#### **ANALYSIS PAPER**

# The Relationship Between Hospital Sepsis Bundle Compliance and Sepsis Mortality

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#### **KEY TAKEAWAYS**

- Statewide SEP-1 Sepsis Bundle compliance has increased over time. Sepsis mortality declined overall but spiked during the COVID-19 pandemic, indicating challenges in sustaining improvements.
- Higher hospital SEP-1 Sepsis Bundle compliance is associated with lower mortality rates, but the correlation weakened over time (from r = -.31 in 2017 to r = -.17 in 2022) and varied significantly by hospital characteristics such as ownership type and transfer volume.
- Investor-owned hospitals and those with smaller sample sizes exhibited weaker or negligible relationships between compliance and mortality, highlighting the role of contextual factors and the need for hospital-specific strategies.

# INTRODUCTION & BACKGROUND

# **Understanding Sepsis and Septic Shock**

According to the Third International Consensus Definitions for Sepsis and Septic Shock (SEP-3),<sup>1</sup> sepsis is a potentially life-threatening condition characterized by organ dysfunction caused by a dysregulated host response to infection. This organ dysfunction reflects the body's inability to maintain normal function and may compromise blood flow to vital tissues and organs, increasing the risk of organ failure and death. Septic shock, a severe form of sepsis associated with extreme risk of mortality, involves persistent low blood pressure requiring vasopressors and high serum lactate levels despite adequate fluids, indicating significant circulatory and metabolic issues.

Sepsis is a prevalent condition in California, affecting approximately 300,000 people annually and contributing to 50% of all in-hospital deaths. The cost of sepsis hospitalizations and treatments exceeds \$62 billion per year in the United States. To address this significant challenge, health care leaders and hospitals nationwide have advocated for standardized practices, including early intervention and the implementation of evidence-based sepsis bundles, to reduce sepsis-related mortality.

#### What Is a Sepsis Bundle?

The Centers for Medicare & Medicaid Services (CMS) introduced the SEP-1 Sepsis Bundle in 2015 as a set of guidelines designed to help hospitals quickly and effectively manage patients with sepsis or septic shock.<sup>2</sup> Also referred to as the Early Management Bundle for Severe Sepsis and Septic Shock, SEP-1 outlines time-sensitive interventions to standardize and improve care. The bundle requires hospitals to complete specific evidence-based interventions within defined timeframes in cases of sepsis or septic shock, such as three hours or six hours after sepsis is recognized. These interventions include:

- Measuring lactate levels (to assess tissue oxygenation and detect severity)
- Drawing blood cultures (before administering antibiotics) to identify the infection source
- Administering broad-spectrum antibiotics to fight the suspected infection
- Providing intravenous fluids to stabilize blood pressure

Use of SEP-1 is a process measure included in the CMS Hospital Inpatient Quality Reporting (HIQR) Program and Hospital Value-Based Purchasing (HVBP) Program.<sup>3</sup> Hospitals are scored on their compliance with the SEP-1 protocol, which measures the percentage of eligible patients who receive all required components of timely, evidence- based care for sepsis

<sup>&</sup>lt;sup>1</sup> https://jamanetwork.com/journals/jama/fullarticle/2492881

<sup>&</sup>lt;sup>2</sup> https://qualitynet.cms.gov/inpatient/specifications-manuals/sepsis-resources

https://cmit.cms.gov/cmit/%23/MeasureView?variantId=778&sectionNumber=1

and septic shock. SEP-1 Bundle compliance scores range from 0 to 100%, reflecting the proportion of patients receiving all bundle interventions within the defined timeframes.

#### Study Purpose

While the *individual* bundle component interventions all demonstrate evidence that they are directly related to decreases in organ failure, overall reductions in hospital mortality, length of stay, and/or costs of care, it is still a matter of debate whether hospitals with better (higher) SEP-1 Sepsis Bundle compliance indeed have lower SEP-3 sepsis mortality rates. The results of various studies have yielded mixed results, with some showing no association between compliance and mortality <sup>4,5</sup> and others showing higher bundle compliance associated with reduced sepsis mortality.<sup>6,7</sup>

Perhaps the effectiveness of SEP-1 on sepsis mortality rates depends on contextual factors, including hospital infrastructure, patient case mix, and the quality of sepsis management programs. Further research is needed to disentangle the impact of SEP-1 compliance from other performance improvement efforts in sepsis care. Toward this goal, the present study explores changes in SEP-1 Bundle compliance, SEP-3 sepsis mortality, and the correlation between these measures over time in California hospitals.

# **METHODOLOGY**

Trends in Sepsis Bundle compliance (SEP-1) and in-hospital sepsis mortality (SEP-3),<sup>10,11</sup> as well as their relationship (correlation coefficients), were investigated by plotting the statewide values from 2017 to 2022. In addition, factors associated with variation in the rates and relationships were investigated by stratifying the 2022 values by selected hospital characteristics.

The data used for this study were obtained from HQI's Hospital Quality Improvement Platform. HQIP is a comparative quality analytics platform with more than 300 hospital quality measures provided as a free benefit for all CHA member hospitals to help benchmark performance, identify challenges and trends, and improve their quality and patient-safety efforts.<sup>12</sup>

### **RESULTS**

# **How Have SEP-1 and SEP-3 Rates and Their Relationships Varied Over Time?**

Figure 1 on the following page shows trends in SEP-1 compliance and SEP-3 mortality rates, along with their correlation, in California from 2017 to 2022.

<sup>&</sup>lt;sup>4</sup> https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787262

<sup>&</sup>lt;sup>5</sup> https://stacks.cdc.gov/view/cdc/58964

<sup>&</sup>lt;sup>6</sup> https://journal.chestnet.org/article/S0012-3692(21)03623-0/fulltext

<sup>&</sup>lt;sup>7</sup> https://iournal.chestnet.org/article/S0012-3692(20)30437-2/fulltext

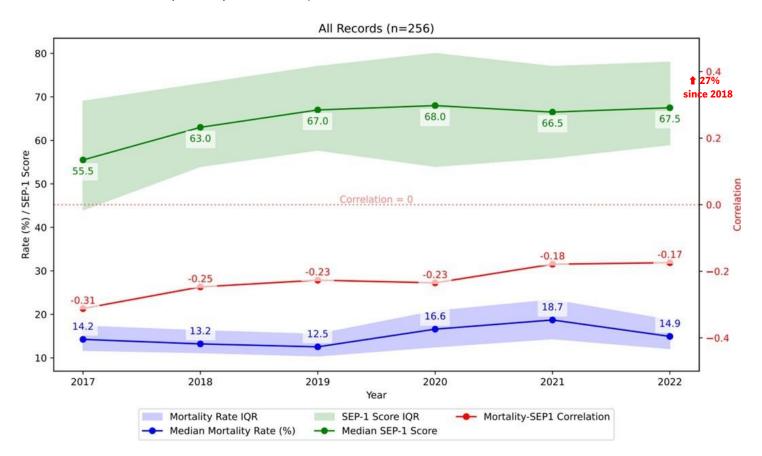
<sup>8</sup> https://bmjopenguality.bmj.com/content/13/4/e002859

<sup>&</sup>lt;sup>9</sup> https://pmc.ncbi.nlm.nih.gov/articles/PMC9722504/

<sup>&</sup>lt;sup>10</sup> Methodology: <a href="https://hainstitute.org/haip-resources-sepsis/">https://hainstitute.org/haip-resources-sepsis/</a>

<sup>&</sup>lt;sup>11</sup> Code sets: https://hqinstitute.org/file/sepsis-mortality-codes/

<sup>12</sup> https://hqinstitute.org/the-hospital-quality-improvement-platform/



**Figure 1.** Statewide Hospital Sepsis Bundle Compliance (SEP-1), In-Hospital Sepsis Mortality (SEP-3), and Their Correlation, CA 2017-2022

#### Trends in Sepsis Bundle Compliance (SEP-1) and In-Hospital Sepsis Mortality Rates (SEP-3)

SEP-1 rates increased from 55.5% in 2017 to 68% in 2020, then slightly declined to 67.5% in 2022. SEP-3 mortality decreased from 14.2% in 2017 to 12.5% in 2019, rose to 18.7% in 2021, and dropped to 14.9% in 2022. These results indicate that California hospitals improved their sepsis bundle compliance over the period, but faced challenges in continuing to reduce sepsis mortality, particularly during the COVID-19 pandemic.

# Trends in the Relationship of Sepsis Bundle Compliance (SEP-1) and In-Hospital Sepsis Mortality Rates (SEP-3)

Throughout this period, an inverse relationship was observed, indicating that higher SEP-1 compliance generally corresponded with lower SEP-3 mortality rates. However, the strength of this relationship weakened over time, demonstrated by the decreasing absolute value of the correlation coefficients. In 2017, the correlation was -.31, signifying a moderate correlation, which was reduced to -.17 by 2022, indicating a weak correlation.

The results suggest that although enhanced compliance with sepsis bundles is generally associated with improved sepsis mortality outcomes, the strength of this association has lessened over time among California hospitals.

#### How do SEP-1 and SEP-3 Rates and their Relationship Vary by Hospital Characteristics?

Table 1 shows Sepsis Bundle compliance (SEP-1), in-hospital sepsis mortality rates (SEP- 3), and their correlation overall and stratified across different hospital characteristics in California for 2022. The data are stratified by hospital transfer volume, tax status, and outpatient/inpatient volume categories.

**Table 1.** Hospital Sepsis Bundle Compliance (SEP-1), In-Hospital Sepsis Mortality (SEP-3), and Their Correlation Stratified by Selected Hospital Characteristics, CA 2022

Group/Strata	Sepsis Bundle Compliance (percentage) (SEP- 1)	Sepsis Mortality (percentage) (SEP-3)	Correlation of SEP-1 & SEP-3
Statewide	67.5	15.5	17
Transfer Volume (1st Quintile)	66.0	16.0	39
Transfer Volume (4 <sup>th</sup> Quintile)	67.5	15.1	36
Investor-Owned	61.5	17.5	.06
Not-For-Profit	71.0	14.9	14
Outpatient Volume (162k+ visits)	67.0	15.9	22
Inpatient Volume (12k+ Discharges)	64.5	15.6	07

# Variation in Sepsis Bundle Compliance (SEP-1) and In-Hospital Sepsis Mortality Rates (SEP-3) by Hospital **Characteristics**

The statewide 2022 rate for Sepsis Bundle compliance (SEP-1) was 67.5% and the corresponding in-hospital sepsis mortality rate (SEP-3) was 15.5%. Across hospital characteristics, SEP-1 compliance and SEP-3 mortality rates exhibit variability.

For example, hospitals in the first quintile of transfer volume have lower SEP-1 compliance (66%) and a higher SEP-3 mortality rate (16%), while those in the fourth quintile of transfer volume have higher compliance (67.5%) and a slightly lower mortality rate (15.1%). Not- for-profit hospitals display higher compliance (71%) and lower mortality (14.9%) compared to investor-owned hospitals, which show lower compliance (61.5%) and higher mortality (17.5%). Similarly, hospitals with higher outpatient volume (67%) and higher inpatient volume (64.5%) show mortality rates of 15.9% and 15.6%, respectively.

These patterns suggest that higher SEP-1 compliance is generally associated with modestly lower mortality rates, but this relationship varies by hospital type and volume, reflecting the influence of additional contextual factors on sepsis outcomes.

# Variation in the Relationship Between Sepsis Bundle Compliance (SEP-1) and In-Hospital Sepsis Mortality Rates (SEP-3) by Hospital Characteristics

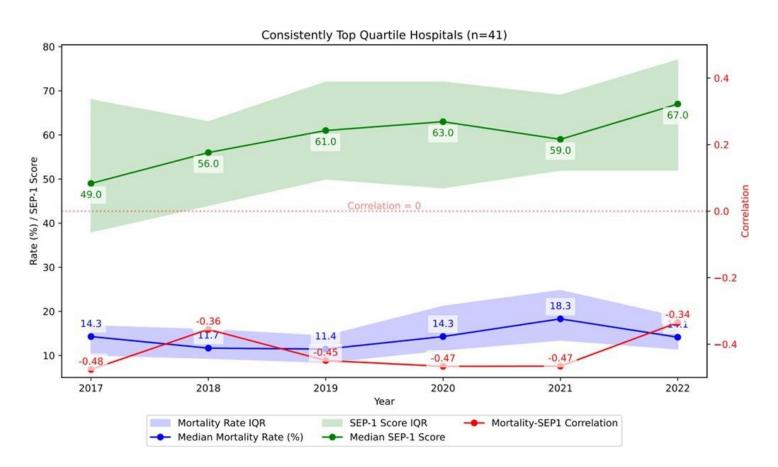
In 2022, the statewide correlation between SEP-1 Sepsis Bundle compliance and SEP-3 in-hospital sepsis mortality was weakly negative (r = -.17), suggesting a slight inverse relationship where higher compliance is modestly associated with lower mortality. However, the strength and direction of this relationship vary across hospital characteristics.

For example, hospitals in the first quintile of transfer volume show a stronger negative correlation (r = -.39), as do those in the fourth quintile of transfer volume (r = -.36), indicating that higher SEP-1 compliance may have a more meaningful association with reduced mortality in these settings. Conversely, investor-owned hospitals exhibit a negligible positive correlation (r = .06), suggesting little to no relationship between compliance and mortality in these facilities. Not-for-profit hospitals show a weak negative correlation (r = -.14), while hospitals with high outpatient volume (r = -.22) and inpatient volume (r = -.07) display varying levels of weak negative correlations. These findings suggest that hospital-specific factors, such as transfer volume and ownership type, may play a significant role in the relationship between SEP-1 compliance and sepsis mortality outcomes, highlighting the need for tailored strategies in sepsis management.

# **Additional Variables/Further Investigative Analysis: Compliance Sample Sizes**

Since the SEP-1 bundle compliance score is sampled, a small sample size can hinder the analysis of the link between bundle compliance and sepsis mortality. To improve the analysis, hospitals were given a supplemental metric: the ratio of the year's SEP-1 sample size to SEP-3 cases. This ratio indicates how well-sampled SEP-1 was for that year. Analyzing hospitals in the top quartile of this ratio revealed stronger correlations between SEP-1 compliance and mortality.

**Figure 2.** Annual SEP-1 Bundle Compliance, Sep-3 Mortality, and their Correlation, California Hospitals with Largest Relative SEP-1 Bundle Sampling



#### **DISCUSSION & CONCLUSION**

The study analyzed the relationship between hospital compliance with the SEP-1 Sepsis Bundle and in-hospital sepsis mortality rates (SEP-3) across California hospitals from 2017 to 2022. Results showed an overall improvement in SEP-1 compliance from 55.5% in 2017 to 68% in 2020, followed by a slight decline to 67.5% in 2022. Sepsis mortality rates decreased from 14.2% in 2017 to 12.5% in 2019, increased sharply during the COVID-19 pandemic to 18.7% in 2021, and dropped again to 14.9% in 2022. While an inverse relationship between SEP-1 compliance and SEP-3 mortality was observed, the correlation weakened over time (from r = -.31 in 2017 to r = -.17 in 2022).

Analysis of 2022 data reveals variability in compliance and mortality rates by hospital characteristics, such as transfer volume, tax status, and patient volume. Investor-owned hospitals and those with low compliance rates showed weaker or negligible associations with mortality outcomes.

The findings suggest that contextual factors — including hospital infrastructure and sepsis management quality — influence the effectiveness of sepsis bundles, emphasizing the need for tailored strategies in improving sepsis care.

Questions or comments about this article should be directed to Emma Goldberg, data analyst, at <a href="mailto:egoldberg@hqinstitute.org">egoldberg@hqinstitute.org</a>.

## **ABOUT US**

The <u>Hospital Quality Institute</u> (HQI) is dedicated to advancing patient safety and quality of care for all Californians. Through strategic partnerships and innovative programs, HQI supports hospitals in achieving excellence by providing data analytics, educational resources, and statewide initiatives focused on performance improvement. HQI oversees and coordinates the <u>Collaborative Health Care Patient Safety Organization</u> (CHPSO).