

CONFLICT OF INTEREST DISCLOSURE

I certify that, to the best of my knowledge, no affiliation or relationship of a financial nature with a commercial interest organization has significantly affected my views on the subject which is being presented.

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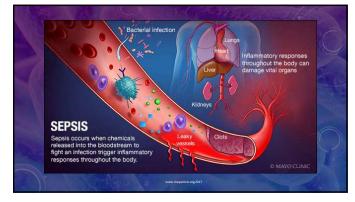
# SURVIVING SEPSIS: LEARNING OBJECTIVES

- Define sepsis and septic shock
- List the cornerstones of management of sepsis
- Describe post sepsis syndrome
- Identify current sepsis treatment guidelines
- Describe common areas of negligence in sepsis malpractice case reviews

#### WHAT IS SEPSIS?

Sepsis is *dysregulated* host response to infection that can lead to life-threatening organ dysfunction.

Infection from: virus, bacteria, fungus or parasites.



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#### WHAT IS SEPTIC SHOCK?

Septic shock is a subset of sepsis with circulatory and cellular/metabolic dysfunction associated with a higher risk of mortality.

If sepsis goes unchecked, it can progress to septic shock

#### SEPTIC SHOCK

- If patient requires vasopressors to maintain a mean arterial pressure (MAP) of >/= 65 mm Hg (despite adequate fluid resuscitation)
- And serum lactate is >/= 2 mmol/l it is defined as septic shock
- The term "severe sepsis" has been abandoned and should not be used
- Concept of SIRS can still be used to describe a systemic response to a sterile hit (e.g., pancreatitis or trauma)

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SEPSIS STATISTICS

- Estimated 20 million sepsis cases per year worldwide with 25% mortality
- Estimated 5 million sepsis-related deaths worldwide in 2017
- At least 1.7 million sepsis cases in the US annually
- At least 350,000 sepsis deaths in the US annually
- Leading cause of hospital deaths, readmissions & treatment costs
   Almost 50% of hospital deaths are related to sepsis

Dantes et al, MMWR, 2023

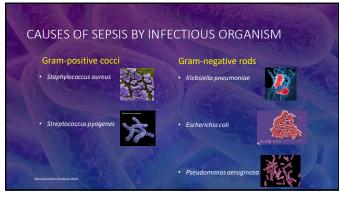
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#### SEPSIS STATISTICS

Townsend et al, Chest, 2022

- 87% of sepsis cases start in the community
- Risk of dying from sepsis increases by 8% for every hour treatment is delayed
- Patients often suffer limb amputations and post sepsis syndrome
- Medicare costs for sepsis admissions & skilled nursing care > \$41.5B annually





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# CAUSES OF SEPSIS BY ORGAN SYSTEM & AGE

- Adults ages 65 and older are 13 times more likely to be hospitalized with sepsis than younger adults
- Particularly in older people, infection starts in urinary tract or lungs
- GI tract and skin are other common sources of sepsis
- Higher risk if weakened immune system or chronic conditions such as diabetes, kidney disease or lung disease, or recent surgery or hospitalization

#### WHO IS AT HIGH RISK OF SEPSIS?

- Age over 60 years or under 1 year
- Immunocompromised e.g., post splenectomy
- Chronic conditions e.g., COPD or diabetes
  Indwelling foreign body e.g., central venous catheter
- Recent hospitalization or surgery
- Malnutrition or immobility

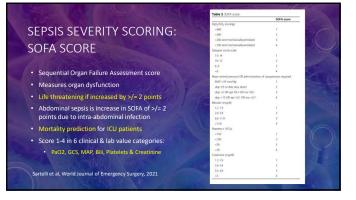
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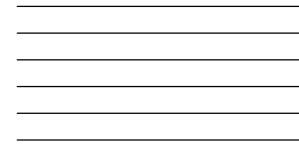


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### SEPSIS SCREENING TOOLS / EARLY WARNING

- National Early Warning Score (NEWS)
- Modified Early Warning Score (MEWS)
- Sequential Organ Failure Assessment (SOFA) criteria
- Tools have a wide variation in specificity and sensitivity
- Important component of identifying sepsis for early intervention







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#### SURVIVING SEPSIS CAMPAIGN 2004

- Introduced at 2002 European Society of Intensive Care Medicine (ESICM)
   annual meeting in Barcelona, with the "Barcelona Declaration"
- 3 organizations: ESICM, Society of Critical Care Medicine and International Sepsis Forum committed to reduce mortality of sepsis by 25% within 5 years
- International guidelines and quality improvement program
- Updated every 4 years and published in Critical Care Medicine
- Worked with Institute for Healthcare improvement to create "bundles"

#### SURVIVING SEPSIS CAMPAIGN 2021

- Endorsed by 20 medical organizations all over the world
- Adults with septic shock on vasopressors, rec. target MAP of ≧ 65 mm Hg
   In RCT, higher MAP targets of 80-85 mm Hg were assoc. with A. Fib.
- Mortality increases when ED to ICU admit time exceeds 6 hours (17 v 13%)

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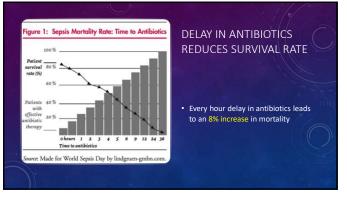


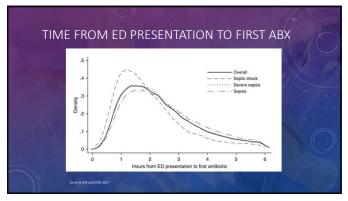
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#### SURVIVING SEPSIS CAMPAIGN 2021 CORNERSTONES OF MANAGEMENT

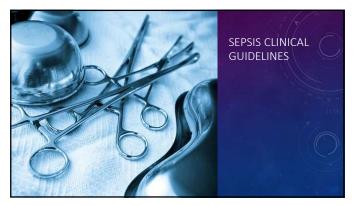
- Fluid and electrolyte resuscitation (initial 30 ml/kg)
- Obtain blood cultures and serum lactate
- Broad spectrum antibiotics within one hour of recognition for septic shock
   and within 3 hours for sepsis without shock
- Source control of the infection (e.g., surgery)
- Glycemic control
- Detailed initial assessment & ongoing re-evaluation of treatment response







	C ADMINISTRATION		
	lospital Mortality Based on the Tin ad and Adjusted Logistic Regression		ic
Model	Odds Ratio for Hospital Mortality, per Elapsed Hour until Antibiotic Administration	95% CI	P Value
Unadjusted	0.89	0.86-0.91	< 0.001
+ Sepsis severity strata	0.96	0.93-0.99	0.013
+ Severity of illness + Demographics	1.08	1.04-1.12	<0.001 <0.001
Fully adjusted model, in each		1.05-1.13	<0.001
Sepsis only	1.09	1.00-1.19	0.046
Severe sepsis only	1.07	1.01-1.24	0.014
Septic shock only	1.14	1.06-1.23	0.001



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#### SOURCE CONTROL FOR GI PERF & SEPTIC SHOCK

- Developed a protocol for early source control immediately after admission
- Prospective observational study: 154 patients with GI perforation & septic shock
- Early goal directed therapy in ER for resuscitation
- Survival was 82.5% on day 28 and 77.9% on day 60
- Survival rate fell as surgery initiation was delayed, 0.29 per hour delay (adjusted OR)
- 60-day survival 0 for times greater than 6 hours
- Time from admission to initiation of surgery for source control is a critical determinant of mortality risk

Azuhata et al, Critical Care, 2014

#### SOURCE CONTROL FOR GI PERFORATION

- Sites of perforation: small intestine (42.9%), colon (40.9%) and upper GI (9.1%)
- Upper GI perforation: omental patch, irrigation & drainage
- If gastric cancer, same with delayed secondary radical operation
- Lower GI perforation: resection of necrotic piece, irrigation & drainage
- No primary anastomosis
- 18 patients (11.7%) required a re-laparotomy
- Second factor assoc. with survival was SOFA score (adjusted odds ratio 0.80)

Azuhata et al, Critical Care, 2014

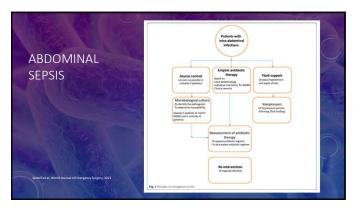
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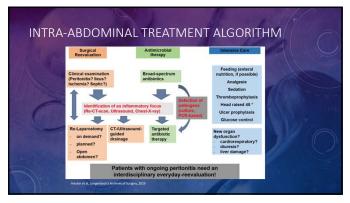
#### CORNERSTONES OF TREATMENT OF INTRAABDOMINAL INFECTION (IAI)

- Early recognition
- Adequate source control
- Broad-spectrum antimicrobial therapy initiated within one hour of diagnosis
- Prompt physiological stabilization with iv fluids

Complicated IAIs have an overall mortality rate of 9.2%

Sartelli et al, World Journal of Emergency Surgery, 2021





# SOURCE CONTROL IN INTRABDOMINAL SEPSIS

Source control is based on 4 elements:

1. Debridement

Removal of infected devices
 Drainage of purulent cavities

4. Decompression of the abdominal cavity

Inadequate source control increases 28-day mortality from 27% to 43%

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#### CMS MANAGEMENT BUNDLE FOR SEPSIS (SEP-1)

- Severe Sepsis and Septic Shock: Management Bundle (SEP-1)
- Emphasized the importance of early sepsis management in US hospitals
- Endorsed in 2013 by National Quality Foundation (NQF)
- Implemented by CMS in October 2015
- Has faced some criticism for its complexity and breadth
- In 2021, NQF re-endorsed the SEP-1 measure for a third time
- Infectious Diseases Society of America (ISDA) and American College of Emergency Physicians (ACEP) appealed this in 2022

# CMS MANAGEMENT BUNDLE FOR SEPSIS (SEP-1)

7 Basic Elements:

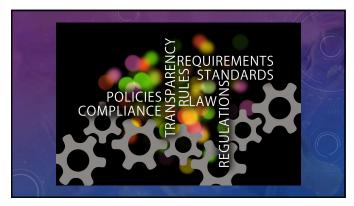
- Measure the patient's initial lactate level.
   Take a blood culture before administering a broad-spectrum antibiotic.
- 3. Administer a broad-spectrum antibiotic within 3 hours.
- 4. Administer 30 mL/kg of crystalloid fluid to patients with low BP or elevated lactate.
- 5. Repeat the lactate if it was elevated initially.
- 6. Administer a vasopressor for patients who remain hypotensive.
- 7. Reassess the patient after a certain period.

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#### 7 SEPSIS CORE ELEMENTS CDC HOSPITAL SEPSIS PROGRAM 2023

CDC. Hospital Sepsis Program Core Elements. 2023

- 1. Hospital Leadership Commitment: dedicating human, financial & IT services
- 2. Accountability: appointing a leader or co-leader responsible for goals & outcomes
- 3. Multi-Professional Expertise: engaging key partners throughout hospital system
- 4. Action: implementing processes to improve identification, mgmt. & recovery
- 5. Tracking: measuring epidemiology, mgmt. & outcomes to assess impact of initiatives
- 6. Reporting: providing info. on sepsis mgmt. & outcomes to relevant partners
- 7. Education: providing sepsis education to healthcare professionals, patients & families



#### COMPLIANCE WITH SEP-1 & MORTALITY

- Effects of compliance with early management bundle on 30-day mortality
- Patient-level Medicare data reported by 3,241 hospitals 10/1/15 to 3/31/17
- Propensity score matched Medicare patients with sepsis
- Compliance defined as completion of all 7 SEP-1 elements
- Primary outcome was a change in 30-day mortality
- Secondary outcomes included changes in length of stay

Townsend et al, Chest, 2022

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#### COMPLIANCE WITH SEP-1 & MORTALITY

- 122,870 patients whose care was compliant matched to same # noncompliant
- Compliance was associated with a reduced 30-day mortality: 21.8% v 27.5%
- Yielding absolute risk reduction of 4.06%
- Compliance was associated with risk-adjusted 30-d mortality (OR 0.82)
- Median length of stay was shorter with complaint care (5 v 6 days)
- Conclusion: compliance with SEP-1 was associated with lower 30-d mortality

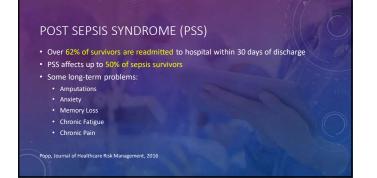
Rendering SEP-1 compliant care may reduce the incidence of avoidable deaths

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#### HOUSTON METHODIST CASE STUDY

- Over 15 years cut sepsis deaths from 35% to 6%
- Formed a sepsis committee in 2008
- Created a scoring system and sepsis teams in ER, ward and ICU
- Also created a critical care recovery clinic to follow patients & prevent readmits
- Estimated they saved almost 2,500 lives and \$50M in costs
- Only hospital recognized by Global Sepsis Alliance for its progress on sepsis

Becker's Clinical Leadership, Carbajal, Sept. 18, 2023



#### POST SEPSIS SYNDROME (PSS)

- **Physical**
- Difficulty sleeping & poor appetite
- Fatigue
   Shortness of breath
- Disabling muscle or joint pain & swellingRepeat infections
- Reduced organ function (e.g., kidney, liver, heart)
- Nightmares & PTSD
- Loss of self-esteem

**Psychological** 

Hallucinations

- Skin rash & hair loss
- Decreased cognitive functioningDepression & mood swings
- Memory loss & difficulty concentrating



# THE "BIG 3" IN MALPRACTICE CLAIMS: VASCULAR, INFECTIONS, & CANCERS

- Misdiagnosis-related harms in malpractice claims
- Analysis of large medical malpractice claims database
- Controlled Risk Insurance Company from 2006-2015
- Analyzed 11,592 diagnostic error cases out of 53,377 closed claims
  Included 7379 high-severity harms (including 53% death)
- Defined as serious, permanent disability, or death
- Big 3 accounted for 74% of high-severity cases
- Newman-Toker et al, Diagnosis, 2019

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#### SEPSIS AND MEDICAL MALPRACTICE

• Failure to diagnose

- Failure to treat
- Delay or inadequate antibiotics
- Failure to obtain source control
- Failure to reintervene with clinical deterioration or lack of improvement

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#### SEPSIS CLAIMS REVIEW – CANADA 2023

- Retrospective review of closed claims 2011 to 2020
- Documented peer expert criticism related to sepsis
- 162 patients, mean age 53 years, mortality 49%

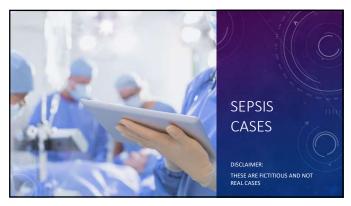
Neilson et al, Critical Care Explorations, 2023

 Main outcomes: describe patients and physicians and classify contributing factors (provider, team, system) & diagnostic pitfalls based on peer expert criticisms.

#### SEPSIS CLAIMS REVIEW – CANADA 2023

- 218 implicated physicians (1.3 MDs/patient)
- 169 (78%) were family medicine, emergency medicine or surgeons
- 49% of patients made multiple outpatient visits leading up to admission
- 39% of patients were admitted to the ICU
- Only 25% presented with fever
- 30% had severe harm such as limb amputation or brain damage
- Deficient assessments, such as failing to consider sepsis or not reassess the patient prior to discharge, contributed to 81% of cases

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#### POSSIBLE CASES/IMAGES

- Line infection sent home with CVC
- New case for RMAP bypass, presented w sepsis, no surgery until septic shock, death
- Or Ashley cases for Colin colon injury
- Or the Southern Oregon case Blommer admit to medicine
- Balloon aspiration/ ARDS case

#### SEPSIS CASE #1: HYSTERECTOMY

- 40-year-old female has laparoscopic hysterectomy for fibroids
- Postop day one has tachycardia to 115 bpm (HR on admission was 79)
- Rates pain as 7/10, narcotics changed from Oxycodone to Dilaudid
- EKG shows sinus tachycardia with HR 119
- Metoprolol ordered by senior gynecology resident on postop day 2
- Discharged home on Dilaudid & metoprolol on postop day 3, with HR of 101
- Advised to follow up with PCP in one week regarding the tachycardia

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# SEPSIS CASE #1: ED PRESENTATION

- Presents to the ED on postop day 4 with shortness of breath and abdo pain
- On exam she is pale, diaphoretic, abdo is tender with guarding
- HR 120, BP 80/50, RR 24, O2 saturation 89% on room air
- Upright chest x-ray ordered
- Labs ordered: lactate, CBC, CMP, amylase, troponin





# EXPERT OPINIONS - SEPSIS CASE #1

- Gynecology resident and attending negligent
- NOT negligent for iatrogenic small bowel perforation
- Delayed recognition and treatment of small bowel perforation
- Sending patient home on a beta blocker for tachycardia versus finding the cause (i.e. small bowel perforation)

Case settled before trial

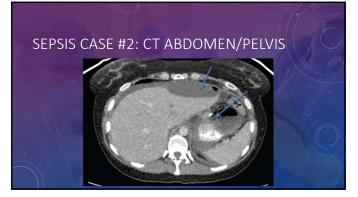
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# SEPSIS CASE #2: GASTRIC BYPASS

- 50-year-old male, BMI 45, has laparoscopic gastric bypass for morbid obesity
- Given Ancef 2 g iv as antibiotic prophylaxis
- Postop day one O2 saturation is 85% on room air, 94% on 2 lpm O2
- Discharged home on postop day 2 on home oxygen

# SEPSIS CASE #2: ED PRESENTATION

- Presents to ED on postop 3 with abdo pain, distention & vomiting
- Has not kept anything down for 24 hours
- BP 140/100, HR 95, RR 22, O2 Sat 79% on RA, 94% on O2 5 lpm
- ED MD says patient is in moderate distress, tender, concern for leak
- Bariatric surgeon called and labs and CT AP ordered with oral & iv contrast



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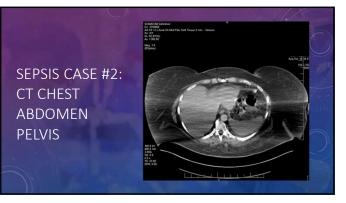
# SEPSIS CASE #2: SURGEON EVALUATION

- Seen next am by bariatric surgeon, notes abdo distention & pedal edema
- Orders chest x-ray (which is normal) and Lasix for possible fluid overload
- States that CT scan is negative and wbc stable at 12
- Is called in the afternoon regarding tachycardia and orders metoprolol

# SEPSIS CASE #2: RAPID RESPONSE

- Rapid response called next evening (POD#5) for tachycardia & tachypnea
- Patient is diaphoretic & complains of 10/10 abdo pain
- Hospitalist transfers patient to ICU for higher level of care
- Surgeon is called and suggests CT chest to rule out PE

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# SEPSIS CASE #2: REOPERATION

- Taken to surgery later that morning (POD#6) for suspected leak
- Given 2 g of Ancef and 500 mg Flagyl intraoperatively
- Is on a NRB and several pressors, no urine output noted last 24 hours
- Surgeon finds leak at gastrojejunal anastomosis and oversews & drains
- Patient is transferred back to ICU in critical condition
- Broad-spectrum antibiotics ordered by Intensivist
- Patient develops multi system organ failure and dies the next day

# EXPERT OPINIONS – CASE #2

• Bariatric surgeon is negligent (not for the leak)

- Inadequate prophylactic antibiotics at time of gastric bypas
- Delay in diagnosis of leak, sepsis and septic shock leading to death
- 3-day delay in diagnosis and treatment of sepsis

with antibiotics & source control

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#### EXPERT TIPS FOR REVIEWING SEPSIS CASES

Timing is everything:

- Appropriate prophylactic antibiotics for surgery?
- Vitals, fluid resuscitation, antibiotics and source control
- Check the MAR for actual time of 1st dose of antibiotics and were they broad enough?
- Sepsis protocol: close monitoring, serial serum lactate and clinical reassessment
- Any unnecessary delays or prolonged surgery?

Source control is not necessarily one and done

# EXPERT TIPS FOR REVIEWING SEPSIS CASES

- Review all radiology imaging and/or have a radiology expert
- Make a table or graph of the vitals and urine output and labs e.g. lactate, wbc
- Can calculate SOFA or other sepsis scores yourself even if not in the record
- Review the audit trail to see who saw early warning scores and when

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# QUESTION #1

Sepsis is currently defined as: (choose the best answer)

- A Hypotension or tachycardia due to bacteria in the bloodstream.
   B A dysregulated host response to infection that can cause organ dysfunction.
- C An infection that is severe and requires hospitalization.
- D Metabolic dysfunction due to infection.
- E Systemic dysregulation that requires vasopressor blood pressure support.

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# QUESTION #2

Septic shock is currently defined as: (choose all correct answers)

- A Hypotension or tachycardia due to bacteria in the bloodstream.
- B A dysregulated host response to infection that can cause organ dysfunction.
- C A subset of sepsis with circulatory and cellular/metabolic dysfunction.
- D A patient requires vasopressors to maintain a mean arterial pressure (MAP) of >/= 65 mm Hg despite adequate fluid resuscitation.
- E A patient has a serum lactate of >/= 2 mmol/l despite fluid resuscitation.



# QUESTION #4

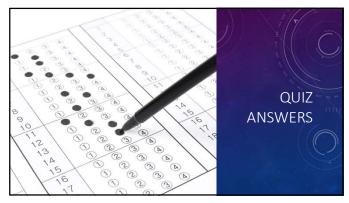
Every hour delay in antibiotics for sepsis results in: (choose the best answer)

A An 8% increase in mortality.

B An 8% increase in septic shock.

- C A 1% increase in mortality.
- D A 1% increase in septic shock.
- E A 5% increase in risk of being sued for medical negligence

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# ANSWER TO QUESTION #1

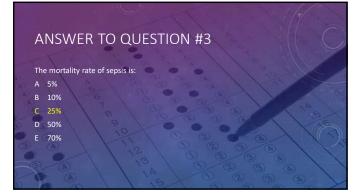
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- B A dysregulated host response to infection that can cause organ dysfunction.
- C An infection that is severe and requires hospitalization.
- D Metabolic dysfunction due to infection.
- E Systemic dysregulation that requires vasopressor blood pressure support.

# ANSWER TO QUESTION #2

- Septic shock is currently defined as: (choose all correct answers)
- A Hypotension or tachycardia due to bacteria in the bloodstream.
- B A dysregulated host response to infection that can cause organ dysfunction. C A subset of sepsis with circulatory and cellular/metabolic dysfunction.
- D A patient requires vasopressors to maintain a mean arterial pressure (MAP) of >/= 65 mm Hg despite adequate fluid resuscitation.
- A patient has a serum lactate of >/= 2 mmol/l despite fluid resuscitation.

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# **ANSWER TO QUESTION #4** Every hour delay in antibiotics for sepsis results in: (choose the best answer) A An 8% increase in mortality. B An 8% increase in septic shock. C A 1% increase in mortality. D A 1% increase in septic shock. 0 E A 5% increase in risk of being sued for medical negligence.

# SEPSIS SUMMARY

- The longer sepsis progresses, the higher risk of septic shock and mortality.
- If treatment is started within the first few hours, mortality is reduced.
- Each hour of delay in antibiotics +/- surgical source control increases mortality.
- Early and aggressive treatment of sepsis is crucial.

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#### INTERNET RESOURCES

- The Sepsis Alliance www.sepsis.org
- Global Sepsis Alliance www.global-sepsis-alliance.org
- World Sepsis Day <u>www.worldsepsisday.org</u>
- NELA project 2019 : 1 in 5 patients do not receive antibiotics on time

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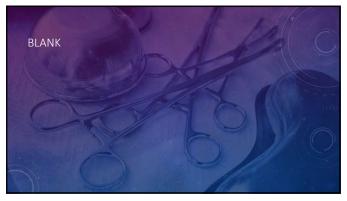
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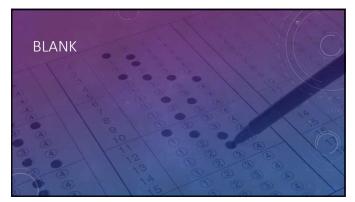
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# SEPSIS CASE #3

- Aspiration at induction of anesthesia
- ARDS
- Prolonged course
- Recovers but has Wernicke-Korsakoff syndrome

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