is responsible for reviewing the patient's medical record to evaluate recent infectious episodes, recent antibiotic use, previous cultures (both clinical and surveillance), and risk factors for resistant organisms or other pathogens in order to provide the most appropriate antimicrobials for the individual patient. Following this timely assessment, the pharmacist either compounds or facilitates delivery of all antibiotics to the bedside and assists with preparation and administration as needed. The pharmacist also assists with fluid/vasopressor resuscitation, hemodynamic monitoring, and assessment for corticosteroid administration. Following the initial resuscitation, the pharmacist communicates the interventions to the primary pharmacist covering the patient, as well as documents their attendance and interventions in the medical record. The instructions given to pharmacy residents regarding the role of the pharmacist during sepsis bundles are displayed in Figure 1. The nursing rapid response team assists the primary nurse with physical/clinical assessment, laboratory orders, medication administration, and documentation as necessary. Bed control and materials management assists with process of care, between unit transfers, and additional supply procurement if necessary.

Sepsis cart—In order to facilitate resuscitation, "sepsis carts" were created with supplies and medications necessary per institutional protocol including: basic nursing supplies, culture bottles, supplies and kits for arterial and central venous catheterization, single medication doses of broad-spectrum antibiotics, including piperacillin-tazobactam, vancomycin, and levofloxacin, as well as norepinephrine, vasopressin, hydrocortisone, and resuscitation fluids. These sepsis carts were placed throughout the facility's intensive care areas, emergency departments, Post-Anesthesia Care Units (PACU), and transitional medical floors ("step-down" units) and included algorithms from the Surviving Sepsis Campaign.

Outcomes

The primary outcome was defined as the proportion of patients who received appropriate (pathogen susceptible) antibiotic therapy within 1 hour of sepsis onset. Time to antibiotic administration was determined by documented nursing administration times on the medication administration record (MAR). Pathogen antibiotic susceptibility was determined by standard Clinical and Laboratory Standards Institute (CLSI) methodology. Secondary outcomes for those with septic shock included the proportion of patients who achieved the target hemodynamic goals (MAP $\geq$ 65 mmHg and CVP of 8–12 mmHg) within six hours of onset. Septic shock patients with no assessment for CVP within 6 hours were not considered to achieve that specific hemodynamic goal. Clinical outcomes including in-hospital

mortality, ventilator-free days, disposition at discharge, intensive care unit (ICU) length of stay, and hospital length of stay were collected as well.

Statistical Analysis

All study data were collected and managed using REDCap (Research Electronic Data Capture).¹³ Dichotomous outcomes were analyzed by chi square analysis or Fisher's exact test. The student's t-test or Mann-Whitney U test was used for normally or non-normally distributed continuous variables as appropriate. For the primary endpoint, assuming a baseline antibiotic administration rate of 0.5 (i.e. 50% of patients) within 1 hour, achieving 80% power to detect a treatment difference of 0.3 (i.e. 30 absolute percentage point improvement vs. controls), requires an estimated sample size of 45 in each group.

Primary and secondary outcomes are reported as Odds Ratios (OR) with 95% confidence intervals (CI). An $\alpha < 0.05$ was considered statistically significant for hypothesis testing. Data was analyzed using STATA 12 SE (Statacorp, TX, USA).

Results

During the time period studied, the coordinated sepsis bundle was activated on 49 patients; data on 59 control patients was collected for comparison. Baseline demographic and clinical characteristics are reported in Table 1. Patients in the CaRTS group were comparable to controls by age, gender, admitting service, and location at sepsis onset. Both groups had similar rates of positive blood cultures (59.2% vs. 55.9%), however, CaRTS patients were more likely to have a urinary source of infection (26.5% vs. 6.8%), while controls had more positive pulmonary (20.4% vs. 44.1%) and abdominal source cultures (4.1% vs. 23.7%). CaRTS and control patients had similar rates of SIRS and sepsis criteria, but CaRTS patients were more likely to be hypotensive at baseline (44.9% vs. 23.7%) and had significantly higher APACHE II scores (27 ± 8 vs. 23 ± 8). CaRTS patients also had a significantly higher proportion of patients requiring vasopressor support (59% vs. 37%).

Table 2 reports the primary and secondary outcomes. The odds of antibiotics being administered within 1 hour in the CaRTS group were approximately 20x higher compared to controls (OR 22.4, 95% CI: 7.5–69). The median time to appropriate antibiotic administration in the CaRTS group compared to the control group was 0.65 hours vs. 2.4 hours (not shown in table). The percentage of organisms susceptible to initial empiric therapy was similar in both groups (89.8% vs. 86.4%). CaRTS patients achieved non-statistically significant higher odds of MAP ≥ 65 mmHg at 6 hours (OR 2.2, 95% CI: 0.7 – 7.7), but had a significantly higher odds of CVP ≥ 8 mmHg at 6 hours (OR 2.4, 95% CI: 1.0–5.6) compared to controls. There were no significant differences in length of stay, disposition on discharge, or mortality.

Discussion

In this retrospective, case-control study of a coordinated hospital-wide sepsis response system that included a pharmacist responder, a significant reduction in the time to antibiotic administration and improvement in early resuscitation were demonstrated. The time to

antibiotic administration is strongly associated with patient outcomes in septic shock.^{14,15} The development of a process to ensure the prompt availability and administration of appropriate empiric broad-spectrum antibiotics is critical for sepsis management and a major focus of the CaRTS intervention. Timely antibiotic administration is based on three factors: 1) determination of the most appropriate antibiotic regimen based on local susceptibility data and patient specific information, 2) delivery of ordered antibiotics, and 3) the rapid administration of antibiotics once available. As mentioned previously, our institution utilizes a pharmacist on-call program. This 24-hour pharmacist responder can compound and facilitate administration of antibiotics at the bedside. Activities of this nature may include admixing antibiotics, priming lines, and programming pumps for antibiotic administration if needed. For those antibiotics not stocked on the units or where non-standard doses are desired (i.e. loading dose of vancomycin), the pharmacist facilitates the rapid delivery from central pharmacy. The pharmacist is also responsible for reviewing the patient's medical record to evaluate recent infectious episodes, previous cultures (both clinical and surveillance), and risk factors for resistant organisms or other pathogens (e.g. fungal, viral) in order to provide the most appropriate antimicrobials for the individual patient. Common interventions include broadening the antibiotic spectrum or double coverage in patients with a history of multi-drug resistant organisms, the addition of antifungal coverage in appropriate scenarios, and researching patient allergies to prescribe beta-lactams if at all possible. The pharmacist is also a drug information resource for many common bedside questions during these resuscitations (e.g. intravenous compatibility, questions of which antibiotic to give first if limited access). Finally, the pharmacist serves as a consistent reminder that timely antibiotic administration is critical during the resuscitation of a septic patient. The perception that other interventions such as laboratory tests, line placement, or other intravenous medications are more important than antibiotics may contribute to delays in administration. This is demonstrated by the median time to antibiotic administration of 2.4 hours in the control group. Previous quality assurance studies had indicated delays in administration as well, despite many antibiotics being located on the floor and appropriate delivery times from central pharmacy. A common insight from nurses during the development of this bundle was that with all of the patient care issues ongoing, admixing and administering antibiotics was difficult in light of other critical patient issues. The accessibility of antibiotics on the units did not change over the time periods studied; many have been and are stored in automated dispensing cabinets on the medical floors. During the development of this bundle, a consensus among the multidisciplinary group was that people, not supplies, would be a driving force for change in the way we resuscitate septic patients. The major change in this before and after study was a concerted, multidisciplinary effort that included the pharmacist whose responsibility was to ensure the proper selection of and rapid administration of antibiotics.

The success of this strategy is demonstrated in significant improvement in time to appropriate antibiotic administration. In their recommendations regarding early, appropriate antibiotic therapy, the Surviving Sepsis Campaign guidelines note that "although the weight of the evidence supports prompt administration of antibiotics (within the first hour of recognition)...the feasibility with which clinicians may achieve this ideal state has not been scientifically validated."² Even within published reports of successful implementation of

sepsis bundles and order sets, the time to antibiotic administration commonly remains greater than one hour.^{5–6,8} In some cases, time to appropriate antibiotic administration may exceed three hours.⁹ To our knowledge, the median time to antibiotic administration of 0.65 hours in our study is the lowest time to antibiotics reported within a sepsis bundle in the published literature. Additionally, many of these previous reported sepsis bundles focus on patients in the emergency department.^{4–8} The development of sepsis and septic shock is not limited to the emergency department, as highlighted in table 1. The structure of the current bundle allows for a coordinated response, regardless of location in the hospital.

We present here the case for the pharmacist responder to be integrally involved with this “golden hour” of resuscitating the septic patient. Pharmacists routinely respond to cardiopulmonary arrests to assist with critical care management- the “golden hour” of sepsis resuscitation is arguably not too dissimilar with even stronger evidence for pharmacotherapy interventions. With an increase in mortality for every hour of delayed antibiotic therapy, the processes of care for sepsis resuscitation within the “golden hour” should be viewed with as much fervor as for myocardial infarction or stroke.¹⁵ While the implementation of sepsis bundles have previously been associated with a reduction in mortality and other favorable outcomes, this is the first such bundle described to our knowledge with specific responsibilities assigned to the pharmacist.^{4–8}

The second major focus of the coordinated response was successful implementation of early goal-directed therapy. The readily available supplies and human resources dispatched likely contributed to the increased number of patients who met hemodynamic goals. The study was not adequately powered to detect differences in clinical outcomes included resolution of infection, length of stay or survival. The in-hospital mortality rates (48.9% vs 54.2%) were similar in both groups despite the fact that patients in the CaRTS group had a higher acuity of illness and were more likely to be hypotensive and on vasopressors at the initiation of sepsis resuscitation, suggesting a more acutely ill population at higher risk of death.

A limitation of this study is our retrospective inclusion of cases and use of historical controls for comparison. CaRTS patients are actively identified by hospital staff for a significant sepsis intervention, while controls were identified by DRG codes and validated with retrospective chart review. There is potential for selection bias due to control cases being identified retrospectively via chart review. Although CaRTS and control patients had a full sepsis protocol or equivalent orders entered, they did not always meet conventional criteria for sepsis or septic shock per our chart review. This may highlight the limitations in relying on coding when retrospectively identifying cases through chart review but we included these patients under an assumption of “intent-to-treat”. Although the number of CaRTS patients was large enough to meet our sample size requirement, the number of activations is relatively low indicating poor compliance with the order set. The definition of time zero (sepsis onset) in the historical control group may also be a threat to validity. An objective surrogate for the deterioration associated with sepsis was used to define time zero. It should be noted that this time zero is not explicitly the onset of sepsis and more reflects the clinician’s concern for or recognition of potential sepsis. Indeed, delayed recognition is detrimental to patient outcomes in sepsis, and may explain the higher mortality rates seen in our study.

Regardless of hospital setting, the logistics of optimizing time to first dose of antibiotics remain a clinical challenge for practitioners caring for patients suspected of developing sepsis and septic shock. Delays in many processes, most importantly recognition, may hinder achievement of this goal. Regardless of whether it is selection, ordering, delivery, or facilitation with administering antibiotics, pharmacy departments can play a major role in improving the care of this patient population by working with medical and nursing staff, both clinically and logistically, on ensuring the right antibiotics for the right patient within one hour of recognition.

Conclusions

This study demonstrated that a multidisciplinary coordinated response to sepsis (CaRTS) intervention which included a pharmacist responder was able to dramatically improve the time to appropriate antibiotic administration. The inclusion of a clinical pharmacist in the initial response was a key factor in improving the timely administration of appropriate antibiotics and a feasible tool for improving the care of patients with sepsis and septic shock.

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**Institutional Septic Shock Resuscitation Response
Pharmacist Role**

1. When the Septic Shock order set is activated, the Pharm.D. on call will receive a text page similar to the following:
Sepsis Shock Bundle
1TIC-183-D
MCCLAIN, TEST
011002383-0154
2. Facilitation of Antibiotic administration
(The order set includes orders for fixed doses of Vancomycin and Pip/Tazo x1)
Please help facilitate the obtaining of cultures prior to antibiotic doses if possible.
 - a. **Review patient allergies prior to administration**, if PCN allergy is significant facilitate the ordering and STAT delivery of Aztreonam dose.
 - b. Assess patient weight and renal function to determine appropriate Vancomycin dose. Facilitate the ordering and delivery of additional dose if necessary.
 - c. Review patient history for previous cultures and risk factors for infections from viral, fungal or MDR sources. (i.e. BMT patients, transplant, surveillance cultures with MDR bacteria, etc.)
 - d. Place orders for appropriate empiric antibiotic therapy tailored to the patient and subsequent levels or lab monitoring needed.
3. Assist with preparation of vasopressor therapy
 - a. The sepsis cart includes drip kits for norepinephrine and vasopressin. Assist with preparation and labeling if necessary.
 - b. Facilitate the ordering and delivery of other vasopressor agents if warranted. Epinephrine drip kits are not included but are in most ICU pyxis machines. Phenylephrine can be obtained from central.
 - c. Hydrocortisone 100mg x 1 is on the cart. If appropriate, facilitate the administration and ordering of subsequent doses.
4. Documentation
 - a. Please document all your activities in the Pharmacotherapy consult note and pass-off appropriate items to the pharmacist carrying for the patient.
5. Assistance
 - a. If you need help, please call _____.

Figure 1.
Pharmacist's role in response to sepsis bundle activation.

Table 1

Baseline demographic and clinical characteristics of CaRTS patients and historical controls.

	Intervention group		P-value
Characteristic	CaRTS (N=49)	Control (N=59)	
Age (yrs, mean $\pm$ SD)	58 $\pm$ 17	57 $\pm$ 15	0.79
Gender, no. male (%)	25 (51)	37 (62.7)	0.22
Location at sepsis onset, no. (%)			
General or transitional medical floor	15 (30.6)	11 (18.6)	0.15
Emergency department	15 (30.6)	18 (30.5)	0.99
Intensive care unit	19 (38.8)	30 (50.8)	0.21
Admitting service, no. (%)			
Medical intensive care unit	14 (28.6)	24 (40.7)	0.19
Internal medicine	7 (14.3)	10 (16.9)	0.71
Trauma/general surgery	10 (20.4)	12 (20.3)	0.99
Other ^a	18 (36.7)	13 (22.0)	0.14
Positive culture source, no. (%)^b			
Blood	29 (59.2)	33 (55.9)	0.73
Lung	10 (20.4)	26 (44.1)	<0.001
Urine	13 (26.5)	4 (6.8)	0.007
Abdominal culture	2 (4.1)	14 (23.7)	0.005
Severity of illness			
2 SIRS criteria no. (%)	49 (100)	56 (94)	0.11
Sepsis criteria, no. (%)	43 (87.8)	49 (83.1)	0.5
Systolic blood pressure <90 mmHg at baseline	21 (44.9)	14 (23.7)	0.04
APACHE II score (mean $\pm$ SD)	27 $\pm$ 8	23 $\pm$ 8	0.03
SOFA score (median no.)	9	8	0.59
Shock criteria, no. (%)	23 (46.9)	18 (30.5)	0.07
Any vasopressor initiated	29 (59)	22 (37)	0.02

^a - other services include cardiothoracic surgery, neurology, hematology/oncology, transplant surgery.^b - as defined by positive culture at time of disease; patients could have more than one site of infection.

Table 2

Primary and secondary outcomes among CaRTS patients and historical controls.

Outcome	CaRTS (N=49)	Control (N=59)	OR (95% CI) ^a
Primary outcome: Antibiotics			
Antibiotics administered within 1 hour, no.(%)	41 (77.5)	11 (23.7)	22.4 (7.5–69)
Secondary outcomes: Hemodynamic goals, no.(%)^b			
MAP 65 mmHg within 6 hours	43 (87.7)	45 (76.3)	2.2 (0.7 – 7.7)
CVP 8 mmHg within 6 hours	26 (53.1)	19 (32.2)	2.4 (1.0–5.6)
Disposition on discharge, no. (%)			
Home	8 (16.3)	14 (23.7)	0.6 (0.2–1.8)
Long-term acute care or nursing facility	19 (38.8)	14 (23.7)	2.0 (0.8–5.1)
Death	24 (48.9)	32 (54.2)	0.5 (0.2–1.2)
Length of Stay			P-value^c
Intensive care unit, median (IQR) ^d	8 (3–15)	8 (2–17)	0.83
Total hospital length of stay, median (IQR)	15 (8–44)	12 (7–24)	0.14

^a95% confidence intervals (CI) for the Odds Ratio (OR).

^bMAP –mean arterial pressure, CVP – central venous pressure.

^c-Mann-Whitney U test.

^dIQR – interquartile range.