

Differences in the CMS and HMS Sepsis Initiatives

EXECUTIVE SUMMARY

The following table summarizes key similarities and differences between the Centers for Medicare & Medicaid Services (CMS) Sepsis 1 (SEP-1) measure and the Michigan Hospital Medicine Safety (HMS) Consortium's Sepsis initiative. Both initiatives focus on severe sepsis according to the Sepsis-3 definition (i.e., hospitalizations with infection-related acute organ dysfunction). Additionally, both initiatives collect data on recommended care elements, such as those included <u>Surviving Sepsis Campaign</u> bundles.

HMS captures additional data elements to break down process measures into more granular steps (e.g., time to antibiotic order, time from order to administration) and examine process measures in a variety of sub-populations (e.g., fluid administration in patients with hypotension vs just those initiated on vasopressors) and apply specific exclusionary criteria (e.g. ESRD, reduced left ventricular ejection fraction, or severe/critical aortic stenosis). Such granularity is essential to supporting focused, hospital-specific quality improvement. Additionally, the HMS cohort identification strategy uses ICD-10-CM codes beyond severe sepsis / septic shock which allows capture of "missed sepsis" patients. This also ensures the threshold for entry into the cohort is consistent across hospitals and not dependent on hospital recognition and labeling of sepsis, which is known to vary over time and across hospitals. Finally, HMS uses a severity adjustment model incorporating granular physiologic data to facilitate robust comparison of risk-adjusted outcomes among Michigan hospitals.

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	CMS	HMS	KEY POINTS
Cohort Identification	• Discharges age 18+ with an <u>ICD-</u> <u>10-CM Principal or Other</u> <u>Diagnosis Code of Sepsis,</u> <u>Severe Sepsis, or Septic Shock.</u>	• Discharges age 18+ with an ICD-10-CM Principal Diagnosis Code of Sepsis, Influenza, COVID-19, Acute Respiratory Failure, or Pneumonia with objective evidence of suspected infection and acute organ dysfunction on encounter day 1 or 2.	 HMS cohort includes COVID-19 patients (CMS excludes). HMS cohort has broader list of primary discharge ICD-10-CM codes than CMS. HMS excludes patients who had surgery in the first 48 hours of the hospital encounter or transferred from another hospital. HMS requires objective evidence of sepsis (suspected infection plus acute organ dysfunction) during encounter day 1 or 2, akin to <u>CDC's Adult Sepsis Event</u> surveillance definition for community-acquired sepsis (CMS includes hospital-acquired sepsis).
Process Measures	 Bundle is an all or nothing measure focused on initial sepsis care only. Applies crude exclusion criteria only. 	 Reports show individual process measures Examines sepsis care throughout the hospitalization. 	 The scope of HMS sepsis is broader than just the first 6 hours of care addressed in SEP-1. This includes early sepsis care, care of the septic patient in the critical care and wards, care upon discharge and outcomes in the 90 days following hospital discharge. HMS provides precise exclusion criteria per measure (e.g., excluding patients with ESRD, reduced left ventricular ejection fraction, and/or severe/critical aortic stenosis from fluid resuscitation measures).
Outcome Measures	• Does not examine outcomes, although CMS is planning a future sepsis outcome measure.	 Measures risk-adjusted mortality. Captures patient-reported outcomes post-discharge. 	• HMS 30-day and 90-day mortality outcomes are risk adjusted. The risk- adjustment model includes demographics, comorbidities, and granular physiologic data collected within 6 hours of presentation. The risk- adjustment model was developed and validated in HMS hospitalizations following best practices laid out in a <u>September 2021 CMS guidance</u>

	CMS	HMS	KEY POINTS
Time Zero	 Severe Sepsis: <u>Time</u> at which documentation of an infection + 2 SIRS + 1 Organ Dysfunction occurs. All 3 events must occur within 6 hours of each other. Septic Shock: Time at which Septic Shock criteria are met 	• Patient's presentation to the hospital	 HMS uses hospital presentation as time zero because this is exogenous, and can't be biased by delayed collection of vitals and labs. Additionally, it is easy to abstract with accuracy. CMS time zero is labor-intensive, and delays in collection of vital signs and laboratories may impact the time zero.
Sampling	 Hospitals submit cases on a monthly or quarterly basis. For hospitals with >77 eligible cases per quarter, a random sample is submitted. Minimum required number varies from 78 to 311 depending on total eligible <u>cases</u>. 	 Data collection occurs in 2-week cycles. Hospitals abstract 18 cases per cycle, which equals 20-95% of estimated eligible cases identified by ICD-10-CM coding. Cases are sampled for abstraction using pseudo-randomization based on minute of discharge timestamp. 	
Organ Dysfunctions	 SIRS: 1 Temp <36 C or >38.3 HR >90 RR >20 WBC <4,000 or >12,000 or >10% bands Organ Dysfunction: Systolic BP <90 or MAP <65 Systolic BP decrease of 40 mmHg Lactate >2 Creatinine >2 (excluding CKD, ESRD) INR >1.5 (without anticoagulation) Platelets <100,000 Total Bilirubin >2 Start time for NIV or Mechanical ventilation Urine Output, 0.5 mL/kg/hour for 2 consecutive hours (in patients with hourly documentation). Septic Shock: Presence of Severe Sepsis criteria (above) AND persistent hypotension OR tissue hypoperfusion (Lactate >4) 	 Organ Dysfunction: Initiation of a new vasopressor infusion Initiation of respiratory support >4L NC oxygen excluding patients with home oxygen use or an ICD- 10 codes for chronic respiratory failure (J96.11 & J96.21) Doubling of serum creatinine relative to baseline, excluding patients with ICD-10-CM code for end-stage renal disease (N18.6) Total bilirubin ≥ 2.0 mg/dL and increase by 100% from baseline Platelet count <100 cells/µL AND ≥50% decline from baseline Serum lactate >2.0 mmol/L Presentation of altered mental status 	 HMS: Does not require SIRS criteria. Labs values used to define an organ dysfunction are relative to a baseline organ function (as defined by best lab values during hospitalization) which aligns with the <u>CDC's Hospital Toolkit for Adult Sepsis Surveillance definition</u>. Organ dysfunction(s) must occur on hospital day 1 or 2. Includes presentation of altered mental status as an acute organ dysfunction (this is excluded from CDC and other definitions because it is difficult to automatically extract from administrative or electronic health record data). Does not include INR or urine output as organ dysfunction(s) because INR is impacted by medications and charting of urine output is often unreliable. Has a lower threshold of respiratory support to be included as organ dysfunction because we are reliably able to capture supplemental oxygen therapy. Flu, COVID, Respiratory Failure and Pneumonia cases must have respiratory dysfunction to help ensure that the organ dysfunction is truly infection-related. Sepsis cases may qualify by any of the 6 acute organ dysfunctions. Captures timely data on blood pressure, lactate, and vasopressor initiation for identification of patients with septic shock.

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