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Identification and Treatment of Sepsis

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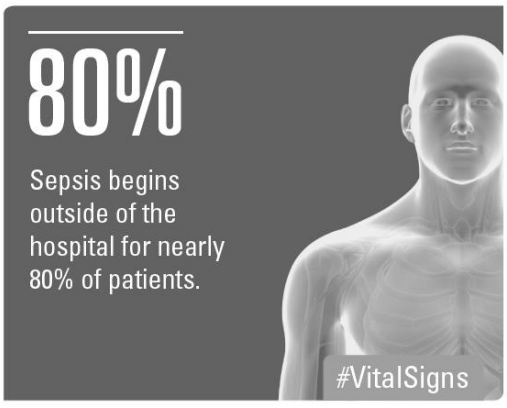
Purposes of Presentation

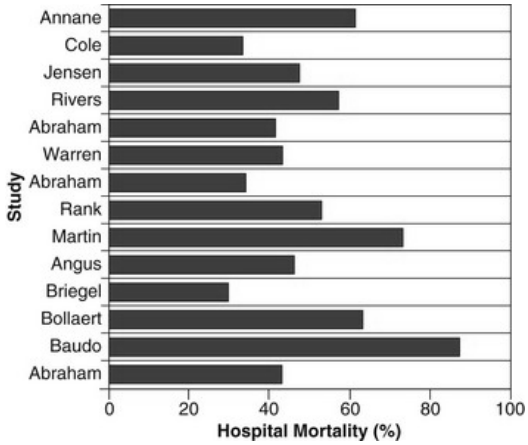
- Discuss historical versus new state of knowledge
- Identify treatment strategies
- Identify innovative approaches to improving sepsis outcomes

Cases More than Doubled Between 2000 and 2008



Epidemiology

Compilation of septic shock mortality



Epidemiology

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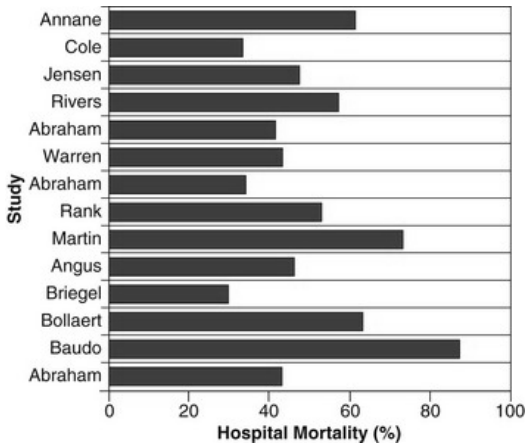
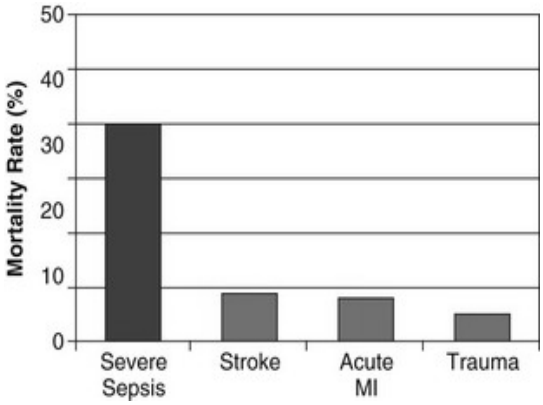


Incidence (cases per 100,000 population)



(Trzeciak, Dellinger, and Parrillo, 2016)

Epidemiology

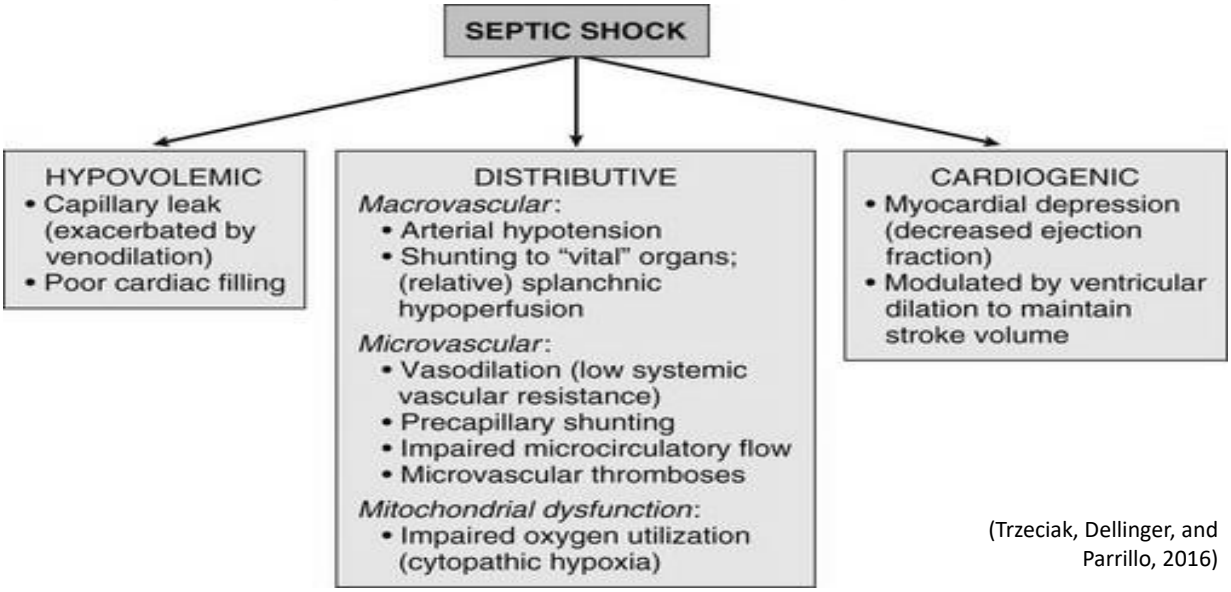
- Sepsis is the leading cause of death among critically ill patients and is responsible for as many deaths annually in the United States as acute myocardial infarction
- In a recent large multicenter registry study, septic patients with both arterial hypotension and severe lactic acidosis experienced a 46% mortality rate, whereas the mortality rate for arterial hypotension or severe lactic acidosis alone was 37% and 30%, respectively
- Overall, severe sepsis, in general, ranks as the tenth leading cause of death in the United States, with 215,000 deaths annually and an estimated 30% in-hospital mortality rate
- A comparison of the mortality rate for severe sepsis to other high profile diseases that may require critical care (such as acute ischemic stroke, acute myocardial infarction, and trauma) demonstrates the importance of improving recognition and treatment of sepsis

Epidemiology

- The apparent disparity in mortality rates across these diseases may be explained in part by differences in the conventional approach to treatment, as acute ischemic stroke, acute myocardial infarction, and trauma are all typically treated with aggressive interventions in a time-sensitive fashion
- Similar to the “golden hour” concept for trauma care that was first recognized more than 30 years ago, we now understand that early aggressive interventions for sepsis can also have an impact on outcome

(Trzeciak, Dellinger, and Parrillo, 2016)

Hemodynamic Profile in Septic Shock



(Trzeciak, Dellinger, and Parrillo, 2016)

Distributive Shock

- Septic shock is characterized by peripheral maldistribution of blood flow to tissues such that tissue hypoperfusion abnormalities can persist despite a normal or high cardiac output
- Septic shock is characterized by peripheral maldistribution of blood flow to tissues such that tissue hypoperfusion abnormalities can persist despite a normal or high cardiac output
- This is called "distributive shock"
- This maldistribution of blood flow may occur at both microcirculatory and macrocirculatory levels
- At the level of the macrocirculation, the autoregulation of blood flow within any single organ system in a normal host can typically maintain effective tissue perfusion over a wide range of systemic pressures (usually ranging from a mean arterial pressure [MAP] of 50 to 150mmHg)

Distributive Shock

- However, there is heterogeneity of blood flow distribution throughout the body in septic shock due to preferential shunting of blood flow to vital organs (e.g., the brain and myocardium)
- The gastrointestinal tract may be the earliest organ system to experience tissue hypoperfusion in septic shock, as blood is shunted away from the splanchnic circulation in order to preserve blood flow to the brain, myocardium, and skeletal muscles
- Ischemic injury to the gastrointestinal tract may be a source of ongoing systemic inflammation in septic shock

(Trzeciak, Dellinger, and Parrillo, 2016)

In the United States…

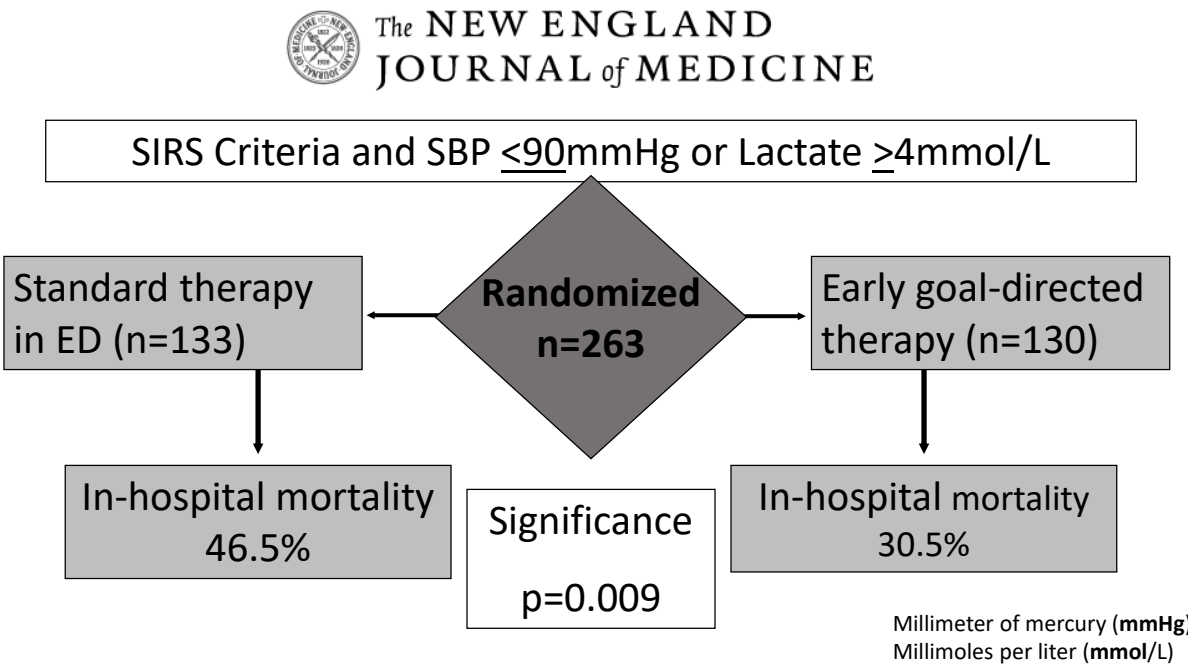
- More than 1.5 million people develop sepsis
- At least 250,000 Americans die as a result
- Sepsis develops outside the hospital
- Accounts for 1 in 3 hospital deaths
- "Detecting sepsis early and starting immediate treatment is often the difference between life and death" CDC Director Brenda Fitzgerald, M.D.

Early Goal-Directed Therapy (EGDT)

History of EGDT

- Prior to 2001, no standard for early management of severe sepsis and septic shock
- The prevailing mortality was over 40-50%
- Early goal-directed therapy (EGDT) was compared to standard care in a landmark clinical trial

Rivers, E. Nguyen, B., Havstad, M.A., Ressler, J., Muzzin, A., Knoblich, B., Peterson, E., Tomlanovich, M. for the early goal directed therapy group. (2001). *New England Journal of Medicine, 345,*(19)1368-1377.



Millimeter of mercury (**mmHg**)
Millimoles per liter (**mmol**/L)

EGDT Validation and Adoption

- Similar outcomes reported in over 70 observational and randomized controlled studies comprising over 70,000 patients
- EGDT was largely incorporated into the first 6 hours of sepsis management (resuscitation bundle)

"Early Interventions in Severe Sepsis and Septic Shock: A Review of the Evidence One Decade Later"

- Meta-analysis of over 50 publications looked at only the past decade of evidence
  - Relative risk reduction (RRR) of 0.37
  - Absolute risk reduction (ARR) of 18.3%
  - Number needed to treat (NNT) of 5.45
  - Crude mortality reduction of 17.7%

Rivers, E.P., Katranji, M., Jaehne, K.A., Brown, S., Abou Dagher, G., Cannon, C. and Coba, V. (2012). Early interventions in severe sepsis and septic shock: A review of the evidence one decade later. *Minerva Anestesiologica,78(6),* 712-24.

Comparison of Sepsis Intervention Studies Using the Resuscitation Bundle Compared to the Original EGDT Study

	Summary of implementation study		Rivers et al.	
	Before or Control	After	Control	EGDT
Number of patients	9527	9884	133	130
APACHE II score	24.2	24.2	20.4	21.4
Sex, % Males	58.15	57.3	50.4	50.8
Age (years)	63.8	62.9	64.4	67.1
Mortality before (SD)**	46.8 (26)%	29.1 (12)%	46.5%	30.5%
Relative risk reduction	0.37		0.34	
Absolute risk reduction	18.3%		16.0%	
NNT	5.45		6.25	

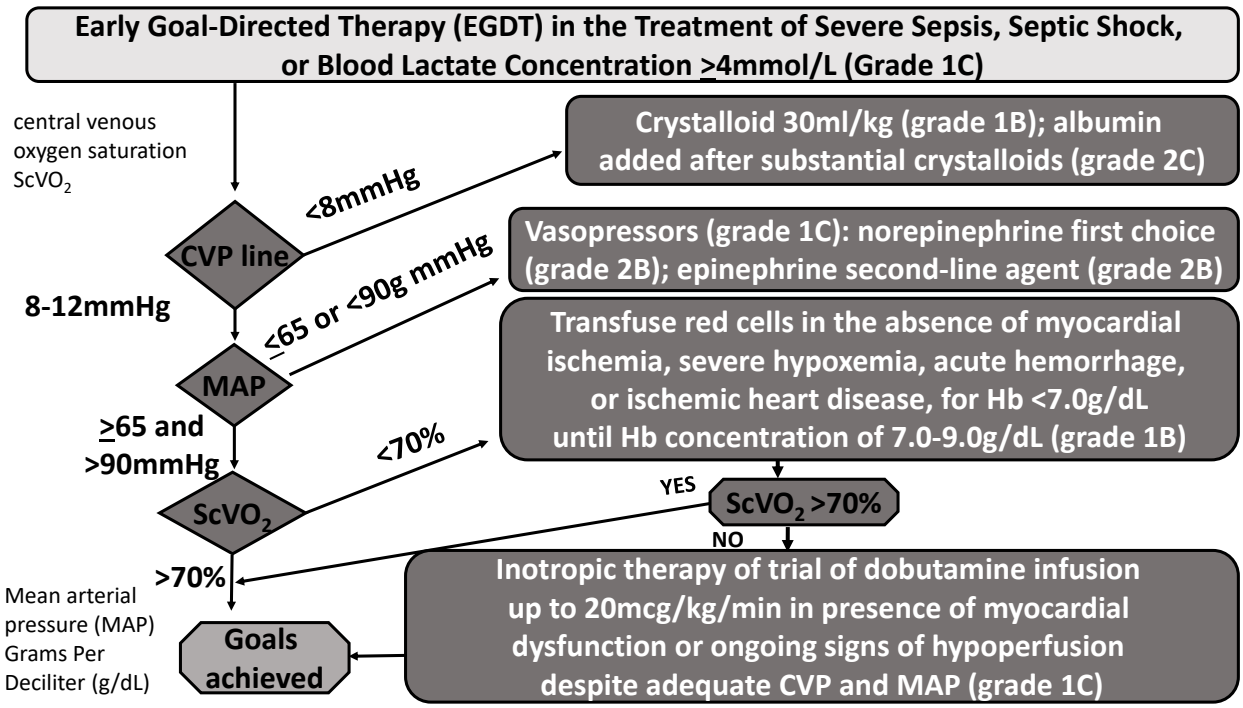
Note. Includes before and after concurrent implementation studies. **The average mortality of each study. NNT=number needed to treat. Adapted from "Early Interventions in Severe Sepsis and Septic Shock: A Review of the Evidence One Decade Later", by E.P. Rivers, M. Katranji, K.A. Jaehne, S. Brown, G. Abou Dagher, C. Cannon, and V. Coba, 2012, *Minerva Anestesiologica 78(6),* 712-24. Copyright 2012 by Edizioni Minerva Medica.

Table 3. Change in achievement of bundle targets

	Initial Quarter Achieved, %	Final Quarter Achieved, %[a]	*p* Value Compared With Initial
Initial care bundle (first 6 hrs of presentation)			
Measure lactate	61.0	78.7	≤.0001
Blood cultures before antibiotics	64.5	78.3	≤.0001
Broad-spectrum antibiotics	60.4	67.9	.0002
Fluids and vasopressors	59.8	77.0	≤.0001
CVP >8 mm Hg	26.3	38.0	≤.0001
$Scvo_2$ >70%	13.3	24.3	≤.0001
All resuscitative measures	10.9	21.5	≤.0001
Management bundle (first 24 hrs after presentation)			
Steroid policy	58.5	73.9	≤.0001
Administration of drotrecogin alfa policy	47.4	53.5	.003
Glucose control	51.4	56.8	.0009
Plateau pressure control	80.8	83.8	.24
All management measures	18.4	25.5	≤.0001

CVP, central venous pressure; $Scvo_2$, central venous oxygen saturation.

[a]Represents the last quarter of data submission from each institution during the 2-yr data analysis perio institution participation.



New Evidence Arises from 2013 and 2014 Clinical Trials

Early goal-directed therapy in severe sepsis and septic shock: insights and comparisons to ProCESS, ProMISe, and ARISE

H. Bryant Nguyen, Anja Kathrin Jaehne, Namita Jayaprakash, Matthew W. Semler, Sara Hegab, Angel Coz Yataco, Geneva Tatem, Dhafer Salem, Steven Moore, Kamran Boka, Jasreen Kaur Gill, Jayna Gardner-Gray, Jacqueline Pflaum, Juan Pablo Domecq, Gina Hurst, Justin B. Belsky, Raymond Fowkes, Ronald B. Elkin, Steven Q. Simpson, Jay L. Falk, Daniel J. Singer and Emanuel P. Rivers

Critical Care 2016 **20**:160 | **DOI:** 10.1186/s13054-016-1288-3 | © Nguyen et al. 2016

Published: 1 July 2016

EGDT Challenges Arise

- A trio of trials; Protocolized Care for Early Septic Shock (ProCESS), Australasian Resuscitation In Sepsis Evaluation (ARISE), and Protocolised Management in Sepsis (ProMISe) were performed
  - Trials question need for elements of EGDT or the need for protocolized care
- Comparing trial conduction methodology and sepsis mortality trends is essential for an appropriate interpretation of these trials' conclusions
- Challenges are reflected in the Centers for Medicare and Medicaid Services (CMS) Sepsis Core Measure provider assessment options

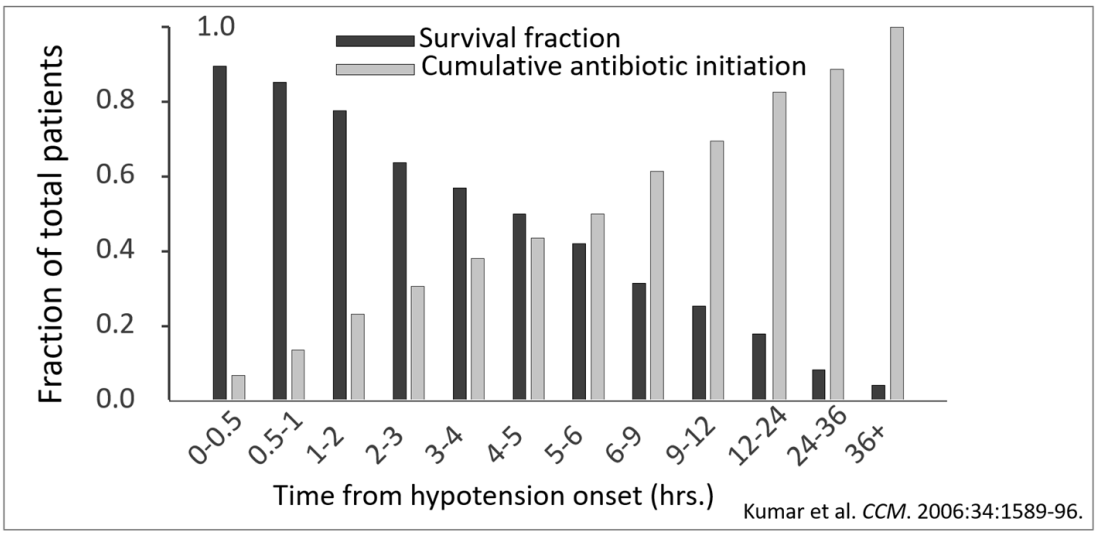
Nguyen, H. B., Jaehne, A. K., Jayaprakash, N., Semler, M. W., Hegab, S., Yataco, A. C., … Falk, J. L. (2016). Early goal-directed therapy in severe sepsis and septic shock: insights and comparisons to ProCESS, ProMISe, and ARISE. *Critical Care*, *20*, 1–16. https://doi.org/10.1186/s13054-016-1288-3

Conclusion of EGDT vs. Alternative Strategies

- EGDT has been shown to have internal and external validity in reducing mortality
- The trio of trials suggest alternative strategies can provide an equal reduction in mortality
- Due to multiple methodological differences when compared to the original EGDT trial **(including undefined usual care)**, there is no external validity of these alternative strategies

Nguyen, H. B., Jaehne, A. K., Jayaprakash, N., Semler, M. W., Hegab, S., Yataco, A. C., … Falk, J. L. (2016). Early goal-directed therapy in severe sepsis and septic shock: insights and comparisons to ProCESS, ProMISe, and ARISE. *Critical Care*, *20*, 1–16. https://doi.org/10.1186/s13054-016-1288-3

Cumulative Initiation of Effective Antimicrobial Therapy and Survival in Septic Shock



For Each Hour's Delay in Administering Antibiotics in Septic Shock, Mortality Increases by 7.6%

Sepsis Antibiotic Recommendations

- Give all antimicrobials simultaneously
- Broad-spectrum coverage targeted for suspected type of infection
- Keep available on units to avoid pharmacy delays

Choice of Vasopressors to Correct Hypotension in Septic Shock

- Norepinephrine is the recommended first-line agent (grade 2B)
- Epinephrine (added to or substituted for norepinephrine)
  - Administer through a central catheter (grade 1C)
  - Arterial line placed for monitoring (UG-ungraded)
- Vasopressin or dopamine may be considered as second-line agents
  - Vasopressin 0.03 units/min can be added to norepinephrine, but not recommended as sole vasopressor or at higher doses (UG)

Choice of Vasopressors to Correct Hypotension in Septic Shock

  - Dopamine alternative only in highly selected patients (e.g., patients with low risk of tachyarrhythmias and an absolute relative bradycardia (grade 2C)
  - Phenylephrine not recommended (grade 1C)

CMS Sepsis Core Measure

SSC Sepsis Bundle Elements

Must be completed in the first 3 hours for severe sepsis or septic shock!

1. Serum lactate measured
2. Blood cultures prior to antibiotic administration
3. Broad-spectrum antibiotics goal of one hour
4. Treat hypotension and/or elevated lactate (>2mmol/L) with crystalloid fluids of 30ml/kg

Must be completed in the first 6 hours for severe sepsis or septic shock:

1. Apply vasopressors for ongoing hypotension that does not respond to initial fluid resuscitation to maintain a mean arterial pressure (MAP) >65mmHg
2. In the event of persistent arterial hypotension despite volume resuscitation (septic shock) or initial lactate >4mmol/L (36mg/dl):
   - Maintain central venous pressure (CVP) >8mmHg
   - Maintain $ScVO_2$ >70%
3. Re-measure lactate if initial lactate was elevated (>2mmol/L)

SSC Sepsis Management Considerations

1. Administer low-dose steroids by a standard policy
2. Maintain adequate glycemic control
3. Prevent excessive inspiratory plateau pressures

CMS Sepsis Core Measure Inclusions and Exclusions

- Includes
  - Inpatients age 18 and over with an ICD-10-CM principal or other diagnosis code of sepsis, severe sepsis, or septic shock
- Excludes
  - Patients under the age of 18 years
  - Patients with a length of stay (LOS) of greater than 120 days
  - Patients with a directive for comfort measures documented by the provider within 3 hours of presentation of severe sepsis
  - Patients with a directive for comfort measures documented by the provider within 6 hours of presentation
  - Patients receiving intravenous antibiotics for more than 24 hours prior to presentation with severe sepsis

CMS Sepsis Core Measure Inclusions and Exclusions

- Patient is a transfer from another hospital or ambulatory surgery center
- Patients or surrogate refuses care
  - i.e. blood draw, fluid administration, or antibiotics
  - Must be documented by provider or have a witnessed consent form stating the refusal of care present in the medical record
  - Consent form can be witnessed by nurse or provider

Challenges and Opportunities

Surviving Sepsis Campaign Definition of Time Zero

- Will always be when the chart annotation suggests signs and symptoms are all present
- May be from nursing charting, laboratory flow sheets, physician documentation, and/or anything with a time stamp
- Will equal triage time if all signs and symptoms are present at triage

American College of Chest Physicians/Society of Critical Care Medicine (ACCP/SCCM) Redefining Sepsis

New Definition of Sepsis

- Sepsis is life-threatening organ dysfunction caused by a dysregulated host response to infection

New Definition of Septic Shock

- Septic shock is a subset of sepsis in which profound circulatory, cellular, and metabolic abnormalities are associated with a greater risk of mortality than sepsis alone

New Sepsis Definitions

- Advantages
  - Incorporates most up-to-date thinking on sepsis pathobiology
  - Provides closest approximation possible to describing “what sepsis is”
- Concerns
  - Of limited practical utility as they contain elements that cannot be clinically identified
  - “Organ dysfunction”
  - “Dysregulated host response”

Issues with the 1991 and 2001 Definitions

- Systemic inflammatory response syndrome (SIRS)-based definition eliminated
- “Severe sepsis” is problematic
  - Different assessment criteria yield different results
- SIRS sensitivity
  - SIRS is an appropriate response to infection or any other stimulus that activates inflammation
- Sepsis versus severe sepsis is confusing
  - Most people say “sepsis” when they mean “severe sepsis”
  - What the initial two task forces called “sepsis” is what most people call “infection”

Diagnosing Sepsis

SIRS

- Temperature >38°C (100.4°F) or <36°C (96.8°F)
- Heart rate >90 beats/min
- Respiratory rate >20 breaths/min or partial pressure of carbon dioxide in arterial blood ($PaCO_2$) <32mmHg or use of a ventilator
- WBC >12,000 or <4,000/m^3 or >10% immature neutrophils (bands)
- If at least TWO of the above are present, and current or recent infection…you have SEPSIS

Bone RC, Balk RA, Cerra FB, Dellinger RP, Fein AM, Knaus WA, … Sibbald WJ. (2009). Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. The ACCP/SCCM Consensus Conference Committee. American College of Chest Physicians/Society of Critical Care Medicine. 1992. *CHEST*, *136*(5), e28.

ACCP/SCCM Consensus Sepsis Definitions

Sepsis = SIRS + ***infection***

Severe Sepsis = SIRS + ***infection*** + *end organ damage (lactate ≥2)*

Septic Shock = SIRS + ***infection*** + *end organ damage (lactate ≥4) + refractory hypotension* (<90mmHg or <40% below baseline)

Bone RC, Balk RA, Cerra FB, Dellinger RP, Fein AM, Knaus WA, … Sibbald WJ. (2009). Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis. The ACCP/SCCM Consensus Conference Committee. American College of Chest Physicians/Society of Critical Care Medicine. 1992. *CHEST*, *136*(5), e28.

New Recommendations Aim to Redefine Definition and Enhance Diagnosis of Sepsis, Septic Shock

- New method to assess for organ dysfunction is sequential (sepsis-related) organ failure assessment (SOFA)
- The new diagnostic tool is named quickSOFA or qSOFA
- If a patient has two or three components of qSOFA, the patient should be examined for organ failure
- The qSOFA assessment:
  1. An alteration in mental status
  2. A decrease in systolic blood pressure of less than 100mmHg
  3. A respiration rate greater than 22 breaths/min

SIRS versus qSOFA Screening by Clinicians

SIRS versus qSOFA Screening by Clinicians

- New recommendations aim to redefine definition and enhance diagnosis of sepsis, septic shock
- 1991 “Sepsis-1”
- 2001 “Sepsis-2”
- The task force recommends that its report be designated “Sepsis-3” recognizing the two earlier iterations to define sepsis

"Neutropenic sepsis: Prevention and management in people with cancer" NICE Clinical Guidelines

Defines Neutropenia and Fever

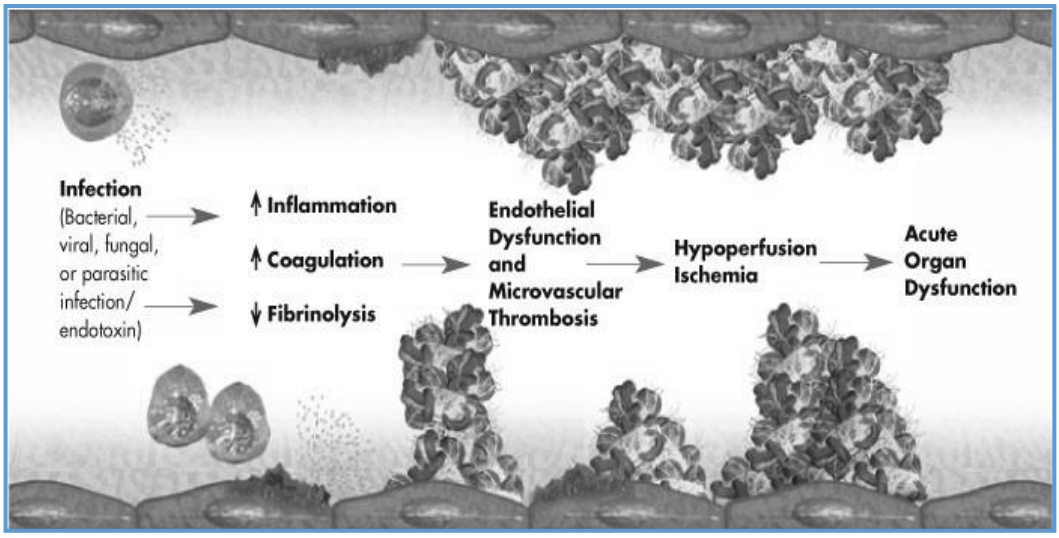
- Diagnose neutropenic sepsis in patients having anticancer treatment whose neutrophil count is 0.5 x 109 per liter or lower and who have either:
  - ❑ - a temperature higher than 38°C

    or
  - ❑ - other signs or symptoms consistent with clinically significant sepsis

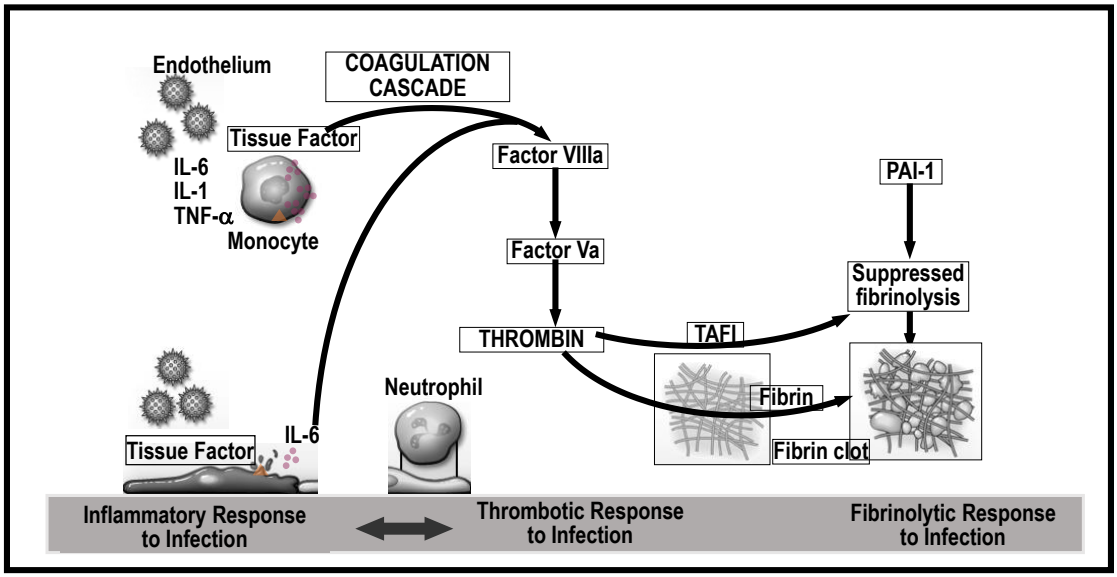
Educate Caregivers and Peers

- The usual signs of infection are fever, pus, pain, swelling, and redness and may not show up as the ANC gets lower
- These signs are caused by neutrophils fighting off germs
- Monocytes can still cause fever in the person who has neutropenia
- In severe neutropenia, a fever may be the only sign of an infection

Diagnostic Recommendations



Pathobiology of Sepsis



Microcirculatory Failure in Sepsis

Microcirculatory Failure in Sepsis

- The causes of microcirculatory flow alterations in sepsis are multifactorial and include
  - Endothelial cell dysfunction
  - Increased leukocyte adhesion
  - Microthrombi formation
  - Rheologic abnormalities
  - Altered local perfusion pressures due to regional redistribution of blood flow, and
  - Functional shunting
- The proinflammatory cytokines released in sepsis cause diffuse endothelial cell activation, which is associated with
  - Neutrophil activation
  - Expression of endothelial adhesion molecules (i.e., integrins and selectins)
  - Localization of white blood cells to areas of microvascular injury

(Trzeciak, Dellinger, and Parrillo, 2016)

Microcirculatory Failure in Sepsis

- Pan-endothelial cell injury increases microvascular permeability with the influx of proinflammatory cells into the tissues; this is hypothesized to be an important pathogenic step in the development of acute system organ dysfunction in sepsis
- Leukocyte adhesion of white blood cells to the microvessel endothelial surface (primarily in the postcapillary venule) further impedes microcirculatory blood flow
- The endothelial injury also triggers the activation of the coagulation cascade via expression of tissue factor on the microvascular endothelium, resulting in fibrin deposition and microvascular thrombosis that may further impair microcirculatory flow
- All of these mechanisms collectively contribute to microcirculatory failure in septic shock

(Trzeciak, Dellinger, and Parrillo, 2016)

Innovations to Improve Outcomes

- Recognition
  - Lactic acid
  - Physiologic change detection
  - Biomarkers
  - Data analytics
- Treatment
  - Communication
  - Escalation
  - Challenge scopes of practice
- Monitoring
  - Special units

Innovations to Improve Outcomes

- Challenge barriers
  - Attitudes
  - Assumptions
  - Knowledge
- Caregiver competency
  - Simulation
  - Gaming

Conclusion

SEPSIS™
IT'S ABOUT TIME

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Identification and Treatment of Sepsis

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