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Empiric Antibiotics for Sepsis

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Disclosures of Financial Relationships

Has disclosed relationships with entities producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients.

Research and Grant Support

Blue Cross Blue Shield, MI

Advisory Boards

NONE

Speakers Bureau

NONE

Board Member

NONE

Goals & Objectives

- Discuss antibiotic timing and selection in sepsis
- Review the data and suggest frameworks for guidance
- Highlight the importance of de-escalation
- Assess COVID-19 community-onset co-infections and hospital-acquired infections and antibiotic use

Empiric Antibiotics in Sepsis

Antibiotics in Sepsis

When should I start antibiotics?

Which antibiotics should I start?

Antibiotic Initiation Timing in Sepsis

Antibiotics in Sepsis

Surviving Sepsis Campaign recommends:

Broad-spectrum antibiotic(s) should be started as soon as possible after recognition, and within 1 hour of severe sepsis and shock



Antibiotics in Sepsis

- Bias exists in studies on either side of the debate
 - Retrospective, are adjustments appropriate?
 - When is time zero?
 - Source of infection?
 - Source control achieved?
 - Appropriate antibiotic coverage?
 - Appropriate antibiotic dosing?

Benefits of Antibiotics in Sepsis

Early antibiotics in sepsis are associated with decreased risk of in-hospital mortality

- Retrospective
- 2700 ICU patients
- After onset hypoTN, 7.6% decrease in survival per hour delay of abx
- Excluded if abx before hypoTN, median time to abx was 6 hrs, high overall mortality 56.2%

- Prospectively obtained data, Retrospective analysis
- 17,990 severe sepsis and shock in 165 ICUs
- Linear increase in risk of mortality with each hour delay in abx
- Limited to patients with more severe disease (admitted to ICU)

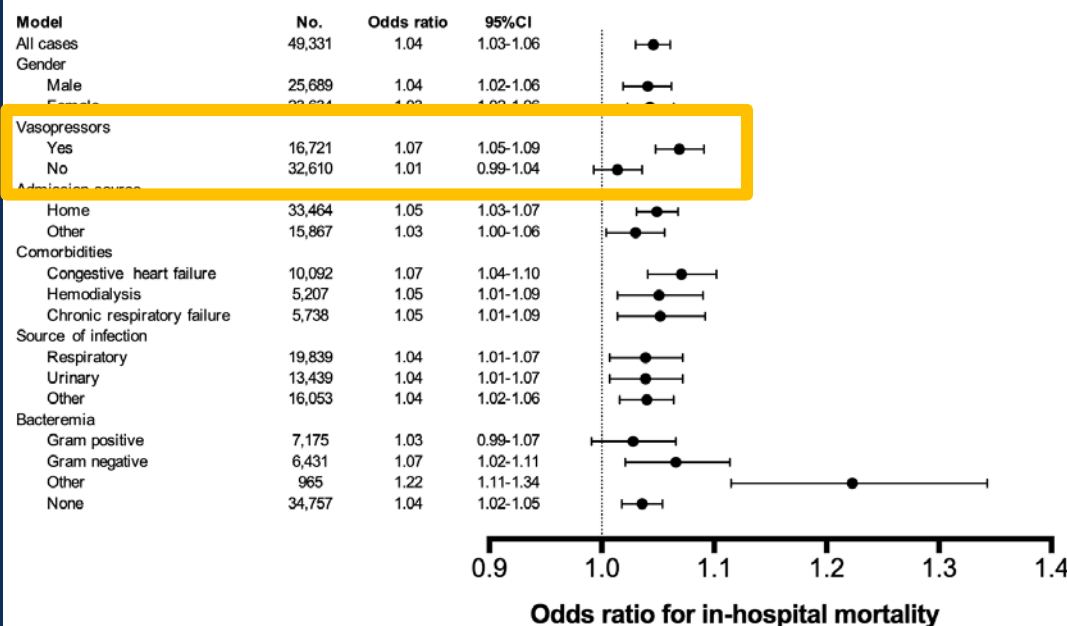
- Retrospective
- 3900 ED patients with severe sepsis
- Increased time to abx associated with increased progression to shock
- No data on source or source control, adequacy of abx coverage/dosing

Benefits of Antibiotics in Sepsis

Benefit of early antibiotics is greater for patients with increased severity of illness

- Retrospective
- 50,000 sepsis/septic shock in 149 NY hospitals
- 3 hr bundle completed within 12 hrs
- Longer time to abx associated with higher risk of in-hospital mortality
- Greatest with those on vasopressors

Figure S3. Risk-adjusted odd ratios of in-hospital mortality with 95% confidence interval for each hour until administration of broad spectrum antibiotics from primary model and multiple *a priori* subgroups



Benefits of Antibiotics in Sepsis

Benefit of early antibiotics is greater for patients with increased severity of illness

- Retrospective
- 50,000 sepsis/septic shock in 149 NY hospitals
- 3 hr bundle completed within 12 hrs
- Longer time to abx associated with higher risk of in-hospital mortality
- Greatest with those on vasopressors

- Retrospective
- 35,000 sepsis in EDs in Northern California
- Abx within 6 hrs
- Each hour delay in abx associated with 9% increased odds of in-hospital mortality
- Greatest difference in those with septic shock: 1.8% increase in mortality/hr

Benefits of Antibiotics in Sepsis

Benefit of early antibiotics is greater for patients with increased severity of illness

- Retrospective
- 35,000 sepsis in EDs in Northern California
- Abx within 6 hrs
- Each hour delay in abx associated with 9% increased odds of in-hospital mortality
- Greatest difference in those with septic shock: 1.8% increase in mortality/hr

Table 3. Odds Ratios for Hospital Mortality Based on the Time of Antibiotic Administration in Unadjusted and Adjusted Logistic Regression Models

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	1.08	1.04–1.12	<0.001
+ Demographics	1.09	1.05–1.13	<0.001
Fully adjusted model, in each subgroup			
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

Benefits of Antibiotics in Sepsis

Decrease in mortality with early antibiotics not seen in all studies

- Observational cohort
- 1400 SICU
- Aggressive vs conservative (abx after objective sign of infection)
- Pressors/unstable abx at intensivist's discretion
- Aggressive abx use associated with increased risk of mortality

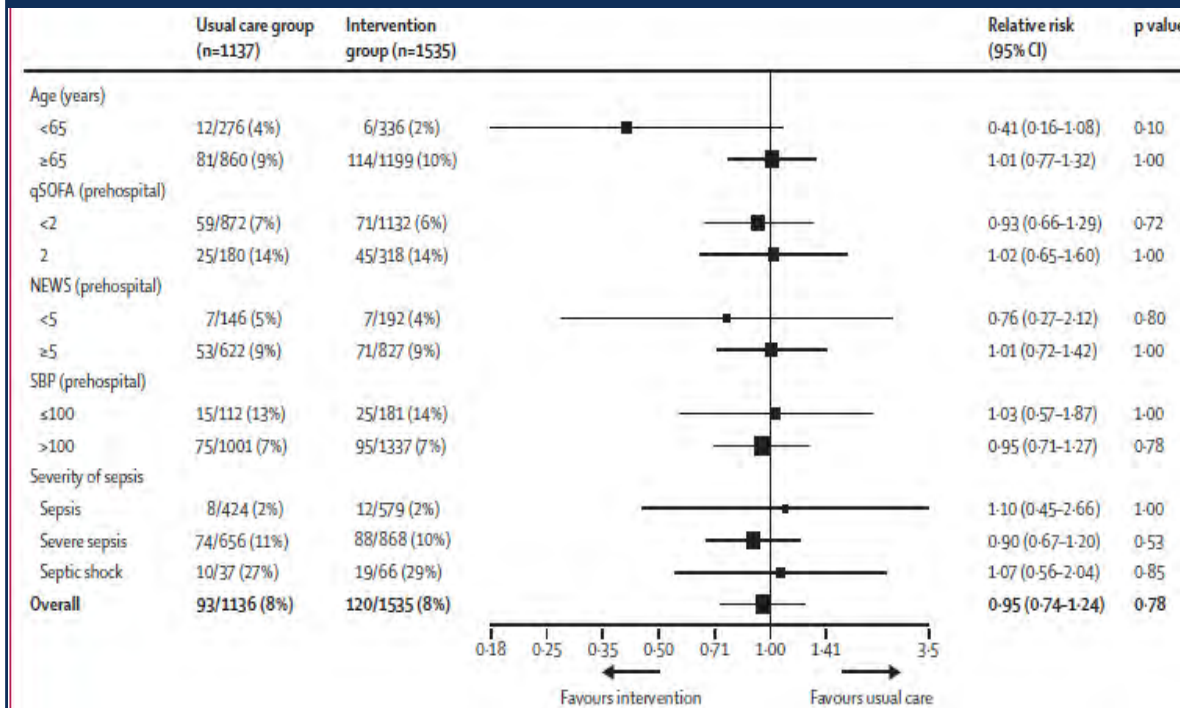
- Systematic review
- Severe sepsis or shock
- 11 studies, 16000 ED triage, 11000 from recognition of sepsis/shock
- No mortality benefit of abx within 3 hrs ED triage or 1 hr of severe sepsis or shock
- No patient level data, smaller sample, no report of 1st hr in ED

- Prospective
- 1100 mild and severe sepsis in ED, abx within 6 hrs
- No difference with decreased time to abx
- Mortality rate 10%

Benefits of Antibiotics in Sepsis

Decrease in mortality with early antibiotics not seen in all studies

- PHANTASi trial
- Randomized, controlled, open label, 2700 EMS patients Netherlands
- Diagnosed or suspected infection, fever, and either HR >90 or RR >20
- 1:1 CTX + fluids + oxygen in ambulance vs usual care
- 8% 28-day mortality in both groups, no difference
- Small sample size, low mortality rate, very few patients with shock



Harms of Antibiotics

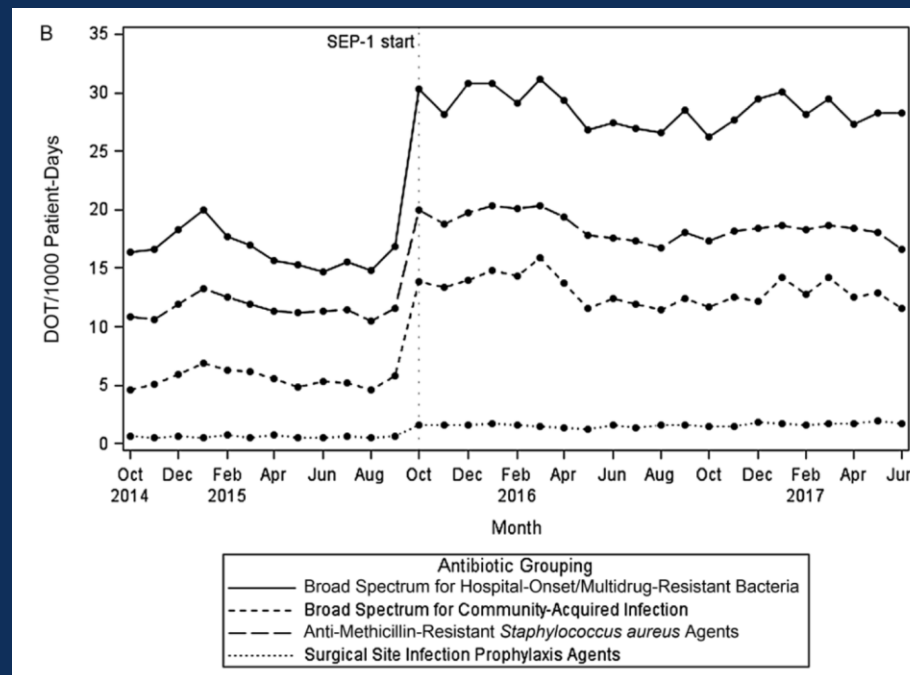
- Adverse events in 20% of hospitalized patients given an abx
- Increased antibiotic use is associated with:
 - Increased *C. difficile*
 - Increased Multi-drug resistant organisms (for your patient and their neighbor)
 - Increased length of stay

Harms of Broad-spectrum Antibiotics

- Broader abx associated with higher mortality
 - Anti-MRSA therapy in pneumonia associated with increased risk of death, kidney injury, CDI, VRE, GNR infections
 - Unnecessarily broad-spectrum abx associated with increased mortality
- The Pathobiome
 - sustains inflammation, immunosuppression, and contribute to multiple organ failure

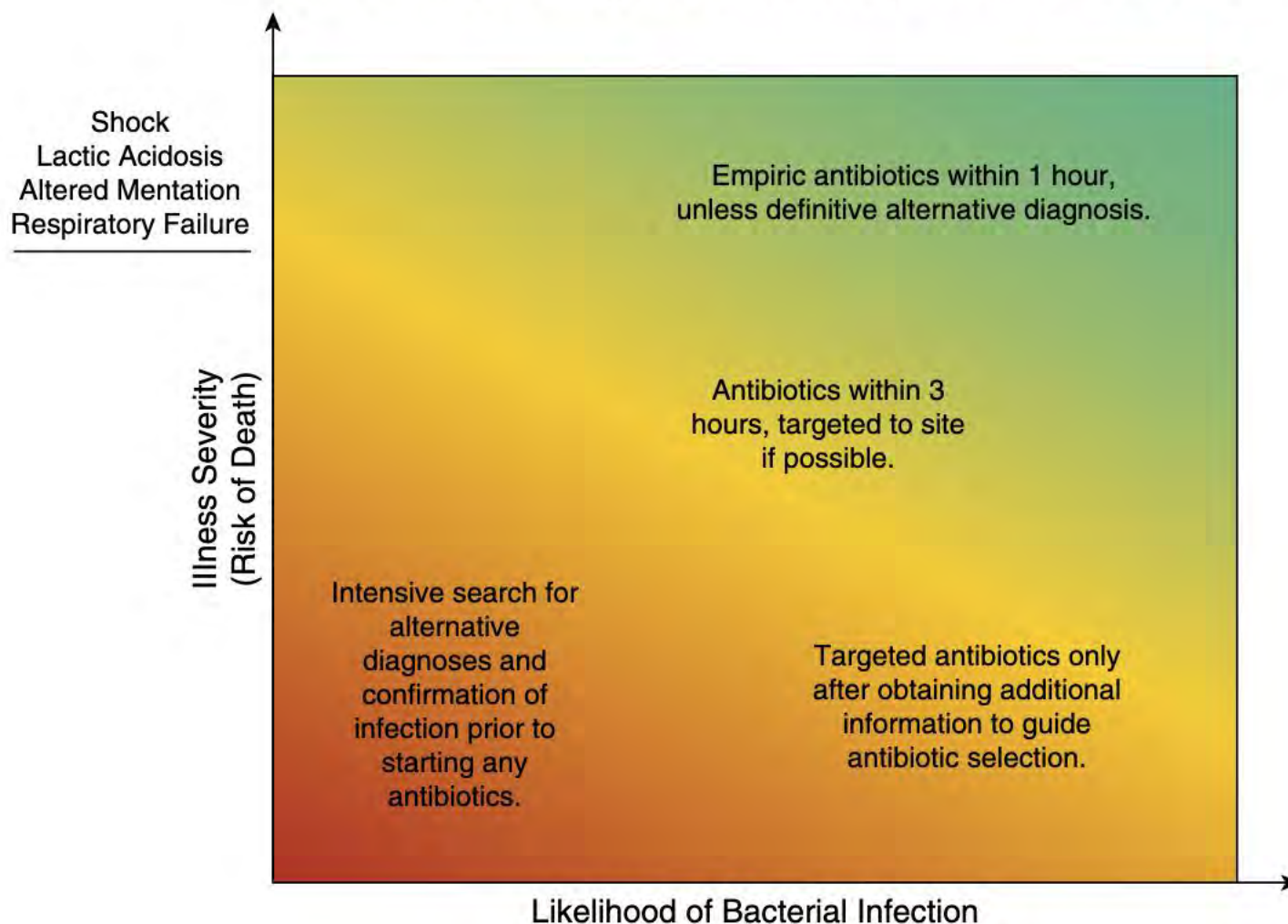
SEP-1 Impact on Abx Use

- Associated with increased broad-spectrum antibiotic use among severe sepsis
- Suggests importance of de-escalation

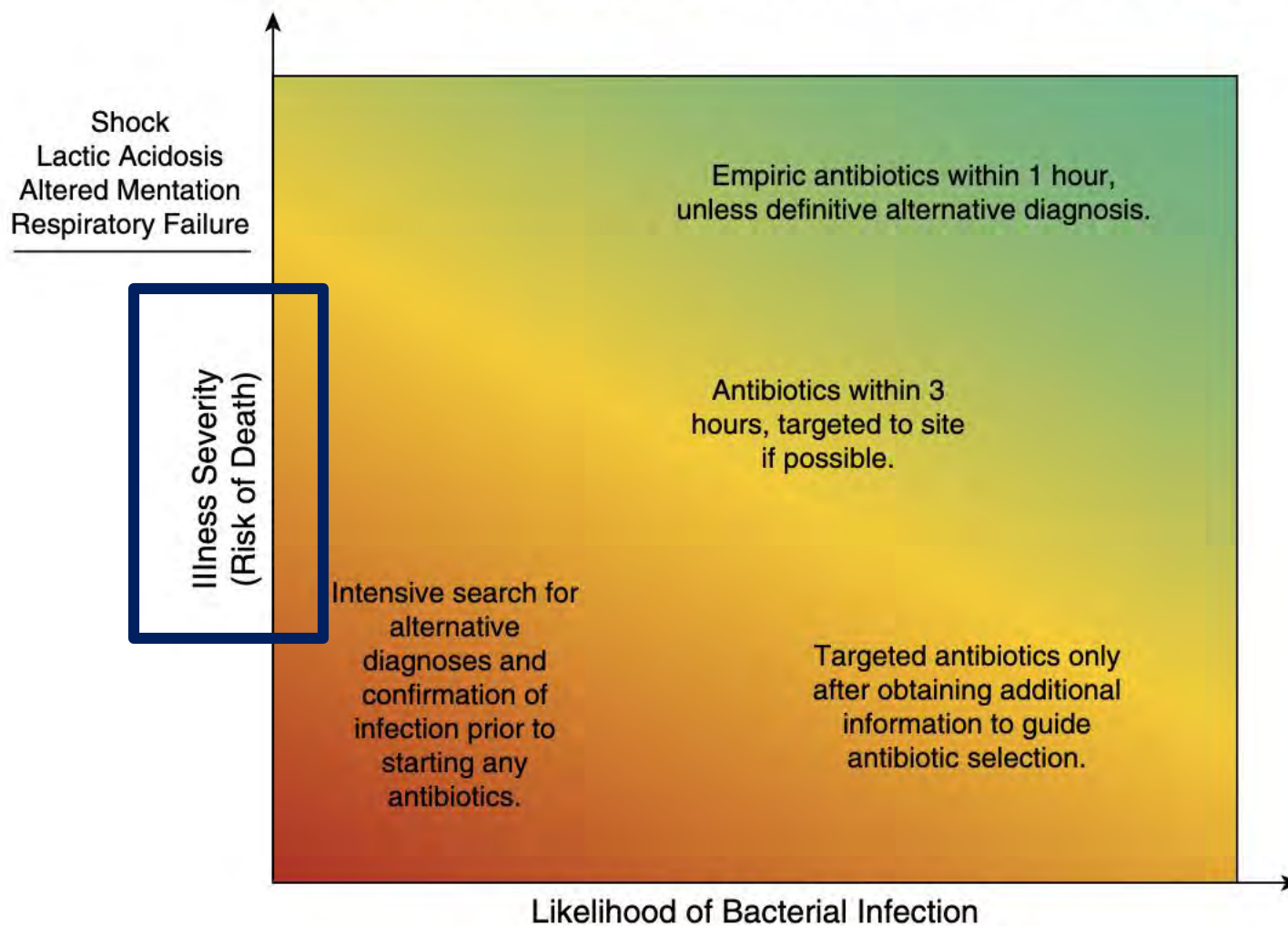




Framework for Timing and Broadness of Initial Antimicrobials

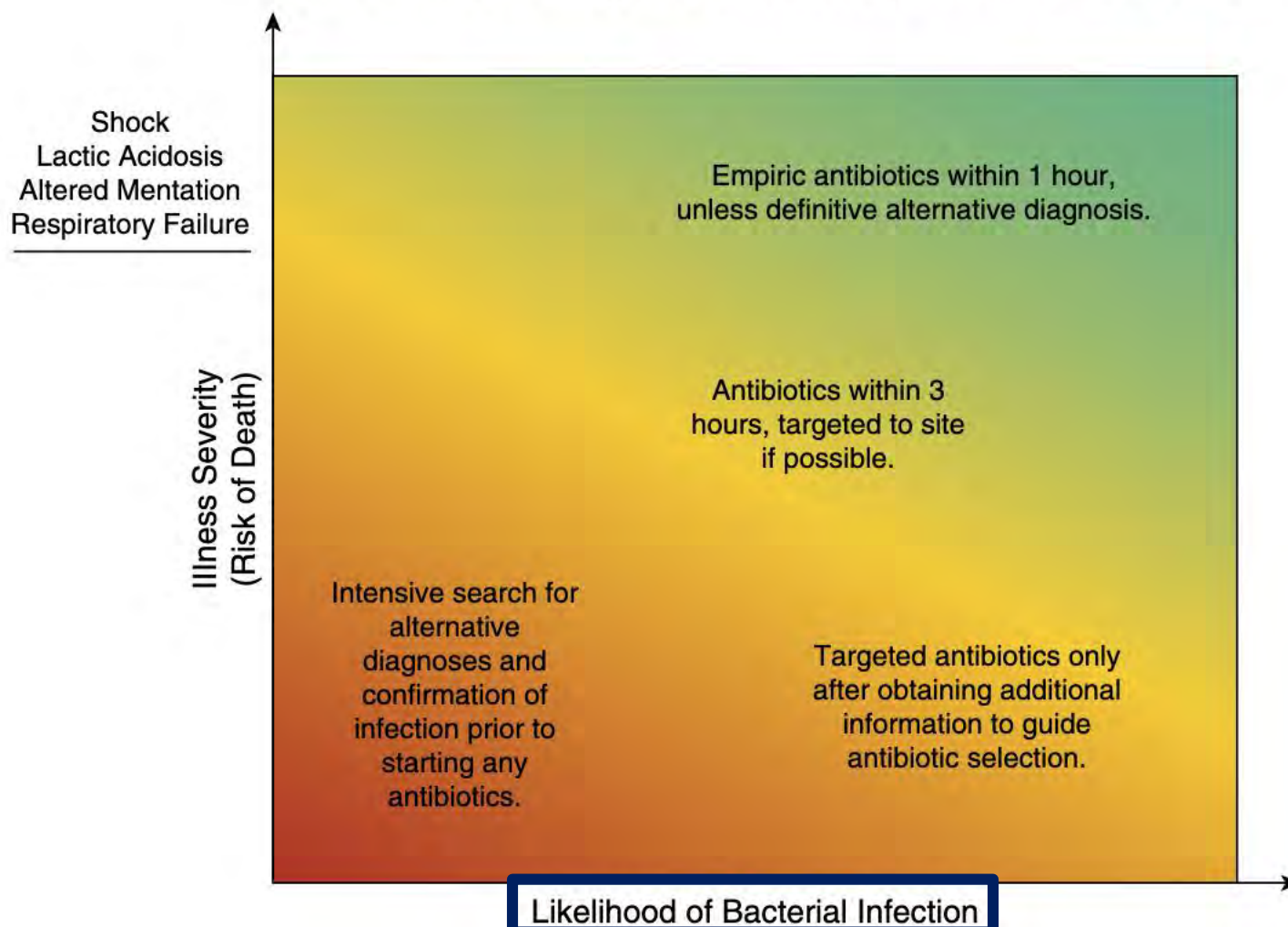


Framework for Timing and Broadness of Initial Antimicrobials



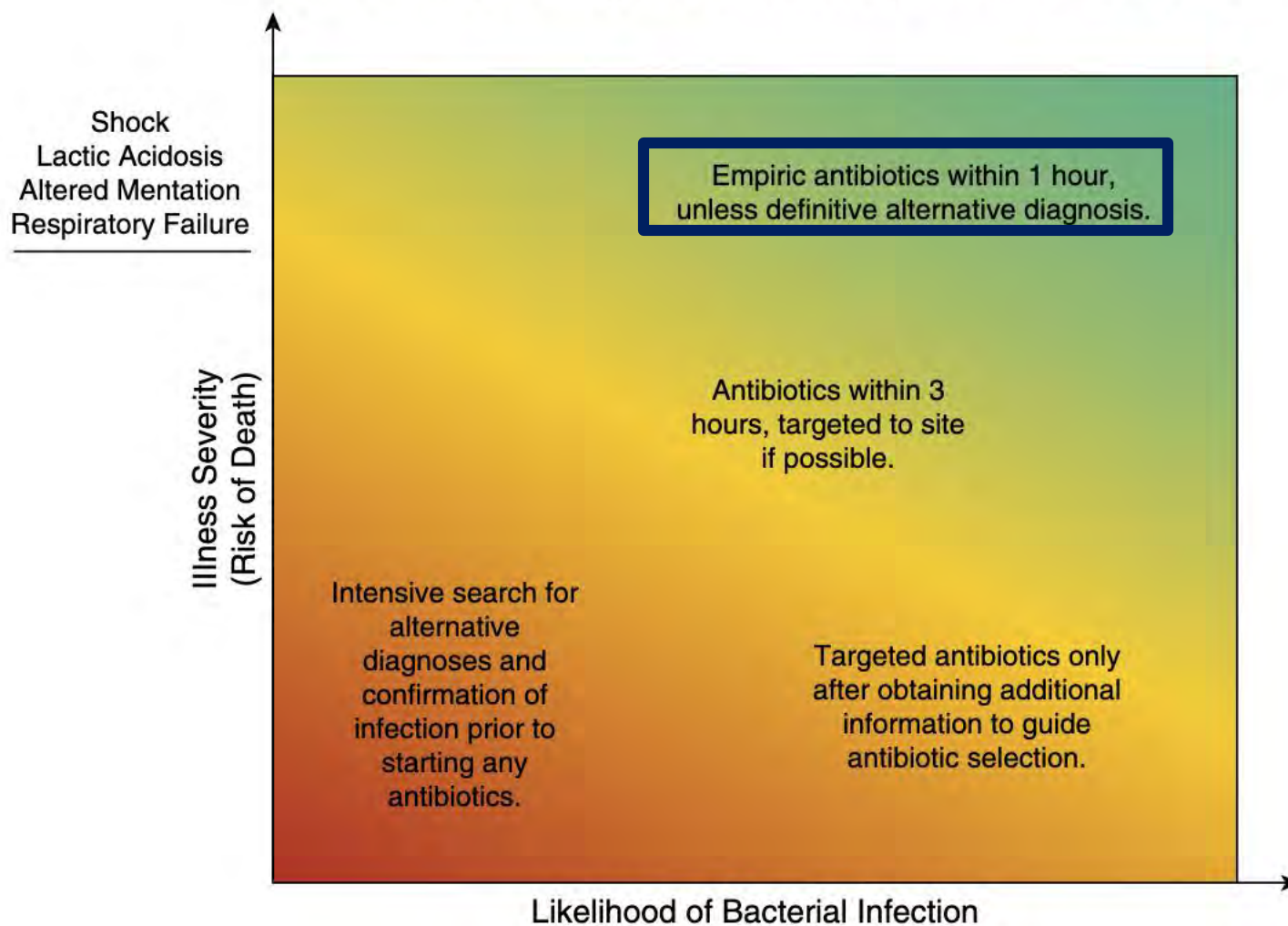


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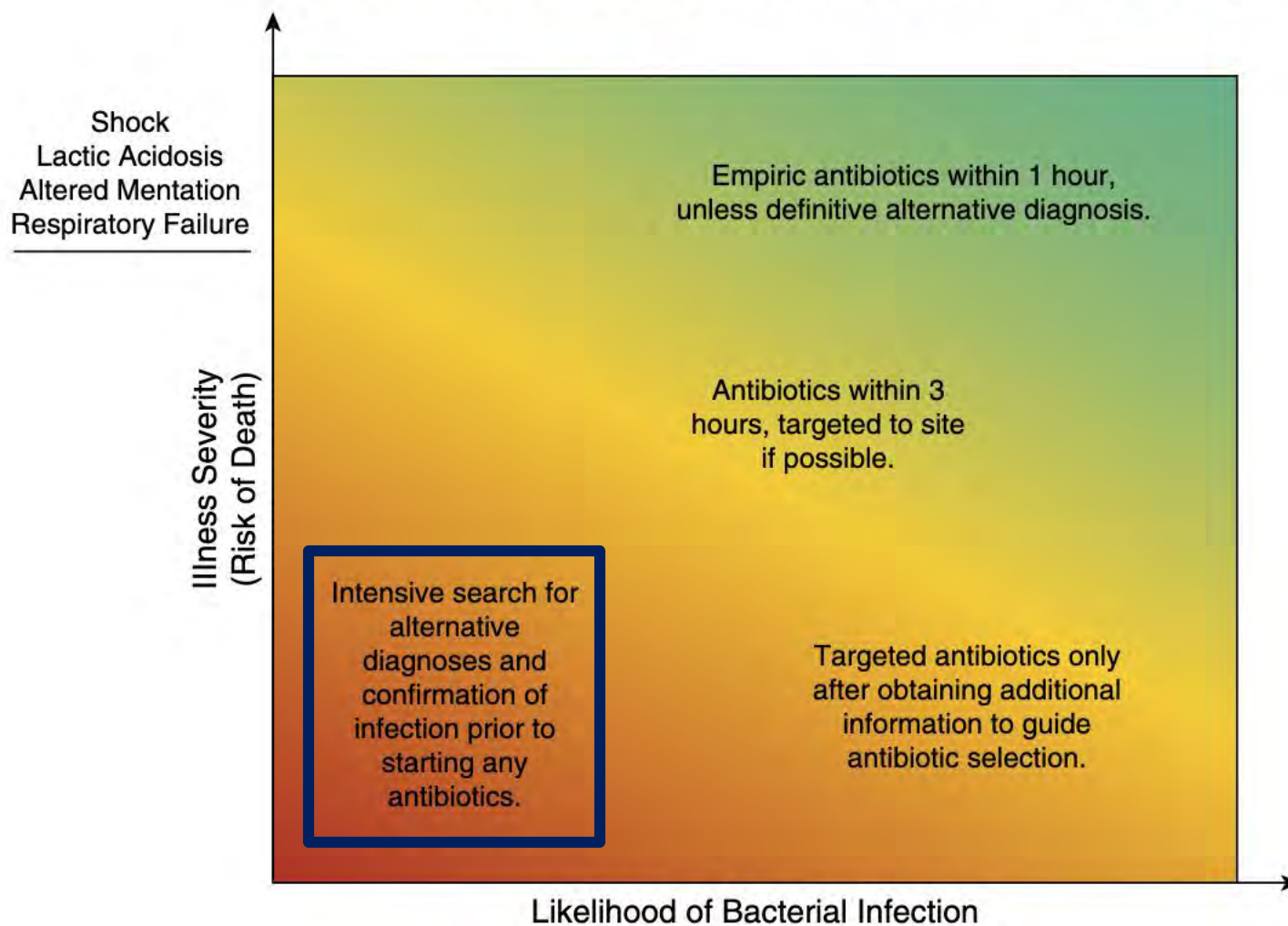


Framework for Timing and Broadness of Initial Antimicrobials



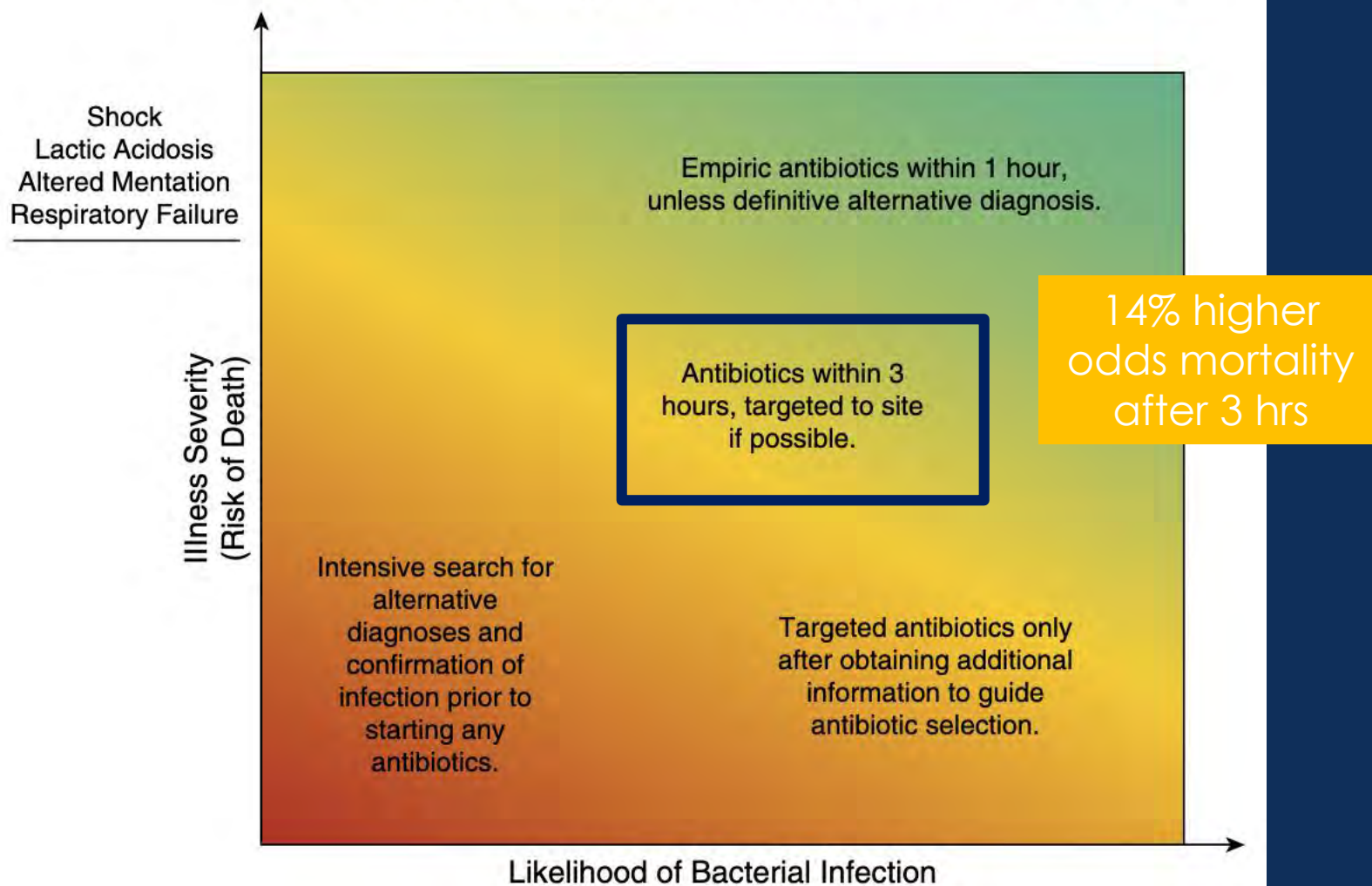


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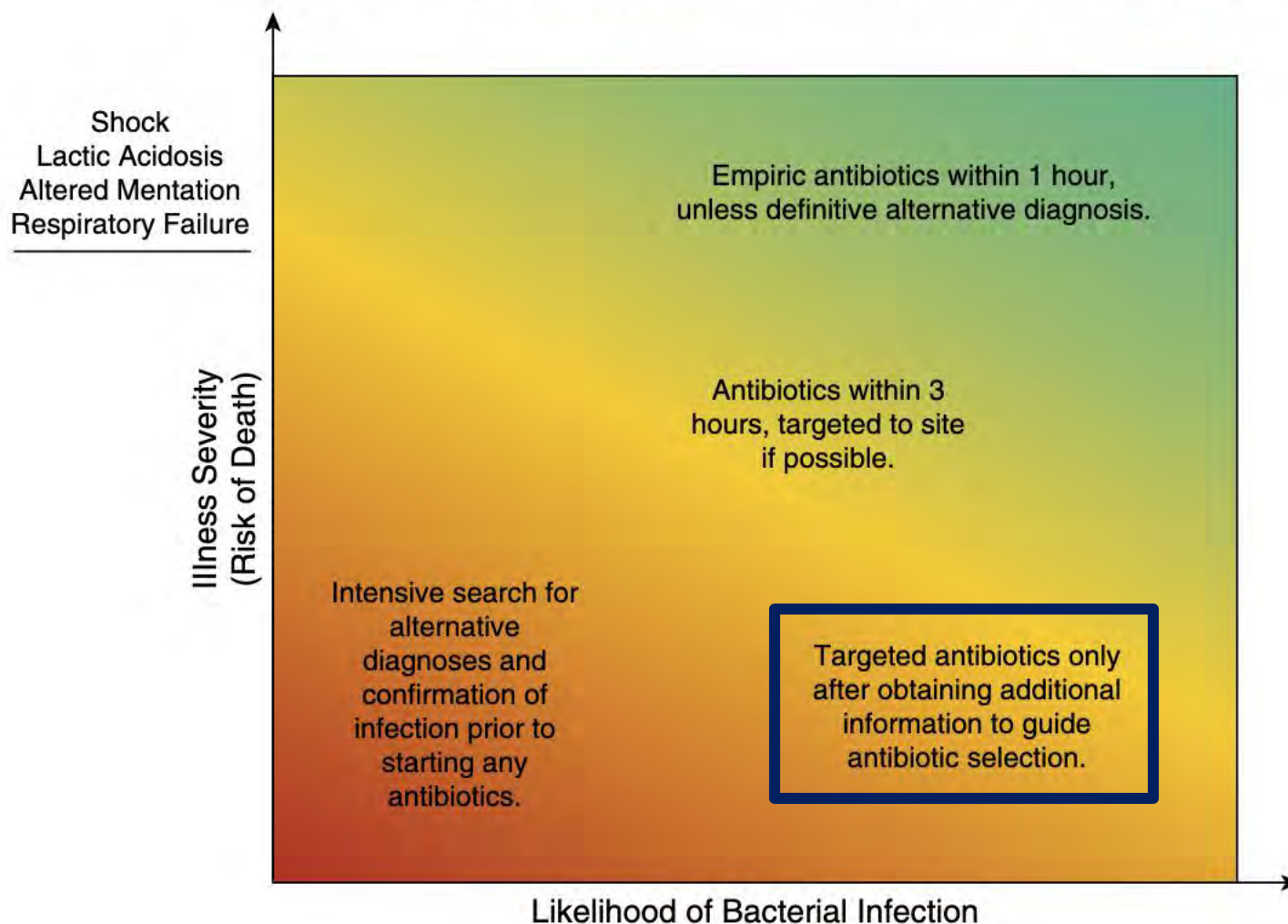


Framework for Timing and Broadness of Initial Antimicrobials





Framework for Timing and Broadness of Initial Antimicrobials



Antibiotic Selection in Sepsis

Antibiotic Selection

Source



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graph TD; Source[Source] --> Undifferentiated[Undifferentiated]; Source --> PresumedSource[Presumed Source]; Undifferentiated --> BroadCoverage["Broad Coverage:  
MRSA + MDR Gram-negative"]; PresumedSource --> TargetSource["Target the source:  
Use site/syndrome specific guidelines to determine community-onset vs broader coverage"]
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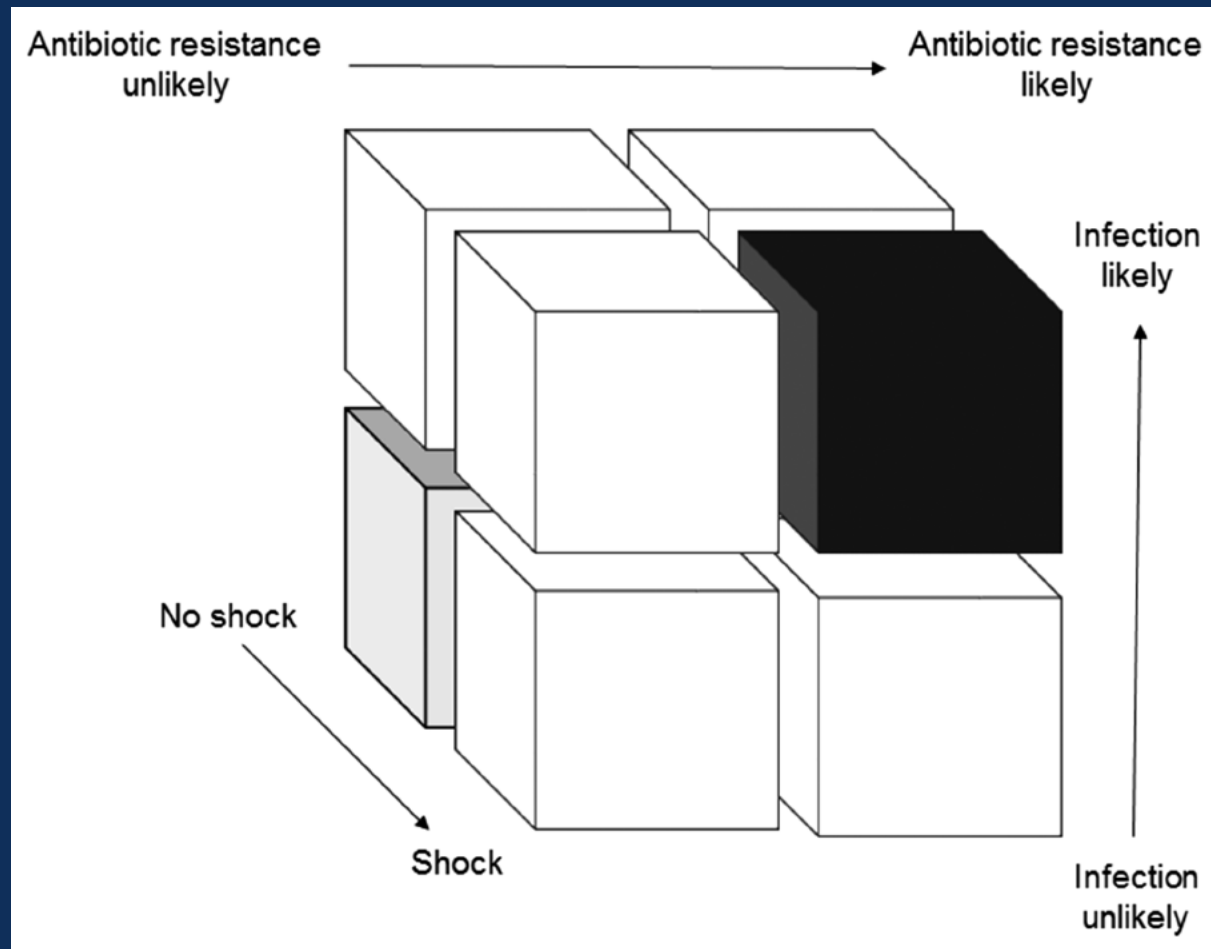
Undifferentiated

Broad Coverage:
MRSA + MDR Gram-negative

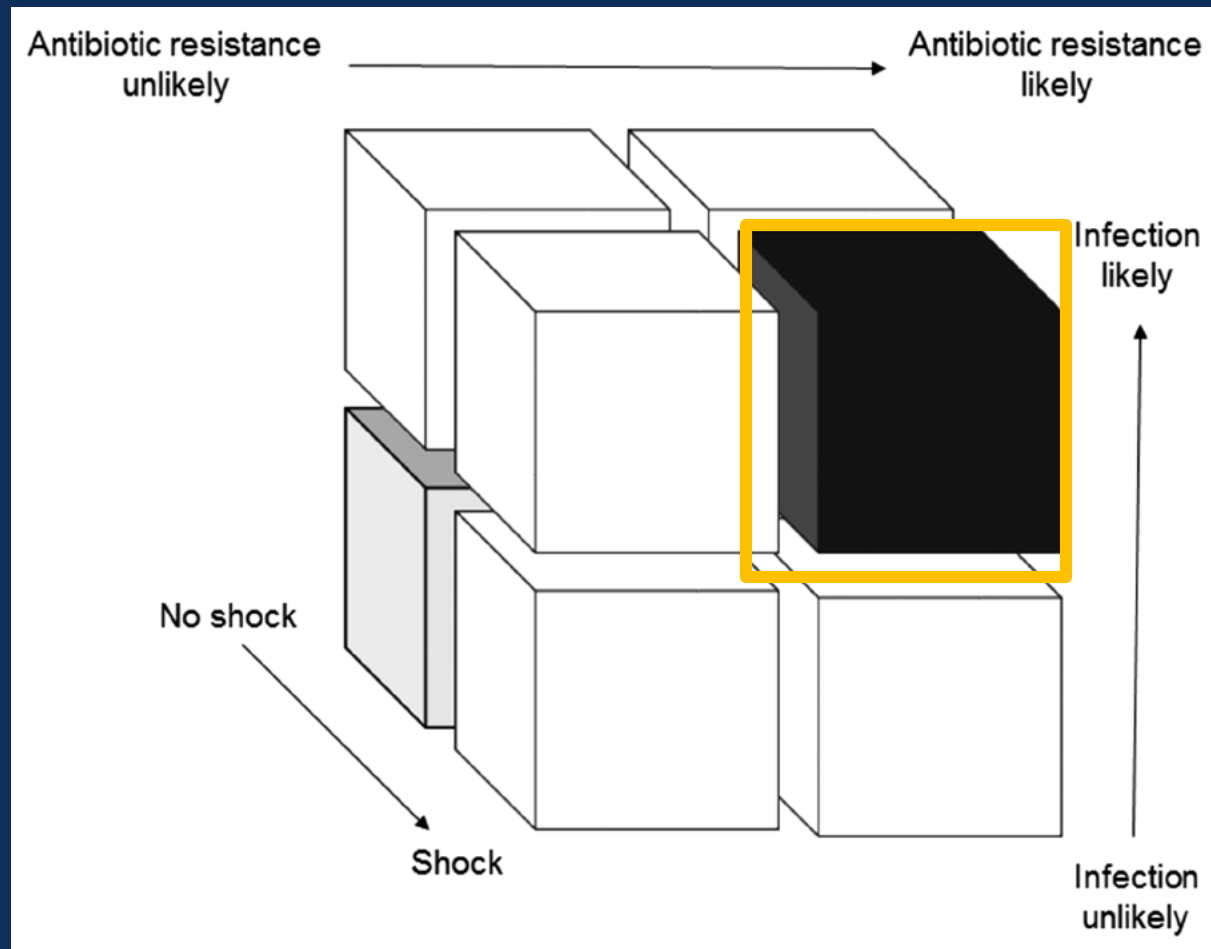
Presumed Source

Target the source:
Use site/syndrome specific guidelines to determine community-onset vs broader coverage

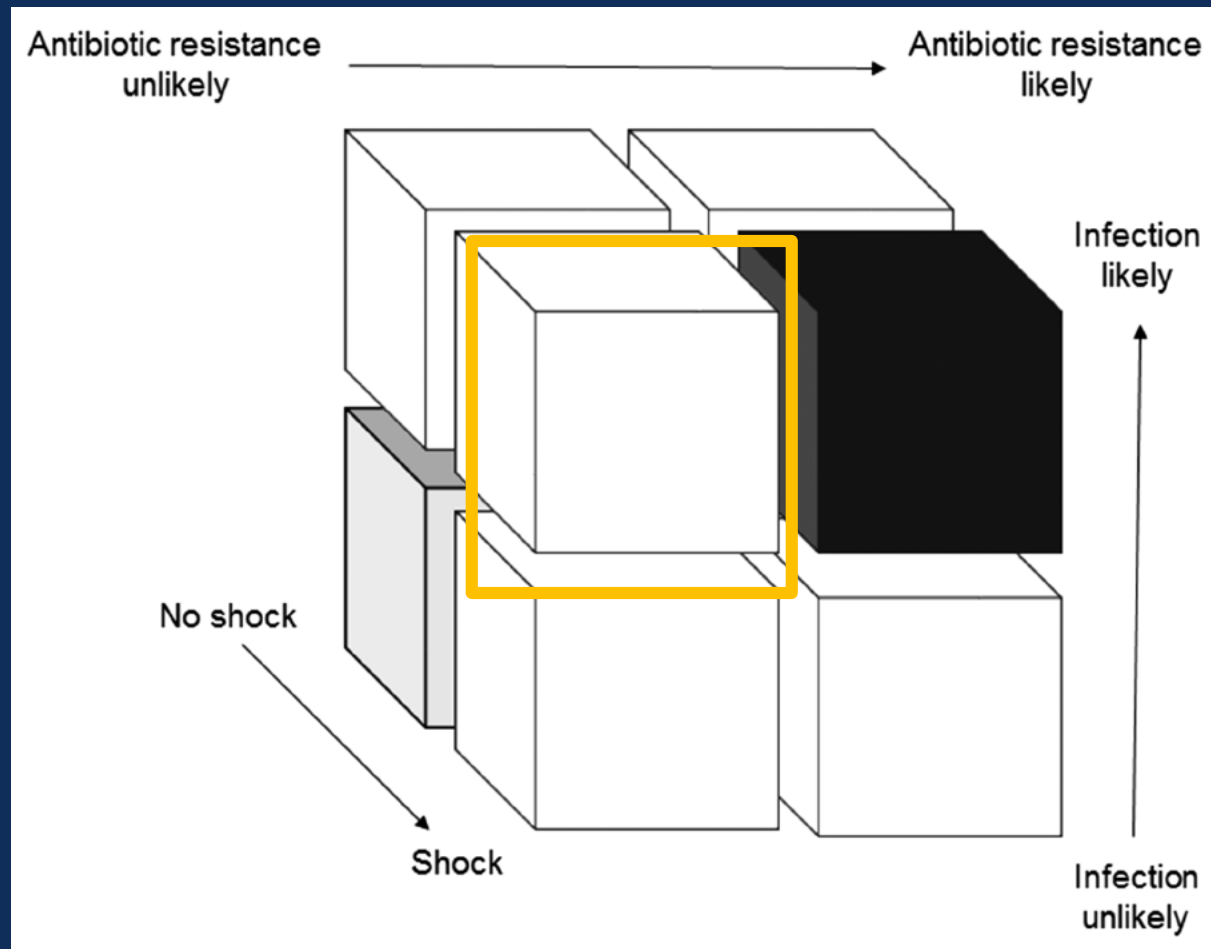
Antibiotic Selection: Framework



Antibiotic Selection: Framework



Antibiotic Selection: Framework



Antibiotic Selection: Pneumonia

Table 4. Initial Treatment Strategies for Inpatients with Community-acquired Pneumonia by Level of Severity and Risk for Drug Resistance

	Standard Regimen	Prior Respiratory Isolation of MRSA	Prior Respiratory Isolation of <i>Pseudomonas aeruginosa</i>	Recent Hospitalization and Parenteral Antibiotics and Locally Validated Risk Factors for MRSA	Recent Hospitalization and Parenteral Antibiotics and Locally Validated Risk Factors for <i>P. aeruginosa</i>
Nonsevere inpatient pneumonia*	β-Lactam + macrolide [†] or respiratory fluoroquinolone [‡]	Add MRSA coverage [§] and obtain cultures/nasal PCR to allow deescalation or confirmation of need for continued therapy	Add coverage for <i>P. aeruginosa</i> and obtain cultures to allow deescalation or confirmation of need for continued therapy	Obtain cultures but withhold MRSA coverage unless culture results are positive. If rapid nasal PCR is available, withhold additional empiric therapy against MRSA if rapid testing is negative or add coverage if PCR is positive and obtain cultures	Obtain cultures but initiate coverage for <i>P. aeruginosa</i> only if culture results are positive
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Definition of abbreviations: ATS = American Thoracic Society; CAP = community-acquired pneumonia; HAP = hospital-acquired pneumonia; IDSA = Infectious Diseases Society of America; MRSA = methicillin-resistant *Staphylococcus aureus*; VAP = ventilator-associated pneumonia.

*As defined by 2007 ATS/IDSA CAP severity criteria guidelines (see Table 1).

[†]Ampicillin + sulbactam 1.5–3 g every 6 hours, cefotaxime 1–2 g every 8 hours, ceftriaxone 1–2 g daily, or ceftaroline 600 mg every 12 hours AND azithromycin 500 mg daily or clarithromycin 500 mg twice daily.

[‡]Levofloxacin 750 mg daily or moxifloxacin 400 mg daily.

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Antibiotic De-escalation in Sepsis

De-escalation in Sepsis

- Over 1-3 days:
 - Clinical course observed
 - Diagnostic information returns
- This is when to reevaluate the antibiotics (both selection and necessity)
- Every day of antibiotics counts
 - Each additional day increases the risk of harms
 - CDI, AKI

Communication in Sepsis

- Communicate at transfer of care
 - Aid in de-escalation efforts
- Why were the antibiotics started?
 - If questionable, tell the accepting team
 - Empowers them to discontinue antibiotics if appropriate as more diagnostic information returns

COVID-19 and Empiric Antibiotic Use

COVID-19 coinfection

- Living meta-analysis
- 38 studies, 6945 patients, but mostly smaller studies

Community-onset
4.9%

**Hospital-onset,
secondary infection**
16.0%

Critically ill
16.0%

EMPIRIC ANTIBACTERIAL THERAPY AND COMMUNITY-ONSET BACTERIAL CO-INFECTION IN PATIENTS HOSPITALIZED WITH COVID-19: A MULTI-HOSPITAL COHORT STUDY

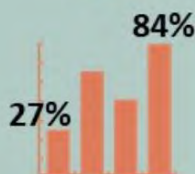
1705 patients hospitalized with COVID-19 in 38 Michigan Hospitals

Early Empiric Antibacterial Therapy

Prescribed to 56.6% of Patients



Varied Widely Across Hospitals



Decreased Over Time



Community-onset Bacterial Infections Rare

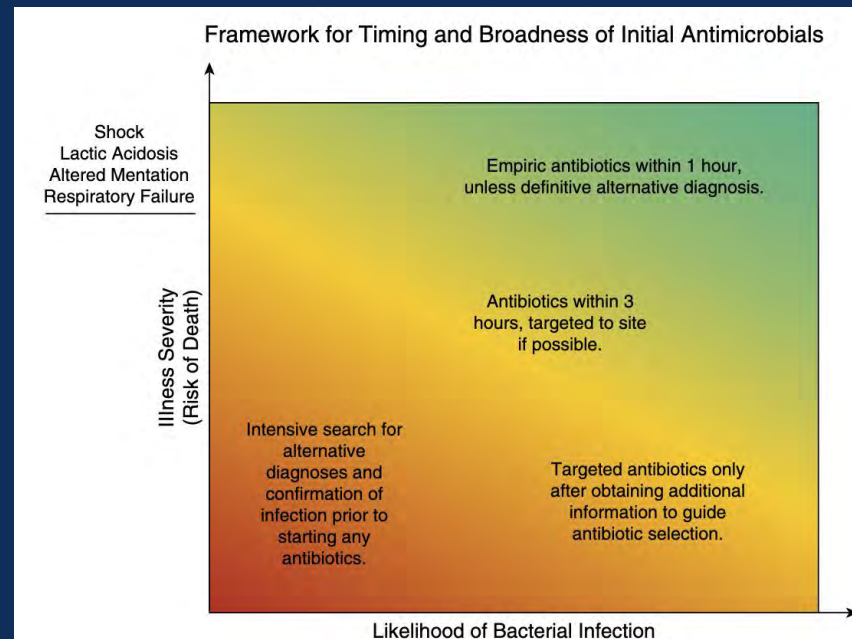


Stewardship Needed! Considerations:

- ✓ Diagnostic testing very limited
- ✓ Empiric antibacterials linked to long COVID19 turnaround times
- ✓ Procalcitonin $<0.1\text{ng/mL}$ → negative predictive value 98.3% for confirmed co-infection

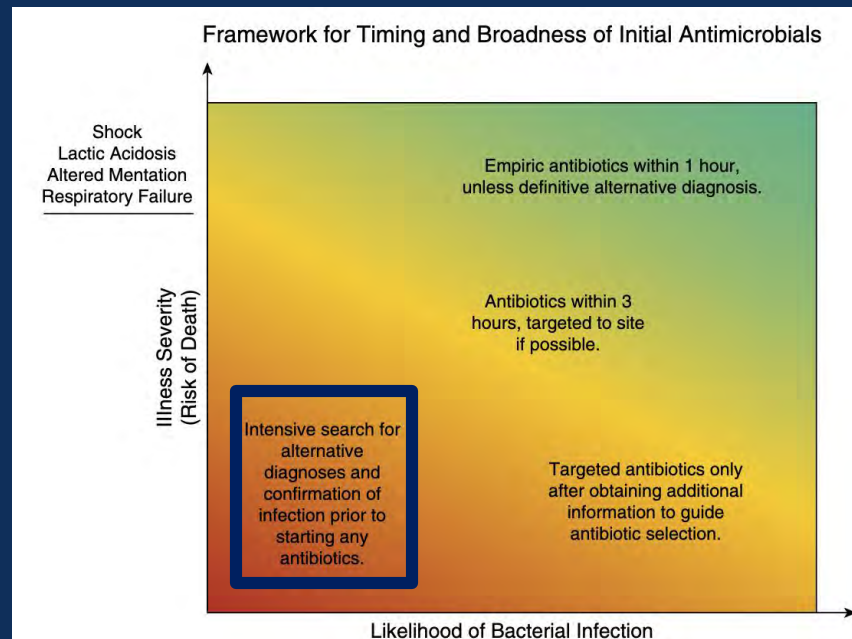
Takeaways: Antibiotics in COVID-19

- Community-onset:
 - Consistently seeing low rates
- Hospital-onset, secondary infections:
 - Will depend on severity of illness, higher rates in the ICU



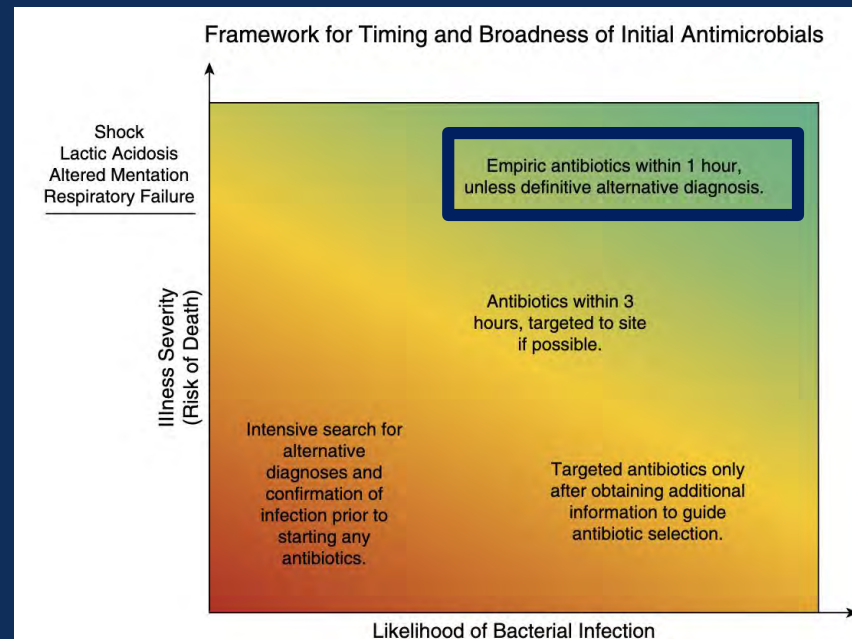
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Lunch



Sepsis & National Policy





Reena Duseja, MD, MS

Chief Medical Officer, Quality Measurement and Value Based Incentives
Group Centers for Clinical Standards and Quality

Centers for Medicare & Medicaid Services (CMS)



Severe Sepsis and Septic Shock: Management Bundle in CMS' Hospital Inpatient Quality Reporting Program

Reena Duseja, MD, MS
Chief Medical Officer,
Quality Measurement and Value Based Incentives Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid

October 1, 2020

The Burden of Sepsis

- 40 percent increase in the rate of Medicare beneficiaries hospitalized with sepsis over the past seven years
- Associated costs totaled more than \$41 billion in 2018
- The average length of stay (LOS) for sepsis patients in U.S. hospitals is approximately 75% greater than for most other conditions.

Buchman TG, Simpson SQ, Sciarretta KL, et al. Sepsis Among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012–2018. *Crit Care Med* 2020; 48:276–288

Hall MJ, Williams SN, DeFrances CJ, et al. Inpatient Care for Septicemia or Sepsis: A Challenge for Patients And Hospitals, 2000–2008. National Center for Health Statistics. Data Brief No. 62. June 2011.

SEP-1 Measure Background

- Measure steward: Henry Ford Hospital
- National Quality Forum (NQF) endorsed (#0500)
 - First endorsed in 2008
 - Currently endorsed (last endorsement July 13, 2017)
- Hospital Inpatient Quality Reporting (IQR) Program adopted the measure in the 2015 Inpatient Prospective Payment System (IPPS) Final rule beginning with the Fiscal Year (FY 2017) Payment Determination
 - Hospitals began submitting measure data on October 1, 2015

SEP-1 Measure Background

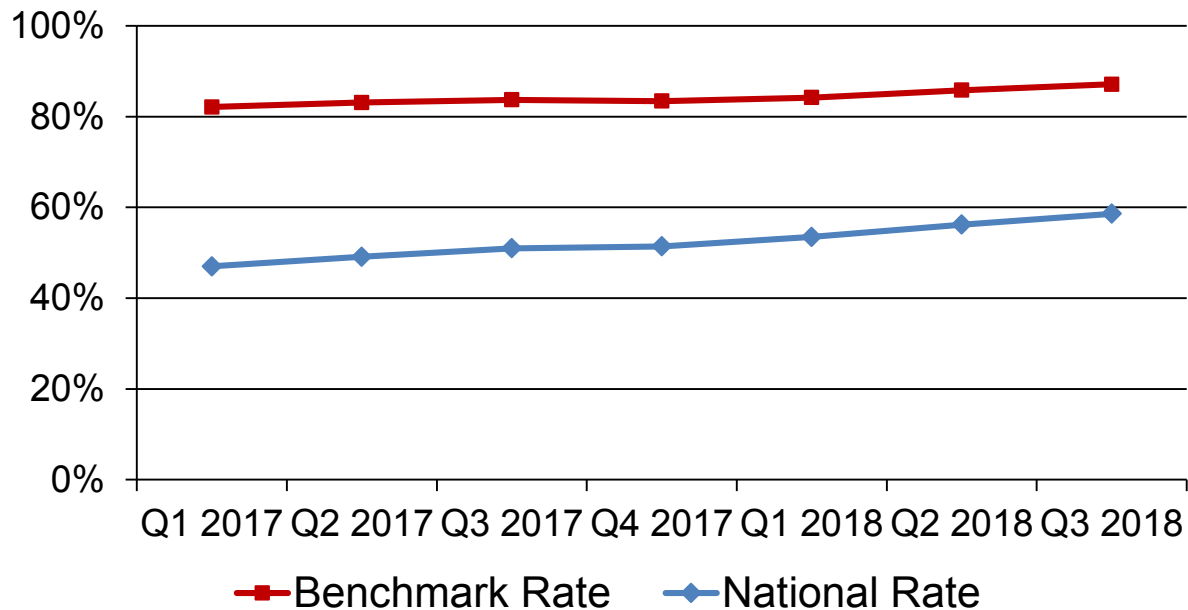
- Public reporting of the SEP-1 measure began in July 2018
- Multiple non-substantive measure updates
 - Improve understanding and reduce abstraction burden

SEP-1: Completing The Bundles

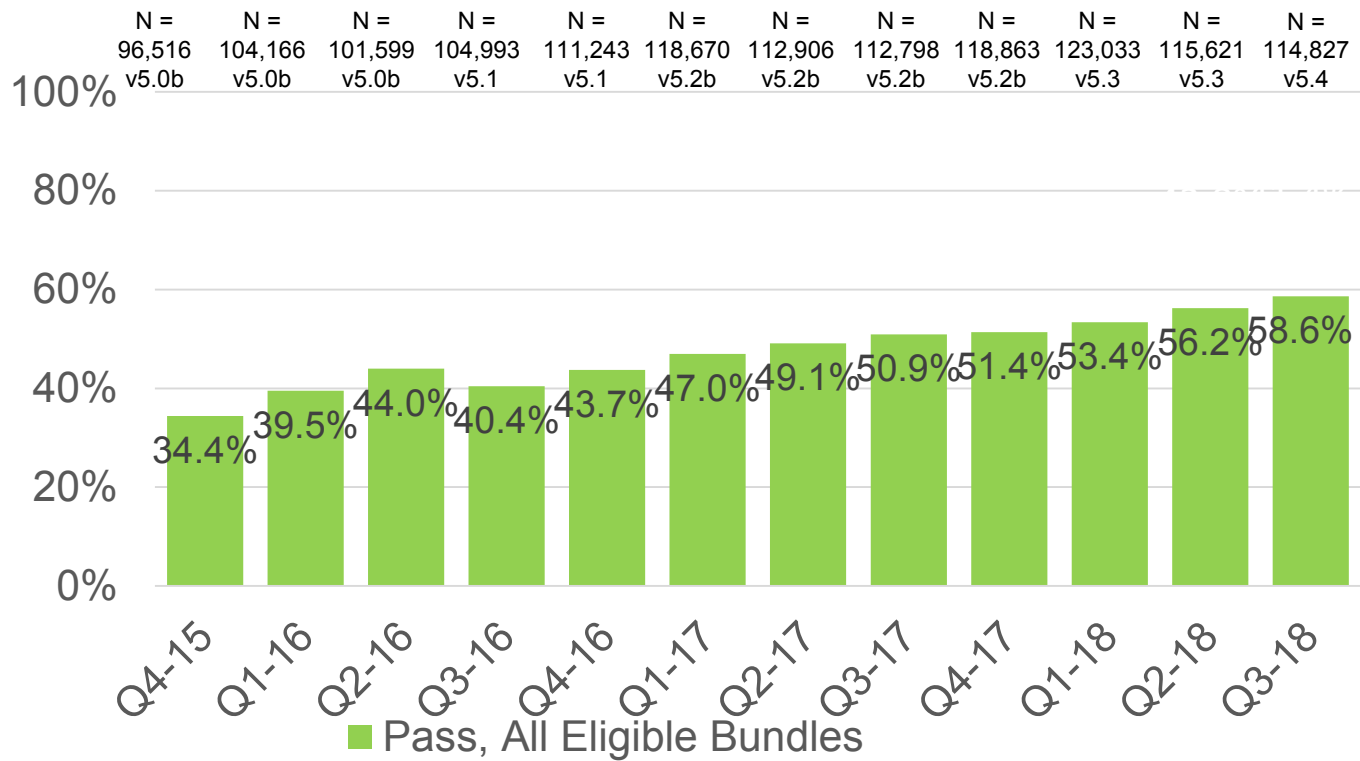
Required Action	Severe Sepsis		Septic Shock	
	3-Hr Bundle	6-Hr Bundle	3-Hr Bundle	6-Hr Bundle
Initial Lactate Collection	Yes	Must be completed within 3-hrs of Severe Sepsis Presentation		
Blood Culture Collection	Yes			
Initial Antibiotic Started	Yes			
Repeat Lactate Collection (if Initial Lactate is > 2)	N/A	Yes	Completed within 6-hrs of Severe Sepsis presentation	
30 mL/kg Crystalloid Fluids Started	N/A	N/A	Yes	Completed within 3-hrs of initial hypotension and/or septic shock
Vasopressor Given (if hypotension persists)	N/A	N/A	Completed within 6-hrs of septic shock	Yes
Repeat Volume Status Assessment	N/A	N/A		Yes

SEP-1 Benchmark Report

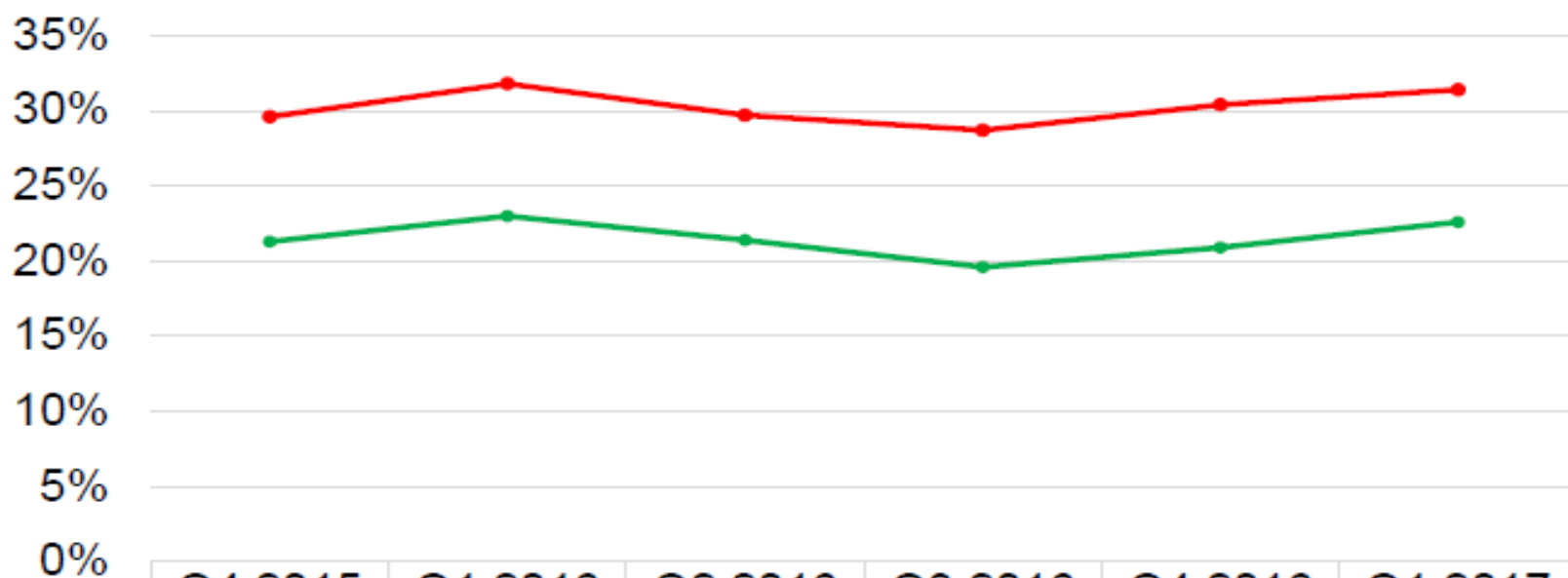
SEP-1: Early Management Bundle, Severe Sepsis/Septic Shock
Overall Performance



Breakdown of SEP-1: Overall Performance for Eligible Population



SEP-1 Mortality Rate Trend* for Eligible Population



	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017
Delta	8.3%	8.8%	8.3%	9.1%	9.5%	8.8%
Passed	21.3%	23.0%	21.4%	19.6%	20.9%	22.6%
Did Not Pass	29.6%	31.8%	29.7%	28.7%	30.4%	31.4%
	(v5.0b)	(v5.0b)	(v5.0b)	(v5.1)	(v5.1)	(v5.2a)

*Mortality analysis is limited to Medicare patients. Results of analysis are not risk-adjusted.
Differences in mortality rates are statistically significant.

CMS Current and Future Plans

- Ongoing evaluation of sepsis literature to inform measure updates as necessary
- Formation of an Expert Workgroup through CMS' measure support contractor
- Ongoing sepsis webinars
- Collaborating with other Agencies on sepsis
- CMS is tackling sepsis in post-acute care settings and is developing a measure for early detection and treatment of healthcare-associated infections.
- CMS is removing barriers to developing new antimicrobial therapies to treat drug-resistant infections.

Sepsis Hospital Outcome Measure

- CMS has convened a Technical Expert Panel to evaluate feasibility of developing a sepsis outcome measure in hospital setting
- This effort is in line with CMS's goals to prioritize measures that are outcome focused and focusing on metrics that matter most to patients

Meaningful Measures 1.0



● Promote Effective Communication & Coordination of Care

Meaningful Measure Areas:

- Medication Management
- Admissions and Readmissions to Hospitals
- Transfer of Health Information and Interoperability

● Promote Effective Prevention & Treatment of Chronic Disease

Meaningful Measure Areas:

- Preventive Care
- Management of Chronic Conditions
- Prevention, Treatment, and Management of Mental Health
- Prevention and Treatment of Opioid and Substance Use Disorders
- Risk Adjusted Mortality

● Work with Communities to Promote Best Practices of Healthy Living

Meaningful Measure Areas:

- Equity of Care
- Community Engagement

● Make Care Affordable

Meaningful Measure Areas:

- Appropriate Use of Healthcare
- Patient-focused Episode of Care
- Risk Adjusted Total Cost of Care

● Make Care Safer by Reducing Harm Caused in the Delivery of Care

Meaningful Measure Areas:

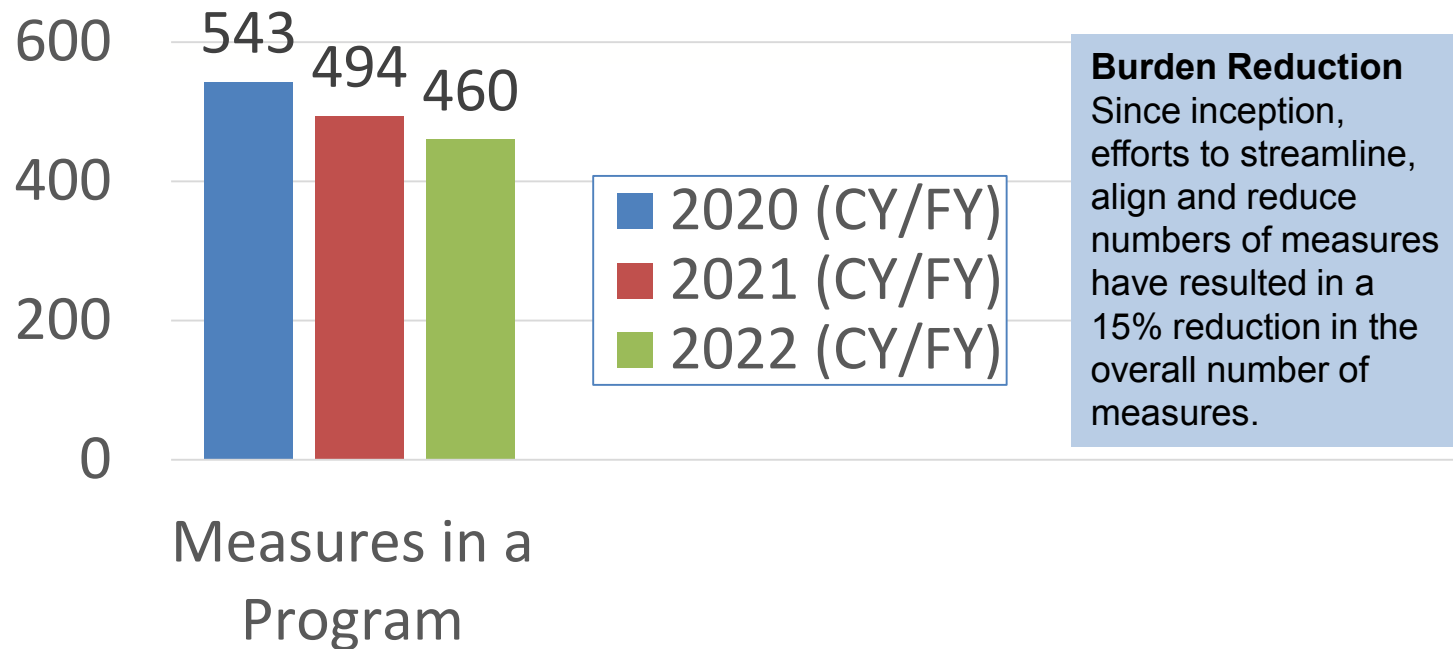
- Healthcare-associated Infections
- Preventable Healthcare Harm

● Strengthen Person & Family Engagement as Partners in their Care

Meaningful Measure Areas:

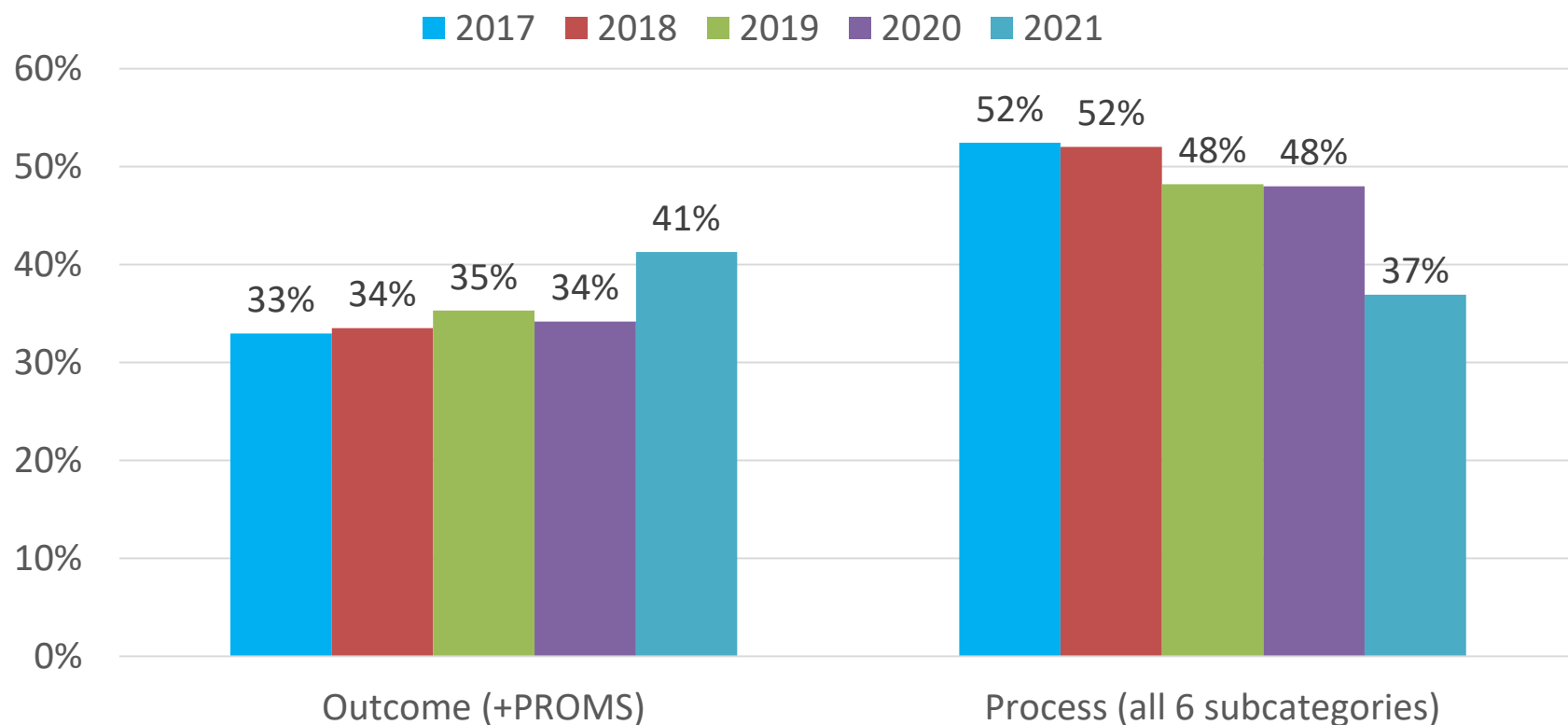
- Care is Personalized and Aligned with Patient's Goals
- End of Life Care according to Preferences
- Patient's Experience of Care
- Functional Outcomes

Meaningful Measures 1.0 - Accomplishments



Meaningful Measures 1.0 - Accomplishments

Changes in Outcomes and Process Measures for ALL Programs



Improved Portfolio

Outcome measures increased almost 25% across programs and the percentage of process measures has dropped from 52% in 2017 to 37% in 2021.



Meaningful Measures 2.0

Goals of MM 2.0

Utilize only quality measures of highest value and impact focused on key quality domains

Align measures across value-based programs and across partners, including CMS, federal and private entities

Engage patients through transparency, patient centered measures, and patient reported outcomes

Transform measures to fully-digital by 2030, and incorporate all-payer data

Develop and implement measures that reflect social and economic determinants



Current Alignment Initiatives Across Stakeholders

- Alignment within CMS (across Centers – CCSQ, CM, CMCS, CCIIO, CMMI)
- Alignment across Federal Government
- Alignment through consensus (NQF)
- Alignment with other payers and others – Core Quality Measures Collaborative (AHIP/NQF/CMS)
- Alignment with measure developers – some already piloting their measures as electronic (NCQA)



Final Thoughts on Sepsis

CMS is

- committed to improving the care of patients with severe sepsis and septic shock
- committed to reducing mortality associated with severe sepsis and septic shock
- committed to improving the SEP-1 measure and implementing measure updates as appropriate, necessary, and based on empirical evidence
- committed to working with clinicians, stakeholders, and the public to raise awareness about sepsis

How to contact CMS

- Please submit questions about sepsis [via the Question and Answer page](#) available on www.QualityNet.org.
- Sepsis Webinars: 3-4 times a year. Information available on www.QualityNet.org

Email: reena.duseja@cms.hhs.gov



Runa Gokhale, MD, MPH

Medical Officer, Centers for Disease Control and Prevention (CDC) Division
of Healthcare Quality Promotion





Working Together to Make an Impact on Sepsis: The Role of CDC

CDR Runa Hatti Gokhale, MD, MPH
Medical Officer
Division of Healthcare Quality Promotion

October 1, 2020

Speaker Disclosures

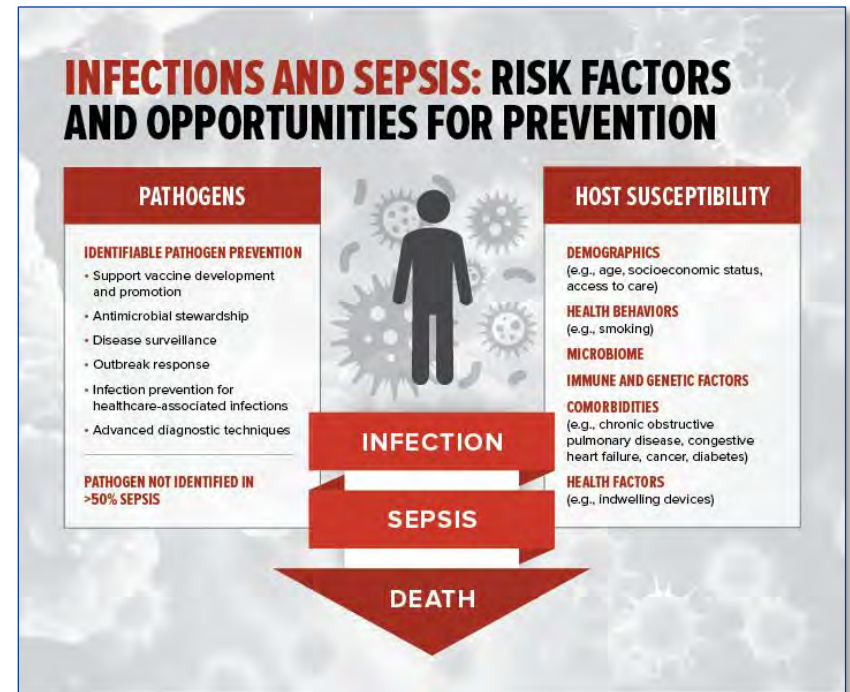
The speaker has no financial relationships or disclosures.

The conclusions in this talk are the speaker's and do not necessarily represent the Centers for Disease Control and Prevention.

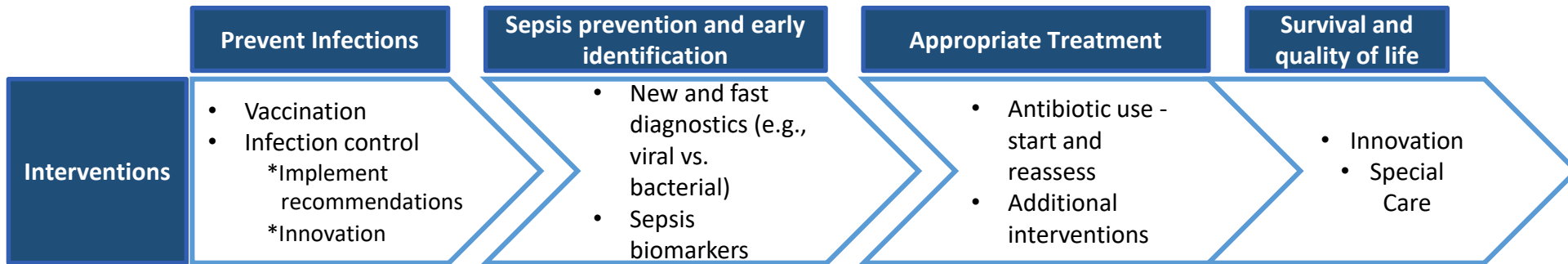


A public health perspective on sepsis

- **Prevention:** Sepsis prevention opportunities span the continuum of care and merge existing infection prevention strategies with chronic disease management and improved education.¹



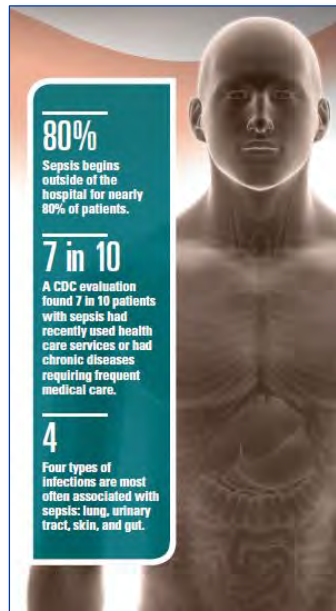
Thinking Holistically to Protect Patients



CDC priority activities for reducing the impact of sepsis

- Data
 - Describe national sepsis epidemiology and document national sepsis trends in adults and children
 - Optimize surveillance definitions for sepsis tracking and reduction
- Innovation
 - Establish and implement prevention strategies for reducing sepsis burden and mortality
- Education
 - Promote sepsis awareness and early recognition, as well as timely and appropriate antibiotic use in sepsis, among clinicians and the public
- Collaboration
 - Ensure that other public health efforts, such as antimicrobial stewardship, do not conflict with sepsis care needs
 - Promote and expand the reach of CDC sepsis activities through strategic partnerships and ongoing promotion

Estimating sepsis burden, characterizing those at higher risk, and identifying intervention access points



- Most patients had:
 - Sepsis onset outside the hospital
 - Recent encounters with the healthcare system

Research

JAMA | Original Investigation

Incidence and Trends of Sepsis in US Hospitals Using Clinical vs Claims Data, 2009-2014

Chanu Rhee, MD, MPH; Raymund Dantes, MD, MPH; Lauren Epstein, MD, MS; David J. Murphy, MD, PhD; Christopher W. Seymour, MD, MSc; Theodore J. Iwashyna, MD, PhD; Sameer S. Kadri, MD, MS; Derek C. Angus, MD, MPH; Robert L. Danner, MD; Anthony E. Fiore, MD, MPH; John A. Jernigan, MD, MS; Greg S. Martin, MD, MSc; Edward Septimus, MD; David K. Warren, MD, MPH; Anita Karcz, MD, MBA; Christina Chan, MPH; John T. Menchaca, BA; Rui Wang, PhD; Susan Gruber, PhD; Michael Klompas, MD, MPH; for the CDC Prevention Epicenter Program

- Estimated 1.7 million cases of sepsis among adult patients and nearly 270,000 deaths
- Sepsis was present in nearly 1/3 of all hospitalizations that culminated in death

JAMA Network | Open.

Original Investigation | Public Health

Assessment of Health Care Exposures and Outcomes in Adult Patients With Sepsis and Septic Shock

Katherine Fay, MD; Mathew R. P. Sapiano, PhD; Runa Gokhale, MD; Raymund Dantes, MD; Nicola Thompson, PhD; David E. Katz, MD; Susan M. Ray, MD; Lucy E. Wilson, MD; Rebecca Perlmutter, MPH; Joelle Nadle, MPH; Deborah Godine, RN; Linda Frank, BSN; Geoff Brousseau, MPH; Helen Johnston, MPH; Wendy Bamberg, MD; Ghinwa Dumyati, MD; Deborah Nielson, MSN; Ruth Lynfield, MD; Malini DeSilva, MD; Marion Kainer, MBBS; Alexia Zhang, MPH; Valerie Ocampo, MPH; Monika Samper, BS; Rebecca Pierce, PhD; Lourdes Irizarry, MD; Marla Sievers, MPH; Meghan Maloney, MPH; Anthony Fiore, MD; Shelley S. Magill, MD, PhD; Lauren Epstein, MD

Networks and partners for surveillance, research, implementation, evaluation, and innovation

Prevention Epicenters

Estimated Prevention Epicenters National Reach

333

healthcare facilities

2.6 million

hospital admissions

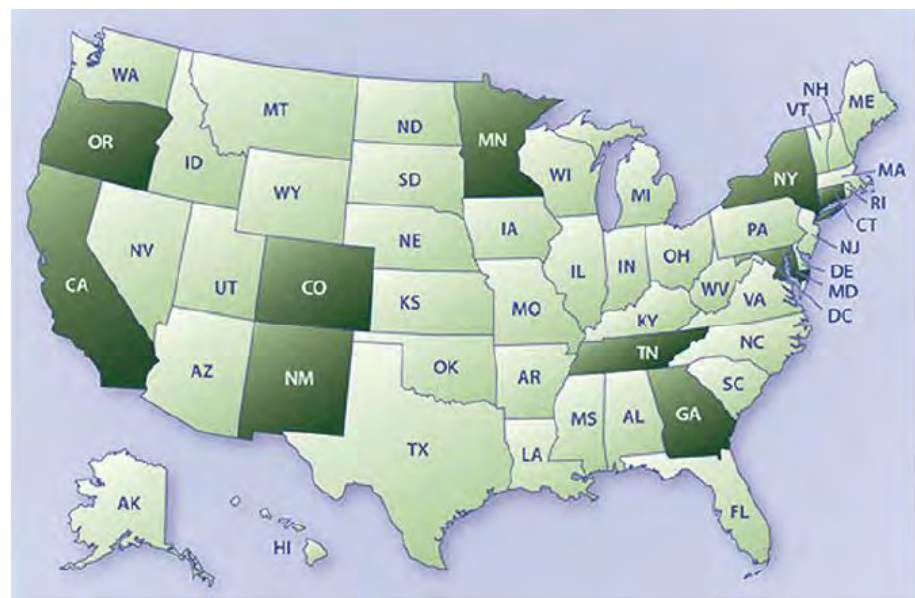
1.5 million

unique patients per year

Locations



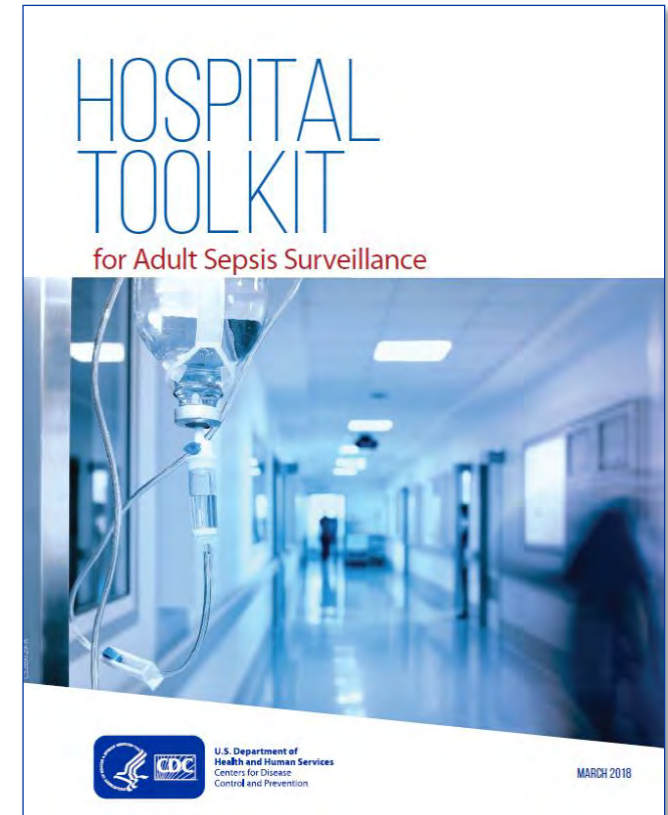
Emerging Infections Program (EIP)



10 EIP States

The CDC Sepsis Surveillance Toolkit Helps Hospitals Track Outcomes

- Enables healthcare professionals who are interested in tracking healthcare facility-level sepsis incidence and outcomes using an objective definition based on clinical data
- Data may be obtained and processed directly from an electronic health record, but could also be obtained using manual chart review
- Data are useful for understanding the effectiveness of local sepsis prevention, early recognition, and treatment programs



Get Ahead of Sepsis (GAOS) educational effort

**GET AHEAD
OF SEPSIS**

KNOW THE RISKS. SPOT THE SIGNS. ACT FAST.

- In September 2017, in conjunction with Sepsis Awareness Month, CDC launched **Get Ahead of Sepsis (GAOS)**, a national educational effort to protect Americans from the devastating effects of sepsis. This initiative emphasizes the importance of early recognition and timely treatment of sepsis, as well as the importance of preventing infections that can lead to sepsis.
- **Target audiences:** Consumers and healthcare professionals
- **Results (September 2017-July 2020):**
 - **376+ million** reached via **7** public service announcements (PSAs)
 - **42+ million** reached via paid media with **538,000+** URL clicks on paid ads
 - **12+ million** organic social media engagements

Materials



Paid Ads



DHQP supports efforts to improve sepsis prevention and patient outcomes internationally

- India neonatal sepsis prevention collaboration with Johns Hopkins
 - Measure and reduce neonatal sepsis
- South Africa NICU sepsis prevention
 - Collaboration with Ohio State University, ICAN, Bara hospital, and Gates Foundation
 - Multi-modal strategy to reduce neonatal sepsis including IPC and pharmacy targeted interventions
- Vietnam
 - Multi-site program (adult and neonatal) to reduce bloodstream infections involving quality improvement approaches
 - Collaboration with MOH, PATH, local hospitals
- WHO collaboration
 - CDC participated in development of WHO's first Global Report on the Epidemiology and Burden of Sepsis, released at the World Sepsis Congress Spotlight: Sepsis, Pandemics, and Antimicrobial Resistance – Global Health Threats of the 21st Century on September 9, 2020.

Increasing impact and integrating sepsis into agency priorities

- Integrate sepsis and other CDC priorities, including:
 - COVID-19
 - Combatting antibiotic resistance
 - Antibiotic stewardship
 - Influenza prevention
 - Hand hygiene
 - Chronic conditions
 - Cancer
 - Vaccines
 - Maternal health
- Integrate sepsis early recognition and management to routine clinical practices
- Integrate sepsis programs with other federal and local programs (e.g., HIINs, stewardship)
- Integrate sepsis plans with other federal, state, and local plans

Sepsis and COVID-19

- Sepsis can be a complication of COVID-19 infection
- Patients with severe infections or sepsis may have avoided seeking timely care due to fear of COVID-19



Emergency department **visits declined 41%-64%** from January to April 2020¹ and **42% year over year**²

1. Jeffery, M. M., et al. (2020). "Trends in Emergency Department Visits and Hospital Admissions in Health Care Systems in 5 States in the First Months of the COVID-19 Pandemic in the US." *JAMA Intern Med*.

2. Hartnett KP, Kite-Powell A, DeVies J, et al. Impact of the COVID-19 Pandemic on Emergency Department Visits — United States, January 1, 2019–May 30, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:699–704. DOI: <http://dx.doi.org/10.15585/mmwr.mm6923e1external icon>

Sepsis and COVID-19

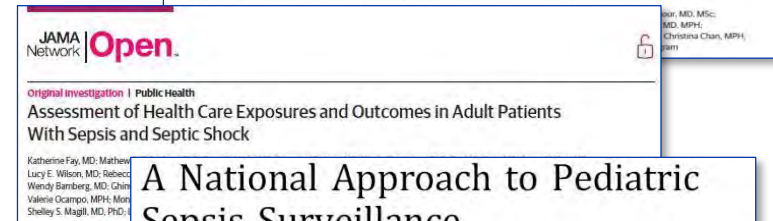
COVID-19 has “unmasked” several challenges and highlighted opportunities for improvement:

- Gaps in delivery of care
 - Across healthcare delivery system
 - Need to integrate sepsis early detection and management in all settings
 - Approach tailored to all patients and settings
- Health equity and access
- Early detection
 - Diagnostic testing
 - Innovation
- Infection prevention and control

CDC's Division of Health Care Quality Promotion ongoing sepsis work

- Understanding the epidemiology of sepsis
- Developing tools for tracking sepsis
- Working with partners including the CDC Prevention Epicenters, and other Federal agencies
- Promoting early recognition and timely treatment of sepsis
- Encourage infection prevention through infection control, vaccination programs, chronic disease management, and appropriate antibiotic use
- Preventing infections in health care settings and in the community

Epidemiology
of sepsis



A National Approach to Pediatric Sepsis Surveillance

Heather E. Hsu, MD, MPH,* Francisca Abanyie, MD, MPH,* Michael Patrick W. Brady, MD, MSc,* Richard J. Brilli, MD, FAAP, MCCM,* Lauren Epstein, MD, MSc,* Anthony E. Fiore, MD, MPH,* Jeffrey ... MD, FRCP(C), ... D, MPH,* Karen ... MPH*



Partners

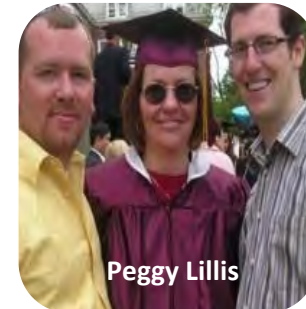
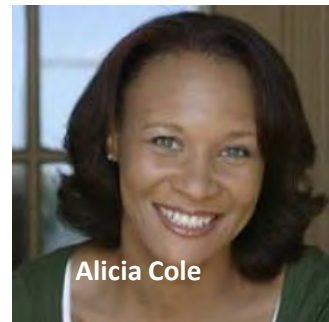
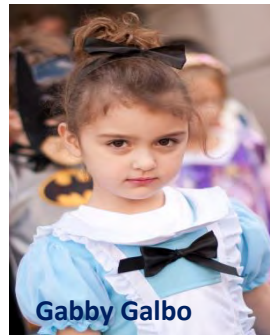


Tools

Sepsis is a priority for the U.S. Department of Health and Human Services (HHS)

- HHS is committed to preventing severe illness and deaths caused by infections (sepsis)
- Many HHS agencies and programs contribute to shared sepsis goals, including ASPR, CDC, CMS, FDA, and NIH, and others
- CDC's unique contributions include subject matter expertise from:
 - Epidemiologists, clinicians, infection preventionists, statisticians, modelers, microbiologists, environmental health specialists, health communications experts, and more
 - Established partnering with medical professional organizations, healthcare systems, patient safety advocates, and local/state public health

Protecting patients from sepsis is our goal and our responsibility



And millions more...



Question & Answer

Moderator: Hallie Prescott, MD, MSc



Break



Post-Hospital Management





Hallie Prescott, MD, MSc

Professor of Internal Medicine, Pulmonary & Critical Care at Michigan Medicine

Vice chair of the Surviving Sepsis Campaign Guidelines & council member of the



Enhancing Recovery from Sepsis

Hallie Prescott, MD, MSc

Associate Professor of Internal Medicine,
Pulmonary & Critical Care at Michigan Medicine
HMS Sepsis Physician Lead



Outline

Longer-term sequelae of sepsis

Longer-term sequelae of COVID-19

Recommended practices across the continuum

Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study

Kristina E Rudd, Sarah Charlotte Johnson, Kareha M Agesa, Katya Anne Shackelford, Derrick Tsoi, Daniel Rhodes Kievlan, Danny V Colombara, Kevin S Ikuta, Niranjan Kissoon, Simon Finfer, Carolin Fleischmann-Struzek, Flavia R Machado, Konrad K Reinhart, Kathryn Rowan, Christopher W Seymour, R Scott Watson, T Eoin West, Fatima Marinho, Simon I Hay, Rafael Lozano, Alan D Lopez, Derek C Angus, Christopher J L Murray, Mohsen Naghavi



An estimated **37.9 million** patients survive hospitalization for (severe) sepsis each year.

48.9 million cases

11 million deaths

An estimated **29,000** Michiganders survive hospitalization for (severe) sepsis each year.

Discharge Disposition	Percent
Expired or did not recover in the hospital	10.3%
Hospice – Medical facility	5.4%
Hospice - Home	2.8%
Died or discharged to hospice	18.5%



Sepsis was once considered an acute disease with rare long-term sequelae.

Interview with an ICU trialist, 2004

Is there a residue in sepsis survivors who have had multi-organ failures or dysfunctions?

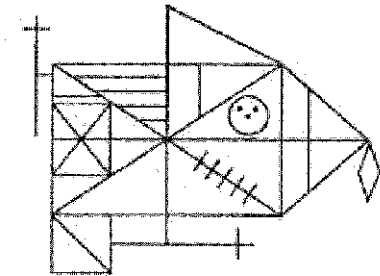
Interview with an ICU trialist, 2004

Is there a residue in sepsis survivors who have had multi-organ failures or dysfunctions?

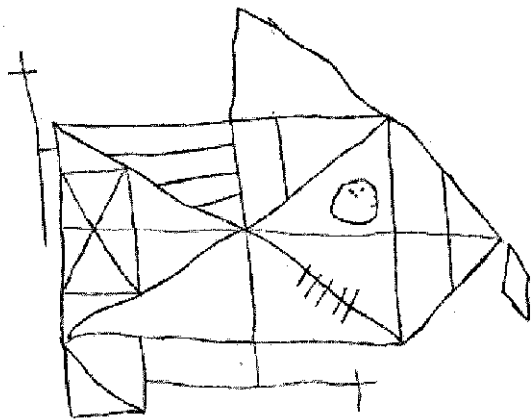
“Most people return to normal or near-normal lives even if they have had severe organ failures...”

Most surviving patients come back to being normal.”

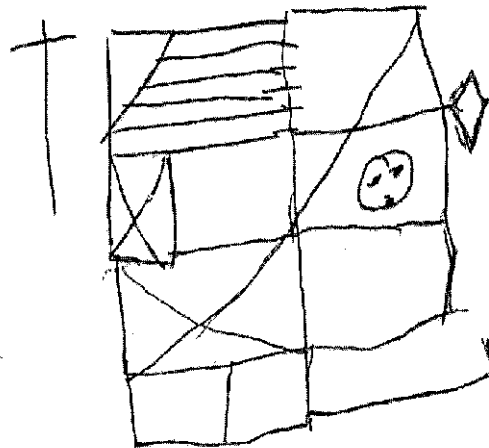
Early cohorts hinted at a problem



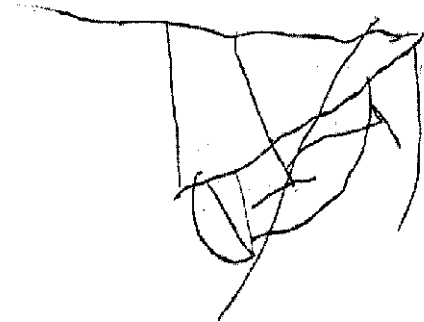
asked to copy above picture, results below:



Near normal rendition by unimpaired 69 y/o pulmonary embolus survivor



Moderate to severely impaired 89 y/o Pneumonia survivor



Severely impaired 72 y/o ARDS survivor

Long-term Cognitive Impairment and Functional Disability Among Survivors of Severe Sepsis

In national sample with baseline measurement,
new and persistent disability is common after sepsis.

Editorial

October 27, 2010

The Lingering Consequences of Sepsis

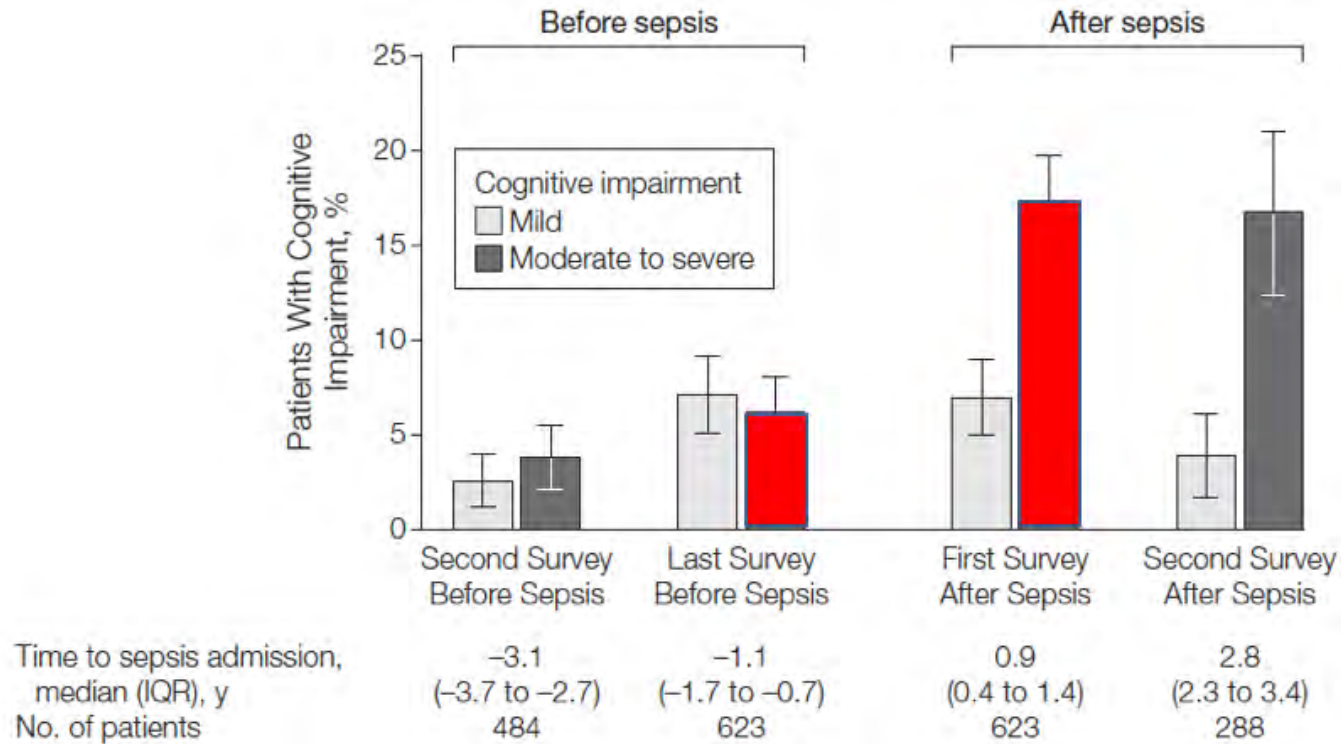
A Hidden Public Health Disaster?

Derek C. Angus, MD, MPH

JAMA. 2010;304(16):1833-1834. doi:10.1001/jama.2010.1546

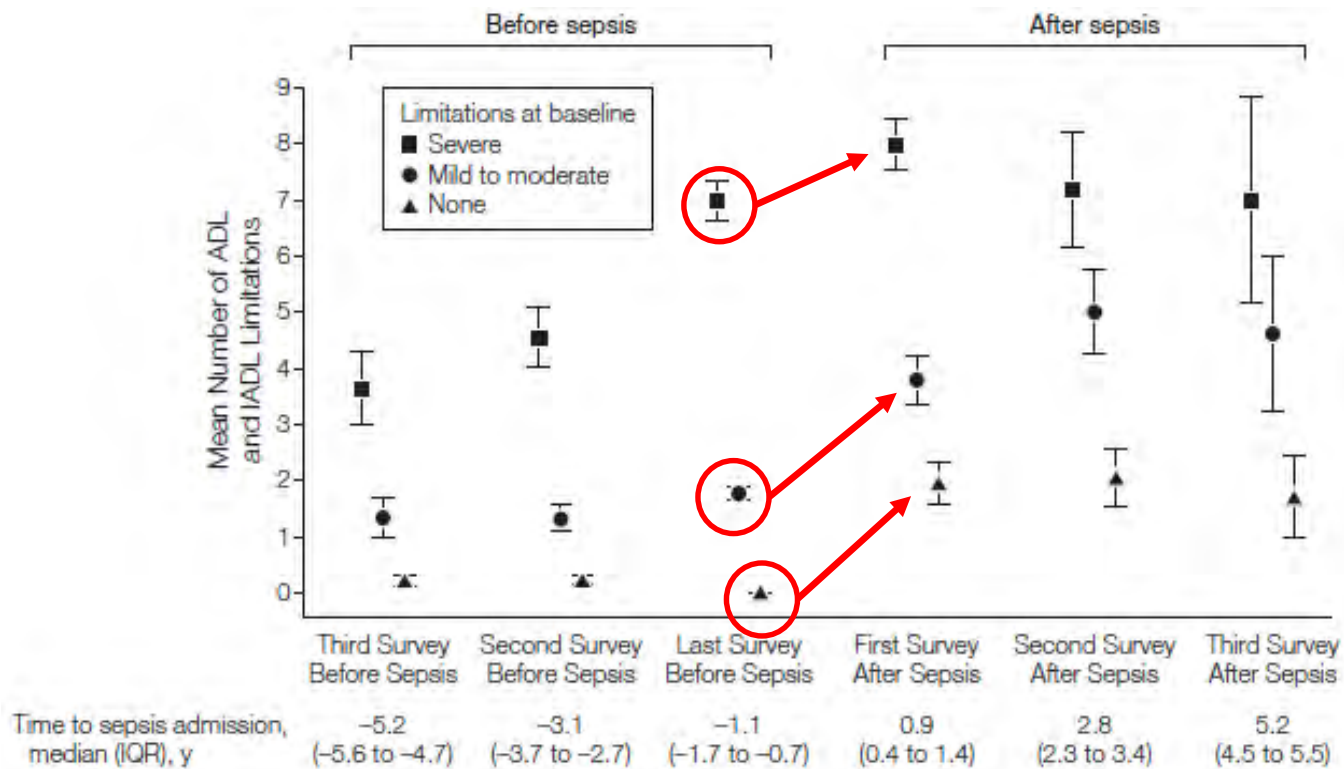
Moderate-Severe Cognitive Impairment

- 6% → 17%
- 3.5-fold increased odds



Functional Disability

- 1-2 new limitations



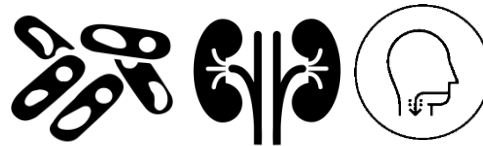
New and lasting morbidity is common after sepsis



3-fold increase in
mod-severe
cognitive impairment



1-2 new
functional
limitations
(ADLs)



Increased risk of re-hospitalization
for recurrent sepsis, acute kidney
injury, and aspiration

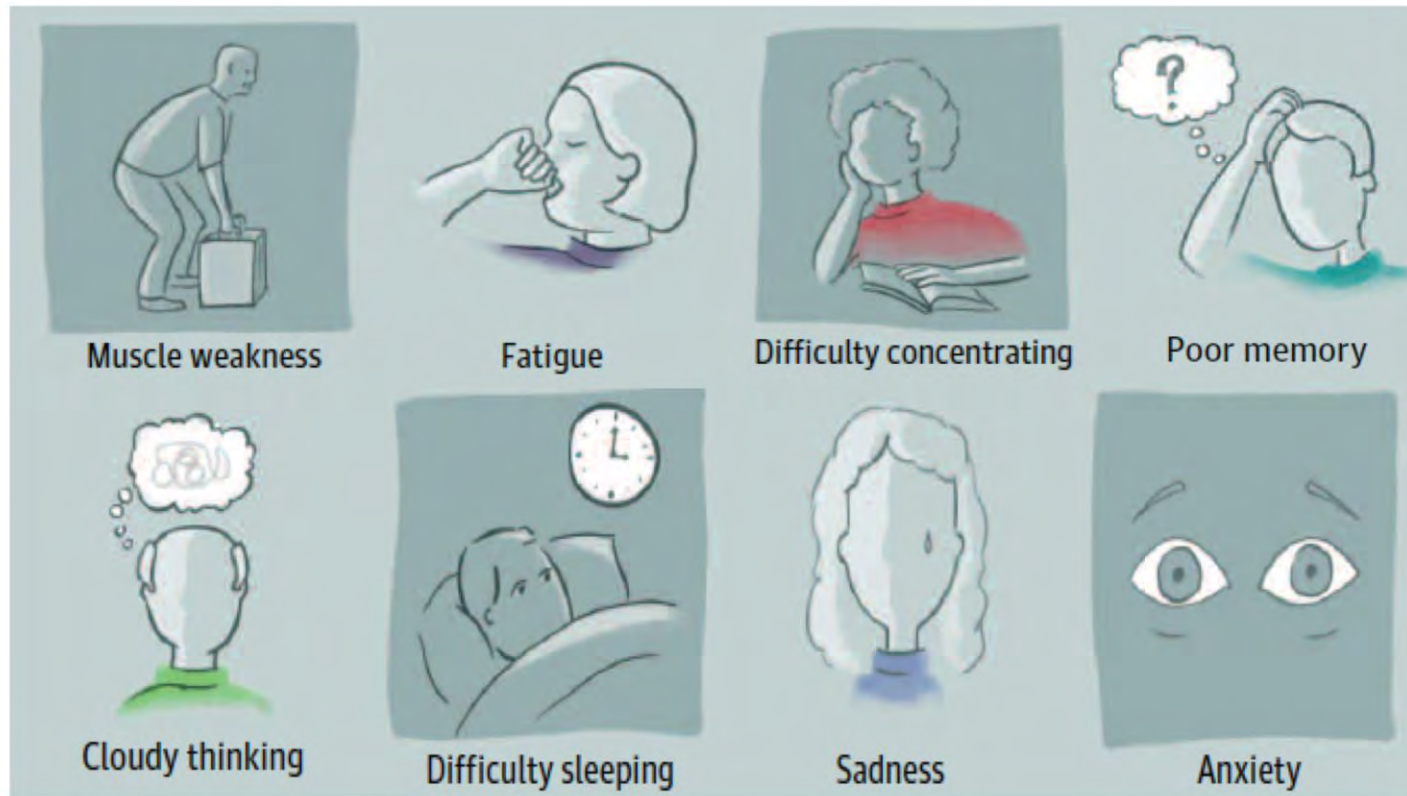


1 in 5 with late death
not explained by
pre-sepsis health status

55% of previously employed patients
return to work within 6 months

Iwashyna, *et al. JAMA*, 2010.
Shah, *et al. AJRCCM*, 2013.
Yende, *et al. AJRCCM*, 2014.
Prescott, *et al. JAMA*, 2015.
Shen, *et al. Crit Care Med*, 2016.
Ou, *et al. AJRCCM*, 2016.
Prescott, *et al. BMJ*, 2016.
McPeake, *et al. AnnalsATS*, 2019.

Milder sequelae are even more common



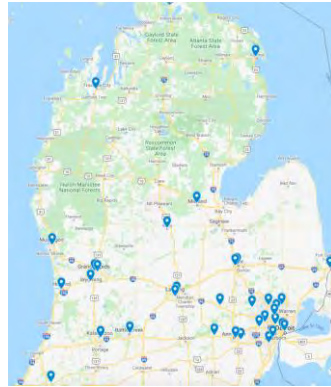
Recovery From Severe COVID-19

Leveraging the Lessons of Survival From Sepsis

Little is known

Sequelae are anticipated to be similar

Higher severity since normal care processes are disrupted



38 Hospital Sample

N=488 patients completed 60d
telephone follow-up

- ~7% post-discharge mortality (day 0-60 post-discharge)
- 60% of previously employed patients were back to work.
- 40% unable to resume prior activities
- 25% “emotionally impacted” by COVID-19 hospitalization
- 4% self-reported cognitive issues (9% in ICU-treated)
- 35% financially impacted (12% used up all savings)

JAMA | Review

Enhancing Recovery From Sepsis A Review

Hallie C. Prescott, MD, MSc; Derek C. Angus, MD, MPH



Early Hospital Care



Towards
Discharge



After Discharge



Early Hospital Care

Timely antibiotics, resuscitation, source control
Pain, agitation, delirium management
Early mobility



Towards Discharge

De-escalation and De-resuscitation
Prepare patients about what to expect
Reconcile and titrate discharge medications



After Discharge

Promote ongoing functional recovery
Focus on “Big 5” causes of preventable readmission
Peer support
Care alignment

Association between Adherence to Recommended Care and Outcomes for Adult Survivors of Sepsis

Stephanie Parks Taylor¹, Shih-Hsiung Chou², Marielys Figueroa Sierra¹, Thomas P. Shuman¹, Andrew D. McWilliams^{1,2,3}, Brice T. Taylor^{1,4}, Mark Russo⁵, Susan L. Evans⁶, Whitney Rossman², Stephanie Murphy³, Kyle Cunningham⁶, and Marc A. Kowalkowski²

Population: 189 sepsis survivors

Exposure:

- 62% had medications optimized

- 65% had screening for new impairments

- 46% were monitored for common/preventable causes of health deterioration

- 58% had care alignment processes documented

- Only 11% got all 4 practices**

Outcomes. Receipt of these recommended practices was associated with lower odds of rehospitalization or death

Structured, proactive care coordination versus usual care for Improving Morbidity during Post-Acute Care Transitions for Sepsis (IMPACTS): a pragmatic, randomized controlled trial



Marc Kowalkowski^{1*} , Shih-Hsiung Chou¹, Andrew McWilliams^{1,2}, Cathryn Lashley³, Stephanie Murphy⁴, Whitney Rossman¹, Alfred Papali⁵, Alan Heffner⁶, Mark Russo⁷, Larry Burke⁸, Michael Gibbs⁶, Stephanie P. Taylor² and On behalf of Atrium Health ACORN Investigators

Patients 706 patients with sepsis at 10 US hospitals

Intervention centrally located nurse navigator support to facilitate best-practice post-sepsis care strategies for patients during + after hospitalization

Summary

New and lasting morbidity is common after sepsis

Similar sequelae are anticipated after severe COVID-19

Recommended practices are associated with improved outcomes

Focus should be on the delivery of best supportive care



Jake McSparron, MD

Assistant Professor of Internal Medicine, Pulmonary & Critical Care at
Michigan Medicine



Life after the ICU: How To Manage Post-ICU Care

Jakob I. McSparron

Associate Professor of Internal Medicine,
Associate Director, Critical Care Medicine Unit
Director, UM-PULSE Clinic



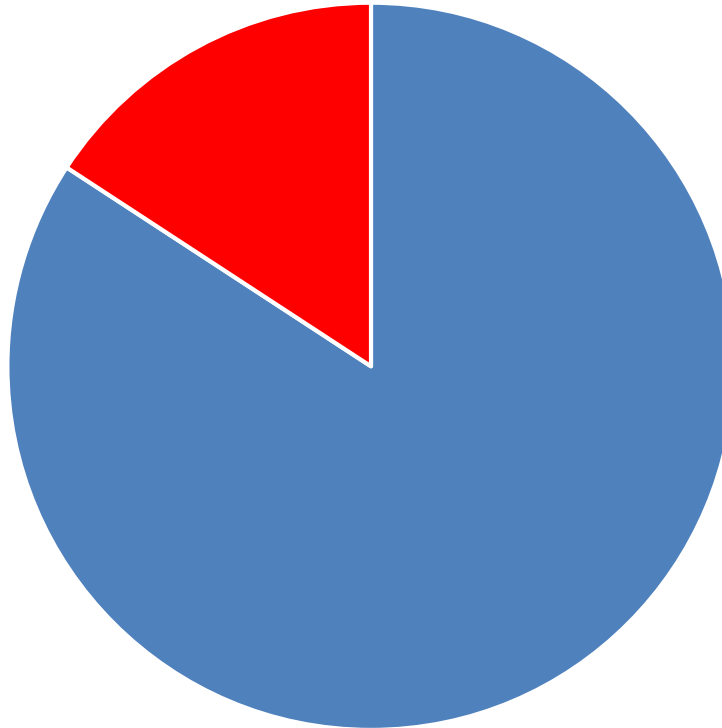
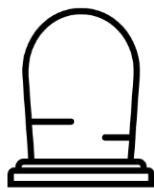
Disclosures

- None

Objectives

- Define Post-intensive Care Syndrome (PICS)
- Describe strategies to prevent PICS
- Review strategies to manage PICS
 - ICU follow-up clinic

More patients are surviving critical illness



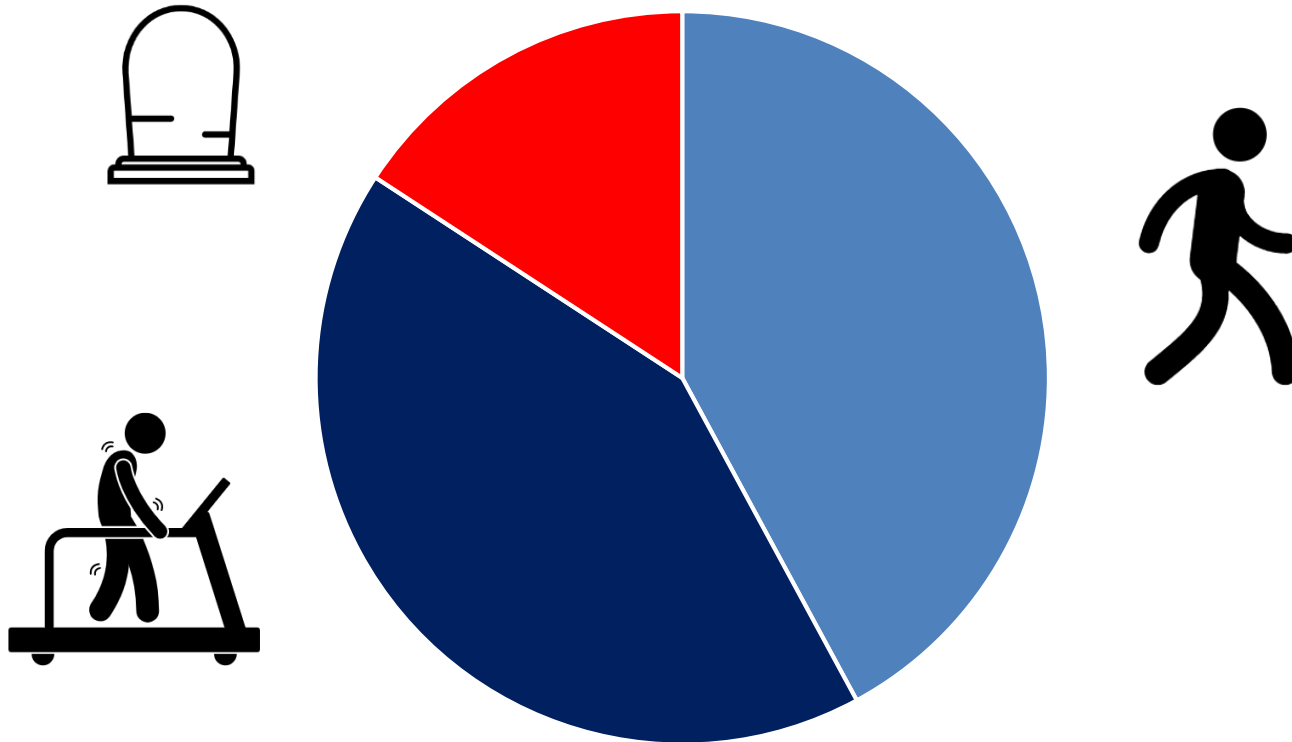
Case 1

- 59F critical care nurse admitted to hospital with sepsis due to group C strep bacteremia
- C7-T1 discitis/osteomyelitis
- Discharged after 8 days
- 3 months after discharge: severe fatigue, pain in shoulder, insomnia, nightmares, anxiety, inability to be in public places, and inability to work due to difficulty concentrating and severe anxiety
- 8 months after discharge: fatigue and pain much improved, ongoing anxiety about being in public, not yet working due to ongoing difficulty focusing and anxiety

Case 2

- 46M with HIV, EtOH abuse, depression admitted to hospital with variceal hemorrhage
- Course complicated by hypoxemic respiratory failure and septic shock due to pneumonia, DVTs, encephalopathy
 - ICU: 21 days
 - Hospital: 31 days
- 2 weeks after discharge: severe shoulder pain, able to walk with walker, severe fatigue and dyspnea on exertion, unable to work due to pain and mobility limitations
- Not taking nadolol, no follow up EGD, no appointment with hepatology

More patients are surviving critical illness



Defining Post Intensive Care Syndrome

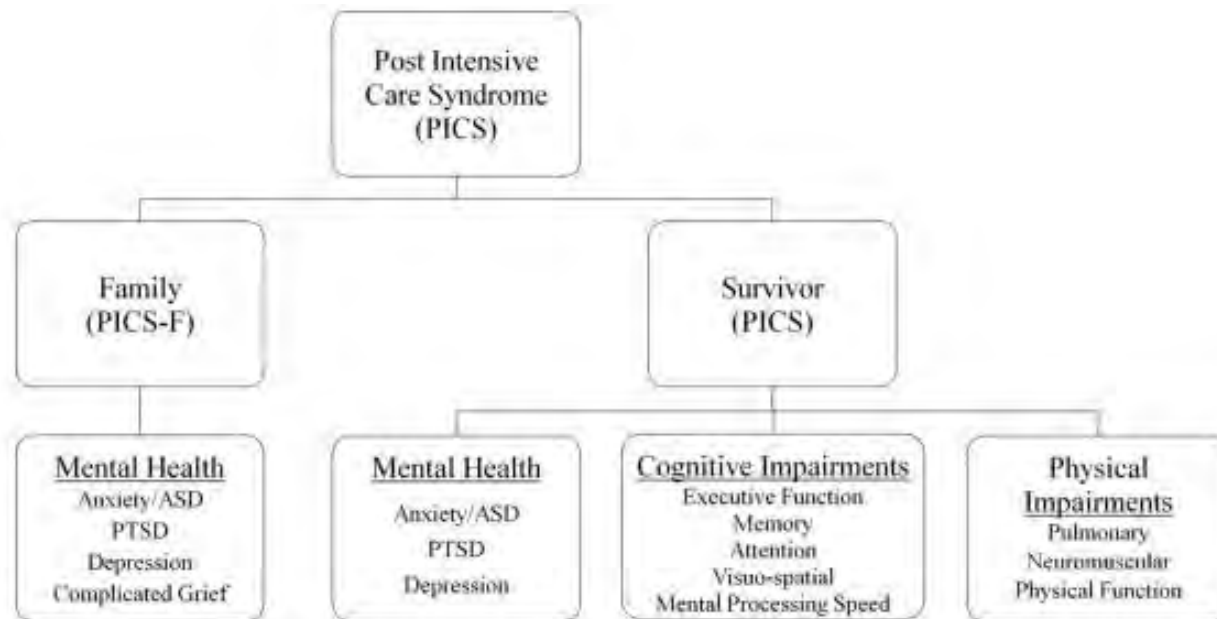
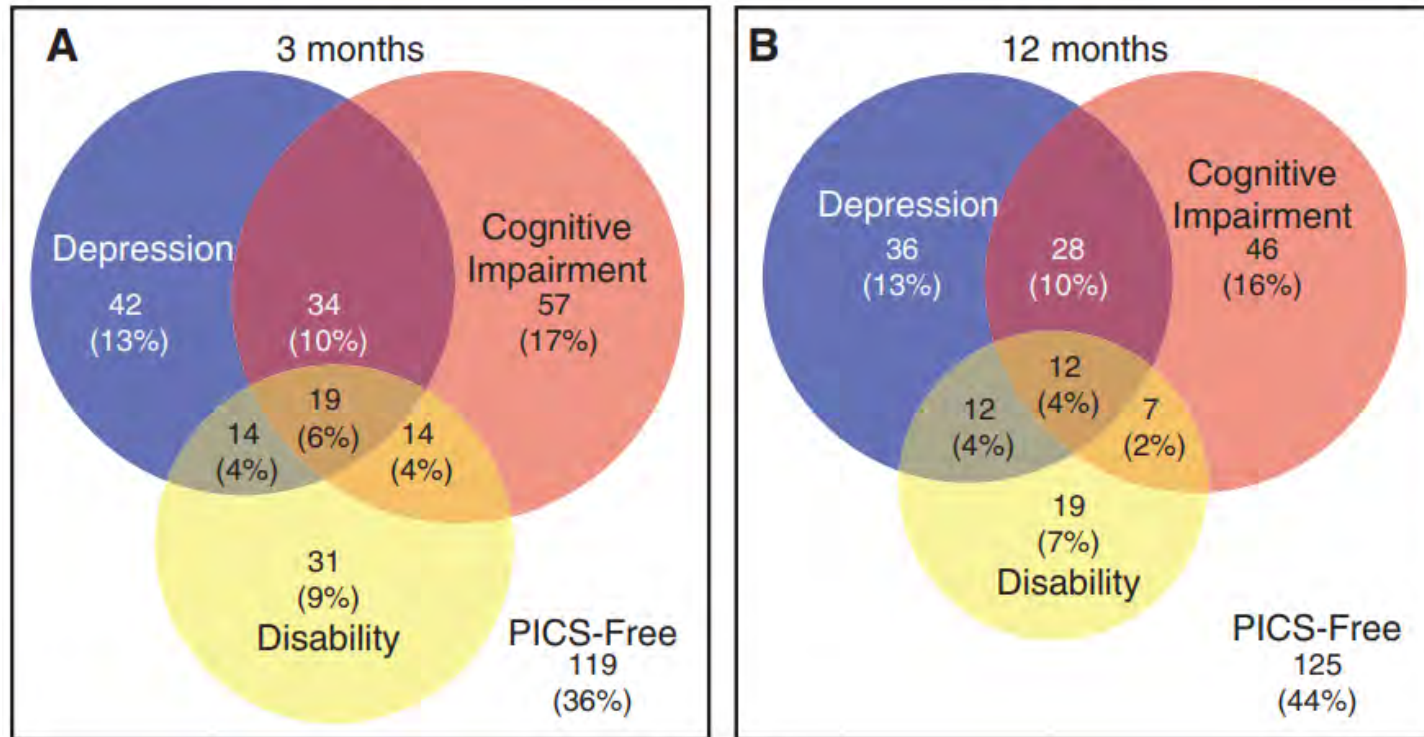


Figure 1. Postintensive care syndrome (PICS) conceptual diagram. *ASD*, acute stress disorder; *PTSD*, posttraumatic stress disorder.

Needham et al. Crit Care Med 2012

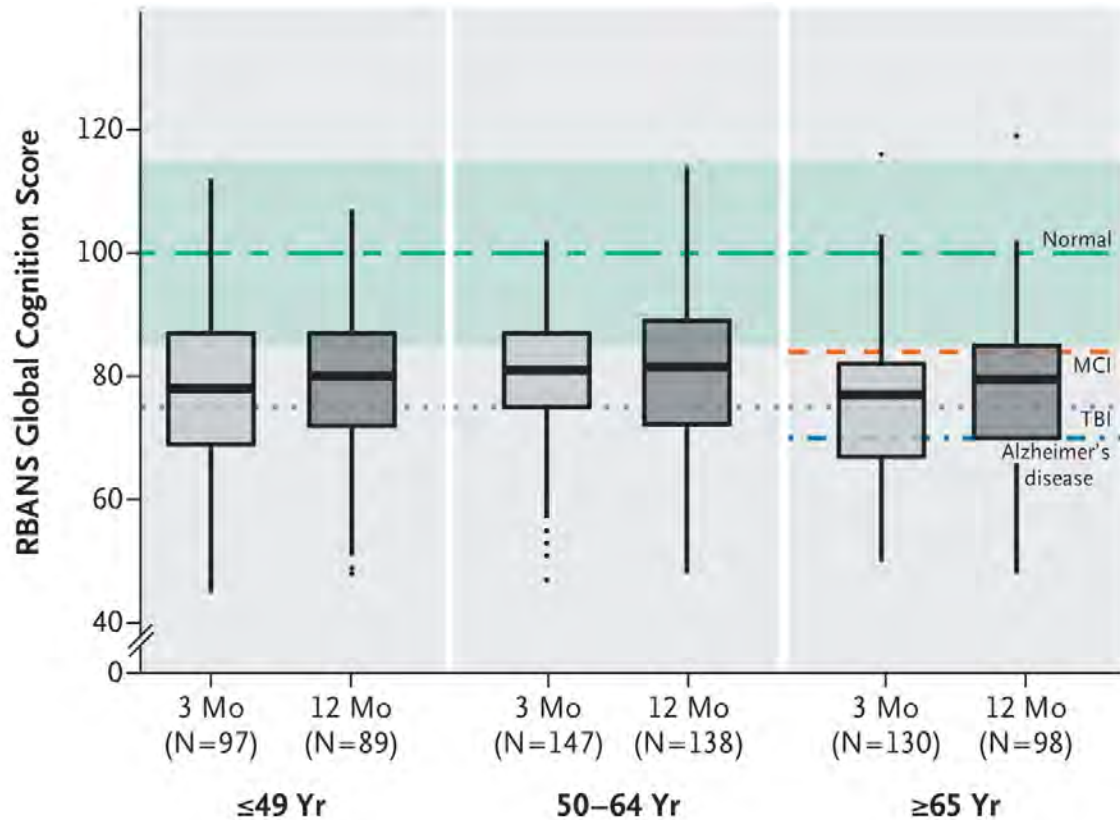
The majority of ICU survivors experience PICS



Marra et al. Crit Care Med 2018



Cognitive Deficits Persist



Pandharipande PP et al. N Engl J Med. 2013



Mobility issues and pain persist



Mobility

- 64% of survivors



Pain

- 73% with moderate / severe pain



ICU Acquired Weakness

- 25% of survivors

Griffiths et al. Crit Care. 2013; Jackson et al. Lancet Respir Med. 2014

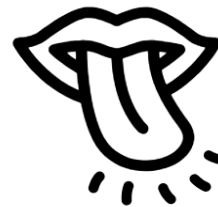
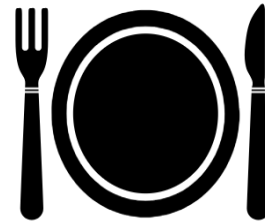


Psychiatric Illness is Common

	3 Months	12 Months
Depression	<ul style="list-style-type: none">- 30% (no history of depression)- 52% (history of depression)	<ul style="list-style-type: none">- 29% (no history of depression)- 43% (history of depression)
Post-Traumatic Stress Disorder	<ul style="list-style-type: none">- 7 %- 19-29% (symptoms of PTSD)	<ul style="list-style-type: none">- 7%- 19-28% (symptoms of PTSD)
Anxiety	<ul style="list-style-type: none">- 27-38%	<ul style="list-style-type: none">- 25-42%


Jackson JC et al. Lancet Respir Med. 2014
Nikayin, et al. Gen. Hosp. Psychiatry. 2016

Other manifestations of PICS



Prevention of PICS: Avoid Iatrogenic Harms

Symptoms Pain, Agitation, Delirium Guidelines	Monitoring Tools	Care ABCDEF Bundle
Pain	Critical-Care Pain Observation Tool (CPOT) NRS Numeric Rating Scale BPS Behavioral Pain Scale	A: Assess, Prevent and Manage Pain B: Both Spontaneous Awakening Trials (SAT) and Spontaneous Breathing Trials (SBT)
Agitation	Richmond Agitation- Sedation Scale (RASS) Sedation-Agitation Scale (SAS)	C: Choice of Analgesia and Sedation D: Delirium: Assess, Prevent and Manage
Delirium	Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) Intensive Care Delirium Screening Checklist (ICDSC)	E: Early Mobility and Exercise F: Family Engagement and Empowerment

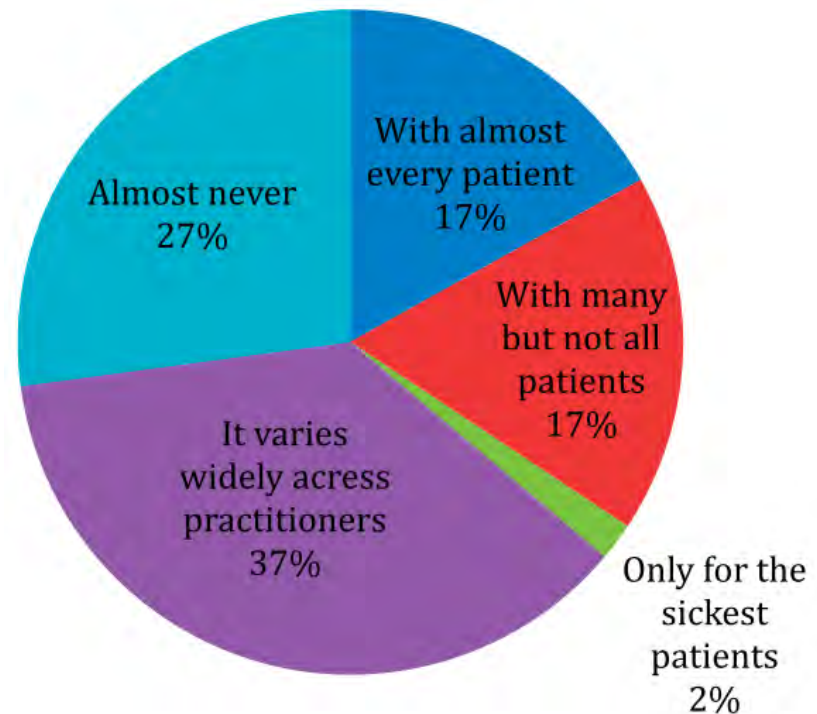
 Online Special Article

Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU

Girard, et al. Lancet. 2008
SCCM.org
Devlin, et al. Crit Care Med. 2018

Informing patients and caregivers about PICS

Do medical teams in your ICU have formal discussions with patients or family members regarding challenges and changes to their lives after ICU discharge?



Govindan, et al. Ann Am Thorac Soc. 2014

Recognition of PICS

- Maintain a high level of suspicion
- Screen all survivors of critical illness for cognitive, psychiatric, and physical manifestations of PICS



Treatment of PICS



Multiple Disciplines



Huggins EL et al. AACN Adv Crit Care. 2016

The evidence is limited...

Rehabilitation Interventions for Postintensive Care Syndrome: A Systematic Review*

Juliane Mehlhorn, MD¹; Antje Freytag, PhD¹; Konrad Schmidt, MD¹; Frank M. Brunkhorst, MD^{2,3}; Juergen Graf, MD⁴; Ute Troitzsch⁵; Peter Schlattmann, PhD⁶; Michel Wensing, PhD^{1,7}; Jochen Gensichen, MD, MPH, MSc¹

Conclusion: Interventions which have substantial effects in post-ICU patients are rare. Positive effects were seen for ICU-diary interventions for posttraumatic stress disorder. More interventions for the growing number of ICU survivors are needed. (*Crit Care Med* 2014; 42:1263–1271)

Melhorn, et al. Crit Care Med. 2016

Post ICU Clinics

Original Investigation | CARING FOR THE CRITICALLY ILL PATIENT

Effect of a Primary Care Management Intervention on Mental Health-Related Quality of Life Among Survivors of Sepsis

A Randomized

The PRaCTICaL study of nurse led, intensive care follow-up programmes for improving long term outcomes from critical illness: a pragmatic randomised controlled trial

EDITORIAL

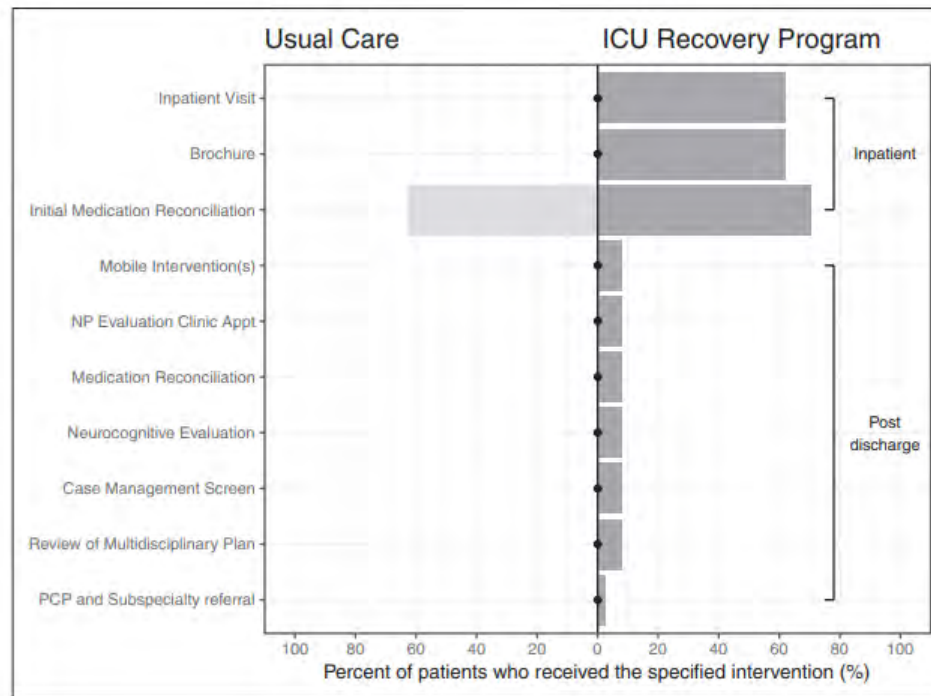
Should ICU clinicians follow patients after ICU discharge? Yes

Schmidt, et al. JAMA 2016
Cuthbertson, et al. BMJ 2009
Meyer, et al. Intensive Care Med 2018

Post ICU Clinics

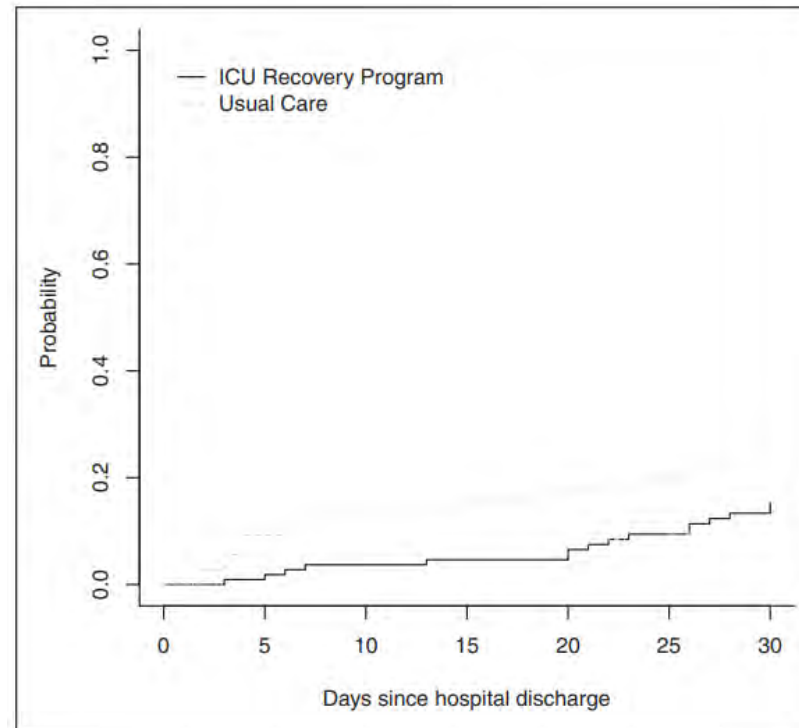
Randomized Clinical Program for Survivors

Sarah L. Bloom, AGACNP-BC¹
Li Wang, MS⁴; Daniel W. Byrne



Bloom, et al. Crit Care Med 2019

Post ICU Clinics



Bloom, et al. Crit Care Med 2019

Follow-up after ICU discharge has benefits for...

The patient	The family	The ICU staff	The organisation/ provider	Primary care physician	The economy/public health	Research
Safety netting and coordination of ongoing care...address omissions in care/FU (follow-up)/meds	Provide understanding and information	Realignment of purpose	Achieve NICE 83 and quality standard and GPICS	Improve ability to provide post-ICU care through info/support	Reduced reattendance/readmission to hospital and use of emergency services	Provides an environment in which to study survivorship/outcomes and recruit to studies
Provide information/knowledge	Signpost to resources and support	Contextualisation of daily efforts	(Guidelines for the provision of intensive care services) recommendations		More return to independence	
Contextualisation of life event	Expression of gratitude and emotional link to the unit	Reduce burnout/disillusionment	Improve pt and family experience		More return to work/gainful employment	
Improve HRQOL (Health-Related Quality of Life)		Learn, improve, humanise care	Quality agenda		Reduce carer burden	
Signpost to social and welfare benefits			Patient- and family-centred care			

Meyer, et al. Intensive Care Med 2018

University of Michigan Post ICU Longitudinal Survivor Experience (UM-PULSE)



CAIRO



One-Stop Shop: New Clinic Bundles Key Services After ICU Discharge

Rooted in research, a Michigan Medicine clinic aims to help intensive care unit patients receive proper follow-up care and prevent readmissions.



UM-PULSE

- Patients:

- Sepsis
- Shock
- Acute respiratory failure
- Delirium
- AKI

- Seen at 2 weeks and 6 months



- Spirometry, 6 min walk, grip strength

- Pharmacy consultation with comprehensive medication review

- Social work consultation with cognitive testing

- Physician clinical evaluation

- Wrap-up

Information Collected

As part of the visit, the patient also completed several standardized assessments. They reported:

- Trouble on 1 activities of daily living, on a scale of 0-11 (which is interpreted as lower = less difficulty).
- 44% on the WHO Disability Assessment Score 2.0, which is interpreted as a higher % means more difficulty.
- An Insomnia score of 16 which is interpreted as:
 - 0-7 = No clinically significant insomnia
 - 8-14 = Subthreshold insomnia
 - 15-21 = Clinical insomnia (moderate severity)
 - 22-28 = Clinical insomnia (severe)
- A PHQ-9 score of 23, which is potentially consistent with:
 - 1-4 Minimal depression
 - 5-9 Mild depression
 - 10-14 Moderate depression
 - 15-19 Moderately severe depression
 - 20-27 Severe depression
- An EQ-5D-5L score of 10, on a scale of 5 to 25 (which is interpreted as lower is better).
- A PTSS score of 48, on a scale of 14 to 98 (which is interpreted as lower is better).
- The patient's caregiver indicated an AD8 score of 4 which is interpreted as:
 - 0 - 1: Normal cognition
 - 2 or greater: Cognitive impairment is likely to be present

Safety Threats



Wrong wound care supplies, incorrect dosing of Wellbutrin.

Patient has not had cardiology follow up.

Patient is not safe to return to work as nurse ICU.

Patient not safe to return to work as a bus driver.

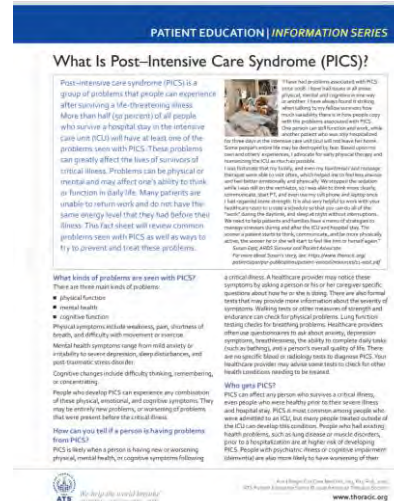
Unsafe use of natural supplements.

Not adherent to anticoagulation

Patient ability to function safely at home; unable to get to PT, follow up appts.

Falling on anticoagulation; hypotensive on multiple meds.

Resources



www.mycucare.org

Postsepsis Morbidity Page: Prescott and Angus, JAMA, 2018
Kosinski et al. Am J Respir Crit Care Med. 2020 Apr 15

www.cairorecovery.org

HMS
MICHIGAN HOSPITAL
MEDICINE SAFETY CONSORTIUM

MHA
Keystone Center
A Certified Patient Safety Organization

Take Home Points

- We need to care for an increasing number of survivors of critical illness
- PICS is a new deficit or worsening function in physical, psychiatric, or cognitive domain
- The majority of ICU survivors experience PICS
- A multidisciplinary approach can address various aspects of PICS
- ICU follow-up may benefit patients and clinicians

Questions?





HMS Sepsis Initiative: Data Collection Sneak Peek

Hallie Prescott, MD, MSc

Professor of Internal Medicine, Pulmonary & Critical Care at Michigan Medicine

Vice chair of the Surviving Sepsis Campaign Guidelines & council member of the



HMS Sepsis Initiative

2020

2021

2022+



Sepsis Pilot Data Collection

Pilot data collection begins Q1 2021 at 10-15 volunteer hospitals

- .5 FTE for data collection provided

HMS Sepsis pilot application is due today!

- Must be an existing HMS hospital to participate

Hospitals selected will be notified mid/late October



Guiding Principles

Harmonize with other sepsis initiatives

CMS Sep-1, Surviving Sepsis Campaign

Focus on care across the continuum, not just first 6 hours

Early sepsis care → peri-discharge care

Focus on community-acquired sepsis (~85% of all sepsis)

Incorporate non-mortality outcomes (function, readmissions)

Harmonize with other HMS initiatives

Sepsis Cohort Identification



Step 1: List Generation

Pull in and log all hospitalizations (and observations stays) that populate the identification list with a qualifying primary discharge diagnosis



Step 2: Exclude Surgical Patients

Exclude patients with billed OR time within 48 hours of admission (excluding common procedures- IR, endoscopy)

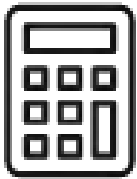
Case totals will be tracked to assess frequency for potential future inclusion



Step 3: Apply Standard Exclusions

Pregnant, pediatric, comfort care/hospice, transfers, *etc*

Sepsis Cohort Identification



Step 4: Organ Function Calculator

The abstractor will enter clinical data on organ (dys)function during first 3 days of hospitalization.

Organ Dysfunction= Eligible for Abstraction

Organ Function Calculator

Evidence of Organ Dysfunction on Admission (days 1-3)



Cardiovascular
Treatment with
vasopressor



Hematological
Decreasing
platelet



Liver
Increasing
bilirubin



Respiratory
Increasing need for
respiratory support



Neurological
Altered mental
status



Renal/Kidney
Increasing
creatinine



Lactate
Increasing lactate



Medications
Antibiotic/Antiviral
/Antifungal
Administration

Sepsis Patient Level Data Collection Strategy

Enrollment &
Pre-Hospitalization

Discharge

During Hospitalization

Early Management (Sep-1)- Days 1-4
Transition out of ICU (if applicable)

90 Day Post Hospitalization



Early Sepsis Bundle (Sep-1 Bundle)

- Time of first antibiotic order
- Time of first antibiotic administration
- Sequencing of antibiotics (*e.g.* pip/tazo prior to vancomycin)
- Blood cultures prior to antibiotics
- Initial lactate: time, value
- Repeat lactate: time, value
- Initial fluid resuscitation: type and volume of fluid
- Fluid type: balanced fluid, saline
- Timing, type, route of first vasopressor

Hospital Treatment beyond first 6 hours

- Adjunctive steroids
- Subsequent fluid volume/type
- Weight (fluid overload)
- Antibiotic narrowing (stopping MRSA/pseudomonas coverage)
- Delirium monitoring
- PT/OT referral
- Medication starts/stops

Peri-discharge

- Medications
- Post-hospital follow-up
- Interim contact
- Palliative care assessment/referral

Potential Planned Outcomes

- Progression to severe illness – organ dysfunction, ICU
- Risk-adjusted mortality
- Return to work
- Financial toxicity
- Readmissions (MVC linkage)
- Facility placement
- World Health Organization Disability Assessment
(i.e. cognition, mobility, self-care, getting along, life activities, participation)

Questions

Contact me with further questions or suggestions:

hprescot@med.umich.edu





Closing Remarks

Scott Flanders, MD

HMS Program Director

Professor of Medicine, Chief Clinical Strategy Officer, Michigan Medicine



More Information

<https://mi-hms.org/>

Twitter: @HMS_MI

<https://www.mha.org/>



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