Assessment of Compliance to 2016 Surviving Sepsis Campaign Bundles among Adult Patients Admitted at ManilaMed–Medical Center Manila Diagnosed with Sepsis

Cherry Lois M. Benjamin, M.D.*; and Evalyn Roxas, M.D.**

Abstract

Introduction: Sepsis is an emerging problem that needs to be recognized early and addressed promptly with hydration and appropriate antibiotics. This study aims to assess the adherence to surviving sepsis campaign (SSC) bundle within three hours and six hours, length of hospital stay and mortality among adult patients admitted at ManilaMed–Medical Center Manila diagnosed with sepsis.

Methods: A retrospective cohort study was performed in all adult patients admitted at ManilaMed–Medical Center Manila diagnosed with sepsis and septic shock from January to September 2017. Parameters for SSC bundle for three and six hours were used to assess compliance. Outcomes such as length of hospital stay and mortality were determined.

Results: This study included a total of 85 subjects and majority are females (56%). Mean age of study subject was 67.5±17.67 years. Adherence to SSC bundle in three and six hours were observed particularly in blood cultures (45%), administering broad-spectrum antibiotics (69%), fluid resuscitation at 30 mL/kg for hypotensive patients (22%) and administering vasopressors (78%) to maintain systemic perfusion. However, adherence to other parameters of the bundle was not observed, namely: measurement and re-measurement of lactate levels and measurement of CVP and SCVO2. In terms of outcome, the average length of hospital stay is 11 days and mortality was 42%.

Discussion: Sepsis is a fatal disease if not promptly recognized and addressed. The SSC bundle was formulated to guide clinicians and other healthcare providers in managing sepsis or septic shock patients. Some of the parameters are absent or are not routinely done in some institution, maximizing the resources that are present is ideal.

Conclusion: The compliance rate is deemed submaximal since eyeing for a 90-100% compliance rate is recommendable in a tertiary hospital. Emphasis on early identification, obtaining blood cultures and timely initiation of antimicrobials should be done.

Keywords: sepsis, surviving sepsis campaign bundle 2016, compliance

Introduction

Sepsis is an emerging medical problem that needs to be recognized early and addressed promptly with hydration and appropriate antibiotics. The incidence of sepsis is increasing in line with the aging population with more comorbidities.[1] Sepsis is associated with high morbidity and mortality and accounted for $23.7 billion in health care expenditures in 2013. Infection prevention strategies (e.g., vaccination, reducing transmission of pathogens in health careenvironments, and appropriate management of chronic diseases) are likely to have a substantial impact on reducing sepsis. In addition, current efforts led by Centers for Disease Control and Prevention (CDC) and partners to improve sepsis surveillance will enhance analysis of risk factors and infections leading to sepsis and provide a more objective measure to track trends and evaluate interventions, informing overall prevention, recognition, and treatment efforts.[2]

Worldwide, sepsis is one of the most common deadly diseases. It is one of the few conditions to strike with equal ferocity in resource-poor areas and in the developed world. Globally, 20-30 million patients are estimated to be afflicted every year. Every hour, about 1,000 people and each day around 24,000 people die from sepsis worldwide. Despite accounting for over eight million lives lost annually, sepsis is one of the least well known diseases.[5]

In a prospective cohort observational study done in University of the Philippines-Philippine General Hospital (UP-PGH), sepsis had a prevalence of 25% and a 34% all cause mortality in this population. They had lined out independent

* Resident, Department of Internal Medicine, ManilaMed–Medical Center Manila, Manila, Philippines
** Consultant, Department of Internal Medicine, ManilaMed–Medical Center Manila, Manila, Philippines

Corresponding author: Cherry Lois M. Benjamin, M.D., ManilaMed–Medical Center Manila, Manila, Philippines
Email: cherrybenjamin@yahoo.com

factors that are linked to mortality such as inappropriate antimicrobial therapy and nosocomial acquisition of infection. Addressing these factors would have benefit on health resource allocation. [14]

Sepsis is not a specific illness but rather a syndrome encompassing a still-uncertain pathobiology. Sepsis is different from infection being the former results from an aberrant or dysregulated host response and the presence of organ dysfunction. At present, it can be identified by a constellation of clinical signs and symptoms in a patient with suspected infection. Previous definition involving Systemic Inflammatory Response Syndrome (SIRS) in the criteria are not advocated anymore because SIRS do not necessarily indicate a dysregulated, life-threatening response. [2,3]

Scoring systems for organ dysfunction has been assessed, one of which is the Sequential Organ Failure Assessment (SOFA). A higher SOFA score is associated with increased probability of mortality. This scoring system includes the following parameters: PaO2, platelet count, creatinine level, and bilirubin level. However, this scoring system is not well known outside the critical care community. [2,3]

Recent guidelines have evaluated parameters in identifying dysregulated host response that most likely would reflect sepsis. The baseline SOFA score should be assumed to be zero unless the patient is known to have preexisting (acute or chronic) organ dysfunction before the onset of infection. Patients with a SOFA score of two or more had an overall mortality risk of approximately 10% in a general hospital population with presumed infection. Depending on a patient's baseline level of risk, a SOFA score of two or greater identified a 2- to 25-fold increased risk of dying compared with patients with a SOFA score less than two. The SOFA score is not intended to be use as a tool for patient management but as a means to clinically characterize a septic patient.[2]

The quick SOFA (qSOFA) comprise altered mentation, systolic blood pressure of 100 mm Hg or less, and respiratory rate of 22/min or greater, provides simple bedside criteria to identify adult patients with suspected infection who are likely to have poor outcomes. Although qSOFA is less robust than a SOFA score of two or greater in the intensive care unit (ICU), it does not require laboratory tests and can be assessed quickly and repeatedly. It was suggested that qSOFA criteria be used to prompt clinicians to further investigate for organ dysfunction, to initiate or escalate therapy as appropriate, and to consider referral to critical care or increase the frequency of monitoring. A positive qSOFA should also prompt consideration of possible infection in patients not previously recognized as infected.[2]

Sepsis management requires a multi-disciplinary team (physicians, nurses, pharmacy, respiratory, dieticians, and administration) and multispecialty collaboration (medicine, surgery, and emergency medicine) to maximize the chance for success. Evaluation of process change requires consistent education, protocol development and implementation, data collection, measurement of indicators, and feedback to facilitate the continuous performance improvement. In partnership with the Institute for Healthcare Improvement, phase III of the Surviving Sepsis Campaign (SSC) targeted the implementation of a core set ("bundle") of recommendations in hospital environments where change in behavior and clinical impact were measured. The 2016 SSC guidelines and bundles can be used as the basis of a sepsis performance improvement program. Application of the SSC sepsis bundles led to sustained, continuous quality improvement in sepsis care and was associated with reduced mortality.[3]

The 2016 SSC bundles have set parameters that should be accomplished within three hours and six hours. The following should be performed within three hours: 1) measure lactate level; 2) obtain blood cultures prior to administration of antibiotics; 3) administer broad spectrum antibiotics; 4) administer 30 mL/kg crystalloid for hypotension or lactate 4mmol/L; and in six hours; 5) apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (MAP) ≥65 mm Hg; 6) in the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate 4 mmol/L (36 mg/dL): measure central venous pressure (CVP); measure central venous oxygen saturation (ScvO2); 7) remeasure lactate if initial lactate was elevated. [3]

Establishing vascular access and initiating aggressive fluid resuscitation are the first priorities when managing patients with severe sepsis or septic shock. Prompt infusion of antimicrobial agents should also be a priority and may require additional vascular access ports. The administration of effective intravenous antimicrobials within the first hour of recognition of septic shock (grade 1B) and severe sepsis without septic shock (grade 1C) should be the goal of therapy. Initial empiric anti-infective therapy includes one or more drugs that have activity against all likely pathogens (bacterial and/or fungal or viral) and that penetrate in adequate concentrations into the tissues presumed to be the source of sepsis. The antimicrobial regimen should be reassessed daily for potential de-escalation to prevent the development of resistance, to reduce toxicity, and to reduce costs.[3]

In a Systemic Review for the Global Burden of Sepsis, which covered years 1979-2013, Hospital mortality was 15% for sepsis and 25% for severe sepsis during this period of time. There were no population-level sepsis incidence estimates from lower income countries. A tentative extrapolation from high-income-country data suggests global estimates of 30.7 million sepsis and 23.8 million severe sepsis cases, with potentially six million deaths each year.[4]

Nursing-related implications for early detection and treatment of sepsis include assessing patients for signs of infection, obtaining cultures for suspected infection, providing medical treatments for sepsis, and infection-prevention measures.[6]

Awareness of the risk factors, clinical signs and symptoms, pathophysiology, and updates in the management of sepsis can enhance the nursing care for patients with severe sepsis and promote best practices for sepsis care in the ICU. Infection-prevention measures for sepsis include general infection control practices, hand-washing principles, and measures to prevent nosocomial infections (oral care and proper positioning to prevent nosocomial pneumonia, care of invasive catheters, skin care, wound care, identifying patients at risk for infection, prioritizing cultures for patients with suspected infection, and providing astute clinical assessment for early detection of sepsis).[7]

Recently, an update was released combinining the three and six hour bundles into a single "hour- 1 bundle". In this 2018 update, the following should had been initiated upon presentation at the emergency room or any healthcare facility: measure lactate, obtaining blood cultures prior to initiation of antibiotics, administering broad spectrum antibiotics, fluid administration 30 mL/kg of crystalloid for hypotension or lactate level >/= 4mmol/L and initiation of vasopressors if persistently hypotensive after fluid resuscitation to maintain MAP >/= 65 mmHg. The last three parameters have strong recommendations.[13]

Education of healthcare providers and being equipped with facilities would increase success rates in sepsis treatment. The treatment of sepsis involves a multidisciplinary approach. Early identification of those at risk of sepsis and early detection of patients with sepsis would have a great impact in the outcome of these patients. This study will provide data that would help in developing an organized approach in patients with sepsis starting from diagnosing, treatment and discharge of septic patient. In the future, this study may pave the way in structuring a clinical pathway for sepsis in this institution.

The researchers aim to assess the adherence to 2016 SSC bundle within three hours and six hours among adult patients admitted at ManilaMed diagnosed with sepsis from January 2017 to September 2017. More specifially, the researchers aim:
1.   To determine if parameters of 2016 SSC bundle that needs to be done in three hours were performed namely:
   a. measure lactate levels
   b. blood cultures withdrawn prior to institution of antibiotics
   c. administer broad spectrum antibiotics
   d. administer 30 mL/kg crystalloid for hypotension or lactate 4 mmol
2.   To determine if other parameters of 2016 SSC bundle

that needs to be done in six hours were performed namely:
   a. apply vasopressors (for hypotension that does not respond to initial fluid resuscitation) to maintain a mean arterial pressure (map) ≥ 65 mm hg
   b. in the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate 4 mmol/l (36 mg/dl): measure central venous pressure (cvp); measure central venous oxygen saturation (scvo2)
   c. remeasure lactate if initial lactate was elevated.
3.   To determine the outcome in terms of length of hospital stay in days and mortality.
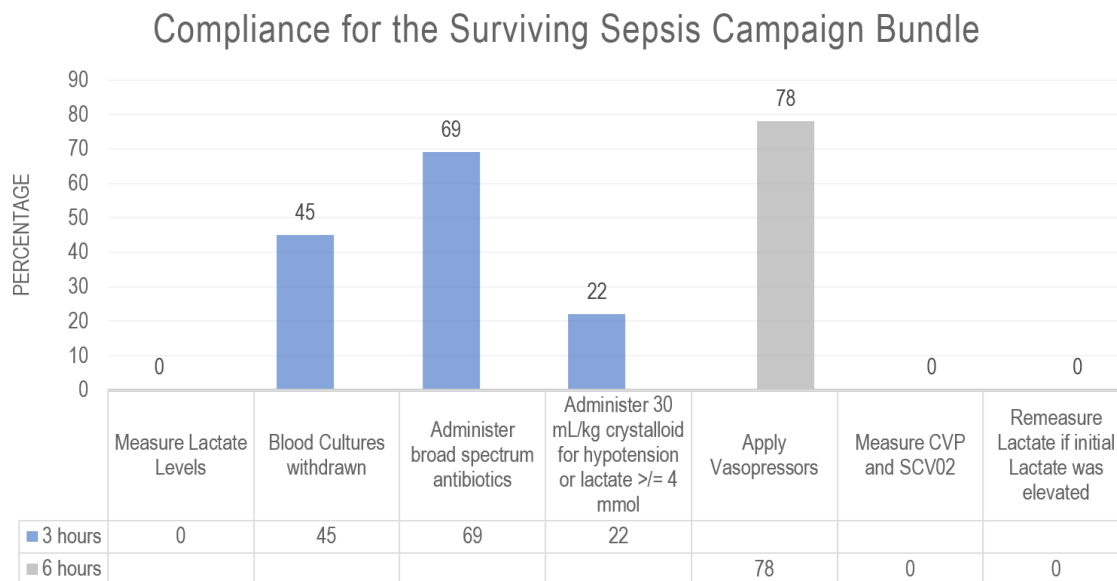
Methods

The study was done in Manila Medical Center, a private tertiary hospital. This included adult patients (18 years old and above) diagnosed with sepsis and septic shock admitted in ManilaMed-Medical Center Manila from January 2017 to September 2017. This employed a retrospective cohort, ambi-directional and total enumeration methodology.

All adult patients diagnosed with sepsis and septic shock during the time period admitted from the emergency room and regular room were included in the study. The diagnosis of sepsis such as presence of infection, tachypnea, fever, tachycardia and even hypotension in cases of septic shock was deemed appropriate in this study because it was written in the admitting form and signed by eligible consultants involve in the care of these patients.

All adult patients admitted due to hypovolemic or cardiogenic shock and other cause of diseases other than sepsis will not be included in the study.

Chart review were done to assess the parameters of the SSC bundle that needs to be done in three hours and six hours were performed. The duration of time will be based on the chart (nurse's notes, admitting form and emergency room (ER) form), time in which the patient was seen and assessed at the ER or ward and the time parameters were performed. Length of hospital stay was determined by the number of days from the time the patient was admitted until discharge or expired. The case will be deemed as mortality if immediate cause of death that is written in death certificate is sepsis or septic shock. All documents used will be returned to the medical records section and copies of the charts, if obtained, will be disposed using paper shredder to ensure confidentiality of the participants and data.

Internal medicine census was reviewed starting January 2017 until September 2017. All patients with admitting and/or discharge diagnosis with sepsis or septic shock were included in the study. A total of 110 patiets were identified from the census. A written consent was obtained from the Medical Director's office to access the charts of the study

Compliance for the Surviving Sepsis Campaign Bundle

	Measure Lactate Levels	Blood Cultures withdrawn	Administer broad spectrum antibiotics	Administer 30 mL/kg crystalloid for hypotension or lactate >/= 4 mmol	Apply Vasopressors	Measure CVP and SCV02	Remeasure Lactate if initial Lactate was elevated
■ 3 hours	0	45	69	22			
■ 6 hours					78	0	0

Figure 1. Compliance for the SSC bundle

population. Chart review was done. Exlusion criteria were applied. Twenty five were exluded in the study. Reason for exlusion were as follows: chart not found in four patients, 11 were noted to be double entry from IMU census and entered at the floors census when it was transferred out, immediate cause of mortality written in death certificate is not sepsis or septic shock in three patients, discharge diagnosis is not sepsis or septic shock in six patients and one patient was not admitted on January 2017. Hence, only 85 patients were analyzed and included in the study.

Surviving Sepsis Campaign (SCC) bundles that needs to be done in three hours and six hours were checked if done in each patient using data collection form (see Appendix). Demographics such as age and sex were also included. Length of hospital stay and outcome were identified.

All data gathered were handled with confidentiality. Identities of the patient will not be divulged. Instead, code numbers will be used. The study complied with the Data Privacy Act of 2012. Results of this study will be offered for use to implement Manila Med – Medical Center Manila hospital guidelines and policies for management of patients with sepsis.

Total of 85 subjects were included and compliance for the SSC bundle in three and six hours were computed as the number of subjects in which the exposure was performed divided by the total number of subjects who satisfied the inclusion criteria and were included in the data collection process. Data gathered are deemed categorical and are presented in percentage as frequencies.

The average length of hospital stay was determined by the sum of length of hospital stay divided by total number of patient discharged. Among patients admitted due to

Table I. Summary of results	
Study population	n/N (%)
Age range in years [range (mean)]	20-98 (67.5 ± 17.67)
Female	48 of 85 (56%)
Male	37 of 85 (44%)
Percent compliance for the SSC bundle in three hours	
Measure lactate levels	0
Blood cultures withdrawn	38 of 85 (45%)
Administer broad spectrum antibiotics	59 of 85 (69%)
Administer 30 mL/kg crystalloid for hypotension or lactate >/= 4 mmol	6 of 27 (22%)
Percent compliance for the SSC bundle in six hours	
Apply vasopressors	21 of 27 (78%)
Measure CVP and SCVO2	0
Remeasure lactate if initial lactate is elevated	0
Outcome measures	
Average length of stay [mean (SD)]	11.14 (11.38)
Mortality [n(%)]	36 (42.35)

sepsis and/or septic shock, percentage of mortality was determined by the number of subjects who died during the hospital stay divided by the total number of subjects included in the study.

Definition of terms:

Broad spectrum antibiotics - antibiotic having a wide range of activity against both gram negative and gram positive organisms (Source: medilexicon)

Vasopressors - powerful class of drugs that induce vasoconstriction and elevate mean arterial pressure (Source: UpToDate)

Central venous pressure (CVP) - the blood pressure in the large veins of the body, as distinguished from peripheral venous pressure in an extremity. It is measured with a water manometer that may be attached to the head of a patient's bed and to a central venous catheter

inserted into the vena cava. The normal CVP values are two to 14 cm H2O. (Source: Mosby's Medical Dictionary, 9th edition, 2009)

Scv02: The oxygen saturation of venous blood sampled from the superior vena cava. It is slightly less than the oxygen saturation from the lower body (as measured in the inferior vena cava) because of the increased oxygen saturation that occurs in the brain and upper body. (Source: Medical Dictionary, 2009)

Length of hospital stay: describes the duration of a single episode of hospitalization calculated by subtracting the day of admission to the day of discharge. (Source: Wikipedia)

Results

Sepsis is a fatal disease if not promptly recognized and addressed. The SSC Bundle was formulated to guide clinicians and other healthcare providers in managing sepsis or septic shock patients. However, in some centers where not all of the parameters of SSC bundles are available, utilizing prompt assessment and management of these patients using only what is available would greatly impact the outcome.

Lactate is an important source of energy, thus, necessary for human survival. In tissue hypoxia, which occurs in septic shock, lactate is overproduced by increase in anaerobic glycolysis coupled with decrease in lactate clearance. Patients recovering from septic shock would show a decreasing or normalizing lactate levels.[8] Hence, the need to determine initial lactate levels and to repeat it when initial lactate level is elevated. Lactate is not available and not frequently requested in Manila Med, hence, zero percent compliance in that parameter of the SSC bundle. Association of lactate level with mortality in sepsis showed that the mortality rate is 46.1% among patients with both hypotension and lactate ≥4, 36.7% in septic patients with hypotension alone and 30% in lactate level ≥4 mmol/L.[8]

Also, measurement of CVP and SCVO2, are not routine and are rarely performed and if performed usually the indication is not sepsis. In a recent prospective study done in public hospitals in Brazil, which evaluated the compliance with the SSC six-hour bundle and mortality, it concluded that initiatives to improve quality resulted in reduction in sepsis mortality in public institution, although not in all. Most relevant factor identified in the study than compliance with the six-hour bundle is early recognition of sepsis.[9]

Broad-spectrum antimicrobials were administered within three hours in 69% of study subjects. In some study subjects, antimicrobials administered initially are not considered broad spectrum. Later on, these antimicrobials were shifted to antibiotics with broad-spectrum activity, however, more than three hours have already elapsed. Other confounding

difficulties encountered were financial, family's decision and in times mechanical source of delay. Empiric antibiotic is deemed appropriate if it has in vitro activity against an isolated microorganism before a causative microorganism is identified. In a retrospective study, appropriate antibiotics should be started as soon as possible, for with each hour of delay, survival decreased by 7.6% and survival rate of 42% at the median delay of six hours.[10] Empiric antimicrobial therapy should be started immediately (preferably within 30 minutes) of making the presumptive clinical diagnosis of septic shock in the setting of refractory hypotension.[11]

The compliance for blood cultures within three hours is 45%. It was found out that some cultures requested were not from blood but rather urine, wound, endotracheal aspirate and sputum. In some study subjects, blood cultures were done but more than three hours from the initial assessment of the patient.

In a study done by Rivers et al., restoration of central venous oxygen saturation of >70 percent was set as one of the goals after adequate fluid resuscitation and it was shown that hospital mortality was 30.5% among the group assigned to early goal directed therapy (those who reached the six-hour septic bundle), where 95% of the goal was met. This is in comparison to the standard therapy group (three hour bundle), which showed 46.5 percent hospital mortality.[12] In this study, compliance for fluid resuscitation to maintain systemic perfusion using crystalloid in patients who presented with hypotension at 30mL/kg is 22%. During data gathering, fluids administered are usually less than the recommendation. Vasopressors are initiated immediately hence a higher compliance rate of 78%. Majority of subjects were elderly and congestion was anticipated.

Hospital mortality due to sepsis in this study reached 42% and the average length of hospital stay is 11 days. In a Systemic Review for the Global Burden of Sepsis, which covered years 1979 to 2013, Hospital mortality was 15% for sepsis and 25% for severe sepsis during this period of time. Although there were no population-level sepsis incidence estimates from lower income countries.[4]

Confounding comorbidities and initial APACHE scores were not included in the data gathering. In some study subjects, reasons for not starting broad-spectrum antibiotics and administering recommended fluid for patients diagnosed with sepsis or septic shock were not written or indicated in the charts. Some charts were not retrieved from the medical records section.

Conclusion

Adherence to SSC bundle in three and six hours in Manila Med was observed particularly in blood cultures

(45%), administering broad-spectrum antibiotics (69%), fluid resuscitation at 30 mL/kg for hypotensive patients (22%) and administering vasopressors (78%) to maintain systemic perfusion. However, adherence to other parameters of the bundle was not observed, namely: measurement and re-measurement of lactate levels and measurement of CVP and SCVO2. In terms of outcome, the average length of hospital stay is 11 days and mortality was 42%.

The compliance rate in initiating antibiotics in this study is deemed submaximal since we are in a tertiary hospital and eyeing for a 90-100% compliance rate is justifiable and recommendable. Since some of the parameters are absent or are not routinely done in this institution, maximizing the resources that are present is ideal, such as blood cultures, timely initiation of antibiotics and adequate hydration in patients deemed to have septic shock.

In institutions where there are limited resources, emphasis on early identification, obtaining blood cultures and timely initiation of antimicrobials should be done, ideally within three hours. Education of the front liners is pivotal in fast triaging, prompt assessment and diagnosis of patients initially suspected to have infection, especially in the elderly. These should not focus only on doctors managing the patients, but also nurses. A sepsis kit, more improved fast turn-around time of laboratory, especially in the wards, and fast and easy accesses to antibiotics are one of the few strategies that could be utilized to maximize the time. A multidisciplinary approach should be re-enforced to avoid delay in management, which could entail significant rise in mortality rate in this subset of patients.

Future researches may use this as a pivot in sepsis management study; this time may do a prospective one and may include co-morbidities and initial APACHE score as one of the parameters to correlate length of hospital stay and mortality.

With the new SSC bundle that was released in 2018, this study could provide local data since what were mostly complied parameters in this study is what the 2018 campaign bundles advocate into.

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Appendices

A. Data collection form

ManilaMed✚
M E D I C A L   C E N T E R   M A N I L A

Assessment of Compliance to Surviving Sepsis Campaign Bundles among Adult Patients Admitted at Manila Med – Medical Center Manila Diagnosed with Sepsis

DATA COLLECTION FORM

Patient Code: _____

Name (Optional): _____

Age: _____

Sex: _____

Date Admitted: _____   Date Discharged: _____

Place of Admission: _____   Length of Hospital Stay: _____

Outcome (check if applicable):

Discharged _____   Mortality _____   Morbidity _____

Parameters for Surviving Sepsis Campaign Bundle to be done in <u>Three Hours</u>

(Check if done)

1. _____ Measure Lactate Levels
2. _____ Blood Cultures withdrawn prior to institution of antibiotics
3. _____ Administer Broad Spectrum Antibiotics
4. _____ Administer 30 mL/kg crystalloid for hypotension or lactate >/= 4   mmol

Parameters for Surviving Sepsis Campaign Bundle to be done in <u>Six Hours</u>

(Check if done)

1. _____ Apply vasopressors
2. _____ Measurement of CVP/ScvO2
3. _____ Remeasure Lactate Level if initial lactate was elevated

B. Table of baseline characterisctics

Patient Code	Age	Sex	Date Admitted	Place of Admission	Date Discharged	Length of Hospital Stay	Outcome