Accuracy of Physician Adjudication of Infection in Patients with Systemic Inflammatory Response Syndrome (SIRS)

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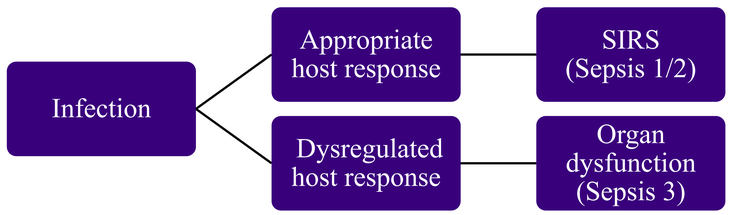
Background

Defining Sepsis:

The definition of sepsis evolves with improved understanding of the pathophysiology, but the presence of infection remains essential for the diagnosis.[1]



Defining Infection:

There are no universal objective definitions for infections. Current clinical trials use a variety of criteria to identify known or suspected infection including [2,3]:

- Collection of bodily fluid culture
- Initiation of antibiotic therapy
- International classification of diseases, ninth revision, clinical modification (ICD-9-CM) codes
- Physician adjudication

Variations in infection criteria can create challenges in the interpretation of new diagnostic studies, utility of prognostic tools, and the impact of therapeutic interventions in sepsis related clinical trials.

Objective

- This was prospective observational study performed in 2 academic medical center Emergency Departments between February 2016 and December 2016.
- We compared physician adjudication of infection to standardized definitions of infection in patients meeting 2 of 4 SIRS criteria.

Methods

- Diagnostic and physiologic data were abstracted from 151 patients with 2 of 4 SIRS who were enrolled in the Emergency Department.
- Each medical record was independently reviewed by 1 Emergency Medicine and 1 Critical Care (CC) physician from a 10-member adjudicating committee to determine the presence of infection, absence of infection or indeterminate. In the case of disagreement, a third CC physician served as the tiebreaker.
- Objective definitions of infection were derived from consensus surveillance definitions.

Vascular	Abdominal	Respiratory	Bone & Joint	Skin & Skin Structure	Genitourinary
Myocarditis Pericarditis Endocarditis Mediastinitis Primary bloodstream Arterial/Venous	Clostridium difficile Gastroenteritis Gastrointestinal[1] Intra –abdominal[2]	Pneumonia Lower airway	Osteomyelitis Disc space Joint or bursa Periprosthetic	Breast Decubitus ulcer Skin[3] Soft tissue	Urinary tract Urinary system

Table 1: Description of objective infections for each system. [1] Excluding C. difficile, gastroenteritis, and appendicitis. [2] Including gallbladder, bile ducts, liver [excluding viral hepatitis], spleen, pancreas, peritoneum, subphrenic or subdiaphragmatic space or other intraabdominal tissue or area not specified elsewhere. [3] Excluding decubitus or burn.

Results

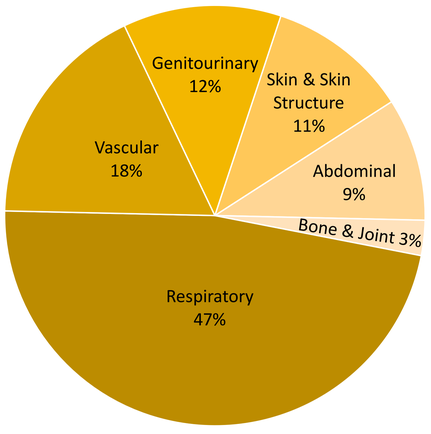


Figure 1: Number of patients determined by consensus surveillance definitions to have an objective infection divided by subgroup. N = 74

Demographics		
Gender		
	Male, *n (%)*	76 (50.3)
	Female, *n (%)*	75 (49.7)
Age, *m*		62.84
Race		
	White, *n (%)*	66 (43.7)
	Black, *n (%)*	58 (38.4)
	Other *n (%)*	27 (17.9)
Hospital location		
	ICU, *n (%)*	44 (29.1)
	Floor, *n (%)*	132 (87.4)
	ED Discharge, *n (%)*	9 (5.9)
In-hospital mortality, *n (%)*		9 (6.0)
SOFA score, *m, M (IQR)*		2.97, 2(0,4)

Table 2: Baseline characteristics for all patients with and without infection. 34 patients spent time on the floor and in the ICU. n= 151. m, mean; M, median; IQR, interquartile range; SOFA, Sequential Organ Failure Assessment.

Results continued

Objective Definition of Infection	Adjudication: Infected	Indeterminate	Not Infected	Total
Not Infected	4	11	62	**77**
Infected	53	8 *(5[1])*	13 *(13[1])*	**74**
Total	**57**	**19**	**75**	**151**

Table 3: Comparison of physician adjudication and objective definition of infection. [1]Number of patients meeting objective definition for respiratory infection.

- Percent agreement between physician adjudicator and objective definition was 93% for the presence of infection and 82.7% for the absence of infection.
- 19 total patients were adjudicated as indeterminate, 8 of which met one objective definition of infection.
- 75 total patients were adjudicated as not infected, 13 of which met one objective definition of infection.
- The greatest discordance between physician adjudicated infection and objective definitions occurred in patients with a respiratory infection.

Conclusions

- Objective definitions of infection may be a reproducible and reliable method to determine the presence of infection for use by clinical investigators. A standard definition may decrease the variability in the diagnosis of sepsis and allow comparability among clinical trials.
- Next steps,
  - Refining the objective definition of respiratory infections to exclude patients presenting with cardiogenic pulmonary edema.
  - Application to a larger patient population.

References

1. Singer, Mervyn et al. "The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)." *JAMA*315.8 (2016): 801–810. *PMC*.
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3. Freund, Yonathan et al. "Prognostic Accuracy of Sepsis-3 Criteria for In-Hospital Mortality Among Patients With Suspected Infection Presenting to the Emergency Department. *JAMA*317.3 (2017):301–308. *PMC*

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