

Introduction

- Sepsis is a dysregulated immune response to infection causing organ dysfunction¹. It is the **leading cause of in-hospital death** in the USA.
- Progression of sepsis is extremely fast, requiring **rapid detection** and treatment action to prevent resulting morbidity and mortality.
- The symptoms of sepsis are non-specific and** may easily be mistaken for those of other life-threatening conditions.
- Most cases of sepsis present at emergency departments (ED), where there is **a major unmet need for rapid sepsis risk assessment**².
- It is known that **immune cell activation alters biomechanical properties**, and investigational tests based on this principle show promise³.
- This study evaluated the ordering patterns of a novel host response (HR) test within a protocolized screening and guideline-directed treatment pathway across five distinct EDs.

Methods

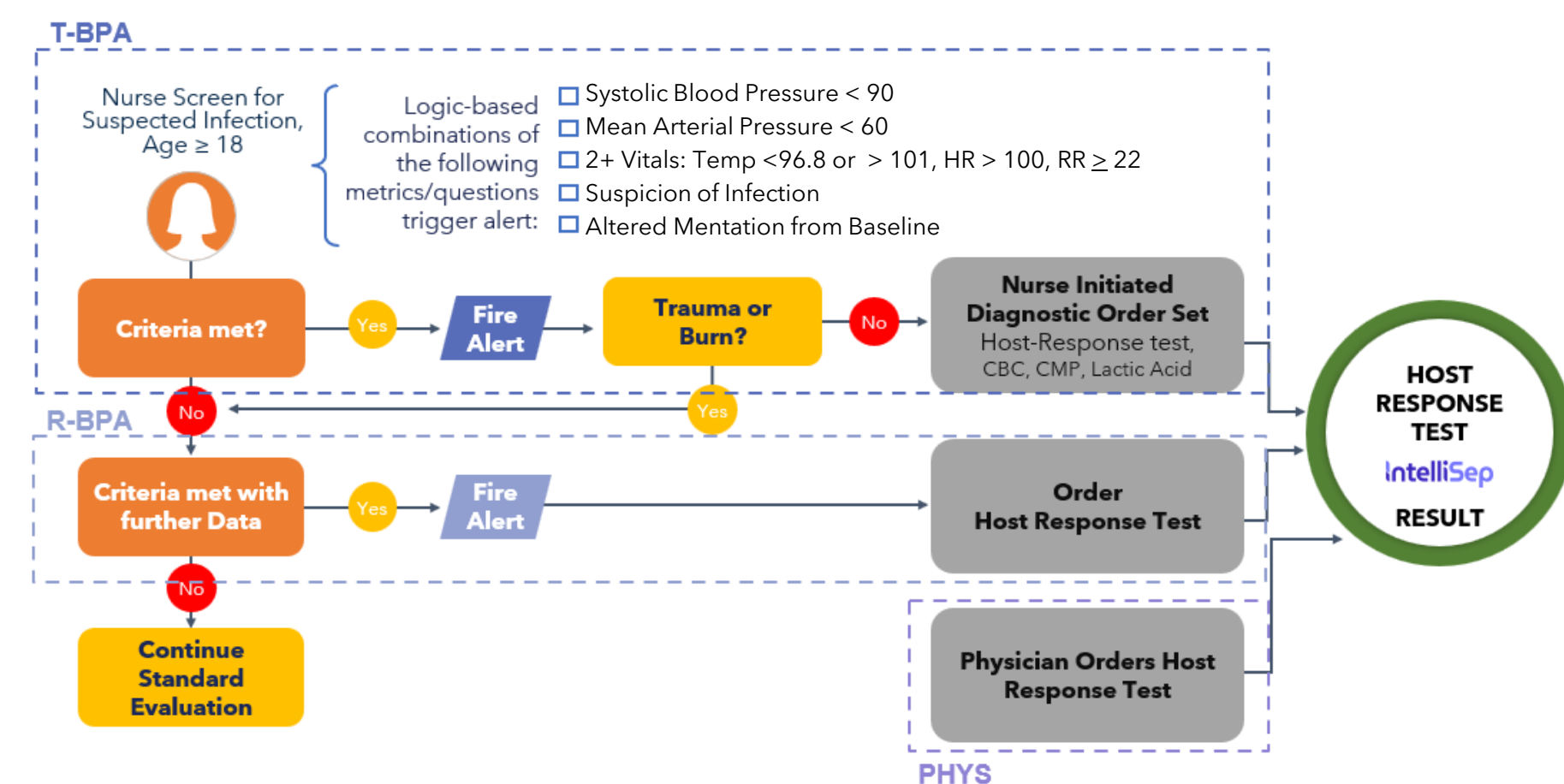


Figure 1: Protocolized screening pathway implemented at all 5 emergency departments within the same system.

The IntelliSep test

- The IntelliSep test is FDA-cleared⁴, semi-quantitative, and **measures leukocyte biophysical properties** via deformability cytometry to assess cellular host response.
- Intended for adults with suspected infection in the ED; aids in early detection of sepsis with organ dysfunction within 3 days of testing.
- Requires K2 EDTA whole blood; delivers an IntelliSep Index (ISI) score (0.1–10.0) in **under 10 minutes**.
- ISI score stratified into 3 bands: Band 1 (low risk) to Band 3 (high risk of sepsis with organ dysfunction)⁵.
- Neutrophil and monocyte properties (deformability, density, size) shift with degranulation, NET formation, or maturation, differing between septic and quiescent cells⁶⁻⁸.

See the IntelliSep Test Instructions for Use for all cleared claims and performance data.

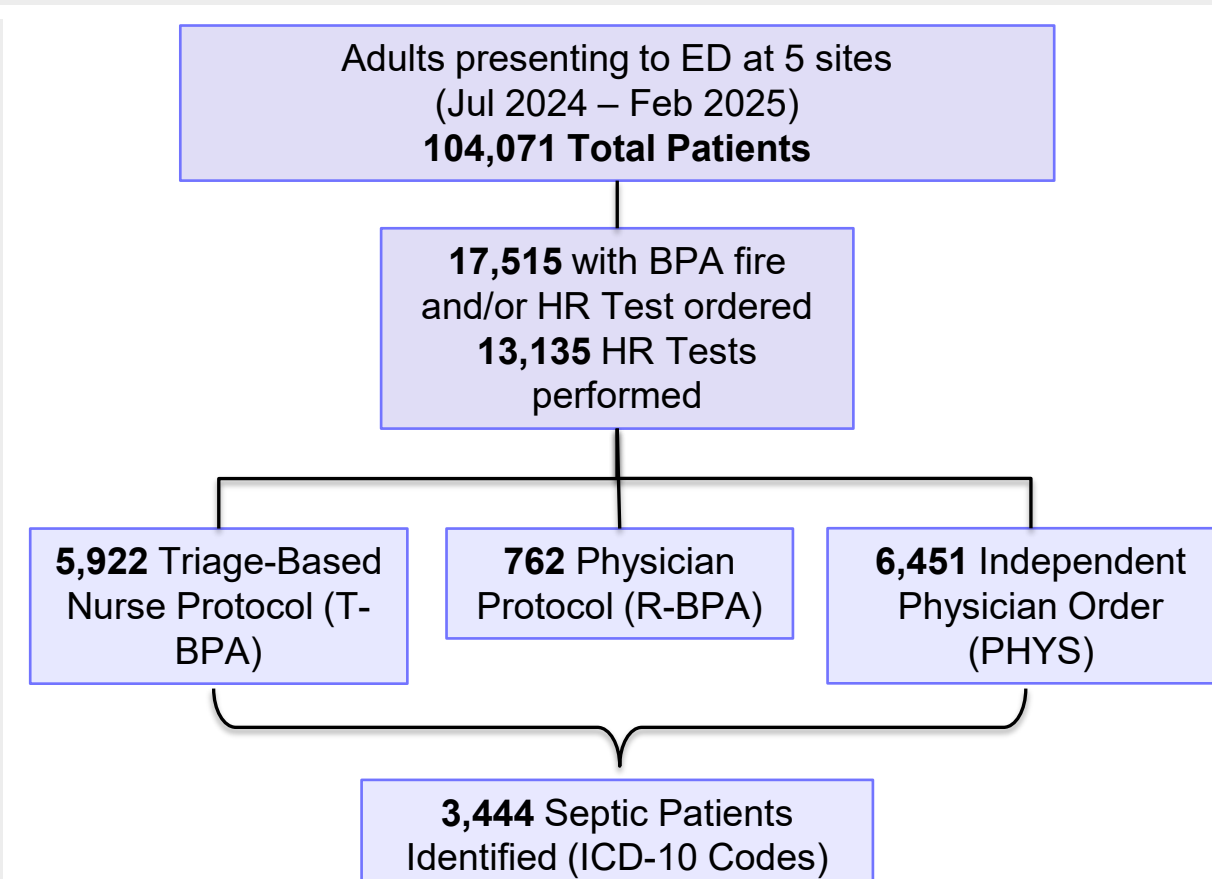
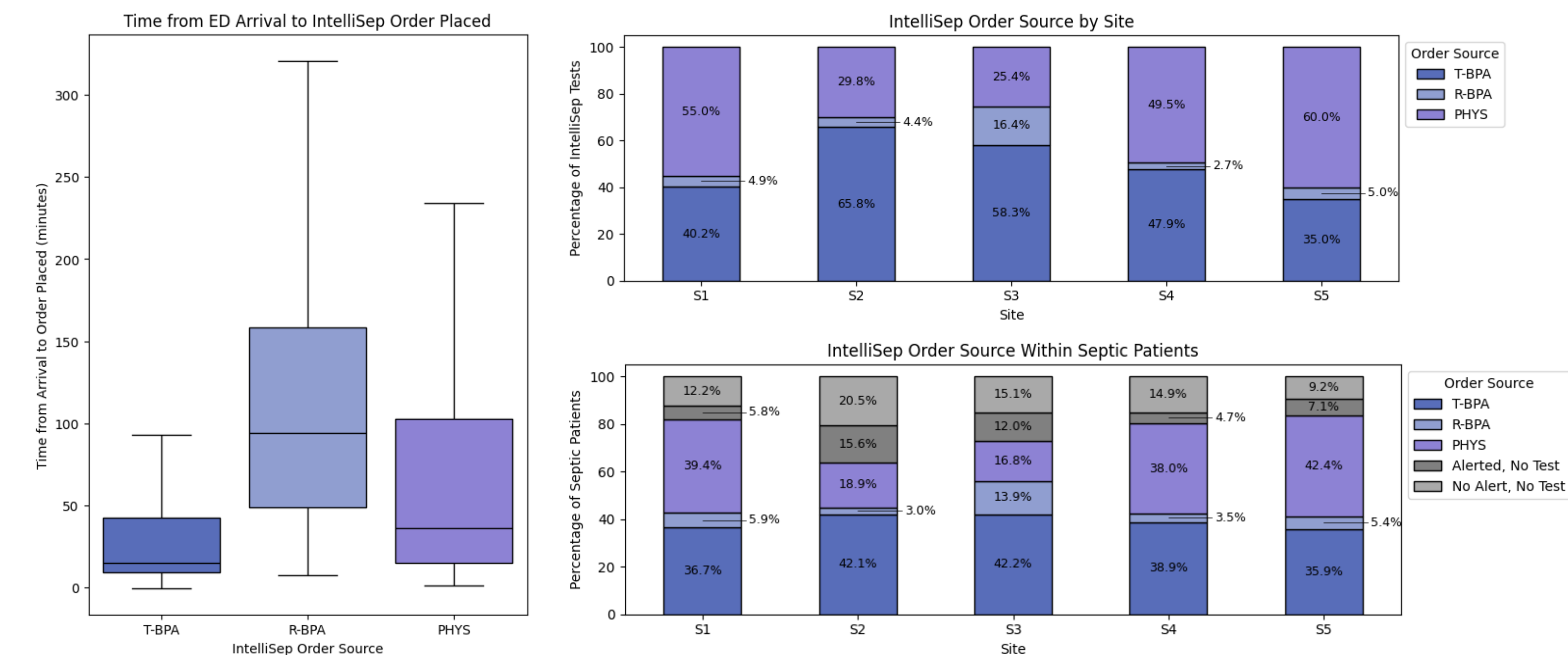


Figure 2: Flowchart of study cohort, test ordering pathways, and septic patients included in analysis.

Results & Discussion

- Of 104,701 ED patients across five sites, 17,515 (16.8%) had a BPA fire and/or HR Test ordered, resulting in 13,135 completed tests.
- Test ordering was distributed as 45.1% T-BPA (5,922), 5.8% R-BPA (762), and 49.1% PHYS orders (6,451), with site-level variation in each pathway.
- Over 96% of PHYS orders (6,199) occurred without a prior alert, indicating provider-driven testing expanded beyond automated BPA protocols.
- Median time to order differed significantly: T-BPA 15.0 minutes, R-BPA 94.0 minutes, and PHYS 36.4 minutes, with PHYS generally intermediate.
- Among 3,444 septic patients, 38.4% were captured by T-BPA, 6.3% by R-BPA, and 33.9% by PHYS orders, with notable site-specific variation.
- An additional 21.4% of septic patients (738 individuals) were not captured by any testing pathway, underscoring persistent gaps in detection despite multiple ordering mechanisms.



Conclusions & Clinical Implications

- Independent physician ordering increased testing volume and improved capture of septic patients beyond protocol-based alerts.
- Site-specific variation in utilization, timing, and alert performance persisted despite standardized workflows.
- Tailored implementation, including provider discretion outside protocols, is needed to optimize adoption, prevent missed cases, and improve early sepsis detection.

Acknowledgements

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References

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