

Impact of CMS “Time Zero” Criteria on SEP-1 Compliance and Sepsis Outcomes in the ED

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Introduction & Aims

Sepsis and Septic Shock

- Life-threatening response to infection, leading to organ dysfunction and high mortality
- Septic shock, a severe subset, results in hypotension and higher mortality

Impact of Sepsis

- 1/3 hospital deaths involve sepsis; 1/5 sepsis patients die or are discharged to hospice

CMS SEP-1 Sepsis Bundles

- 3-Hour: Antibiotics, blood cultures, lactate levels
- 6-Hour: Repeat lactate, vasopressors, tissue perfusion

Challenges with “Time Zero” (“t-zero”)

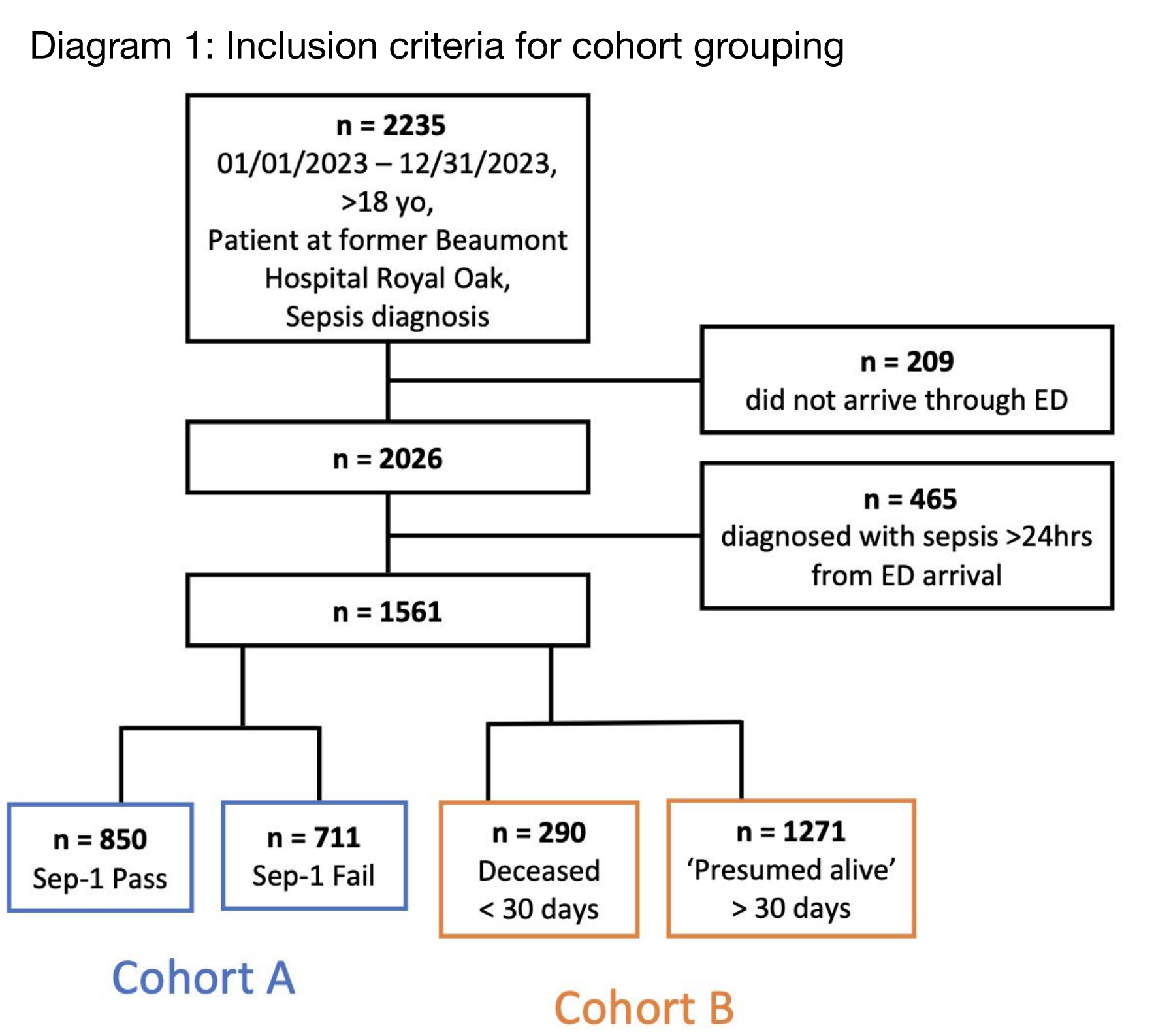
- The point of suspected sepsis and treatment initiation based on infection, SIRS criteria, and organ dysfunction
- Current debate whether t-zero is too strict and delays treatment, leading to worse outcomes

Study Aims:

- Characterize the timing of CMS t-zero criteria and assess the validity of SEP-1 guidelines
- Evaluate SEP-1 pass/fail rates and inpatient mortality outcomes for ED sepsis patients

Methods

- Retrospective chart review of adult (≥18) Corewell Health University Hospital ED patients diagnosed with sepsis from Jan 2022-Dec 2022
- Used in-house automated algorithm to extract data:
 - CMS SEP-1 t-zero and 3-hour bundle criteria
 - SEP-1 pass/fail rates
 - 30-day mortality



Results

Table 1. Baseline Characteristics of Patients by SEP-1 3-Hour Bundle Compliance

Variable	All (n=1561)	SEP-1 Pass (n=850)	SEP-1 Fail (n=711)	p-value
Age, median (IQR)	69 (57–79)	69 (57–78)	69 (56–79)	0.88
Female, n (%)	722 (46.3)	384 (45.2)	338 (47.5)	0.36
Race, n (%)				0.72
White	1020 (65.3)	549 (64.6)	471 (66.2)	
Black	403 (25.8)	228 (26.8)	175 (24.6)	
Asian	38 (2.4)	21 (2.5)	17 (2.4)	
Other	90 (5.8)	48 (5.7)	42 (5.9)	
ND	10 (0.6)	4 (0.5)	6 (0.8)	

Table 2. Patient Characteristics Stratified by 30-Day Mortality

Variable	All (n=1561)	Deceased ≤30d (n=290)	Alive >30d (n=1271)	p-value
Age, median (IQR)	69	75	68	<0.001
Female, n (%)	722 (46.3)	149 (51.4)	573 (45.1)	0.05
Race, n (%)				0.29
White	1020 (65.3)	196 (67.6)	824 (64.8)	
Black	403 (25.8)	71 (24.5)	332 (26.1)	
Asian	38 (2.4)	3 (1.0)	35 (2.8)	
Other	90 (5.8)	15 (5.2)	75 (5.9)	
ND	10 (0.6)	5 (1.7)	5 (0.4)	

Table 3. Multivariable Analysis of Factors Associated with SEP-1 3-Hour Bundle Compliance

Variable	Adjusted OR	95% CI	p-value
ΔT: ED to DOI (per hour)	0.8	0.70–0.92	<0.001
Non-ischemic heart disease	0.64	0.50–0.81	<0.001
Parkinson’s disease	4.91	1.40–17.20	0.004
Depressive disorder	1.36	1.07–1.74	0.01
Hypothyroidism	0.71	0.54–0.94	0.02
Alzheimer’s disease	1.97	1.03–3.77	0.04
Non-Alzheimer dementia	0.73	0.53–1.00	0.05

Table 4. Multivariable Analysis of Factors Associated with 30-Day Mortality in ED Sepsis Patients

Variable	Adjusted OR	95% CI	p-value
Age (per year)	1.03	1.02–1.04	<0.001
ΔT: ED to Sepsis t-0 (hr)	0.87	0.81–0.94	<0.001
ΔT: ED to SIRS (hr)	1.14	1.05–1.23	0.001
Male sex	0.64	0.47–0.84	0.002
Non-ischemic heart disease	1.55	1.14–2.11	0.005
Osteoporosis	0.42	0.22–0.83	0.007
Acute MI	1.55	1.12–2.14	0.009
Hyperlipidemia	0.66	0.48–0.90	0.009
Asthma	0.59	0.37–0.95	0.02
Pelvic fracture	2.18	1.05–4.53	0.04
Lung cancer	1.79	1.01–3.18	0.05

Conclusions

- Just over half** of the 1,561 ED patients with sepsis met CMS SEP-1 3-hour bundle requirements
- Baseline demographics (age, sex, race) **were not associated** with SEP-1 bundle compliance, suggesting that patient demographics alone do not explain variation in SEP-1 performance
- Earlier recognition** of sepsis was **strongly associated with improved outcomes**. Shorter time from ED arrival to sepsis identification was associated with both increased SEP-1 bundle completion and lower 30-day mortality
- Mortality** was primarily driven by patient factors, including increasing age, cardiovascular disease, acute myocardial infarction, malignancy, and major injury
- Several comorbidities demonstrated **lower mortality**, which may reflect residual confounding, differences in healthcare utilization, or documentation patterns

Implications

- Improving **early identification systems in the ED** may represent a key opportunity to improve outcomes
- Future quality metrics may benefit from **greater flexibility in defining sepsis onset** and incorporating clinical judgment
- Additional multicenter studies are needed to further evaluate how SEP-1 metrics relate to meaningful patient outcomes

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